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Integrated Guidelines for Prevention, Treatment and Management of HIV, Sexually Transmitted Infections and Viral Hepatitis

2026 Edition

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Integrated Guidelines for the Treatment and Prevention of HIV, Sexually Transmitted Infections and Viral Hepatitis contain relevant information required by healthcare providers to manage HIV, Sexually Transmitted infections and Viral Hepatitis. All reasonable precautions have been taken by NASCOP to verify the information contained in this guideline document.

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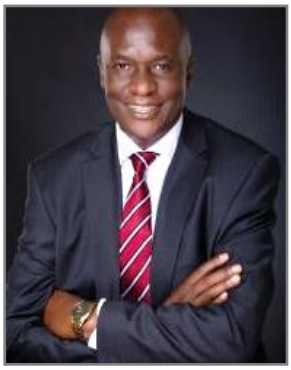
FOREWORD



Kenya remains steadfast in its commitment to end AIDS, Sexually Transmitted Infections (STIs), and Viral Hepatitis (VH) epidemics by 2030. This 2026 edition of the Integrated Guidelines for the Treatment and Prevention of HIV, STIs, and Viral Hepatitis in Kenya represents a strategic pivot in the national response to HIV and related conditions, building upon the 2022 guidelines and responding to evolving public health priorities.

This edition introduces a significant shift from syndromic management to clinical and etiological diagnosis and treatment of STIs, enhancing diagnostic accuracy and improving clinical outcomes in line with global standards. Additionally, this guideline provides for improved VH diagnostics, expanded and simplified treatment criteria for adolescents and adults, and expanded eligibility for antiviral prophylaxis for pregnant women for prevention of vertical transmission of Hepatitis B Virus. This reinforces Kenya's dedication to the triple elimination of vertical transmission of HIV, syphilis, and Hepatitis B, a critical step toward safeguarding maternal and child health.

Considering the shifting donor landscape, this guideline emphasizes the integration of services to maximize efficiency and sustainability. It also highlights the introduction of safer, long-acting therapeutic options for HIV prevention, reflecting advancements in biomedical interventions.

While Kenya has made commendable progress in HIV prevention, care, and treatment driven by innovations in medicines, diagnostics, and patient-centered service delivery, Advanced HIV Disease continues to present a significant public health challenge.

These guidelines aim to expand access to essential diagnostics and therapeutics to address the leading causes of morbidity and mortality among people living with HIV. The document serves as a comprehensive resource for healthcare providers, policymakers, and implementing partners, offering practical guidance on integrated, patient-centred service delivery. It includes key recommendations on testing prevention, linkage to care, and treatment of HIV, STIs, and VH. Presented in a simplified format using a public health approach, these guidelines are intended for use by service providers at all levels of the health sector.

This guideline will serve as a robust framework to advance universal access to HIV, STI, and VH services, accelerating progress toward ending them as public health threats.

Dr. Patrick Amoth, CBS

Director General for Health,
Ministry of Health.

PREFACE

The Integrated Guidelines for the Prevention, Treatment and Management of HIV, Sexually Transmitted Infections (STIs), and Viral Hepatitis (VH) represent a significant milestone in strengthening Kenya's response to communicable diseases of major public health importance. This edition builds upon the 2022 Kenya HIV Prevention and Treatment Guidelines and responds to emerging scientific evidence, evolving epidemiological trends, and the need for more efficient, person-centered service delivery.

The integration of HIV, STIs, and Viral Hepatitis guidance reflects the shared modes of transmission, overlapping affected populations, and common service delivery platforms. Fragmented approaches limit efficiency and continuity of care. These guidelines therefore adopt a harmonized public health approach to promote comprehensive prevention, timely diagnosis, effective treatment, and long-term retention in care across the life course.

The revision process was consultative, and evidence driven. It involved technical experts from the Ministry of Health, NASCOP, county health departments, academic institutions, professional bodies, communities and implementing partners. Global normative guidance and current scientific literature were reviewed and contextualized to the Kenyan setting. The process included technical working group deliberations, stakeholder consultations, and validation to ensure alignment with national health policies and international standards.

Key updates in this edition include the transition toward etiological diagnosis and management of STIs, strengthened Viral Hepatitis screening and treatment pathways, expanded HIV prevention options including long-acting biomedical interventions, updated treatment options, revised DSD strategy and enhanced guidance on the management of Advanced HIV Disease. The guideline further reinforces integrated maternal and child health platforms to advance the triple elimination of vertical transmission of HIV, syphilis, and Hepatitis B.

Structured in a simplified, user-friendly format grounded in a public health approach, this document provides practical recommendations, standardized treatment regimens, and service delivery algorithms suitable for all levels of care. It is intended for healthcare providers, Programme managers, policymakers, training institutions, and implementing partners involved in HIV, STI, and Viral Hepatitis services.

Effective implementation will require coordinated dissemination, capacity strengthening, sustained commodity security, and continuous quality improvement. It is our expectation that these guidelines will enhance integration, improve health outcomes, and accelerate Kenya's progress toward ending HIV, STIs, and Viral Hepatitis as public health threats by 2030.

Dr. Issak Bashir

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Ministry of Health.

ACKNOWLEDGEMENT

The **Integrated Guidelines for the Treatment and Prevention of HIV, Sexually Transmitted Infections, and Viral Hepatitis (2026)** were revised through an inclusive and consultative process led by the NASCOP HIV Care and Treatment section. This update was built upon the **2022 Kenya HIV Prevention and Treatment Guidelines,** through the collective efforts, expertise and insights of committed individuals from various institutions.

I would like therefore to acknowledge all the institutions, both local and international, as well as government state departments and divisions whose staff devoted long hours, virtually and in person, to the writing, the reviewing and finalization of this document.

I also extend my utmost gratitude to the officers from the Ministry of Health, NASCOP, and partner institutions who provided leadership and coordination throughout the process. Special mention to the secretariat of the Guidelines Review committee for their relentless efforts in ensuring the production of a high-quality, evidence-based document.

The document wouldn't have been complete without the key role of the technical advisors and reviewers who ensured the document is up to date and aligned with other global guidance with the latest scientific evidence. Special thanks go to the consultants for their professionalism, dedication, and valuable technical support throughout this process.

Finally, I acknowledge the development and implementation partners for both financial and technical support provided for the review, printing, and launch of this document.

Dr. Andrew. M. Mulwa

Head, Division of National AIDS & STI Control Program
Ministry of Health

PREAMBLE

The integrated guideline presents a transformative shift in Kenya's health response to the prevention, diagnosis, treatment, and management of HIV, viral hepatitis, and STIs. It is embedded in harmonized protocols, person-centred care, and streamlined service delivery models that align with the WHO 2022–2030 Global Health Sector Strategies (GHSS), which emphasize strategic service integration, universal health coverage (UHC), and the elimination of these diseases as public health threats by 2030.

Integration approach in service delivery of HIV, STI, and viral hepatitis services within the broader primary health care framework enhances access, efficiency, cost-effectiveness, and continuity of care. The goal is to build a resilient and accountable health system that safeguards past gains in HIV epidemic control. Meanwhile, allowing for delivery of efficient, dignified, and stigma-free care for HIV, STIs, and Viral Hepatitis, for all individuals through standard packages of care. Effective integration requires strengthening critical enablers such as responsive leadership and governance, flexible human resources, modernized information systems, stable health financing, and consistent health product supply plans.

To achieve person-centred care, integration must extend beyond the consultation room to include the entire patient journey. This requires seamless coordination in every relevant service delivery point (outpatient departments (OPD), antenatal care (ANC), adolescent-friendly services, harm reduction programs, or chronic care clinics) with the aim of meeting recipients of care where they are with a full package of services that include.

- **Combined screening and testing** for HIV, STIs, and viral hepatitis at all service delivery points
- **Co-located treatment and management services**, enabling clients to access antiretroviral therapy (ART), STI treatment, hepatitis B vaccination or hepatitis C treatment, and care for other comorbidities during a single clinical visit
- **Shared health records and robust follow-up systems**, promoting continuity of care, better case management, and efficient referrals across service areas
- **Integrated health education and counselling**, equipping clients with accurate information on co-infections, comorbidities such as non-communicable diseases (NCDs), transmission risks, and available prevention options
- **Consolidated supply chains, laboratory networks, and monitoring systems**, to enhance efficiency, prevent stock-outs, and ensure sustained availability of diagnostics, medications, nutrition health products and prevention commodities
- **Cross training and skill transferring among healthcare workers**, building multi-skilled teams capable of providing holistic, non-fragmented care to all clients
- **Enabling leadership and governance structures at national and county levels** to oversee, facilitate and promote service delivery through an integrated approach.

It is recommended, therefore, that HIV services be delivered in a chronic care approach that is designed to ensure that patients can access multiple health services during each clinical visit. This can be implemented as a chronic care clinic in the Outpatient department (OPD), within a Chronic Care Centre to manage all chronic illnesses, or in an HIV Comprehensive Care Centre.

This guideline also reinforces Kenya's commitment to the global goal of triple elimination of vertical transmission (VT) of HIV, syphilis, and hepatitis B. Achieving triple elimination requires a fully integrated maternal and child health platform that ensures universal access to antenatal screening, timely treatment, and comprehensive follow-up for all three infections. By embedding HIV, STI, and hepatitis B interventions into routine antenatal and postnatal care, this guideline accelerates Kenya's path toward eliminating vertical transmission, safeguarding maternal and infant health, and fulfilling its UHC and Sustainable Development Goal (SDG) commitments.

In another major shift, this guideline discontinues the use of syndromic management for STIs, which has long been the standard in Kenya, especially in lower-level health facilities. This transition is driven by the limitations of syndromic management, particularly its inability to detect asymptomatic infections and growing concerns over antimicrobial resistance (AMR). Kenya adopts a clinical and etiological diagnostic approach for STI management, emphasizing laboratory-based confirmation of infections to enhance diagnostic accuracy and treatment outcomes. Clinical diagnosis will only be used in facilities without laboratory capabilities until full etiological capacity is realized. This shift aligns Kenya with global best practices and reinforces the commitment to evidence-based, integrated care for all.

This guideline provides standardized, evidence-based tools and protocols to guide healthcare providers, policy makers, program managers, development partners, and community-based organizations across all health system levels. It is also designed to improve service delivery, enhance the client experience, and contribute meaningfully to Kenya's vision for Universal Health Coverage (UHC) and the 2030 goal of ending HIV, viral hepatitis, and STIs as public health threats.

TABLE OF CONTENTS

SECTION 1: HIV PREVENTION, CARE & TREATMENT 1

1.1 HIV Testing Services and Linkage to Treatment and Prevention 1

1.1.1 Facility-Based Testing 1
1.1.2 Community-Based Testing 1
1.1.3 HIV Testing Services (HTS) Strategies 2
1.1.4 Package of HIV Testing Services 4
1.1.5 HIV, Syphilis, and Hepatitis B Testing for Pregnant and Breastfeeding Women 7
1.1.6 Approaches to Improve Linkage to Treatment and Prevention Services 11
1.1.7 Inconclusive HIV status 12

1.2 Post-Exposure Prophylaxis (PEP) 14

1.2.1 Integration of HIV, HBV, and STI Services in PEP Provision 14
1.2.2 Eligibility Criteria for PEP 14
1.2.3 Recommended ARV Regimens for PEP 15
1.2.4 PEP Management and Follow-Up 15
1.2.5 Risk Reduction and Special Considerations in PEP Provision 16
1.2.6 Preventing HIV Exposure 17

1.3 Pre-Exposure Prophylaxis (PrEP) 17

1.3.1 Indication and Contraindication for PrEP, Risk Assessment and Criteria for Eligibility 17
1.3.2 HIV Risk Assessment 18
1.3.3 Criteria for PrEP Eligibility 19
1.3.4 PrEP Comprehensive Service Package 19
1.3.5 PrEP Discontinuation, Restarting and Switching 24

1.4 Initial Evaluation for Care and Treatment of PLHIV 27

1.4.1 Initial Clinical Evaluation and Follow up for PLHIV 27
1.4.2 Initial Laboratory Evaluation of PLHIV 28
1.4.3 Follow-up of PLHIV after ART initiation 30
1.4.4 Clinical and Laboratory Monitoring for PLHIV 33
1.4.5 Differentiated service delivery models 35
1.4.6 Care for older persons (≥ 50 years of age) 36

1.5 Standard Package of Care For PLHIV 39

1.5.1 Package of Care for PLHIV 39
1.5.2 Non-communicable Diseases Screening and Management 43
1.5.3 Mental Health Screening and Management 60
1.5.4 Nutrition Services 72
1.5.5 Prevention of Other Infections 79

1.6 Adherence Preparation, Support and Monitoring 82

1.6.1 Adherence Preparation Before ART Initiation 83
1.6.2 Adherence Support 87
1.6.3 Adherence Monitoring 88
1.6.4 Enhanced Adherence Counselling 95
1.6.5 Undetectable = Untransmittable (U=U) 97
1.6.6 HIV Re-engagement to Care 97

1.7 Antiretroviral Therapy in Infants, Children, Adolescents and Adults 100

1.7.1 Eligibility for ART 100
1.7.2 Timing of ART Initiation 100
1.7.3 Initial ART Regimens for Infants, Children, Adolescents and Adults 101
1.7.4 Monitoring and Changing ART 104
1.7.5 Subsequent ART Regimens in Infants, Children, Adolescents and Adults 115

1.8 Advanced HIV Disease (AHD) and HIV Related Co-Infections 116

1.8.1 Comprehensive Management of Advanced HIV Disease 116
1.8.2 Screening, diagnosis and prevention components of the package of care for children and adolescents with AHD 118

1.8.3 TB/HIV Co-infection 119
1.8.4 Management of Cryptococcal Meningitis (CM) 132

SECTION 2: ELIMINATION OF VERTICAL TRANSMISSION OF HIV, SYPHILIS, AND HEPATITIS B VIRUS 139

2.1 PACKAGE OF SERVICES FOR PREGNANT AND BREASTFEEDING WOMEN 139

2.1.1 HIV Risk Stratification for Women of Reproductive Age 141
2.1.2 Risk Categorization for PBFW Living with HIV 142
2.1.3 Antiretroviral Therapy for HIV-positive Pregnant and Breastfeeding Women 145
2.1.4 Approach to Triple Elimination of Vertical Transmission of HIV, Syphilis & Hepatitis B 145
2.1.5 Postnatal Infant Prophylaxis Dosing for Infants at High and Low Risk of Vertical Transmission of HIV 150
2.1.6 Infant Prophylaxis Dosing: ABC+3TC+DTG 14 week -Regimen for Infants at High Risk of Vertical Transmission of HIV 150
2.1.7 Maternal, Infant, Young Child & Adolescent Nutrition (MIYCAN) in the Context of HIV 151

SECTION 3: MANAGEMENT AND CONTROL OF SEXUALLY TRANSMITTED INFECTIONS . 155

3.1 PREVENTION OF STIS 156

3.2 CONTROL OF STIS 158

3.2.1 Risk Factors for STI's Acquisition and Transmission 158
3.2.2 Screening for STI's 158
3.2.3 Advocacy for Prevention, Management and Control of STIs 160

3.3 MANAGEMENT OF STI 161

3.3.1 Aetiological STI Case Management 161
3.3.2 Clinical STI Case Management 162
3.3.3 Laboratory Diagnostic Tests for STIs 163

3.4 DISEASES CHARACTERIZED BY GENITAL, ANAL, OR PERIANAL ULCERS 163

3.5 DISEASES CHARACTERIZED BY URETHRITIS/VAGINITIS AND CERVICITIS 169

3.5.1 Chlamydia 170
3.5.2 Gonorrhoea 170
3.5.3 Mycoplasma Genitalium 171
3.5.4 Bacterial Vaginosis 171
3.5.5 Trichomoniasis 171
3.5.6 Candidiasis 172
3.5.7 Pelvic Inflammatory Disease (PID) 177
3.5.8 Epididymitis 179
3.5.9 Proctitis, Proctocolitis, and Enteritis 181
3.5.10 Anogenital Warts 181

3.6 ECTOPARASITIC INFECTIONS 183

3.6.1 Pediculosis Pubis 183
3.6.2 Scabies 184

3.7 NEONATAL CONJUNCTIVITIS (OPHTHALMIA NEONATORUM- ON) 184

3.8 DISEASES CHARACTERISED BY OROPHARYNGITIS 185

3.9 DISEASES FOLLOWING SEXUAL ASSAULT 185

SECTION 4: CONTROL AND MANAGEMENT OF VIRAL HEPATITIS 186

4.1 HEPATOTROPIC VIRUSES 186

4.2 ACUTE VIRAL HEPATITIS 187

4.3 CHRONIC VIRAL HEPATITIS 187

4.4 PREVENTION OF VIRAL HEPATITIS 187

4.5 DIAGNOSIS OF VIRAL HEPATITIS 188

4.5.1 Laboratory testing for screening and diagnosis of viral hepatitis 189
4.5.2 Serological Tests 189
4.5.3 Molecular Tests 189
4.6 HEPATITIS B VIRUS (HBV) 190
4.6.1 Epidemiology and Basic Information Hepatitis B Virus (HBV) 190
4.6.2 HBV Transmission and high-risk groups 191
4.6.3 Testing for HBV 192
4.6.4 Diagnosis of HBV 193
4.6.5 Initial Evaluation /Assessment of Treatment Eligibility 194
4.6.6 General Care measures 195
4.6.7 Treatment for persons with Chronic Hepatitis B (CHB) infection 195
4.6.8 Monitoring Treatment for persons with Chronic Hepatitis B (CHB) infection 197
4.6.9 Treatment Duration 197
4.6.10 Retreatment 198
4.6.11 Hepatocellular Carcinoma (HCC)Surveillance 198
4.7 HEPATITIS C VIRUS (HCV) 201
4.7.1 HCV Transmission and high-risk groups 202
4.7.2 Prevention of HCV 202
4.7.3 Diagnosis of HCV 202
4.7.4 Treatment of HCV 203
4.7.5 Drug Interactions in treatment of HCV 205
4.7.6 Monitoring of Hepatitis C Treatment 206
4.7.7 Retreatment Following Treatment failure 206
4.8 HEPATITIS D VIRUS (HDV) 208
4.8.1 Clinical Course, Diagnosis and Management of Hepatitis D Virus (HDV) Infection 208
SECTION 5: SPECIAL POPULATION 209
5.1 KEY AND VULNERABLE POPULATIONS (KVPS) 209
5.2 ADOLESCENTS AND YOUNG PEOPLE (AYP) 213
5.3 PEOPLE IN HUMANITARIAN AND EMERGENCY SETTINGS 215
5.4 PEOPLE WHO INJECT DRUGS (PWID) 216
SECTION 6: MONITORING EVALUATION AND SURVEILLANCE 218
6.1 PURPOSE AND SCOPE 218
6.2 GUIDING PRINCIPLES 218
6.3 DIGITAL HEALTH SYSTEMS AND ELECTRONIC MEDICAL RECORDS 218
6.4 INTEGRATED SURVEILLANCE SYSTEMS 219
6.4.1 Case Surveillance and Mandatory Reporting 219
6.4.2 HIV Incidence Surveillance through Use of Recency Assays 219
6.4.3 HIV Drug Resistance Surveillance 219
6.4.4 STI Surveillance 219
6.4.5 Viral Hepatitis Surveillance 219
6.4.6 Integrated Biological and Behavioural Surveillance 220
6.4.7 Integrated population-based surveys 220
6.4.8 Use of Emergency Operations Centers for Coordinating Public Health Response 220
6.5 UNIFIED MONITORING AND EVALUATION FRAMEWORK 220
6.6 DATA USE AND ACCOUNTABILITY MECHANISM 220
6.7 INSTITUTIONAL ARRANGEMENTS AND CAPACITY BUILDING 220
6.8 RESEARCH AND EVALUATION 221
6.9 MONITORING AND REPORTING 221
6.10 REFERENCE AND RELATED DOCUMENTS 221

ANNEX 1. WHO CLINICAL STAGING OF HIV INFECTION IN INFANTS AND CHILDREN 222
ANNEX 2. WHO CLINICAL STAGING OF HIV INFECTION IN ADOLESCENTS AND ADULTS 223
ANNEX 3: DSD MODELS FOR CHILDREN, ADOLESCENTS, ADULTS AND PREGNANT AND BREASTFEEDING WOMEN 224
ANNEX 4. ROUTINE IMMUNIZATION SCHEDULE IN KENYA 231
ANNEX 5: PAEDIATRIC DISCLOSURE PROCEDURE 233
ANNEX 6. HEADSSS ASSESSMENT TOOL FOR ADOLESCENTS AND YOUNG PERSONS 234
ANNEX 7. ART READINESS ASSESSMENT FORM 235
ANNEX 8. INITIAL, SUBSEQUENT AND CONSTRUCTIVE ART REGIMENS 236
ANNEX 9. MANAGEMENT PROTOCOL FOR PATIENTS SWITCHING TO 3RD LINE ART 237
ANNEX 10A: SIMPLIFIED DOSING OF CHILD-FRIENDLY SOLID & ORAL LIQUID FORMULATIONS FOR ONCE-DAILY DOSING IN INFANTS & CHILDREN > 4 WEEKS OF AGE[1] 239
ANNEX 10B: SIMPLIFIED DOSING OF DARUNAVIR SOLID FORMULATIONS FOR ONCE-DAILY DOSING IN INFANTS & CHILDREN > 4 WEEKS OF AGE 240
ANNEX 11: DOSING OF SOLID AND LIQUID FORMULATIONS FOR TWICE-DAILY DOSING IN INFANTS AND CHILDREN 4 WEEKS OF AGE AND OLDER[1] 241
ANNEX 12: DOSING CHARTS FOR ART (ABC+3TC+DTG) FOR TERM INFANTS (>37WEEKS), 0-4 WEEKS >2KG 242
ANNEX 12B: PAEDIATRIC ABACAVIR-LAMIVUDINE-DOLUTEGRAVIR (PALD) ADMINISTRATION INSTRUCTIONS 243
ANNEX 13: DOSING CHART FOR ART FOR INFANTS <37 WEEKS (PREMATURE INFANTS) 244
ANNEX 14A. TWICE DAILY ADMINISTRATION OF ART LIQUID FORMULATIONS FOR INFANTS LESS THAN 4 WEEKS OF AGE 244
ANNEX 14B: USE OF PROTEASE INHIBITORS IN ADULTS 245
ANNEX 15A: SIMPLIFIED DOSING OF INH AND CTX PROPHYLAXIS FOR INFANTS AND CHILDREN WHO ARE AT LEAST 4 WEEKS OF AGE 246
ANNEX 15B: DOSING CHARTS FOR TB PREVENTATIVE THERAPY USING 3HP (DRUG SENSITIVE TB) AND LEVOFLOXACIN (DRUG RESISTANT TB) 246
ANNEX 16. DOSING FOR RTV SUPER-BOOSTING OF LPV/R FOR CHILDREN RECEIVING RIFAMPICIN-CONTAINING TB TREATMENT* 248
ANNEX 17: INFANT PROPHYLAXIS DOSING CHARTS 249
Annex 17a. Infant prophylaxis with AZT+NVP (6 weeks) and Extended Infant Prophylaxis Using Nevirapine for Term Infants >37 weeks: Low Risk of Vertical Transmission 249
Annex 17b: Triple Prophylaxis Dosing using ABC+3TC+DTG for Term Infants (≥37 weeks Gestation) with birth weight > 2kg, at High Risk of Vertical Transmission 249
Annex 17c: AZT/3TC/NVP Infant Prophylaxis Dosing for Premature Infants <37 weeks Gestation at High Risk of HIV Acquisition 249
ANNEX 18. DANGER SIGNS FOR THE MOTHER AND BABY 250
ANNEX 19. TEN STEPS TO SUCCESSFUL BREASTFEEDING 252
ANNEX 20. DIAGNOSIS AND MANAGEMENT OF MALNUTRITION IN CHILDREN UNDER 5 YEARS 253
ANNEX 21. DIAGNOSIS AND MANAGEMENT OF MALNUTRITION IN OLDER CHILDREN AND ADOLESCENTS (>5-17 YEARS) 254
ANNEX 22. DIAGNOSIS AND MANAGEMENT OF MALNUTRITION FOR ADULTS 255
ANNEX 23. HOUSEHOLD HUNGER SCORE 256

Annex 24. Drug Nutrient Interactions & Management of Side Effects Associated with ARVs and Drugs for Opportunistic Infections 257
Annex 25. Side Effects Associated with TB Drugs and Food Intake Recommendations ... 259
Annex 26. Use of Nucleoside & Nucleotide Reverse Transcriptase Inhibitors in Adults 260
Annex 27. Use of Non-Nucleoside Reverse Transcriptase Inhibitors for Adults 262
Annex 28. Use of Protease Inhibitors in Adults 263
Annex 29. Integrase Strand Transfer Inhibitors - INSTIs 264
Annex 30. Drug-drug Interactions - NNRTIs 265
Annex 31. Drug-Drug Interactions – PIs 268
Annex 32. Drug-Drug Interactions – Integrase Inhibitors 274
Annex 33. Health Facility Assessment to Provide Community ART Distribution 276
Annex 34. Formula for estimation of Creatinine clearance 277
Annex 35. PHQ-9 Depression Screening Tool 278
Annex 36. GAD -7 (Generalized Anxiety Disorder) 279
Annex 37. HIV Screening Eligibility Tool 280
Annex 38. Risk of renal failure by uACR and eGFR (Urine albumin to Creatinine Ratio) 281
Annex 39: Contraceptive Methods for PLHIV Based on WHO 2018 Medical Eligibility Criteria 282
Annex 40. Pre-Conception Counselling Messages and Services for PLHIV 283
Annex 41. Cotrimoxazole preventive therapy 284
Annex 42. Management of Drug-Associated Skin Rash 284
Annex 43. Screening Algorithms for Pulmonary Tuberculosis for children and Adults. 285
Annex 44. Screening and Diagnosis Algorithms for Extrapulmonary Tuberculosis for Adults 286
Annex 45: Pulmonary Tuberculosis Diagnostic Algorithms for Adults 287
Annex 46. Consultation Pathway for Integrated HIV/STI/Hepatitis Virus Prevention and Treatment 288
Annex 47. Transitioning from Adolescent to Adult HIV Services 289
List of Contributors 290
List of Reviewers 292
Guideline review coordination team 293
Consultant 293
Designers 293

LIST OF FIGURES

Figure 1.1: HIV testing services algorithm 6
Figure 1.2: HIV dual testing services algorithm 8
Figure 1.3: Early Infant Diagnosis Algorithm 10
Figure 1.4: Categories of DSD models for different settings 36
Figure 1.5: Management of Hypertension among PLHIV 47
Figure 1.6: Screening and diagnosis of type II diabetes mellitus in PLHIV 50
Figure 1.7: Treatment of PLHIV with Type 2 Diabetes Mellitus 51
Figure 1.8: Algorithm for Screening and Monitoring Chronic Kidney Disease 53
Figure 1.9: Cervical Cancer Screening 58
Figure 1.10: Components of Self-care 61
Figure 1.11: Management of depression 63
Figure 1.12: Generalized Anxiety Disorder Management Protocol 66
Figure 1.13: Management of Post-Traumatic Stress Disorder 68
Figure 1.14: Screening, admission and treatment guide for Severe Acute Malnutrition 75
Figure 1.15: Management of Malnutrition in Adults with HIV 76
Figure 1.16: Choice of route of nutrition administration (Adapted from JPEN 1993; 17 (4): 1SA) 78
Figure 1.17: Adherence preparation, monitoring and support for the first 3 months of ART 83
Figure 1.18: Re-engagement to Care after Missed Appointment 99
Figure 1.19: General Principles for Managing Adverse Drug Reactions 107
Figure 1.20: Managing single drug substitution 108
Figure 1.21: Managing TDF associated renal toxicity 109
Figure 1.22: Viral Load Monitoring and Management of Viremia for Patients on ART 114
Figure 1.23: Simplified algorithm for diagnosis of PULMONARY TB in children aged < 15 years of age 120
Figure 1.24: Simplified algorithm for diagnosis of EXTRA-PULMONARY TB in children aged < 15 years of age 121
Figure 1.25: TB diagnostic algorithm above 15 years 122
Figure 1.26: Use of LF-LAM for Diagnosis of TB among PLHIV 125
Figure 1.27: Routine Screening for Cryptococcal Meningitis for HIV-infected Adults and Adolescents 134
Figure 2.1: Risk stratification and Management for HIV Negative Women in MNCH 142

Figure 2.2: Vertical HIV Transmission risk categorization and package of care for women who are known positive and breastfeeding in MNCH settings 143
Figure 2.3: Enhanced Package of care for infants at high risk of vertical transmission among newly diagnosed pregnant and breastfeeding women in MNCH settings 144
Figure 2.4: Algorithm on using antiviral prophylaxis for preventing vertical transmission and eligibility for antiviral therapy for pregnant adults and adolescents 148
Figure 2.5: Algorithm for management of infants exposed to HBV 149
Figure 2.6: Complementary feeding recommendations for children aged 6-24 months 153
Figure 3.1: Reactivity of serological tests by stage of syphilis & effect of treatment (adopted from WHO) 168
Figure 3.2: Management of patient with anogenital ulcers 169
Figure 3.3: Management of Patients with Urethritis flow chart 174
Figure 3.4: Management of Patients with persistent/ recurrent Urethritis flow chart 175
Figure 3.5: Management of Patients with Vaginitis flow chart 176
Figure 3.6: Management Options for Patients with Vaginitis flow chart 177
Figure 3.7: Examination and management of sexually active woman with lower abdominal pain 179
Figure 3.8: Testicular Pain Management 180
Figure 3.9: Management of warts in women 182
Figure 3.10: Management of warts in men 183
Figure 4.1: Algorithm for Testing, initial assessment, treatment and monitoring of persons with CHB (adopted from WHO) 199
Figure 4.2: Algorithm for diagnosis, treatment and monitoring HCV infection in adults, adolescents and children >3years 207

LIST OF TABLES

Table 1.1 Testing Recommendations for Different Populations 2

Table 1.2 HIV Testing Services Package 5

Table 1.3: Results Interpretation from Dual HIV/syphilis Testing 9

Table 1.4: Presumptive Diagnosis of HIV in children <18 months 11

Table 1.5: Approaches to Improve Linkage to Treatment and Prevention Services 12

Table 1.6: Approach to Inconclusive HIV Status 12

Table 1.7: Approach to clients on ART with Non-Reactive HIV Antibody Test Result 13

Table 1.8: Eligibility Criteria for HIV PEP 14

Table 1.9: Exposures not requiring PEP 15

Table 1.10: Recommended Antiretroviral Regimens for HIV PEP 15

Table 1.11: Summary of PEP Management and Follow-Up 15

Table 1.12: Special Considerations for Risk Reduction Counselling 17

Table 1.13: HIV Risk Screening questions 19

Table 1.14: Comprehensive Package for Initiating and Continuing PrEP 19

Table 1.15: Available PrEP ARV Regimens for HIV Prevention Options and Use Considerations 21

Table 1.16: Integrated Clinical and Laboratory Management for PrEP Clients at Baseline and Follow-Up 22

Table 1.17: Package of service and Follow-Up for PrEP 23

Table 1.18: Contraindication to Starting PrEP and Criteria for PrEP discontinuation 24

Table 1.19: Clinical Guidance for managing missed doses and restarting PrEP 24

Table 1.20: PrEP Switching 25

Table 1.21: Comprehensive Initial Clinical Evaluation for PLHIV: Integrated HIV, STI, HBV, Reproductive and Psychosocial Assessment 27

Table 1.22: Baseline Laboratory Investigations for PLHIV 29

Table 1.23: Recommended Follow-Up During First 6 Months of ART Initiation 31

Table 1.24: Criteria for categorization of PLHIV on ART beyond 6 months 31

Table 1.25: The package of care for PLHIV Based on Clinical & Behavioural Criteria 32

Table 1.26: The Minimum Recommended Schedule for Clinical and Laboratory Monitoring of PLHIV During the Initial and Ongoing Phases of Care 33

Table 1.27: 5Ms package of care for PLHIV older than 50 years 37

Table 1.28: Standard Package of Care for PLHIV: Care Components and Adaptations for Special Groups 39

Table 1.29 Standard package of care for HIV-exposed and HIV-infected infants 42
Table 1.30 Standard package of care for adolescents living with HIV 43
Table 1.31: Lifestyle Modifications to Prevent and Manage Cardiovascular Disease in PLHIV 45
Table 1.32: Hypertension Screening, Diagnosis, and Initial Management for Adult PLHIV 46
Table 1.33: Type 2 Diabetes Mellitus Screening, Diagnosis, and Initial Management for PLHIV 48
Table 1.34: Drug dose adjustment for ARVs in adults with CKD 55
Table 1.35: Breast assessment guide 59
Table 1.36: Common cancer symptoms and signs, per organ system 59
Table 1.37: Components of brief intervention therapy 62
Table 1.38: Diagnosis and management of schizophrenia 64
Table 1.39: Signs and Symptoms of PTSD 67
Table 1.40: CRAFFT Screening Interview for Adolescents 69
Table 1.41: CAGE-AID Screening Questions for Adults 70
Table 1.42: Addiction Support Based on Stages of Change 70
Table 1.43: Preferred Pharmacological Treatment Options for Common Mental Disorders 71
Table 1.44: Counselling and Education on Nutritional needs 73
Table 1.45: Interpretation of BMI Results for Adults 74
Table 1.46: Routine Immunization Schedule in Kenya 79
Table 1.47: Vaccinations in Adolescents and Adults Living with HIV 81
Table 1.48: Key Components of Adherence Preparation 84
Table 1.49: Treatment Preparation and Adherence Counselling Guide 84
Table 1.50: Components of HIV Education 86
Table 1.51: Adherence Support and Retention Interventions 87
Table 1.52: Standardized Adherence Monitoring Strategies 89
Table 1.53: Morisky Medication Adherence Scale (MMAS-4) 90
Table 1.54: Morisky Medication Adherence Scale (MMAS-8) 90
Table 1.55: Adherence Rate Based on Pill Counts 91
Table 1.56: Age-appropriate Involvement of Child/Adolescent in HIV Education and Adherence Counselling 92
Table 1.57: Unique Considerations for Caregivers, Children and Adolescents 93
Table 1.58: Adherence Preparation, Monitoring, and Support Approaches for Key Populations and Special Groups 94
Table 1.59: Components of Enhanced Adherence Counselling Sessions 95

Table 1.60: Special Considerations for Timing of ART Initiation....101
Table 1.61: Initial ART Regimens and Dosing for Infants, Children, Adolescents and Adults....102
Table 1.62: Use of Alternative ARVs in Initial Regimens....103
Table 1.63: pALD Dosing chart....104
Table 1.64: Common Significant Adverse Drug Reactions....105
Table 1.65: Diagnosis and Management of Abacavir Hypersensitivity Reaction (AHR)....109
Table 1.66: ARV, CTX and Fluconazole Adjustments in Renal and Hepatic Impairment....110
Table 1.67: Management of Drug-Related Hepatotoxicity....111
Table 1.68: Management of AZT-Associated Bone Marrow Suppression....111
Table 1.69: Interventions for various levels of viral load for clients on ART....113
Table 1.70: Recommendations for Change to Subsequent ART Regimens excluding TB/HIV co-infection....115
Table 1.71: Possible Constructive ART regimens in Children, Adolescents and Adult....116
Table 1.72: Comprehensive Management of Advanced HIV Disease....117
Table 1.73: Package of care for children and adolescents with AHD....118
Table 1.74: TB/HIV Co-Infection Screening, Diagnosis, Treatment and Prevention....123
Table 1.75: Drug Susceptible TB Treatment Regimen for Children, Adolescents and Adults....126
Table 1.76: Recommended TPT Regimens for PLHIV....127
Table 1.77: Follow-Up for Patients on Tuberculosis Preventive Treatment (TPT)....128
Table 1.78: Adverse Drug Reaction (ADR) Management for Patients on TPT....129
Table 1.79: Grading and Management of DILI....130
Table 1.80: Preferred ART Regimens for TB/HIV Co-infection for Patients Starting Initial ART Regimen....131
Table 1.81: Preferred ART Regimens for Patients who Develop TB while Virally Suppressed on current ART Regimen....131
Table 1.82: Recommended ART Regimens for Patients who Develop TB while Failing Current Regimen....132
Table 1.83: Treatment of Cryptococcal Meningitis....135
Table 1.84: Management of Cryptococcal Meningitis (CM) in Clients on ART and Supportive Care.136
Table 1.85: Simplified chart for CM induction therapy using preferred regimen....137
Table 2.1 Essential Package of Services for Triple Elimination of Vertical Transmission of HIV, Syphilis and Hepatitis B....139
Table 2.2 Summary of recommendations for the use of ART for Pregnant and Breastfeeding Women Living with HIV....145

Table 2.3: Approach to Triple Elimination of Vertical Transmission of HIV, Syphilis, and Hepatitis B 145
Table 2.4: Nevirapine and Zidovudine (Birth to 6 weeks) and Extended Nevirapine Prophylaxis for Infants at Low Risk of Vertical Transmission of HIV, and Infants Continuing Infant Prophylaxis 150
Table 2.5: Infant Prophylaxis Dosing: ABC+3TC+ DTG Regimen for Infants at High Risk of HIV Acquisition 150
Table 2.6: Breast feeding recommendation in other conditions 152
Table 2.7: Interpretation of MUAC Results for Children and Pregnant/Lactating Women 154
Table 2.8: Interpretation of Weight for Height Z-scores for Children 154
Table 3.1: STI-Related Complications 155
Table 3.2: Approaches and Key Interventions for STI Prevention 156
Table 3.3: Risk Factors for STI Acquisition and Transmission 158
Table 3.4: The 5 Ps of Taking a Sexual History 159
Table 3.5: Barriers, Consequences and Solutions to Uptake of STI Screening Services 159
Table 3.6: Advocacy matrix 160
Table 3.7: Package of Care for Clients with STI 162
Table 3.8: Signs, symptoms, Diagnosis and Treatment of Diseases characterized by Genital, Anal, or Perianal ulcers 164
Table 3.9: Clinical Classifications and Treatment regimens for Congenital syphilis 168
Table 3.10: Signs symptoms diagnosis and treatment of urethritis, vaginitis and cervicitis 173
Table 3.11: Signs, symptoms, diagnosis and treatment of PID 178
Table 3.12: Aetiology, Signs & symptoms, Diagnosis and Treatment of Epididymitis 180
Table 3.13: Signs, symptoms, diagnosis and treatment of Proctitis, Proctocolitis and Enteritis 181
Table 3.14: Signs, symptoms, diagnosis and treatment of warts 182
Table 4.1: Summary of key feature of different hepatitis viruses 187
Table 4.2: CVH Prevention Approaches and Key Interventions 188
Table 4.3: Summary of essential Laboratory test for screening and diagnosis of viral hepatitis 189
Table 4.4: Natural History of Hepatitis B Virus Infection, Key features and possible outcomes 190
Table 4.5: HBV Transmission and high-risk groups 191
Table 4.6: HBV Testing and Re-testing Recommendations for Different Populations 192
Table 4.7: HBV Diagnostic Markers of Clinical Importance 194
Table 4.8: Assessment of Treatment eligibility for patients who are HBsAg-positive 195
Table 4.9: Preferred and Alternative First-line Antiviral Regimes 196

Table 4.10: Dosing of Antivirals in Children and Adolescents 196
Table 4.11: Entecavir Oral Solution Dosing in Children ≥12 Years 196
Table 4.12: Managing HBV Patients without Cirrhosis 198
Table 4.13: Definition of HBV Relapse 198
Table 4.14: Selected non-invasive tests to assess liver fibrosis 200
Table 4.15: HCV Transmission and high-risk groups 202
Table 4.16: Recommendations for Hepatitis C screening among adults 203
Table 4.17: Recommended DAA Regimens and Duration for Hepatitis C Treatment for adults, adolescents and children >3 years 204
Table 4.18: Recommended DAA Regimens and Duration for Hepatitis C Treatment for Children 204
Table 4.19: Potentially significant drug interactions of sofosbuvir 205
Table 4.20: Potentially significant drug interactions of daclatasvir 206
Table 4.21: Clinical Course, Diagnosis Course, Diagnosis and Management of Hepatitis D 208
Table 5.1: Key and vulnerable populations in Kenya 209
Table 5.2: Integrated programmatic priorities for KVPs 210
Table 5.3: Interventions for Key and Vulnerable Populations 211
Table 5.4: Comprehensive Packages for HIV Prevention and Treatment among KVPs 212
Table 5.5: Integrated HIV, Viral Hepatitis, and STI Programmatic Priorities, Strategies, and Rationale for Adolescents and Young People 213
Table 5.6: Integrated HIV, Viral Hepatitis, and STI Programmatic Priorities, Strategies, and Rationale for Adolescents Girls and Young Women 214
Table 5.7: People who inject drugs (PWID) 216

ACRONYMS AND ABBREVIATIONS

ACRONYM	DEFINITION	ACRONYM	DEFINITION
3HP	3 months of once-weekly Isoniazid plus Rifapentine (TPT regimen)	LAM	Lipoarabinomannan
ABC	Abacavir	LA-CAB	Long-Acting Cabotegravir
ABR	Auditory Brainstem Response	LEN	Lenacapavir
ACE-I	Angiotensin-Converting Enzyme Inhibitor	LFT	Liver Function Test
ACF	Active Case Finding	LF-LAM	Lateral-Flow Urine Lipoarabinomannan Assay
ADR	Adverse Drug Reaction	LGV	Lymphogranuloma Venereum
AE	Adverse Event	LP	Lumbar Puncture
AFP	Alpha-fetoprotein	LPV/r	Lopinavir/ritonavir
AGYW	Adolescent Girls and Young Women	LTBI	Latent Tuberculosis Infection
AHD	Advanced HIV Disease	MAT	Medication-Assisted Treatment
AHI	Acute HIV Infection	MCH	Maternal and Child Health
AHR	Abacavir Hypersensitivity Reaction	MDR	Multidrug Resistant
AIDS	Acquired Immune Deficiency Syndrome	MDT	Multidisciplinary Team
ALT	Alanine Aminotransferase	MG	Mycoplasma genitalium
ANC	Antenatal Care	MIYCN	Maternal, Infant and Young Child Nutrition
ARB	Angiotensin Receptor Blocker	MMAS	Morisky Medication Adherence Scale
ART	Antiretroviral Therapy	MMD	Multi-Month Dispensing
ARV	Antiretroviral (medicine)	MMSE	Mini-Mental State Examination
AST	Aspartate Aminotransferase	MNCH	Maternal, Newborn and Child Health
ATV	Atazanavir	MPS	Malaria Parasite Smear
AYP	Adolescents and Young People	MR	Measles–Rubella
AZT	Zidovudine	MRI	Magnetic Resonance Imaging
BCG	Bacillus Calmette–Guérin	MSM	Men who have Sex with Men
BD	Twice Daily (bis in die)	MSW	Male Sex Workers
BIA	Bioelectrical Impedance Analysis	MTB	Mycobacterium tuberculosis
BMI	Body Mass Index	MTCT	Mother-to-Child Transmission

ACRONYM	DEFINITION	ACRONYM	DEFINITION
BMS	Breast Milk Substitute	**MUAC**	Mid-Upper Arm Circumference
BP	Blood Pressure	**MUST**	Malnutrition Universal Screening Tool
BSA	Body Surface Area	**NAAT**	Nucleic Acid Amplification Test
CAB	Cabotegravir (long acting)	**NACS**	Nutrition Assessment, Counselling and Support
CBC	Complete Blood Count	**NAFLD**	Non-Alcoholic Fatty Liver Disease
CBE	Clinical Breast Examination	**NAT**	Nucleic Acid Test
CGM	Continuous Glucose Monitoring	**NCD**	Non-Communicable Disease
CHB	Chronic Hepatitis B	**NG**	Neisseria gonorrhoeae
CITC	Client-Initiated Testing and Counselling	**NGU**	Non-Gonococcal Urethritis
CKD	Chronic Kidney Disease	**NHRL**	National HIV Reference Laboratory
CLHIV	Children Living with HIV	**NNRTI**	Non-Nucleoside Reverse Transcriptase Inhibitor
CM	Cryptococcal Meningitis	**NRTI**	Nucleos(t)ide Reverse Transcriptase Inhibitor
CNS	Central Nervous System	**NSP**	Needle and Syringe Programme
COPD	Chronic Obstructive Pulmonary Disease	**NVP**	Nevirapine
COVID-19	Coronavirus Disease 2019	**OI**	Opportunistic Infection
CPT	Cotrimoxazole Preventive Therapy	**OPD**	Outpatient Department
CrAg	Cryptococcal Antigen	**OR**	Odds Ratio
CRP	C-reactive Protein	**OST**	Opioid Substitution Therapy
CSE	Comprehensive Sexuality Education	**OTC**	Over the Counter
CSF	Cerebrospinal Fluid	**OVC**	Orphans and Vulnerable Children
CTX	Cotrimoxazole	**PALD**	Paediatric Abacavir/ Lamivudine/ Dolutegravir (ABC/3TC/DTG)
CVD	Cardiovascular Disease	**PAP**	Papanicolaou (smear)
CXR	Chest X-ray	**PBFW**	Pregnant and Breastfeeding Women
DAA	Direct-Acting Antiviral	**PCP**	Pneumocystis pneumonia

ACRONYM	DEFINITION		DEFINITION
DBS	Dried Blood Spot	PCR	Polymerase Chain Reaction
DCV	Daclatasvir	PCV	Pneumococcal Conjugate Vaccine
DILI	Drug-Induced Liver Injury	PDSA	Plan–Do–Study–Act
DM	Diabetes Mellitus	PEG	Polyethylene Glycol
DNA	Deoxyribonucleic Acid	PEP	Post-Exposure Prophylaxis
DR-TB	Drug-Resistant Tuberculosis	PHDP	Positive Health, Dignity and Prevention
DSD	Differentiated Service Delivery	PHQ-9	Patient Health Questionnaire-9
DTG	Dolutegravir	PI	Protease Inhibitor
EAC	Enhanced Adherence Counselling	PID	Pelvic Inflammatory Disease
ECG	Electrocardiogram	PITC	Provider-Initiated Testing and Counselling
EFV	Efavirenz	PJP	Pneumocystis jirovecii pneumonia
EIA	Enzyme Immunoassay	PLHIV	People Living with HIV
EID	Early Infant Diagnosis	PMTCT	Prevention of Mother-to-Child Transmission
EMR	Electronic Medical Record	PNC	Postnatal Care
EMTCT	Elimination of Mother-to-Child Transmission	PO	By mouth (per oral)
ENT	Ear, Nose and Throat	POC	Point of Care
EPI	Expanded Programme on Immunization	PPE	Personal Protective Equipment
ESR	Erythrocyte Sedimentation Rate	PPV	Positive Predictive Value
ETV	Entecavir	PrEP	Pre-Exposure Prophylaxis
FBC	Full Blood Count	PSA	Prostate-Specific Antigen
FBS	Fasting Blood Sugar	PTSD	Post-Traumatic Stress Disorder
FDA	Food and Drug Administration (US)	PWID	People Who Inject Drugs
FDC	Fixed-Dose Combination	QI	Quality Improvement
FIB-4	Fibrosis-4 Index	QID	Four times a day (quarter in die)
FIT	Faecal Immunochemical Test	RAL	Raltegravir
FP	Family Planning	RBS	Random Blood Sugar
FTC	Emtricitabine	RDT	Rapid Diagnostic Test
GAD	Generalized Anxiety Disorder	RFT	Renal Function Test
GBV	Gender-Based Violence	RH	Reproductive Health

ACRONYM	DEFINITION	ACRONYM	DEFINITION
GDS	Geriatric Depression Scale	**RHZE**	Rifampicin, Isoniazid, Pyrazinamide, Ethambutol
GFR	Glomerular Filtration Rate	**RIF**	Rifampicin
GHSS	Global Health Sector Strategies	**RNA**	Ribonucleic Acid
GI	Gastrointestinal	**ROC**	Recipient of care
GU	Genitourinary	**RPR**	Rapid Plasma Reagin
GUD	Genital Ulcer Disease	**RT**	Reverse Transcriptase
HAV	Hepatitis A Virus	**RTV**	Ritonavir
HBeAg	Hepatitis B e Antigen	**RTWG**	Regional Technical Working Group
HBIG	Hepatitis B Immune Globulin	**SBCC**	Social and Behaviour Change Communication
HBsAg	Hepatitis B Surface Antigen	**SC**	Subcutaneous
HBV	Hepatitis B Virus	**SDG**	Sustainable Development Goal
HCC	Hepatocellular Carcinoma	**SGBV**	Sexual and Gender-Based Violence
HCV	Hepatitis C Virus	**SGOT**	Serum Glutamic-Oxaloacetic Transaminase (AST)
HDL	High-Density Lipoprotein	**SGPT**	Serum Glutamic-Pyruvic Transaminase (ALT)
HDV	Hepatitis D Virus	**SMS**	Short Message Service
HEI	HIV-Exposed Infant	**SNS**	Sympathetic Nervous System / Social Networking Strategy
HEV	Hepatitis E Virus	**SOF**	Sofosbuvir
HIS	Health Information System	**SRH**	Sexual and Reproductive Health
HIV	Human Immunodeficiency Virus	**STAT**	Immediately (urgent)
HIVAN	HIV-Associated Nephropathy	**STI(s)**	Sexually Transmitted Infection(s)
HIVST	HIV Self-Testing	**SVR**	Sustained Virological Response
HPV	Human Papillomavirus	**TAF**	Tenofovir Alafenamide
HR	Human Resources	**TB**	Tuberculosis
HRQoL	Health-Related Quality of Life	**TDF**	Tenofovir Disoproxil Fumarate
HSV	Herpes Simplex Virus	**TDS**	Three times daily *(ter die sumendum)*
HTN	Hypertension	**TFT**	Thyroid Function Test
HTS	HIV Testing Services	**TLD**	Tenofovir, Lamivudine, Dolutegravir

ACRONYM	DEFINITION	ACRONYM	DEFINITION
IADL	Instrumental Activities of Daily Living	TP	Treponema pallidum
ICF	Intensified/Intensive Case Finding (TB)	TPHA	Treponema pallidum Hemagglutination Assay
ICP	Increased Intracranial Pressure	TPT	Tuberculosis Preventive Therapy
ICT	Information and Communications Technology	TV	Trichomonas vaginalis
IEC	Information, Education and Communication	TWG	Technical Working Group
IM	Intramuscular	U=U	Undetectable equals Untransmittable
INH	Isoniazid	UHC	Universal Health Coverage
INSTI	Integrase Strand Transfer Inhibitor	UVL	Undetectable Viral Load
IPC	Infection Prevention and Control	VCT	Voluntary Counselling and Testing
IPV	Intimate Partner Violence	VDRL	Venereal Disease Research Laboratory
IRIS	Immune Reconstitution Inflammatory Syndrome	VH	Viral Hepatitis
IU	International Unit	VIA	Visual Inspection with Acetic Acid
IUD	Intrauterine Device	VILI	Visual Inspection with Lugol's Iodine
IV	Intravenous	VL	Viral Load
KEPI	Kenya Expanded Programme on Immunization	VMMC	Voluntary Medical Male Circumcision
KHIS	Kenya Health Information System	VP	Vulnerable Population
KP	Key Population	WASH	Water, Sanitation and Hygiene
KS	Kaposi's Sarcoma	WHO	World Health Organization
KVP	Key and Vulnerable Population		

SUMMARY OF KEY RECOMMENDATIONS

1. HIV Testing Services (HTS) and Linkage to Treatment and Prevention

- HIV testing is voluntary and guided by the 6Cs: consent, confidentiality, counselling, correct results, connection (linkage) and creating enabling environment.
- Deliver HTS in facility-based and community-based settings using targeted strategies such as Index testing, HIV self–testing, voluntary counselling and testing and social networking
- Utilize Client-initiated testing and counselling (CITC) and Provider- initiated testing and counselling (PITC) approaches
- The service package for HTS includes Pre-test, HIV testing, Post-test, Assess for other conditions and Referral and linkage to appropriate health services
- Use the national serial testing algorithm (three reactive assays) for diagnosis in individuals ≥18 months.
- Follow national EID algorithm for infants <18 months, with same-day linkage for PCR-positive infants
- All pregnant and breastfeeding women with an inconclusive HIV antibody test should receive a DNA PCR test to confirm their HIV status.
- All HIV exposed infants should receive a DNA PCR at birth or first contact within two weeks of birth and subsequently at 6 weeks, 6 months, and 12 months of age.
- Antiretroviral for Post-Exposure Prophylaxis (PEP)
- Provide PEP to HIV negative persons within 72 hours of high-risk exposure.
- Offer PrEP to individuals at ongoing risk of HIV after assessing eligibility.
- Link all clients tested positive for HIV to care and treatment and support.

At initiation & follow up: Clients should be offered an integrated package that consists of counselling, screening for sexual and reproductive (SRH) needs, sexually transmitted infections (STIs), mental health, GBV and HBV (HBsAg and vaccine if non-immune)

2. Initial Evaluation for care, treatment and follow-up of PLHIV

- CD4 testing is indicated in PLHIV: newly diagnosed, confirmed treatment failure, return to care after >3 months interruption, severely ill or hospitalised and when guiding OI prophylaxis discontinuation.
- Screen for Advanced HIV Disease (AHD) defined as CD4 <200 cells/mm^3 (≥5 years) or WHO stage 3 and 4, or any child <5 years, except children who have been on ART for more than 1 year and are virally suppressed
- Routine viral load (VL) monitoring:
  - Age 0 – 24 years: at month 3, then every 6 months
  - Age > 25 years: at month6, then month 12 then annually
  - Pregnant or breastfeeding:

        - if already on ART: At confirmation of pregnancy regardless of when the last VL was done, then 6 monthly until complete cessation of breastfeeding and then transition to the recommended VL monitoring schedule.
        - Newly diagnosed HIV: before initiation of ART then after 3 months then every 6 months until complete cessation of breastfeeding and then transition to the recommended VL monitoring schedule.
    - Before any drug substitutions, if no VL available from the previous 6 months
    - 3 months after any regimen modification, including single-drug substitution

3. Standard Package of Care for PLHIV

Consists of 8 components

i. Antiretroviral Therapy

- All PLHIV are eligible for ART on the same day of HIV diagnosis or as soon as ready (except for patients with cryptococcal meningitis and/or TB meningitis and Tuberculoma), irrespective of CD4 cell count, percentage, or WHO staging

ii. Positive Health, Dignity, and Prevention, GBV/IPV & HIV education and Counselling

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

iii. Screening for and prevention of Specific Opportunistic Infections

- Cotrimoxazole Preventive Therapy (CPT) is only recommended in the following subpopulations, unless they have an allergy to sulfa drugs or develop toxicity from CPT
    - All HIV Exposed Infants
    - Children living with HIV < 15 years of age
    - PLHIV ≥ 15 years of age meeting the following criteria:
        - Living in malaria-endemic zones
        - Presenting with WHO stage 3 or 4 event, or meeting the AHD criteria
        - Suspected treatment failure
        - All Pregnant and Breastfeeding women
- When dapsone (as a substitute for CPT) is being used as PCP prophylaxis, it is only recommended for patients in WHO Stage 4 and/or absolute CD4 count ≤ 200 cells/mm3 (or CD4% ≤ 25% for children ≤ 5 years old), and should be discontinued once a patient achieves viral suppression and a sustained CD4 count of > 200 cell/mm3 (or > 25% for children ≤ 5 years old) for at least 6 months

- All adolescent (10+ years) and adult PLHIV with a baseline CD4 count of ≤ 200 cells/mm3 should be screened for cryptococcal infection using the blood CrAg test
- Baseline chest Xray is recommended to all newly diagnosed PLHIV, follow-up should be done only when clinically indicated.
- All PLHIV who screen negative for TB should be provided with TB preventive therapy.
  - 3HP; children, adolescents and adults excluding those on PI, NNRTI and TAF based ART regimens
  - INH; PBFW, those intolerant to 3HP and those on PI, NNRTI and TAF-based ART regimens

iv. Reproductive Health Services

- All PLHIV should be screened for STI at every clinic visit
- Pregnancy status should be determined for all women of reproductive age at every visit and their contraception needs determined and met
- Cervical cancer screening.
  - Target group; women aged 25–49 years,
  - HPV testing is the primary method for women above 30 years (every five years for HIV-negative and every three years if HIV-positive).

    Where HPV testing is unavailable.
  - Annual Visual Inspection with Acetic Acid (VIA) is acceptable,
  - Pap smear is recommended for women under 30 years or those with a Squamocolumnar junction is not fully visible (Type three transformation)

v. Screening for and Management of Non-Communicable Disease

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

vi. Mental Health Screening and Management

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

vii. Nutrition Services

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

- All infants irrespective of HIV status should be exclusively breastfed for the first 6 months of life, with timely introduction of appropriate complementary foods after 6 months, and continued breastfeeding up to 24 months or beyond

viii. Prevention of Other Infections

- PLHIV (including children) should receive vaccinations as recommended by the National Vaccines and Immunization Program, including HPV for girls
- Children living with HIV should receive catch-up vaccines for missed doses

4. Adherence Preparation, Monitoring and Support

- Adherence preparation begins with quality post-test counselling and treatment literacy.
- Assess readiness and provide structured adherence preparation at ART start; reinforce adherence at each visit.
- All patients should receive messaging on Undetectable=Untransmittable (U=U) for prevention of sexual transmission, durable viral load suppression (2 consecutive viral load results of <200 copies/ml).
- U=U messaging DOES NOT APPLY in other settings such as:
  - Pregnant and breastfeeding women LHIV: Prophylaxis should be provided to HIV exposed infants during the breastfeeding period as per the guidelines regardless of the viral load status. The goal of vertical transmission prevention (VTP) is to ensure ALL women achieve and sustain LDL
  - People who inject drugs (PWIDs)
  - Needle-prick injuries
  - Blood transfusion
- Every service delivery point that is providing ARVs for patients (whether ART, PrEP, or PEP) must have a functional system for identifying patients who miss appointment.
- All recipients of care returning to treatment after interruption should receive a tailored package informed by clinical and psychosocial evaluation. The goal is not only to re-initiate treatment, but to address underlying barriers and support long-term retention.
- Disclosure of HIV status should begin at 6 years and progress incrementally, guided by the child's cognitive skills and emotional maturity, with full disclosure achieved by 12 years, and complemented by ongoing post-disclosure support.
- All patients are at risk of new or worsening barriers to adherence, so monitoring, counselling and support should continue despite viral suppression. Utilize differentiated service delivery (DSD) for clients established on ART, including multi-month dispensing and community refill options.
  - Use case management and enhanced adherence counselling for unsuppressed VL; repeat VL per protocol.

5. Antiretroviral Therapy for Infants, Children, Adolescents, and Adults

- The goal of ART is to suppress viral replication with the aim of reducing the patient's VL to undetectable levels
- DTG-anchored regimens are preferred across all age groups as the initial regimen.
- Use tenofovir alafenamide (TAF) in patients meeting the following criteria;
  - PLHIV new and currently on ART ≥60 years of age,
  - All CALHIV currently on ART achieving a weight of ≥25 kg and transitioning from an ABC based regimen
  - All PLHIV currently on ART with comorbidities (diabetes mellitus, hypertension, risk of osteoporosis and chronic renal failure with a creatinine clearance of >30 ml/min).
- Switch or substitute ARVs for toxicity or confirmed treatment failure, guided by VL and resistance testing where available.
- Initiate ART the same day or within 2 weeks of diagnosis once clinically appropriate; defer only for cryptococcal meningitis or TB meningitis.
- Preferred Initial ART regimen for infants, children, adolescents, and adults
  - Under 37 weeks (pre-term) and <2kg Term newborn: AZT+3TC+NVP
  - Birth to 4 weeks (≥37 weeks, 2kg to 2.9kg): ABC+3TC+pDTG
  - > 4 weeks, 3kgs to 24.9 kg: Paediatric ABC+3TC+DTG (pALD)
  - 25kg and above: TAF+3TC+DTG
  - 15 years and above: TAF/TDF+3TC+DTG
- Treatment failure is suspected when a patient has a VL ≥1000 copies/ml after at least 3 months of using ART. Treatment failure is only confirmed when VL is ≥1000 copies/ml after assessing for and addressing poor adherence or other reasons for high VL and then repeating VL after at least 3 months of excellent adherence to allow for viral re-suppression.
- Persistent low-level viremia (pLLV) is defined as having VL 200 - 999 copies/ml on two consecutive measures. These patients are at increased risk of progression to treatment failure, development of ARV resistant and death, therefore require a similar case management approach as patients with initial VL ≥1000 copies/ml.
- All PLHIV with VL ≥200 copies/ml (unsuppressed): Assess for and address potential adherence barriers, including intensifying adherence support, and repeat VL after 3 months of confirmed excellent adherence
  - If repeat VL is <200 copies/ml (suppressed) then continue routine monitoring
  - If repeat VL is 200 - 999 copies/ml (Low Level Viremia), reassess adherence and other causes of viremia and repeat VL after 3 months of confirmed excellent adherence
- If the repeat VL is ≥1000 copies/ml (suspected treatment failure), consult the Regional Technical working Group (RTWG) for drug-resistance testing (DRT) and management based on the results.

6. Advanced HIV disease

- WHO clinical staging should be done in every clinical visit
- CD4 test should be done for:
  - Newly diagnosed with HIV
  - Those returning to care after three or more months of treatment interruption
  - Those with confirmed treatment failure
  - Severely ill or hospitalized PLHIV
- All PLHIV with AHD should be offered a package of services; rapid ART where appropriate, screening/ diagnosis/ prophylaxis (including vaccination)/ management of OIs including TB, cryptococcal disease, pneumonia, malnutrition, diarrheal disease and severe bacterial infections
- STOP AIDS approach for management of AHD in children and adolescents.
  - Screen for OIs and Nutritional status,
  - Treat OIs and malnutrition
  - Optimize ART
  - Prevent; vaccination, Cotrimoxazole and fluconazole prophylaxis, TB preventive therapy

HIV associated with TB

- All healthcare settings should implement TB infection control recommendations to reduce the risk of transmission of TB.
- A baseline chest x-ray is recommended for all PLHIV (Where digital CXR is available, it is preferable). Follow-up Chest x-ray may be done based on symptoms.
- Symptom-based TB screening using the ICF tool MUST be performed for all PLHIV at every clinic visit.
  - Patients who screen negative should be assessed for and initiated on the appropriate TB preventive therapy (TPT) eligibility.
  - Patients who screen positive (presumptive TB) must complete definitive diagnostics pathways
- Molecular WHO-recommended rapid diagnostic tests (mWRDs) should be used as the initial diagnostic test for TB and rifampicin resistance in all presumptive TB cases
- LF-LAM is used as an adjunct rapid point-of-care diagnostic test for PLHIV (including children living with HIV (CALHIV);
  - AHD
  - With danger signs of severe illness
  - Currently admitted in Hospital
  - With presumptive TB in outpatient settings

- Patients diagnosed with TB/HIV co-infection should start anti-TB treatment:
  - Pulmonary; initiate ART as soon as anti-TB medications are tolerated, preferably within 2 weeks
  - TB meningitis; defer for 4 to 8 weeks
- Patients with TB/HIV already on ART should start anti-TB treatment immediately and continue ART (make any required adjustments to the ART regimen based on known drug-drug interactions and monitoring toxicity)
- Always assess ART failure in patients who develop TB after being on ART for ≥ 6 months

Cryptococcus Meningitis

- All adolescents (10+ years) and adult PLHIV with a baseline CD4 count of ≤ 200 cells/mm3 and all those with symptoms should be screened for cryptococcal infection using the blood CrAg test
- Fluconazole prophylaxis treatment should be provided for 12 weeks to all newly diagnosed PLHIV with a CD4 <200 and a negative blood CrAg.
- Lumbar puncture should be done for ALL with a positive blood CrAg
- Recommended induction regimen for CM: Liposomal amphotericin B Single dose 10 mg/kg +Flucytosine: 100 mg/kg/day divided into 4 doses for 14 days+Fluconazole:1200 mg daily (adults); 12 mg/kg/day (children/adolescents, max 800 mg daily) for 14 days.
- Pre-emptive therapy: should be offered for non-meningeal disease (bCrAg positive and negative CSF).
- Defer initiation of ART until after five weeks of cryptococcal meningitis treatment

7. Triple Elimination of vertical transmission of HIV, Syphilis, and HBV

- Prevention of VT of HIV, Syphilis, and Hepatitis B (Triple elimination) should be offered as part of a comprehensive package of fully integrated, routine maternal and child health interventions.
- At 1st ANC visit, test for HIV, HBsAg, and syphilis; retest as per schedule in pregnancy, at delivery, and during breastfeeding.
- All PBFW testing negative for HIV, STI, and hepatitis B should be provided with prevention services.
- Pregnant and Breastfeeding Women with a positive Hepatitis B Surface Antigen test should receive maternal prophylaxis for prevention of vertical transmission
- All children, regardless of exposure to Hepatitis B, should receive the Hepatitis B Vaccine birth dose within 24 hrs of birth followed by the regular EPI vaccine schedule.
- Infants with confirmed perinatal exposure to Hepatitis B should receive Hepatitis B Immunoglobulin in addition to the Hep B birth dose vaccine.
- The preferred Initial ART regimen for pregnant and breastfeeding women is TDF+3TC+DTG
- Vertical transmission risk assessment for all PBFW living with HIV should be conducted at the first ANC visit, in the third trimester, during labour and delivery, and post-natal. This approach will inform infant prophylaxis options. Package of interventions should be tailored to their risk categorization.

- HIV acquisition risk assessment for HIV-negative pregnant and breastfeeding women should be conducted at each ANC and postnatal visit, and provision of PrEP, including Lenacapavir for eligible PBFW and other combination prevention methods.
- All HIV exposed infants (HEI) should be tested with DNA PCR at birth or at first contact at least within 2 weeks of birth, 6 weeks, 6 months, and 12 months. HIV antibody testing at 18, every 6 months thereafter and 6 weeks after complete cessation of breastfeeding.
- All HEIs should receive infant ARV prophylaxis based on risk categorization:
  - High risk of HIV acquisition: Triple prophylaxis using ABC/3TC/DTG for 14 weeks, and thereafter NVP should be given until 6 weeks after complete cessation of breastfeeding.
  - Low risk of HIV acquisition, prophylaxis using AZT+NVP from birth – 6 weeks of age, then NVP continued until 6 weeks after complete cessation of breastfeeding

8. Sexually Transmitted Infections

- Clinical and Aetiological management of STIs

9. Viral Hepatitis

Hepatitis B Virus

- Chronic Hepatitis B (CHB) is defined by the presence of detectable HBsAg for adults and persistence of HBsAg for six months or more in adolescence and children.
- Age of exposure is a key factor in determining the risk of chronic infection ≥ 90% of infants ≤5% of adult.
- HBsAg test is a baseline test to all newly diagnosed HIV and STI patients and those considering PrEP initiation
- Antiviral therapy is rarely required for Acute HBV infection only Supportive care
- Updated recommended options for treatment eligibility to children and adults with CHB: Severity of liver disease OR HBV DNA>2000 IU/mL AND ALT; OR Coinfections Comorbidities and extrahepatic manifestations
- Tenofovir disoproxil fumarate (TDF) or entecavir (ETV) are recommended as preferred regimens.

Hepatitis C Virus

- **One-time** anti HCV testing is recommended for persons with recognized risk
- Routine /periodic (Annual) anti HCV testing for persons with ongoing risk factors

HIV PREVENTION, CARE & TREATMENT

This section provides comprehensive guidance on HIV Prevention, clinical management of individuals living with HIV across the continuum of care. Effective HIV prevention is essential to reducing new infections and supporting national and global epidemic control goals.

The section also outlines key steps for initial evaluation and follow-up, defines the standard package of care for PLHIV, and emphasizes the importance of adherence preparation, monitoring, and support to ensure long-term treatment success and improved quality of life.

HIV care is delivered alongside other essential services that include screening and linkage to care for hepatitis B and STIs, reproductive health services (e.g., contraception, safer conception, and maternal health), mental health and substance use support, GBV prevention and response. These integrated services ensure a holistic, client-centred approach that addresses both clinical needs and broader health and social vulnerabilities.

1.1 HIV Testing Services and Linkage to Treatment and Prevention

HIV testing is voluntary and guided by the 6Cs: consent, confidentiality, counselling, correct results, connection (linkage) and creating an enabling environment.

HIV Testing Services (HTS) in Kenya are mainly delivered in facility-based and community-based settings, using client-centred strategies to identify individuals unaware of their HIV status and link them to appropriate services. A HIV screening eligibility tool (Annex 37) can be used among the general population. The testing recommendations for Pregnant & breastfeeding women, key and Vulnerable populations should be adhered to (Table 1.1).

1.1.1 Facility-Based Testing

Facility-based HTS prioritizes PBFW, those presenting with signs and symptoms of AHD, individuals at high risk of HIV, including those with Sexually Transmitted Infections (STIs), viral hepatitis, multiple sexual partners, key populations, and those with potential exposure to HIV. Use the HTS eligibility screening tool (located in the HTS Operational Manual) to assess HIV risk and determine testing eligibility. HIV testing is offered with informed consent. Link clients who test HIV-positive to care and initiate ART and link HIV-negative clients to appropriate prevention services. Provide disclosure counselling and offer HIV testing to sexual partners and family members. Integrate HTS across all service delivery points, including maternal and child health (MCH), family planning (FP), tuberculosis (TB) clinics, gender-based violence (GBV) units, inpatient/outpatient departments, and key population programs.

1.1.2 Community-Based Testing

Community-based testing extends HTS access to individuals less likely to visit health facilities. These include children and sexual partners of index clients, key and vulnerable populations,

adolescents, youth, orphans, and vulnerable children. HTS in community settings also supports targeted outreach in workplaces and other non-clinical settings.

1.1.3 HIV Testing Services (HTS) Strategies

The national HTS approaches include several client-centred strategies to identify individuals unaware of their HIV status and link them to HIV care or prevention services.

1. **HIV Self-Testing (HIVST)** allows individuals to collect and test their own sample (oral or blood-based) using Ministry of Health–approved self-test kits. Clients can also be assisted by healthcare providers.

   A reactive result from a self-test must be confirmed through the national testing algorithm.

   HIVST is particularly effective for reaching partners of people living with HIV, partners of pregnant women, individuals with sexually transmitted infections, and hard-to-reach groups such as men, adolescents, key populations, and clients starting or continuing on PrEP.

2. **Safe and Ethical Index Testing** involves offering HIV testing to sexual partners, biological children, and needle-sharing contacts of individuals diagnosed with HIV (the index case).

3. **Voluntary Counselling and Testing (VCT)** provides testing to individuals who present themselves based on perceived risk.

4. **Social Network Strategy (SNS)** enables individuals, whether HIV-positive or at high risk, to refer members of their social, sexual, or injecting networks for testing.

Note: Integrated client-centred HIV testing services in all health services delivery points. Assisted or unassisted HIV self -testing can also be offered. Key recommendation for HTS services for different sub population is as described on Table 1.1.

Table 1.1 Testing Recommendations for Different Populations

Population	Recommendation
Infants born to known HIV-positive mothers	• Birth testing should be conducted at birth or first contact within two weeks for all HEIs and ART initiated immediately if infant is HIV positive (See figure 1.3 EID Algorithm) • Conduct a confirmatory HIV DNA PCR and baseline viral load should be taken at the time of ART initiation, if initial HIV DNA PCR results are positive • Conduct Repeat HIV DNA PCR at 6 weeks, 6 months and 12 months for those with negative birth HIV DNA PCR followed by antibody testing at 18 months and every 6 months during breastfeeding, and at 6 weeks after complete cessation of breastfeeding
Infants and children <18 months whose mother's HIV status is unknown	• Establish HIV exposure status of all infants at birth or first contact. This is done through: – HIV antibody testing for mothers with unknown status or who previously tested negative during antenatal care at the 6-week immunization visit or first contact. If the mother declines to be tested or is not available for testing, then conduct a rapid HIV antibody test for the child to determine exposure (if antibody test is positive this confirms HIV exposure)

Population	Recommendation
	• When HIV exposure is confirmed, conduct a DNA PCR to confirm the infant HIV status and start infant prophylaxis immediately. • All infants with negative initial HIV DNA PCR results should continue infant prophylaxis and be followed up as HEIs. • Conduct a follow up testing with DNA PCR testing at 6weeks, 6 months and 12 months, and antibody testing at 18 months and every 6 months during breastfeeding, and at 6 weeks after complete cessation of breastfeeding
Children aged 18 months to 9 years	• Offered HIV testing to children who are screened and found eligible for an HIV test. • Test biological children of adults living with HIV and newly diagnosed adults as soon as possible to confirm the HIV status.
Adolescents and young people (10–24 years)	• HIV testing services should be offered to adolescent and young people who are screened and found eligible for an HIV test. HIV prevention services should be offered to clients who test negative while those who test positive should be linked to HIV care. • Adolescents aged below 15 years should be tested with the written consent of a parent or guardian and are also required to give assent. • Adolescents who are emancipated minors irrespective of age, can give their own consent. • All adolescents and young people should be counselled on the potential benefits and risks of disclosure of their HIV status and empowered and supported to determine if, when, how and to whom to disclose. • For sexually active adolescents, HIV testing and counselling should be offered to their partners and children where appropriate, and STI screening should be integrated into these services. • All uncircumcised adolescent males who test HIV negative should be counselled about the prevention benefits of Voluntary Medical Male Circumcision (VMMC) and linked to VMMC services if they agree
Pregnant and breastfeeding women	• Test at first ANC visit for HIV, hepatitis B virus, and syphilis. • Retest for both HIV and syphilis in the third trimester for women who test negative for both HIV and syphilis at 1st ANC. • At labour and delivery, all women with unknown status and those previously tested HIV negative, even in the third trimester, will be retested • Breastfeeding women are retested postnatally at 6 weeks, at 6 months and every 6 months until complete cessation of breastfeeding, thereafter, follow specific population retesting guidelines. • Retest all postnatal women considered to be at high risk of HIV infection, every 3 months; these include key populations, HIV negative women in a discordant relationship, woman with new or multiple sexual partners of unknown HIV status or injecting behaviour that places them at risk.

Population	Recommendation
	• All pregnant and breastfeeding women who are not tested, opt out, or decline HIV testing during the first contact should be offered HIV counselling and testing in subsequent visits with appropriate referral and linkage for prevention, care, and support services. • All spouses/partners, as well as children of pregnant and breastfeeding women testing HIV positive, should be offered HIV counselling and testing
Sexual/drug injecting partners and biological children of index clients (HIV positive person who is newly diagnosed, previously diagnosed not in care or already in HIV care and not virally suppressed)	• Test all partners, biological children, and needle-sharing contacts of people newly diagnosed or in care. • Provide linkage to ART treatment or prevention services.
Key and vulnerable populations	• Test at first contact irrespective of reason for visit, through targeted outreach, and testing at KVP service delivery points e.g. DICE. • Retest HIV-negative individuals every 3 months for Key Population and 6 months for vulnerable populations.
HIV-negative partner in discordant couples	• Test at ART initiation of the HIV-positive partner, then retest at 6 and 12 months; annually thereafter if viral suppression is maintained.
Recent high-risk exposure (<1 month)	• Test at initial presentation; re-test after 4 weeks, then follow national testing schedule.
Patients with STI or acute HIV symptoms	• Test at initial presentation; re-test after 4 weeks, then follow national testing schedule.
Individuals on PrEP	• Oral PrEP and Dapivirine vaginal ring (DVR): Test at initiation, 1 month, then every 3 months. • Cabotegravir Long-Acting (CAB-LA): Test at initiation and every 2 months. • Lenacapavir (LEN): Test at initiation and every six months during subsequent injections
Individuals on PEP	• Test at initiation • Repeat test at 28 days and 12 weeks
General population	• Screen for eligibility at every visit and test every 2 years if no new risk exposure and re-test 2 years before their exposure is.

1.1.4 Package of HIV Testing Services

The HTS package comprises key components designed to ensure a comprehensive, client-centered approach to HIV diagnosis and linkage to care or prevention services. Table 1.2 describes the core elements delivered during an HTS session.

Table 1.2 HIV Testing Services Package

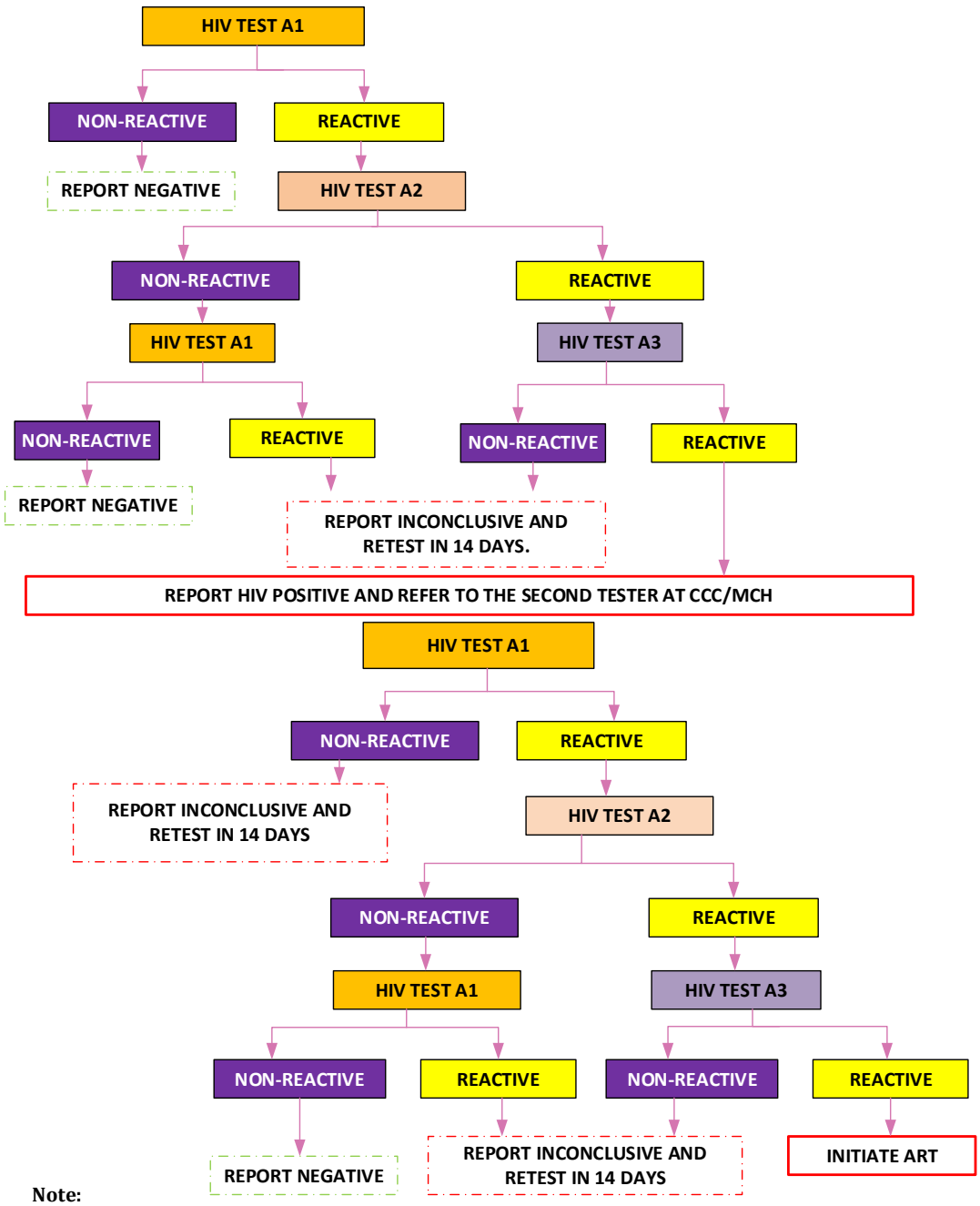
Component	Key Elements
Pre-Test Counselling	• Can be Individual, couple or group-based • Explain the HIV testing process, the importance of knowing one's status, ensure confidentiality, communicate possible outcomes, and communicate the meaning and importance of Undetectable = Untransmittable (U=U) • Assess HIV risk and obtain informed consent • Discuss partner disclosure and the benefits of couple testing and testing of other family members. • Introduce post-test options and services, including prevention services and HIV care and treatment services. • Tailor counselling messages based on client's knowledge of HIV
HIV Testing	• Follow national HTS algorithm • Provide same-day results • During the wait: – Discuss combination prevention; PrEP, PEP, condoms, VMMC, – eMTCT – Screen and provide information for TB, STIs, cancer, IPV/GBV, FP – Take sexual history for index testing • Document in the appropriate register such as HTS, lab, referral, linkage, ANC and Maternity registers, or EMR where applicable • Discuss further on index testing and the role of HIVST for reaching sexual partners as you perform the second and the third test, as per the national algorithm, for the clients who test positive with the screening test
Assessment of Other Conditions	• Screen for STIs and medical conditions and needs. • Refer appropriately
Post-Test Counselling (Test-and-Treat)	• Assess if the client is ready for results and help them to interpret. • Check what the client understands about the results – Allow the client to share his/her initial reactions and verbalize their initial feelings. • Explore and acknowledge clients' immediate feelings and concerns • Offer necessary support – For HIV positive, link to HIV care and treatment services – For HIV Negative, link to prevention services
Referral and Linkage	• Record accurate locator details • Escort or refer for ART, PrEP, or other services • Document outcomes and follow-up for partners

1.1.4.1 HIV Testing for Population Over 18 months

The goal of HIV testing is to:

- Provide an accurate HIV diagnosis.
- Provide same-day HIV test results and appropriate linkage.

The HIV test should be performed according to the National testing algorithm and strategy. **Figure 1.1 illustrates the serial HIV testing algorithm.**



Note:

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

Figure 1.1: HIV testing services algorithm

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

1.1.5 HIV, Syphilis, and Hepatitis B Testing for Pregnant and Breastfeeding Women

Early testing during pregnancy is essential to prevent vertical transmission of HIV, syphilis, and hepatitis B virus. As part of the Triple Elimination initiative, all pregnant women attending ANC should be screened for these three infections at their first visit, with follow-up testing as appropriate.

Recommended Testing Approach:

- At the first ANC visit, offer a dual HIV/Syphilis test and Hepatitis B surface antigen (HBsAg) test to all pregnant women with unknown HIV, syphilis, or hepatitis B status. Once available, the triple test panel can be used to test for the three diseases.
- Repeat HIV/Syphilis testing in the third trimester for women who initially tested negative for HIV and Syphilis.
- Hepatitis B testing is typically conducted once during pregnancy unless repeat testing is clinically indicated (e.g., ongoing risk).
- Offer HIV/Syphilis testing to partners accompanying pregnant women at their first ANC visit.
- If known HIV positive or on ART and Syphilis is unknown, test for syphilis.
- If known Syphilis positive or on treatment, and HIV status is unknown, test for HIV.

Note: Do not use the dual HIV/Syphilis test for:
• Retesting women who are already on ART or have a known HIV-positive status. • Women with a confirmed syphilis diagnosis, already on treatment.

Refer to Figure 1.2 for the algorithm detailing the interpretation of HIV and syphilis test results, as well as the follow-up steps. Hepatitis B testing and management should follow national hepatitis management protocols, including vaccination of exposed infants at birth and linkage of mothers to hepatitis care. Refer to section C of this guideline.

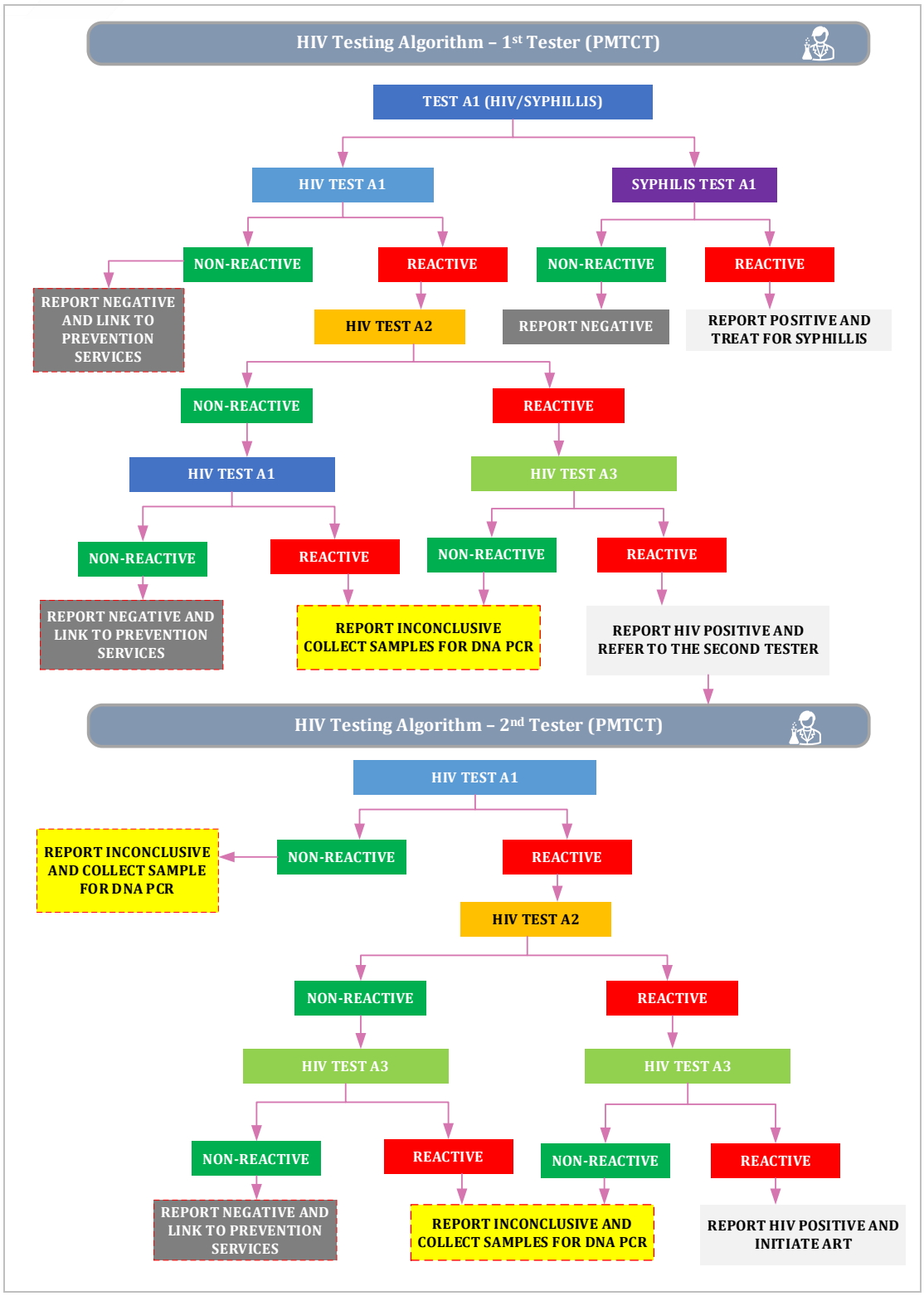


Figure 1.2: HIV dual testing services algorithm

Table 1.3 summarizes the interpretation of results obtained from dual HIV/syphilis testing and outlines appropriate follow-up actions based on different result combinations.

Table 1.3: Results Interpretation from Dual HIV/syphilis Testing

Results	Interpretation
A1 HIV-, Syphilis Test (TP) -	HIV negative, syphilis negative
A1 HIV-, Syphilis Test (TP)+	HIV negative, syphilis positive
A1 HIV+, Syphilis Test (TP)-	Syphilis negative and proceed with A2 for HIV
A1 HIV+, Syphilis Test (TP)+	Syphilis positive and proceed with A2 for HIV
A1 (HIV+); A2+; A3+	HIV-positive
A1(HIV+); A2-; Repeat A1+	HIV-inconclusive (Conduct an HIV DNA PCR to confirm HIV status after 1st inconclusive result.) Start infant prophylaxis following the risk categorization criteria
A1(HIV+); A2-; Repeat A1-	HIV-negative
A1(HIV+); A2+; A3-	HIV- inconclusive (Conduct an HIV DNA PCR to confirm HIV status after 1st inconclusive result.) Start infant prophylaxis following the risk categorization criteria

1.1.5.1 HIV Testing in Infants and Children Under 18 Months

1. Early Infant Diagnosis in Infants and Children (EID)

Figure 1.3 presents the national algorithm for Early Infant Diagnosis (EID) of HIV in infants and children under 18 months.

Algorithm for Early Infant Diagnosis

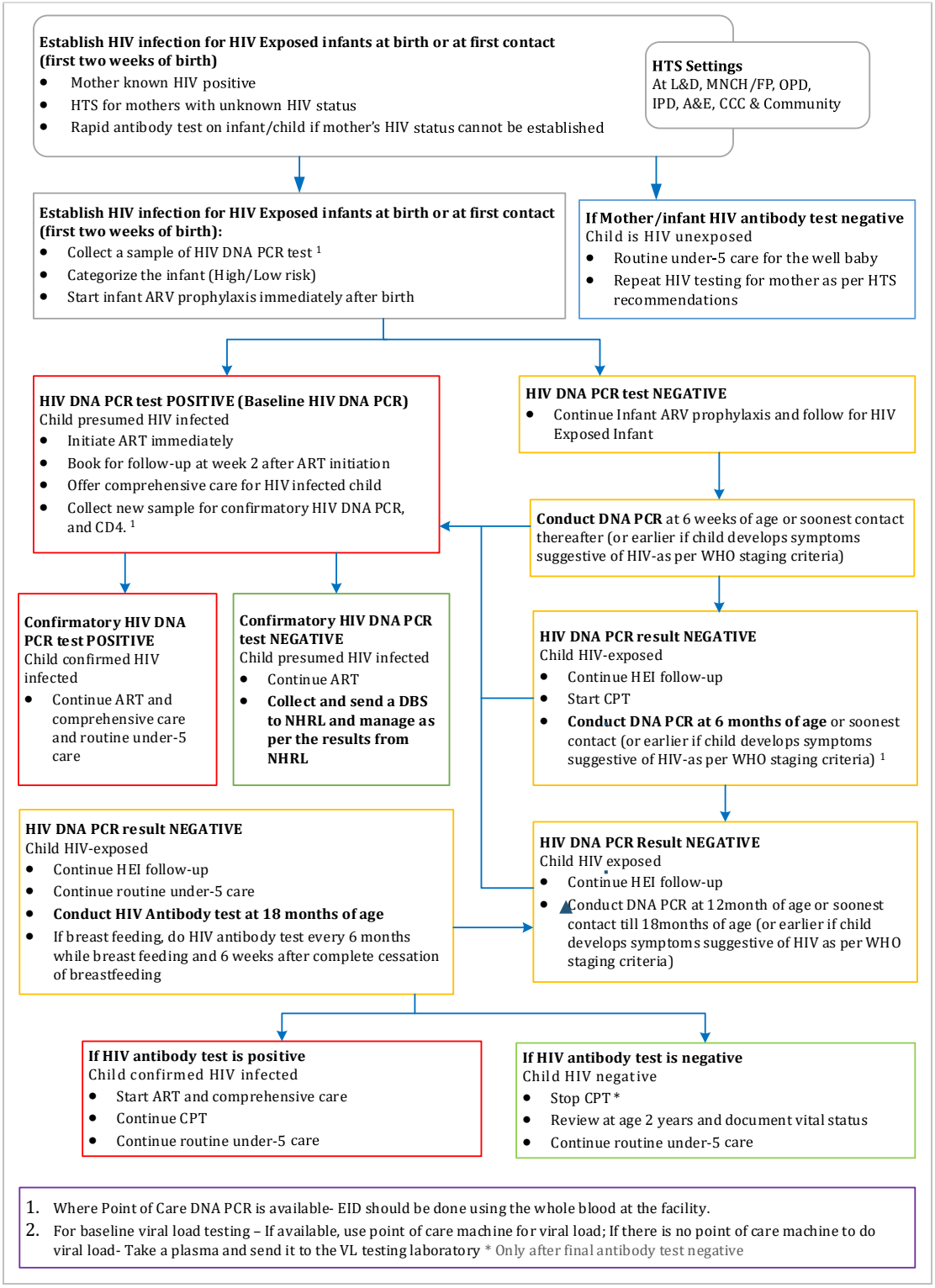


Figure 1.3: Early Infant Diagnosis Algorithm

Point-of-care (POC) testing enables HIV diagnosis by delivering results at the facility where care is provided. This is particularly critical for early infant diagnosis (EID), where delay in result turn-around time can postpone life-saving treatment. POC HIV DNA PCR testing is recommended for infants and young children under 18 months who are HIV-exposed. It can be used for both initial diagnosis and confirmation purposes. By significantly reducing turnaround time, POC testing facilitates immediate ART initiation, improves retention in care, and enhances health outcomes. Whenever feasible, health facilities should prioritize the use of validated point-of-care platforms to accelerate identification and linkage of HIV-infected infants to treatment. Figure 1.3 outlines the HIV testing services algorithm for infants and children.

2. Presumptive HIV Diagnosis in Children <18 Months

In severely ill HIV-exposed infants under 18 months where HIV DNA PCR results are not immediately available, a presumptive diagnosis of HIV infection can be made using clinical criteria. This enables timely initiation of life-saving ART while awaiting confirmation. Table 1.4 describes presumptive diagnosis criteria in Children <18 months while awaiting DNA PCR results.

Table 1.4: Presumptive Diagnosis of HIV in children <18 months

Positive HIV antibody test and symptomatic with 2 or more of the following: ● Oral candidiasis/thrush ● Severe pneumonia ● Severe sepsis
OR
Any of the following: ● Any WHO Clinical Stage 4 condition ● Recent maternal death (if likely to have been HIV-related) or advanced HIV disease in mother ● Child's CD4% < 25%

3. Testing of Hospitalized HIV-Exposed Infants

HIV-exposed infants admitted to the hospital should be retested for HIV, regardless of previous test results. Infants under 18 months should be tested using HIV DNA PCR, while those older than 18 months should receive an HIV antibody test. This is especially important if the child presents with symptoms suggestive of HIV infection. Re-testing should be done even if the timing falls outside the routine testing schedule. If the mother's HIV status is unknown, she should be tested to determine the child's exposure.

1.1.6 Approaches to Improve Linkage to Treatment and Prevention Services

Key actions to strengthen linkage to HIV treatment and prevention services following a positive or negative HIV test result are outlined in table 1.5.

Table 1.5: Approaches to Improve Linkage to Treatment and Prevention Services

Key Area	Action
Information	• Provide clear post-test counselling on available services and next steps • Emphasize early ART initiation and patient involvement in care decisions
Disclosure	• Encourage disclosure to trusted people • Support adolescents to involve peers • For children, initiate age-appropriate disclosure with caregiver support
Barriers to Linkage	• Identify and address barriers during post-test counselling
Systems for Linkage	• Ensure enrolment into care within 14 days of diagnosis • Use escorts, SMS reminders, or community workers to follow up • Offer or refer for HIV prevention to HIV-negative clients
Care Coordination	• Coordinate care for mother–baby pairs and families • Integrate with other services (e.g. TB, FP, nutrition etc)
Linkage Register	• Maintain and update registers • Track linkage monthly and discuss in multidisciplinary team(MDT) meetings

1.1.7 Inconclusive HIV status

An inconclusive HIV test result occurs when a client receives discrepant results across the testing algorithm (e.g., Test 1: Reactive, Test 2: Non-reactive, or Test 1: Reactive, Test 2: Reactive, and Test 3: Non-reactive). This means a definitive HIV diagnosis cannot be made as either positive or negative. Table 1.6 outlines the approach to inconclusive HIV status.

Table 1.6: Approach to Inconclusive HIV Status

Description	Details
When Inconclusive Results Occur	• Cross-reactivity between test kits or client-specific factors may occur. • Testing errors, either from the test kit or the tester. • Seroconversion (window period) occurs early in the stage after infection when antibodies may not be detectable. • The window period refers to the time between HIV exposure and the detection of detectable antibody levels. Different tests may detect antibodies at different stages.
Recommended Actions	• Do not initiate ART or refer for HIV care • Explain clearly to the client: – Not diagnosed as HIV-positive or negative. – Retesting is needed after 14 days. • Schedule follow-up: – Ensure a return visit in 14 days. – Provide reminders or appointment support. • Discuss prevention strategies: – Encourage condom use. – Advice on partner protection. – Consider non-ARV-based intervention

	• For infants of women with inconclusive results – Take a sample from the mother for HIV DNA PCR to confirm status – Start the infant on ARV prophylaxis while waiting for the mother's results – If the mother is confirmed HIV -negative, stop infant ARV prophylaxis; if the mother is confirmed HIV-positive, continue ARV prophylaxis and test the infant as per the EID algorithm
Special Considerations	• Suspected Acute HIV Infection: – Monitor clients with symptoms (fever, sore throat, rash, fatigue). – Emphasize partner protection. • Ongoing High-Risk Clients: – Offer PrEP information. – Encourage return for retesting and explore prevention options.

1.1.7.1 Approach to Clients on ART with a Discrepant HIV Test Result

HIV testing should not be performed on clients already enrolled in HIV care and on ART. However, some clients may self-refer for HIV antibody testing without disclosing their HIV-positive status or ART use before HIV test. Table 1.7 outlines how to manage clients who present with a non-reactive HIV antibody test while on ART.

Table 1.7: Approach to clients on ART with Non-Reactive HIV Antibody Test Result

Clinical scenario	Recommended Action
Clients on ART with a non-reactive HIV antibody test result (Suspect a false-negative result due to ART-induced suppression of antibodies. Do not stop ART instead the following steps are recommended)	Provide counselling- • Explain the potential for suppressed antibody levels due to ART. Reinforce that ART should be continued until status is confirmed.
	Collect confirmatory sample • Draw a sample for HIV DNA PCR testing. Preferably collect whole blood in EDTA and ensure it is transported under cold-chain conditions within 24 hours. DBS may be used as an alternative if EDTA is unavailable.
	• Send sample to National HIV Reference Laboratory (NHRL) • Send to NHRL. Clearly indicate the client is on ART and attach all previous test results (HIV antibody, DNA PCR, viral load).
	If HIV DNA PCR is positive • Confirm HIV-positive status. Provide further counselling and emphasize adherence to ART.
	If HIV DNA PCR is negative • The client may still be HIV-positive with suppressed viral DNA or may be HIV-negative. Stop ART and monitor closely. Repeat viral load testing at 1-, 3- and 6-months post-ART cessation. Confirm HIV-negative status only after conclusive follow-up.

1.2 Post-Exposure Prophylaxis (PEP)

Post-Exposure Prophylaxis (PEP) refers to the short-term use of ART to prevent HIV infection following a recent potential exposure. For optimal efficacy, PEP should be initiated as soon as possible and not later than 72 hours after the exposure event. It is recommended for individuals exposed to HIV through various high-risk scenarios, including:

- Sexual exposure, such as unprotected sex or sexual assault (in both adults and children)
- Occupational exposure, especially among healthcare workers through needle stick injuries or mucosal contact with potentially infectious body fluids
- Non-occupational exposure such as sharing contaminated injection equipment

1.2.1 Integration of HIV, HBV, and STI Services in PEP Provision

In alignment with this integrated guideline, PEP provision must extend beyond HIV prevention alone. All individuals assessed for PEP must concurrently receive screening, prevention, and management for Hepatitis B and STIs, as part of comprehensive post-exposure care. Key integration actions include:

- Hepatitis B screening using HBsAg testing at baseline. Individuals who are HBsAg-negative and unvaccinated should be offered Hepatitis B vaccination without delay, following national immunization schedules.
- STI evaluation should be conducted using either clinical or etiologic approaches based on facility capacity. Prophylactic or presumptive treatment must be provided where clinically indicated, particularly in cases of sexual assault or other high-risk sexual exposures.

1.2.2 Eligibility Criteria for PEP

Eligibility for PEP is based on the type and timing of exposure, and the HIV status of the exposed individual as described in table 1.8.

Table 1.8: Eligibility Criteria for HIV PEP

Criterion	Details
HIV status of exposed individual	Exposed individual is HIV negative however it should not be a prerequisite for PEP initiation
Timing of exposure	Exposure must have occurred within the past 72 hours
Type of exposure	Mucous membrane (e.g. sexual contact, eye/nose/mouth splash), non-intact skin, or percutaneous injury
Type of body fluid	Blood, blood-stained fluids, semen, vaginal secretions, cerebrospinal fluid, amniotic fluid, pleural/pericardial/synovial fluids, or HIV cultures

Exposures Not Requiring PEP

Types of exposures that do not require PEP are described in table 1.9 below.

Table 1.9: Exposures not requiring PEP

Scenario	Rationale
Already known HIV-positive individual	PEP is not indicated in people already diagnosed with HIV
Contact with low-risk fluids (e.g., tears, sweat, urine)	These fluids are not considered significant HIV transmission risks unless visibly blood-stained

1.2.3 Recommended ARV Regimens for PEP

Three-drug antiretroviral regimens are preferred for HIV PEP across all age and weight categories to maximize effectiveness and reduce the risk of resistance. If the third agent (typically a protease inhibitor) is not tolerated, a two-drug regimen may be used temporarily. Table 1.10 describes recommended ARV regimens for HIV PEP.

Table 1.10: Recommended Antiretroviral Regimens for HIV PEP

Age Group	Weight	Preferred Regimen	Alternative Regimen
< 15 years	< 30 kg	ABC + 3TC + DTG	AZT + 3TC + DTG or, ABC + 3TC + LPV/r
	≥ 30 kg	TDF + 3TC or FTC + DTG	TDF + 3TC or FTC + DRV/r or ATV/r
≥ 15 years	Any weight	TDF + 3TC or FTC + DTG	TDF + 3TC or FTC + DRV/r or ATV/r

Note:

- Confirm HIV-negative status before initiating PEP however clients should not be denied PEP in scenarios where RTKs are not readily available
- Evaluate for HBV infection (HBsAg); if negative and unvaccinated, initiate HBV vaccination.
- Screen and treat for STIs, especially in the context of sexual exposure or assault.

1.2.4 PEP Management and Follow-Up

Effective PEP delivery includes timely initiation, clinical assessment, laboratory investigation, counselling, and integration of Hepatitis B and STI services. Table 1.11 outlines recommended PEP management and follow up.

Table 1.11: Summary of PEP Management and Follow-Up

Consideration	Recommendation
Initial Management	• Provide emergency care prioritizing Airway, Breathing, and Circulation (ABC); manage life-threatening conditions as needed. • Counsel on the benefits and risks of PEP and obtain verbal consent for HIV testing. • Offer PEP as soon as high-risk exposure is reported and the exposed individual tests HIV-negative at baseline (if HIV testing not feasible, offer PEP and request to come for HIV test at day 7 during the scheduled follow up
Time of Initiation	• Start as soon as possible, ideally within 72 hours post-exposure.
Duration	• 28 days (dispensing full course at first visit if HIV-negative).

Consideration	Recommendation
Dosing	• Use treatment-dose ARVs; apply weight-based dosing for children.
Baseline Labs	• Test Hb (if AZT), creatinine (if TDF). Do not delay PEP while awaiting results.
Hepatitis B Integration	• Test HBsAg at baseline. If negative and unvaccinated, start HBV vaccination immediately.
Pregnancy Testing	• Offer for women of childbearing age, especially in cases of sexual assault.
STI Integration	• Assess and treat for STIs per national clinical or etiologic guidelines.
Follow-Up	• Follow up at days 7, 14, 28, and 12 weeks. • Monitor for side effects and adherence. • Repeat HIV testing at 28 days and 12 weeks. • Link to HIV care if positive. • Ensure follow-up Hepatitis B vaccination doses are administered if indicated, and review STI treatment response or provide additional management as needed. • For clients at ongoing risk, on completion of PEP transition to PrEP
Counselling	• Provide counselling on; adherence, side effects, risk reduction, trauma, and sexual assault support.
Sexual Assault Care	• Provide STI treatment, emergency contraception, and tetanus toxoid as indicated. • Ensure forensic evidence is collected appropriately. Refer to post-rape care protocols for comprehensive support. • Facilitate reporting to relevant authorities such as police services. • For children and other vulnerable individuals, ensure access to child protection services, psychosocial support, and temporary shelter or safe accommodation as needed.

1.2.5 Risk Reduction and Special Considerations in PEP Provision

Risk reduction counselling is a critical component of PEP provision. It should be incorporated into every consultation to reduce the risk of HIV transmission to others, including sexual partners, children of breastfeeding mothers, and broader community contacts. Key strategies include:

- Consistent and correct use of condoms during sexual activity
- Safe injecting practices to prevent secondary transmission
- Avoiding blood and organ donation until confirmed HIV-negative at 12 weeks post-exposure

Specific guidance for breastfeeding women, children, and adolescents must be considered for risk reduction counselling as outlined in Table 1.12

Table 1.12: Special Considerations for Risk Reduction Counselling

Group	Considerations
Pregnant and breastfeeding women	• Breastfeeding is not a contraindication for PEP. • Discuss risks and benefits of continuing breastfeeding while HIV status is uncertain.
Children	• HIV testing must follow national guidelines • Informed consent must be obtained from a caregiver.
Adolescents	• Testing and PEP should be provided in line with national consent guidance.

1.2.6 Preventing HIV Exposure

To reduce the risk of HIV exposure, the following infection prevention and control (IPC) measures are recommended:

- Use appropriate personal protective equipment (PPE) such as gloves, gowns, and goggles when handling contaminated body fluids.
- Exercise care with sharps, including minimizing blind surgical procedures and ensuring safe handling and disposal.
- Ensure safe disposal of contaminated waste in accordance with IPC protocols.
- Handle soiled linen safely to prevent indirect exposure.
- Implement adequate disinfection procedures for surfaces and equipment.

For individuals not eligible for PEP provide counselling on strategies to limit future exposure risks.

1.3 Pre-Exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis (PrEP) is an effective biomedical HIV prevention intervention that uses antiretroviral (ARV) medication to reduce the risk of HIV acquisition among individuals with an ongoing risk of infection. Implementation of PrEP should be client-centered and delivered as part of comprehensive health services, including sexual and reproductive health care, hepatitis B services, and sexually transmitted infection (STI) prevention and management. To enhance accessibility and uptake, PrEP services should be provided with HCWs trained on PrEP delivery within the following settings:

- Facility-based services: Integrated into existing health service points such as outpatient and inpatient care, Special clinics, maternal and child health (MCH) clinics, contraceptive services, and other routine care platforms.
- Community-based services: Offered in settings that meet minimum requirements to support initiation and continuation of PrEP, including integrated community outreaches, community/private pharmacies, online pharmacies and drop-in centres serving key and vulnerable populations.

1.3.1 Indication and Contraindication for PrEP, Risk Assessment and Criteria for Eligibility

PrEP is indicated for HIV uninfected persons at ongoing risk of HIV acquisition.

Some risk situations that place one at ongoing risk include;

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

Contraindications for PrEP

- Confirmed or suspected acute HIV infection (flu-like symptoms + recent high-risk exposure)
- History of HIV exposure in the last 72hours
- Adolescents under 15 years or weighing <35 kg
- Known or suspected drug allergies to any PrEP products
- Concomitant use of other drugs/medication that are contraindicated with preferred PrEP product
- Renal impairment for oral PrEP & CAB-LA (creatinine clearance <50 ml/min)
- Severe liver disease for CAB-LA
- Inability or unwilling to adhere to PrEP or associated follow-up schedule

1.3.2 HIV Risk Assessment

All individuals accessing health services should be screened for HIV risk and additionally, provided with information on HIV prevention options available including PrEP.

The HIV risk assessment questions are enquiry of behavioural practices that may expose an individual to HIV (Table 1.13).

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

Table 1.13: HIV Risk Screening questions

Screening question refer to the past 6 months & include;
• "Have you had sex with more than one person?"
• "Have you had sex without a condom?"
• "Have you had sex with anyone whose HIV status you do not know?"
• "Are any of your partners at risk of HIV?"
• "Have you had sex with a person who is HIV positive?"
• "Have you received a new diagnosis of a sexually transmitted infection?"
• "Do you desire pregnancy?"
• "Have you used or wanted to use PEP or PrEP before?"
• "Have you injected drugs that were not prescribed by healthcare provider? If yes, did you use syringes, needles or other drug preparation equipment that had already been used by another person?"
• "Have you received money, housing, food or gifts in exchange for sex?"
• "Have you been forced to have sex against your will?"
• "Have you been physically assaulted, including ass2ault by a sexual partner?"
Note: Clients who seek PrEP should be offered if they meet eligibility criteria. Those not eligible should be offered alternative HIV prevention methods.

1.3.3 Criteria for PrEP Eligibility

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

- Confirmed HIV negative status.
- Does not have a current or recent illness consistent with acute HIV infection in combination with history of a preceding high-risk exposure for HIV within the last one month
- No contraindication to use of any of the ARVs recommended for PrEP.
- No history of exposure in the last 72 hours
- Determine if the client is willing to take PrEP as prescribed.

1.3.4 PrEP Comprehensive Service Package

The comprehensive integrated package for initiating and continuing PrEP is as described in table 1.14.

Table 1.14: Comprehensive Package for Initiating and Continuing PrEP

Service Component	Purpose/Assessment Focus	Actions
HIV Testing	Confirm HIV-negative status at baseline and repeat during follow-up visits.	Use national HTS algorithm Assisted HIV self-testing (at initiation) or client self-testing during follow-up can used as an alternative testing strategy for clients on TDF based PrEP and DVR

Service Component	Purpose/Assessment Focus	Actions
		Note: HIVST is not recommended for CAB_LA and Lenacapavir
Willingness to Use PrEP	Client must be willing to adhere to PrEP regimen and follow-up.	Counselling should support informed choice and adherence planning.
Symptom Screening	Exclude acute HIV symptoms, especially after recent exposure.	Refer for confirmatory testing if symptoms suggest acute HIV.
Medical Contraindications	Assess for renal/liver disease before initiating relevant regimens. Assess for medication use that may interact with PrEP method chosen	CAB-LA requires a liver function review; TDF requires a renal function review.
GBV/IPV Screening	Assess for gender-based and intimate partner violence risks.	Link to GBV support services as needed.
Mental Health and Substance Use	Screen for mental illness and substance use that may affect adherence.	Refer for counselling or mental health care as appropriate.
Hepatitis B Screening	Screen using HBsAg testing at baseline.	Provide HBV vaccination for non-immune clients. Do not delay PrEP initiation.
STI Screening and Treatment	Screen all PrEP clients at initial & follow-up visits and treat STIs clinically or etiologically.	Provide presumptive treatment where indicated. Integrate with post-rape care when applicable.
Pregnancy Assessment	Conduct pregnancy testing, assessing intention for PrEP and contraceptive needs.	Do not initiate CAB-LA during pregnancy.
PrEP Education	Provide information on PrEP options, dosing, side effects, missed doses, discontinuation.	Ensure clients understand limitations (does not prevent STIs or pregnancy).
Condom Use and contraceptives	Promote condom use and provide contraceptive options	Counsel on dual protection and pregnancy prevention strategies.
Follow-up Plan	Establish a follow-up schedule and link to additional support as needed.	Maintain continuity through integrated services (e.g., ANC, FP, HIV care). Consider differentiate service models

1.3.4.1 PrEP ARVs Regimen Options

A clear understanding of available PrEP regimen options and their indications, dosing, and special considerations is essential for appropriate and effective service delivery.

Table 1.15: Available PrEP ARV Regimens for HIV Prevention Options and Use Considerations

PrEP Method	Preferred Regimen	Dosing Guidance	Special Considerations
Daily Oral PrEP (TDF/FTC or TDF/3TC)	TDF 300 mg / FTC 200 mg once daily OR TDF 300 mg / 3TC 300 mg once daily OR TAF 25mg / FTC 200mg once daily	Taken daily; with or without food Protection drug levels attained 7days of use	Can be used during conception, pregnancy, and breastfeeding
Event-Driven (ED) PrEP for Men (2-1-1)	TDF/FTC (300/200 mg) OR TDF/3TC (300/300 mg)	2 pills 2–24 hrs before sex, 1 pill 24 hrs and 1 pill 48 hrs after the loading dose Daily dosing if risk is more frequent than 2 times per week and sex cannot be predicted or delayed by 2 hours	Not recommended for those on oestradiol-based hormone therapy
Dapivirine Vaginal Ring (DVR)	25 mg vaginal ring inserted every 28 days	Self/assisted-inserted monthly Protective drug levels attained 24hours after insertion	User-controlled; only protective against vaginal exposure Safe to use during pregnancy but should be removed during labour and re-inserted 6 weeks post-partum
Cabotegravir Long-Acting Injectable (CAB-LA)	600 mg IM every 8 weeks after 2 loading doses	Gluteal or thigh muscle; not initiated in pregnancy/breastfeeding Protective drug levels attained 7days of use	Not for initiation in pregnancy/breastfeeding, but can be continued if pregnancy occurs
Lenacapavir Injectable (LEN)	Initiation: Day 1: 927 mg (3 mL) LEN by SC plus 600 mg LEN orally Day 2: 600 mg LEN orally Then Continuation injections: 927 mg (3 mL) every 26 weeks	2 x 1.5 mL SC injections in separate areas every 26 weeks +/- 2 weeks, from the date of the last injection. Injection sites: abdomen, anterior thigh, or posterior upper arm Protective drug levels attained 2days of use	Safe to use during pregnancy/breastfeeding and patients with severe renal disease

1.3.4.2 *Clinical and Laboratory Management of PrEP Clients During Initiation and Follow-Up*

Integrated clinical and laboratory management for PrEP clients at baseline and follow-up is as described in Table 1.16.

Table 1.16: Integrated Clinical and Laboratory Management for PrEP Clients at Baseline and Follow-Up

Screening/Issue	Clinical Action	Integrated Services	Follow-Up/Notes
HIV-positive at initial evaluation	Do not start PrEP. Provide counselling and link to ART.	Link to HIV care, TB screening, mental health	Document outcome. Counsel on prevention for partners.
HIV-positive after PrEP initiation	Stop PrEP. Confirm diagnosis, collect sample for drug resistance testing. Link to ART.	Psychosocial support, partner testing	Monitor closely; assess for drug resistance
Positive STI screen	Treat per clinical or etiologic approach. Refer where needed.	Partner notification, GBV/IPV screening, mental health support	Rescreen as needed; reinforce prevention.
HBsAg-negative	Start HBV vaccination. Do not delay PrEP	Link to routine immunization	Schedule full HBV vaccine series.
HBsAg-positive	Continuing PrEP (TDF based regimen are preferred. Monitor liver function).	Link to hepatitis care; screen for HIV coinfection	Refer for liver disease management if indicated.
Hepatitis C positive	Continue PrEP. Refer for confirmation and treatment.	Link to hepatitis care, substance use services	Monitor as per national HCV guidelines.
Pregnancy or breastfeeding	PrEP is safe. Continue or initiate.	Offer ANC, Contraception, HIV testing for partner, eMTCT	Reinforce adherence and maternal–child health support.
Flu-like illness after starting PrEP	Test for HIV immediately and repeat after 28 days.	Acute HIV care if positive	If negative, continue PrEP and monitor.
Creatinine clearance < 50 mL/min	Do not initiate TDF-based PrEP. Refer for renal evaluation.	Nutrition and chronic disease support	Recheck after 2 weeks. If normal, restart PrEP.
Side effects (GI, renal)	Mild: reassure. Severe: investigate, treat, switch/stop.	Mental health support, adherence counselling	Switch PrEP method if necessary and available.

1.3.4.3 *Package of service and Follow-Up for PrEP*

Clinical visits should focus on reinforcing adherence, managing side effects, detecting co-infections early, assessing for Intentions to switch between methods, choice counselling and evaluating ongoing risk to ensure safe and effective PrEP use. Table 1.17 consolidates routine follow-up and integrated interventions for PrEP.

Table 1.17: Package of service and Follow-Up for PrEP

	Visit Type		
Service	**Month 1 Visit**	**Clinical Follow up Visit**	**PrEP Refill Visit**
PrEP options and Frequency	Oral PrEP, CAB-LA and DVR 28 days after initiating PrEP	Every Three months for Oral PrEP & DVR, Two monthly for CAB LA and Six Monthly for LEN PrEP)	For PrEP refills mainly for Oral PrEP & DVR for clients who need regular follow-up e.g. month 2,4 5,7

Package of Service	• Adherence assessment and support
	• Screening for side/adverse effects
	• Rule out HIV Infection
	  – HIV testing.
	  – AHI Assessment for imperfect use e.g. Ring user exposed through other routes or oral PrEP user skipped some days.
	• Conduct risk assessments, provide risk-reduction counselling, and review PrEP indications. (offer combination prevention package)
	• Screening, diagnosis and management for other conditions e.g. Hepatitis, STIs, kidney disease (TDF)etc.
	• Client education and counselling (including and/or switching)
	• Prescription & dispensing of PrEP
	• Offer SRH services e.g. Contraceptives and pregnancy testing
	• Referral and linkage as appropriate
		• Adherence assessment and support
		• Screening for side/adverse effects
		• Rule out HIV Infection
		  – HIV testing.
		  – AHI Assessment for imperfect use e.g. Ring user exposed through other routes or oral PrEP user skipped some days.
		• Conduct risk assessment, provide risk-reduction counselling, and review PrEP indications. (offer combination prevention package)
		• Screening, diagnosis and management for other conditions e.g. Hepatitis, STIs, kidney disease (TDF) etc.
		• Client education and counselling (including and/or switching)
		• Prescription & dispensing of PrEP
		• Offer SRH services e.g. Contraceptives and pregnancy testing
		• Referral and linkage as appropriate
			• Risk assessment & risk reduction counselling (Combination prevention package as appropriate)
			• Adherence assessment and support
			• Assess client's willingness to continue/switch PrEP
			• Screening, diagnosis and management for other conditions e.g. Hepatitis, STIs risk of kidney disease (TDF)
			• Refill client's prescription
			• Offer SRH services e.g. Contraceptives and pregnancy testing
			• Referral and linkage as appropriate

1.3.5 PrEP Discontinuation, Restarting and Switching

This section provides guidance on key considerations for discontinuing, restarting and switching PrEP. Table 1.18 outlines contraindication for PrEP initiation and criteria for PrEP discontinuation, Table1.19 describes clinical guidance for PrEP reinitiation and Table 1.20 describes PrEP Switching.

Table 1.18: Contraindication to Starting PrEP and Criteria for PrEP discontinuation

Category	Criteria
Criteria for PrEP discontinuation	• Positive HIV test result during follow-up • Client reports no ongoing HIV risk • Creatinine clearance drops below 50 ml/min • Client requests to stop • Sustained non-adherence to medication or visits

Table 1.19: Clinical Guidance for managing missed doses and restarting PrEP

PrEP Method	Missed doses/ Restart Criteria	Instructions
Daily Oral PrEP	Restart if stopped for >7 days	• HIV test before restarting • If recent (within one month) high-risk exposure: defer and retest after 4 weeks • Recommend condom use during waiting period
	Dosing irregularity: • If a client misses a dose, they should take it as soon as they are able to do so but should not take more than 2 doses in day. • If a client misses multiple doses coinciding with HIV exposure, rule out HIV infection before continuing/ restarting PrEP.	
Event-Driven Oral PrEP	If last use of ED PrEP was >7 days	• Assess if client is due for follow up HIV testing and test where applicable (after a month) • Assess for risk, if recent high-risk exposure while not on PrEP: defer PrEP and retest after 4 weeks • If no high risk starts PrEP with 2-pill loading dose
CAB-LA	If prior injection was initiation injection 1	• If ≤ 8 weeks elapsed since prior injection, resume with Initiation Injection 2 today; schedule a follow up injection in 2 months • If > 8 weeks elapsed since prior injection, **restart** if client meets eligibility criteria • *Note: For restarting give initiation injection 1 and schedule a follow up visit in one month for injection 2*
	If prior injection was initiation 2 or follow up injection	• If ≤ 3 weeks have elapsed since prior injection, **resume** with bimonthly follow up injections

		today; schedule a subsequent follow-up injection in 2 months • If > 12 weeks elapsed since prior injection; **restart** if client meets eligibility criteria • *Note: For restarting give initiation injection 1 and a schedule a follow up visit in one month for injection 2*
Lenacapavir	Restart if >28 weeks since last injection	• HIV testing and full eligibility assessment • Re-initiate the start dose i.e. the Injection and the two oral loading doses
Dapivirine Vaginal Ring	Restart if ring was not in place for more than 7 days	• HIV testing and full eligibility assessment • Restart by inserting a new ring thereafter, continue with new ring every 28 days

Pre-requisites to switching PrEP modalities
• Provide choice counselling and review client's choice. • Consider eligibility and contraindications for the preferred choice. • Test for HIV and review HIV exposure, including coverage of previous and future potential exposures to HIV. • Consider time to effectiveness/lead in period of the desired new method. • Consider guidelines for stopping each method, including waning effectiveness of each PrEP method after discontinuation.

Table 1.20: PrEP Switching

From	To	Instructions
Daily Oral PrEP	ED PrEP	• Advice client to Continue with daily oral PrEP for 2 days from last exposure • Start on ED PrEP as needed
	DVR PrEP	• Advise client to continue dual use for 7 days then stop oral PrEP
	CAB-LA PrEP	• Advise client to continue dual use for 7 days then stop oral PrEP.
	LEN PrEP	• Advise client to continue dual use for 2 days then stop oral PrEP.
ED PrEP	Daily Oral PrEP	• Advise client to start taking oral PrEP once daily going forward
ED PrEP	CAB-LA PrEP	• Start CAB-LA • Advise the client to use oral ED PrEP if a planned sexual exposure is expected within 7 days of initiating CAB-LA • Continue CAB-LA Injections as prescribed.
ED PrEP	LEN PrEP	• Start LEN and stop ED PrEP • Continue LEN Injections as prescribed.
DVR PrEP	Daily Oral PrEP	• Clients continue using potent DVR for 7days after starting TDF based oral PrEP then remove DVR

From	To	Instructions

		• If the DVR is due for removal (after 28days) start oral PrEP and:
		  ○ Counsel client on 7days waiting period
		  ○ Offer condoms

	CAB-LA PrEP	• Clients continue using potent DVR for 7days after starting CAB LA then remove DVR
		• If the DVR is due for removal (after 28days) start oral PrEP and:
		  – Counsel client on 7days waiting period
		  – Offer condoms

	LEN PrEP	• Use dual methods for 2 days then remove the DVR. • Continue with the new method
CAB-LA PrEP	ED PrEP Daily Oral PrEP Ring PrEP LEN PrEP	• If last injection was initiation injection #1, start new PrEP method after 4 weeks of last injection • If last injection was a follow up injection or initiation injection #2 Start new PrEP method 8 weeks after last CAB-LA injection
LEN PrEP	ED PrEP Daily Oral PrEP Ring PrEP CAB-LA PrEP	• Start new PrEP method after 6 months of last LEN-PrEP injection (Regardless of whether it was initiation or continuation injection)
Note: This guidance takes into consideration measures to maximize protection coverage for clients. Notwithstanding, it is important for providers to review the clinical, sexual and product use history of clients, their perceived needs, and specific product properties, when switching or transitioning from one product or strategy to the other. Manage as appropriate for each scenario.		

1.3.5.1 Monitoring Sero-conversion Among PrEP users

PrEP is a highly effective strategy for reducing HIV acquisition, with its protective benefit depending on consistent adherence. Monitoring for sero-conversion during PrEP use is essential to prevent drug resistance

Factors that may lead to HIV seroconversion among PrEP users include:

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

What should be done when a client test HIV positive while on any PrEP method.

- Immediate discontinuation of PrEP
- Counselling of client on positive results
- Collect sample for drug resistance testing (DRT)
- Document seroconversion in client file, and monthly reporting as required.
- Linkage to care and ART (immediate ART initiation).

1.4 Initial Evaluation for Care and Treatment of PLHIV

All individuals newly diagnosed with HIV must undergo a comprehensive initial evaluation to guide timely initiation of ART and ensure holistic, integrated care. This process combines clinical assessment and baseline laboratory investigation to:

- Determine HIV disease stage, comorbidities, and opportunistic infections.
- Identify and address co-existing conditions, including STIs, hepatitis B and C, tuberculosis, and non-communicable diseases.
- Assess reproductive health needs, mental health status, and risk of gender-based violence.
- Inform ART selection, dosing, and supportive interventions.

The initial evaluation must be client-centred, confidential, and culturally sensitive, with linkage to prevention, treatment, and psychosocial services. Baseline laboratory tests should be obtained promptly, and ART initiation must not be delayed if tests are unavailable. An integrated approach ensures early diagnosis and management of co-infections, prevention of onward transmission, and optimization of health outcomes for PLHIV.

1.4.1 Initial Clinical Evaluation and Follow up for PLHIV

The initial clinical evaluation of PLHIV at enrolment is essential for identifying comorbidities, assessing treatment readiness, and tailoring integrated HIV services. This evaluation must include screening for STIs, hepatitis B, reproductive health needs, and GBV in line with the integrated service delivery approach. Table 1.21 outlines the comprehensive initial clinical evaluation for PLHIV.

Table 1.21: Comprehensive Initial Clinical Evaluation for PLHIV: Integrated HIV, STI, HBV, Reproductive and Psychosocial Assessment

History/ Examination Area	Details to Assess
Current and Past Medical History	• Presenting complaints and HIV-related symptoms • Co-existing conditions (TB, cryptococcal meningitis, NCDs) • History of TB and TB contact using ICF tool • Review Mother-Infant Booklet for PBFW and infants • Review immunization status • Medication history: ARVs, PEP, PrEP, Over the counter (OTC) and herbal medicines • Allergies (e.g., sulfa drugs) • Past hospitalizations (review discharge summaries if available), family history, nutritional status
Psychosocial History	• Education, occupation, family structure, caregiving • Mental health screening (Anxiety, depression, grief, trauma) • Substance use (e.g., alcohol, tobacco, khat [miraa], other drugs) • Use CRAFFT (adolescents) or CAGE-AID (adults) • Assess self-stigma, disclosure, support systems • Link to peer support, harm reduction, community services

History/ Examination Area	Details to Assess
	• For children and adolescents, establish if biological parents alive, determine OVC status • Assess for grief and loss for clients who have lost a family member (parent/guardian or sibling/s)
Sexual and Reproductive Health	• STI history and current symptoms • Sexual practices, partner HIV status, disclosure • Contraception use, fertility intentions • Pregnancy status and cervical cancer screening • HPV vaccination, safer conception, dual protection
Gender-Based Violence (GBV) Screening	• Assess for intimate partner or gender-based violence • Offer support, referral to GBV services
Vital Signs and Anthropometry	• Weight, height, MUAC (for children and pregnant women) • Pulse, respiratory rate, temperature, BP, oxygen saturation • Calculate BMI or z-score • Annual bioimpedance (BIA) if available
General Examination	• Screen for pallor, jaundice, oedema, lymphadenopathy, oral lesions, dehydration • Dermatologic signs (herpes zoster, KS, PPE, fungal infections) • Developmental milestones (children)
Systemic Examination	• CNS: Mental status, neuro signs • Abdomen, respiratory, cardiovascular systems • Genital/anal exam: ulcers, discharge, warts, prostate (≥45y) • Speculum and cervical cancer screening (females)
Summary and Classification	• Assign WHO Clinical Stage • List differential diagnoses, plan investigations and referrals • Assess for AHD

1.4.2 Initial Laboratory Evaluation of PLHIV

The comprehensiveness of laboratory tests will depend on presence and or type of suspected concurrent illness. Table 1.22 summarizes the recommended baseline laboratory investigations for all PLHIV. Additional investigations should be based on clinical indication. ART should not be delayed if a laboratory test is not available.

Table 1.22: Baseline Laboratory Investigations for PLHIV

Test	Considerations
HIV Specific Tests	
Confirm and document positive HIV test result	• Positive status should be reconfirmed prior to ART initiation for all patients • Refer to current HIV testing and EID algorithms
CD4 cell count	• For all patients (CD4% for children ≤ 5 years old)
Viral load (HIV-1 RNA)	• All infants after 1st PCR test is positive. Specimen for baseline VL can be drawn at the time of initiating ART; obtaining a VL should not delay ART initiation • Conduct viral load for all known positives on ART at diagnosis of pregnancy, regardless of when previous Viral load was done • All pregnant women newly diagnosed with HIV
Blood Cryptococcal Antigen (bCrAg)	• Reflex testing for blood CrAg if CD4 ≤ 200 cells/mm3 in patients >10 years • If positive, manage as per the cryptococcal meningitis screening algorithm
Other Tests	
Full Blood count (If not available do HB)	• All patients
Pregnancy Test	• Pregnancy status should be determined for all women of reproductive age (based on history of last menstrual period, and if uncertain, irregular, or delayed then a urine pregnancy test should be performed).
LF- LAM	• All PLHIV ≥5 years with CD4 cell count < 200 cells/mm3 or WHO stage 3 and 4 disease) • CLHIV <5 years of age (Unless they have been on ART ≥ 1 year and are clinically stable) • PLHIV with danger signs or severe illness • PLHIV admitted in the Hospital • PLHIV with presumptive TB in outpatient settings
Urinalysis (for protein and glucose)	All patients
Creatinine	All patients initiating ART, Calculate Creatinine Clearance (CrCl)
Syphilis serology (VDRL, TPHA, or RPR)	• All patients with a history of being sexually active
Glucose	• All patients
Plasma lipid profile	• All patients

Test	Considerations
HBsAg	• All adolescent and adult patients (plus children who did not complete routine childhood immunizations). Prioritize pregnant and breastfeeding women and older adults (≥ 50 years).
HCV antibody	• PWID or for patients with history of injection drug use
ALT	• Not recommended as baseline investigation unless there is a specific clinical reason (e.g., patient with history of hepatitis, signs or symptoms of liver disease, or risk of liver disease - alcoholics, HBV or HCV infection, current use of hepatotoxic drugs.)
HPV testing	• For women of reproductive age between 25-49 years conducted at baseline and subsequently every three (3) years (refer to cancer screening guidelines)
Mpox Testing	• For symptomatic individuals

Note:

- It is not possible for ALL facilities providing ART to offer all the laboratory tests recommended for HIV treatment. If a facility does not have on-site capacity to carry out any test, arrangements should be made to transport specimens to a local or regional reference laboratory using sample referral network.
- Baseline Chest X-ray is now recommended for all newly diagnosed PLHIV

1.4.3 Follow-up of PLHIV after ART initiation

Follow-up care is a core component of HIV treatment and an essential determinant of long-term health outcomes. It ensures that PLHIV remain engaged in care, achieve and sustain viral suppression, and receive integrated services that address their broader health needs. Follow-up begins immediately after ART initiation and continues for life. It is designed to:

- Monitor clinical progress, adherence, and treatment response.
- Detect and manage side effects, opportunistic infections, and co-morbid conditions early.
- Reinforce adherence and retention strategies through patient-centred support.
- Provide ongoing prevention, screening, and management for STIs, viral hepatitis, tuberculosis, reproductive health needs, mental health, and gender-based violence.

Follow-Up During the First 6 Months of ART

The first six months after starting ART is a critical period for close monitoring. Patients should be followed up to assess early adherence, manage any side effects or immune reconstitution inflammatory syndrome (IRIS), and provide continuous counselling. Table 1.23 outlines the recommended follow-up schedule and key care components during the first six months after starting ART.

Table 1.23: Recommended Follow-Up During First 6 Months of ART Initiation

Follow-Up Timepoint	Clinical and Supportive Care Activities
Week 2	• Assess early side effects and tolerability of ART • Reinforce adherence counselling • Provide psychosocial support and address stigma or disclosure issues • Screen for symptoms of IRIS
Week 4	• Review ART adherence and resolve early barriers • Screen for opportunistic infections and IRIS • Evaluate mental health and psychosocial well-being • Continue counselling and education
Monthly (Until viral suppression)	• Monitor clinical progress and weight • Ongoing adherence assessment and support • Laboratory monitoring (as clinically indicated) • Provide Reproductive health (RH) counselling, screen for STIs screen for hepatitis B, and GBV • Ensure continuity of care with the same provider/team where possible
At each visit assess weight and conduct complete physical examination. Adjust ART dosing by weight for children.	

Follow-Up for PLHIV Beyond 6 Months of ART

Beyond the initial 6 months of ART, follow-up of PLHIV should be tailored according to clinical stability, treatment adherence, and virologic suppression. Patients are categorized as either established on ART or not established on ART, based on defined clinical and behavioural criteria.

This differentiated approach allows for more efficient service delivery, reducing unnecessary visits for established patients while prioritizing closer monitoring and support for those who are not established or re-engaging in care. Table 1.24 describes categorization criteria for PLHIV on ART for a period beyond six months.

Table 1.24: Criteria for categorization of PLHIV on ART beyond 6 months

Criteria	Established on ART (ALL applicable)	Not Established on ART (ANY applies)
Duration of ART Regimen	≥ 6 months	< 6 months
Active OI in previous 6 months	None	Present
Comorbidities/Chronic Conditions	Well controlled	Poorly controlled
Adherence to scheduled clinic visit and medication in the last 6 months	Adherent	Poor/not adherent
VL within the last 6 months	Suppressed (<200 copies/ml)	Not suppressed (≥200 copies/ml)
Note: Children living with HIV below 5 years of age are established on ART if they have been on treatment for at least 1 year and are virally suppressed.		

Package of care for clients based on clinical and behavioural criteria

The package of care for PLHIV based on categorization is as described in table 1.25

Table 1.25: The package of care for PLHIV Based on Clinical & Behavioural Criteria

	Package of Care	Frequency of Clinic visits	Frequency of ART Refills
Not established	• Standard Package of Care for PLHIV (Refer to section 1.5) • Case management • Clinical Assessment – assess and address factors why ROC is not established on ART • Assessment and provision of package for ROC with AHD (OI screening, diagnosis, and management) • Individual assessment of barriers and motivators - create individualized plan for adherence • Case management • Additional visits as required to address any medical or psychosocial concerns	1 - 3 monthly	1 - 3 monthly
Established	• Standard Package of Care for PLHIV (Refer to section 1.5) • Viral Load and Other routine Investigations (aligned with clinic visits) • Re-assessment of status at Every visit (established vs. not established) • FP: ROCs on injectable contraception should be provided with FP through a fast-tracked process between clinical follow-up visits; oral contraception and condoms should be distributed with ART • Adherence Support • Additional visits as required to address any medical or psychological concerns • Closer follow-up based on ROC preference • Children and adolescents 0-19 should be kept on a 3 monthly clinic visit and MMD model to monitor and support adherence. • Pregnant and breastfeeding women should benefit from multi-month dispensing of ART of up to 3 months while ensuring all the required 8 contacts of ante-natal care visits are adhered to.	6 – 12 monthly	3 - 6 monthly

1.4.4 Clinical and Laboratory Monitoring for PLHIV

Ongoing clinical and laboratory monitoring is essential to ensure the health and treatment success of PLHIV. Routine assessments help detect treatment failure, identify side effects or opportunistic infections, and guide differentiated care approaches. Monitoring also provides an opportunity to integrate other essential health services, including reproductive health, gender-based violence support, and screening for STIs and hepatitis B virus. The frequency and type of monitoring vary depending on the stage of treatment and patient stability. Integration of services at each contact enhances efficiency and patient outcomes. Table 1.26 summarizes the minimum recommended schedule for clinical and laboratory monitoring of PLHIV during the initial and ongoing phases of care. This is a summary of the minimum routine follow-up schedule for PLHIV. Additional appointments, clinical or laboratory evaluation may be performed when indicated.

Table 1.26: The Minimum Recommended Schedule for Clinical and Laboratory Monitoring of PLHIV During the Initial and Ongoing Phases of Care

	Initial Visit	ART preparation	Weeks (after ART)		Months (after ART Initiation)					≥ 6 months
Appointment[1, 2]		Every week[3]	2	4	2	3	4	5	6	Every 1-12 months depending on stability
History and physical exam[4]	✓	✓	✓	✓	✓	✓	✓	✓	✓	At each clinical visit
Adherence assessment and support[5]	✓	✓	✓	✓	✓	✓	✓	✓	✓	At each visit
TB Screening	✓	Every visit, using ICF screening tool								
CD4 count	✓	• Baseline, and then only if patient develops treatment failure (to assess risk of OIs), or if defaults from care (off ART) for at least 3 months • For patients on prophylaxis using dapsone (documented CTX allergy) or maintenance treatment for CM with fluconazole, repeat CD4 every 6 months until CD4 >200 cells/mm3 for two consecutive measures 6 months apart and VL undetectable, after which prophylaxis and CD4 monitoring can be discontinued.								
HIV Viral Load		• For PCR positive HEIs: baseline at the time of ART initiation, at month 3 then every 6 months. • Age 0-24 years: at month 3, then every 6 months • Age ≥ 25 years: at month 3, then month 12, then annually thereafter if suppressed • For all: before any drug substitution for patients on ART for at least 6 months with no valid VL, at month 3 after regimen modification, and then as per population group • Any patient with a detectable VL during routine monitoring, follow viral load monitoring algorithm (Figure 2.19)								

	Initial Visit	ART preparation	Weeks (after ART)	Months (after ART Initiation)	≥ 6 months
HIV Viral Load (pregnant/ breastfeeding)		• Baseline viral load. – Known positive on ART at diagnosis of pregnancy – Known Positive not on ART – Newly diagnosed HIV pregnant and breastfeeding women • For known positive on ART, follow-up viral load will be conducted 6-monthly, after baseline VL, until complete cessation of breastfeeding. • For newly diagnosed PBFW and known positives newly initiated on ART, conduct VL 3 months post ART initiation after baseline VL, then every 6 months until complete cessation of breastfeeding.			
bCrAg	✓	• Baseline for adults and adolescents with CD4 ≤ 200 cells/mm3 (as reflex testing by laboratory), then only if there is clinical suspicion of CM (recommended for ≥10 years)			
Hb	✓	• Baseline, then symptom directed; if on AZT, baseline then weeks 2, 4, and 12			
Pregnancy Status	✓	• At every visit for women of reproductive age (by history +/- urine pregnancy test)			
Urinalysis (protein & glucose)	✓	• Baseline, then annually			
Creatinine	✓	• Baseline, then annually			
Glucose	✓	• Baseline, then annually			
Plasma lipid profile	✓	• Baseline, then annually			
HBsAg	✓	• Baseline, followed by immunization for all patients who screen negative (after viral suppression is confirmed)			
Syphilis serology (VDRL, TPHA, or RPR)	✓	• Baseline, then annually for those at risk and as part of routine ANC profile			
Drug Resistance Testing		• DRT recommended once treatment failure confirmed on a DTG- or PI-based ART Regimen following review and approval by the Regional TWG.			
ALT		• Not recommended for routine baseline or follow-up unless specific clinical indication			
Cervical Cancer	✓	• Screen all women living with HIV for cervical cancer at baseline and according to national guidelines. Integrate cervical cancer screening (via HPV testing, VIA/VILI, or Pap smear) into routine HIV care, especially for women aged 30 years and older. Provide follow-up, treatment, and linkage to services for positive cases. Coordinate with reproductive health services to support integrated care.			

	Initial Visit	ART preparation	Weeks (after ART)	Months (after ART Initiation)	≥ 6 months
STIs	✓	• Screen and treat all PLHIV for STIs at baseline and during follow-up visits if symptomatic or at increased risk. Integrate STI management into routine HIV care.			
Hepatitis B	✓	• Screen all PLHIV for hepatitis B at baseline. Vaccinate those who are negative. Link patients with chronic hepatitis B to appropriate care and monitor if co-infected.			
HCV		• Baseline for PWIDs or with a history of injection drug use			

NOTES:
Recommended investigation should not delay ART initiation.
[1] Patients should be encouraged to return to the HIV clinic for an unscheduled appointment whenever an acute issue arises, instead of seeking care at another facility. Early, after initiation of ART, **and after any regimen modification**, every appointment should include: – Continued adherence counselling and support (started at the initial visit) – Assessment of adherence and correct storage of medication – Assessment for and management of, and patient counselling on side effects of the drugs
[2]Patients who are adherent and virally suppressed at month 3, may not need subsequent monthly appointments until month 6.
[3]All PLHIV qualify for ART and should be initiated as soon as possible including same day if not, and within 2 weeks. For patients who do not start ART on the same day as enrolment into HIV care, should be followed up every week until ART initiation to address whatever issues are delaying ART initiation, for ongoing management of acute medical issues and for treatment preparation and ART readiness assessment.
[4] Children and adolescents, weight and height should be measured and recorded at every visit, with weight-based dosing of ARVs confirmed at every visit. In adults, weight and height should be measured at the initial visit to determine nutritional status and calculate the BMI, and thereafter, weight should be measured at every visit.
[5]The first 2-4 visits are critical for assessing and supporting adherence to ART, managing adverse drug reactions, and treating any acute illnesses including IRIS. Adherence should be assessed at every contact with the clinic.

1.4.5 Differentiated service delivery models

Differentiated Service Delivery (DSD) for HIV Care can be broadly classified as follows:

- **More-intensive service delivery models**; These are facility-based DSD models preferred for people who are not established on ART, who need close follow-up.
- **Less-intensive service delivery models**; These are either facility or community-based models preferred for recipients of care who are established on ART (includes children, adolescents, adults, pregnant and breastfeeding women). These models typically emphasize education and empowerment of recipients of care, streamlined services, and less frequent visits to health facilities.

Differentiated service delivery models for HIV services are as shown in figure 1.4

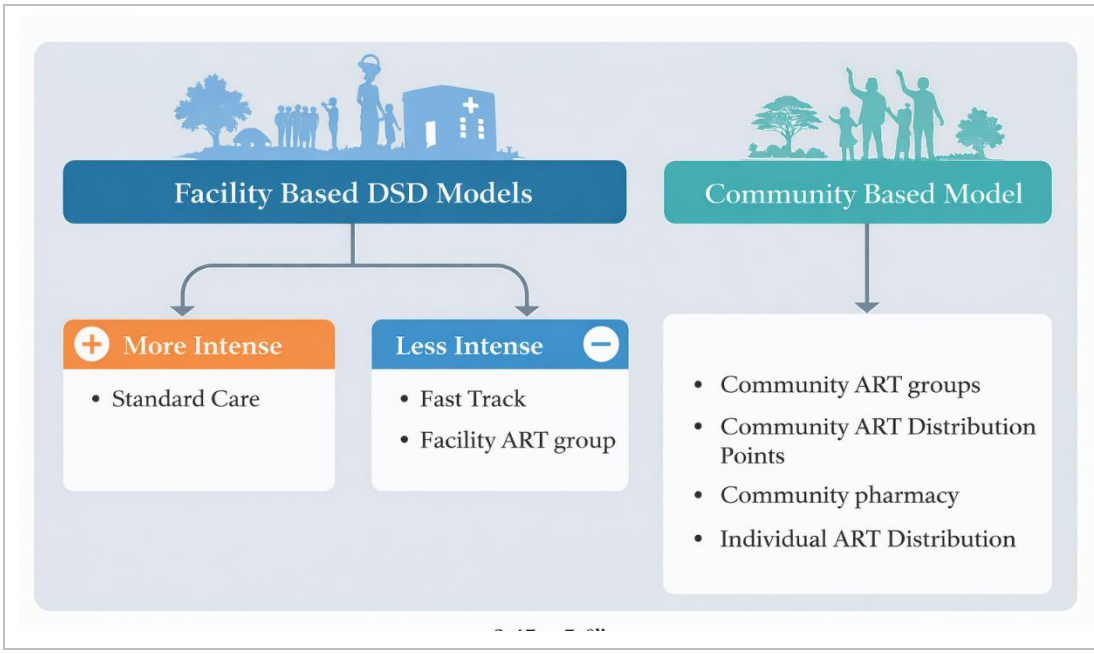


Figure 1.4: Categories of DSD models for different settings

Refer to Annex 3 which describes the DSD considerations for the various sub populations.

1.4.6 Care for older persons (≥ 50 years of age)

The population of older PLHIV may face a range of issues that affect their need for and experience with medicines, including comorbidities, drug interactions, adverse drug reactions, adherence challenges, stigma, medication burden, treatment burden, health-related quality of life (HRQOL), and relationships with healthcare providers.

Differentiated service delivery (DSD) for older People Living with HIV (PLHIV) >50 years is increasingly important as this population grows and presents with these unique clinical and social needs. DSD models for this group should be adapted to account for specific needs of these populations.

Healthcare workers should therefore provide a minimum package of care which covers the highlighted areas as shown in Table 1.27.

Table 1.27: 5Ms package of care for PLHIV older than 50 years

5Ms Domain	Condition	Screening tool	Diagnostic tools	Frequency	Interventions or Care needed
Mind	Cognitive decline / Dementia	Memory (recent and remote recall) Orientation (time, place, person) Attention (Concentration)	Neuroimaging (CT/MRI), lab tests to rule out reversible causes. Mini-Mental State Examination (MMSE), Montreal Cognitive Assessment (MoCA) where available.	Annually	Memory care, referral to specialist, caregiver support
	Depression / Anxiety	Geriatric Depression Scale 15-item (GDS-15), Patient Health Questionnaire 9-item (PHQ-9), Generalized Anxiety Disorder assessment	Clinical psychiatric evaluation	Annually	Counselling, psychosocial support, antidepressants if indicated
	Delirium	Confusion Assessment Method (CAM)	Laboratory tests (electrolytes, CBC, renal and liver function), imaging if indicated	Every hospitalization / acute illness	Identify and treat underlying cause, safe environment
Mobility	Falls risk	Timed Up and Go Test	Gait and balance assessment, bone density scan if fracture risk	Annually	Fall prevention, physiotherapy, provision of walking aids
	Vision	Snellen Chart / Visual Acuity Test	Ophthalmologic examination, fundoscopy, slit lamp	Every 1–2 years	Glasses, cataract surgery referral
	Hearing	Pure Tone Audiometry, Finger rub	Tympanometry, auditory brainstem response (ABR)	Every 1–2 years	Hearing aids, referral to ENT specialist
	Functional status	Activities of Daily Living (ADL), Instrumental Activities of Daily Living (IADL) checklist	Functional performance tests, occupational therapy assessment	Annually	Rehabilitation, caregiver training, mobility support

5Ms Domain	Condition	Screening tool	Diagnostic tools	Frequency	Interventions or Care needed
Medications	Polypharmacy / Medication safety	Pharmacist-led medication reconciliation	Comprehensive medication review using Beers Criteria lab monitoring for drug toxicity where available.	Every 6–12 months	Deprescribing unnecessary drugs, dose adjustment, monitoring drug interactions
	Medication adherence	Pill count, Patient self-report	Therapeutic drug monitoring if indicated	Every visit	Counselling, pill organizers, caregiver support
Morbidities	Hypertension	Blood pressure measurement	Ambulatory blood pressure monitoring, ECG	Every visit	Lifestyle modification, antihypertensives as per guideline
	Diabetes	Fasting Blood Glucose, Glycated Haemoglobin (HbA1c)	Oral glucose tolerance test, continuous glucose monitoring (CGM)	Annually (HbA1c every 6 months if diabetic)	Diet counselling, oral hypoglycaemic/ insulin, foot care education
	Cardiovascular Disease	Lipid profile (total cholesterol, LDL, HDL, triglycerides), Electrocardiogram (ECG)	Echocardiography, stress test, coronary imaging (CT/MRI)	Lipid profile every 5 years (more frequently if high risk); ECG as indicated	Statins, aspirin if indicated, referral for complications
	Respiratory Disease (Asthma, COPD)	Peak Expiratory Flow Rate, Symptom assessment	Spirometry, chest X-ray, arterial blood gas (if severe)	Annually	Inhalers, pulmonary rehabilitation, smoking cessation counselling
	Cancer Screening	Pap smear, Mammogram, Faecal Occult Blood Test, Colonoscopy, Prostate Specific Antigen (PSA)	Biopsy, imaging (CT/MRI/PET) for diagnosis confirmation	As per national guideline	Early detection, referral, treatment
	Oral Health	Comprehensive dental / oral examination	Dental X-rays, periodontal assessment	Annually	Oral hygiene education, dental treatment
Matters Most	Care goals / Preferences	Structured patient and	NA	Annually	Shared decision-making, document

5Ms Domain	Condition	Screening tool	Diagnostic tools	Frequency	Interventions or Care needed
		caregiver interview			advance care planning
	Palliative / End-of-life care	Pain and symptom assessment	Symptom scales, lab tests for organ function if indicated	As needed (progressive or terminal illness)	Pain management, palliative care support, caregiver counselling
	Lifestyle and Health Education	Risk behaviour assessment (smoking, alcohol use, physical inactivity, social engagement)	N/A	Annually	Counselling on healthy lifestyle, community support, peer engagement

1.5 Standard Package of Care For PLHIV

1.5.1 Package of Care for PLHIV

All people living with HIV (PLHIV) should receive a standard package of client- and family-centred services that sustains viral suppression, prevents morbidity and mortality, and integrates sexual and reproductive health, STI and viral hepatitis services, TB prevention and care, mental health, and protection from GBV/IPV. Table 1.28 summarizes care components for all PLHIV and key adaptations for priority and special groups (children, adolescents, pregnant and breastfeeding women, key populations, older PLHIV ≥50 years, and those with advanced HIV disease).

Table 1.28: Standard Package of Care for PLHIV: Care Components and Adaptations for Special Groups

Component	Care Package (All PLHIV)	Adaptations for Special Groups (Children; Adolescents; Pregnant/Breastfeeding; Key Populations incl. FSW/MSM/TG/PWID; Older >50yrs; Advanced HIV Disease)
Antiretroviral Therapy	• Initiate ART for all regardless of WHO stage; aim for same-day/within 14 days. • Adherence preparation and ongoing support; viral load-driven monitoring. • Offer differentiated service delivery (DSD) once established; MMD and convenient refills.	• Children: weight-based dosing; synchronize caregiver–child visits. • Adolescents/youth-friendly counselling; transition planning to adult care. • Pregnant/breastfeeding: align with ANC/PNC; rapid initiation; maintain suppression for EMTCT. • Key populations: flexible hours, privacy, peer support; harm reduction for PWID. • Older ≥50yrs: screen for polypharmacy and drug–drug interactions; simplify regimens where possible. • AHD: expedite ART after ruling out/starting OI therapy as per guidance.

Component	Care Package (All PLHIV)	Adaptations for Special Groups (Children; Adolescents; Pregnant/Breastfeeding; Key Populations incl. FSW/MSM/TG/PWID; Older >50yrs; Advanced HIV Disease)
Positive Health, Dignity and Prevention (PHDP) and HIV Education/Counselling	• Risk-reduction counselling; U=U messaging; disclosure and partner testing support. • Condom provision; linkage to PrEP/PEP for partners at risk; treatment literacy.	• Adolescents: life skills, age-appropriate sexuality education, and peer groups. • Key populations: tailored risk-reduction incl. safer injecting; stigma-free services. • Older >50yrs: sexual health counselling, sensory/cognitive considerations.
GBV/IPV Screening and Response	• Routine, confidential screening; first-line support (LIVES); clinical care incl. emergency contraception, STI prophylaxis, PEP as indicated; safe referral pathways.	• Adolescents/pregnant: safeguard and child protection where relevant. • Key populations and older >50yrs: address unique vulnerability and elder abuse; linkage to legal/psychosocial services.
STI Screening and Management	• Clinical and/or etiologic testing per capacity; partner notification; periodic screening for those at ongoing risk. • Provide condoms and treatment per national protocol; Anti-Microbial Resistance (AMR) surveillance where available.	• Adolescents/youth/key populations: routine periodic screening (e.g., every 3 months for high-risk groups). • Pregnant/breastfeeding: integrate at ANC/PNC; align with triple-elimination efforts. • AHD: treat promptly to reduce complications.
Viral Hepatitis (HBV/HCV)	• HBsAg testing for all; HBV vaccination for the negative; HCV testing for PWID and others at risk; linkage to care/treatment.	• Pregnant: birth-dose HBV for infants of HBsAg-positive mothers; manage maternal HBV. • Key populations (PWID, MSM, prisoners): routine HCV testing; harm-reduction services. • Older ≥50yrs: monitor liver disease and drug interactions; consider fibrosis assessment.
Specific OI Screening and Prevention	• Baseline CXR • TB screening at every contact; TPT for eligible clients. • CPT per guideline; AHD package (CD4, CrAg, LF-LAM) where indicated.	• Children <5yrs and AHD: intensified case finding; CrAg/LF-LAM algorithms • Pregnant: TB screening at ANC; safe TPT timing per guidance
Reproductive Health (RH) Services	• Contraception and safer conception (Refer to Annex 39 and 40), pregnancy testing; cervical cancer	• Adolescents: HEADSSS-aligned assessment; adolescent-friendly contraception. • Pregnant/breastfeeding: integrated ANC/PNC and EMTCT services; align mother–baby visits.

Component	Care Package (All PLHIV)	Adaptations for Special Groups (Children; Adolescents; Pregnant/Breastfeeding; Key Populations incl. FSW/MSM/TG/PWID; Older >50yrs; Advanced HIV Disease)
	screening (HPV testing per national guidance).	• Key populations: non-judgmental, rights-based RH including fertility intentions. • Older ≥50y: menopause/andropause counselling and referral
Mental Health and Substance Use	• Screen for depression/anxiety (e.g., PHQ-2/9); provide counselling or referral; address alcohol and drug use.	• Adolescents: regular psychosocial assessments. • School and caregiver engagement. • Mental health assessment of caregivers. • Key populations/PWID: harm-reduction, Opioid Substitution Therapy (OST) where available • Older ≥50yr: screen for cognitive impairment, delirium, dementia; falls risk
Non-Communicable Diseases (NCDs)	• Screen/manage hypertension, diabetes, dyslipidaemia, CKD; lifestyle counselling.	• Older ≥50yr: annual CVD risk assessment; medication review for polypharmacy. • AHD or long-term ART: monitor renal/bone health as indicated
Nutrition Services	• Nutritional assessment, counselling and support (NACS); address food insecurity; micronutrient support as indicated.	• Children/adolescents: growth monitoring; school-aligned appointments • Pregnant/breastfeeding: maternal nutrition; infant feeding counselling
Immunizations and Prevention of Other Infections	• Routine immunizations per national schedule; malaria prevention; WASH counselling. • Additional vaccination: COVID-19, Mpox and other vaccines as required	• Pregnant/breastfeeding/children: align with Extended Program for Immunization (EPI) and MCH schedules

The standard package of care for HIV exposed and HIV infected infants is as described in table 1.29.

Table 1.29 Standard package of care for HIV-exposed and HIV-infected infants

Standard Package of Care for HIV-exposed and HIV-Infected Infants	
Determination of HIV status of child	• Determine HIV status at first contact through HTS/EID guided by age, and link to HIV prevention or treatment as appropriate. • Screening for exposure using rapid antibody tests for those whose exposure status is unknown.
HIV Exposed Infant	• Determine the risk category of the mother (for risk of VT to the unborn baby or child under 2 years) and provide appropriate care for HEIs as per risk category (Refer to Sect 2.1.3 for risk categorization) • Provide ARV prophylaxis for all HEIs as per the risk category (Sect 2.1.6). • Follow up testing as per EID algorithm. • Regular follow-up and documentation using the HEI register and card
Both HIV exposed and Infected child	• Provide nutritional assessment, counselling, and support (NACS, refer to Section (2.1.9) and monitor growth and development of the child at every visit (Annex 20) • Ensure that all immunizations are provided following the national schedule (Annex 4: Routine immunization schedule in Kenya) • For infants born of Hep B surface Ag positive mothers, refer to Section 2.1.5 for comprehensive prevention and immunization • Clinical assessment at every visit, • Treat any concurrent infections early • Identify, manage, and report adverse drug reactions aggressively, and refer appropriately where specialized care is required. • Screen for opportunistic infections at every visit, and provide prophylaxis (cotrimoxazole, TB Preventive Therapy (TPT). • Deworm every 6 months (starting at 1 year of age) • Provide supplemental Vitamin A every 6 months (starting at age 6 months) • Enrol in HEIs and HIV infected children on Orphans and Vulnerable Children (OVC) program for social protection and other services. • Health education & counselling of the child's caregiver on: – Infant feeding – HIV related symptoms – Adherence: appointments and medication (Cotrimoxazole prophylaxis, ARVs and where relevant anti-TB/ TPT)
HIV Infected child	• ART for all HIV-infected children (confirming correct weight-based dosing of ARVs at every visit) as per the updated recommendations (Section 1.7.3) • Perform clinical and laboratory assessment • Prompt treatment of infections including opportunistic infections • Adherence assessment, counselling, and support. • Educate the caregiver on all aspects of care for the child, treatment literacy, adherence, need for weight-based dose adjustment, availability of support for child disclosure, and follow-up requirements • Provide intensive case management for mother/infant pair until 2 years postpartum; identify defaulters and prioritize this population for tracing. • Provide age-appropriate psychosocial support for the family and child and refer to community-based support programs as appropriate • Ensure that the caregiver and family members are receiving appropriate care, support and treatment

Adolescent living with HIV standard package of care is as described in table 1.30

Table 1.30 Standard package of care for adolescents living with HIV

Standard Package of Care for Adolescents Living with HIV
Clinical care
• Provide immediate linkage to HIV care • Provide ART to all HIV-infected adolescents, assess and categorize their risk for vertical transmission (Section 2.1.3), and provide an appropriate package of care for the risk category • Perform clinical and laboratory assessments. • Clinical assessment at every visit, treat infections early and refer appropriately where specialized care is required • Screen for opportunistic infections and provide prophylaxis (cotrimoxazole, TPT) • Provide NACS and monitor growth and development • Provide/refer for HPV vaccine
Adherence and psychosocial support
• Perform a baseline and regular subsequent psychosocial assessment • Assess the mental health of the adolescent using the HEADSS Tool (Annex 6) • Disclosure support (Refer to Adherence, Monitoring and support section) • Assess for and support disclosure of HIV status to the adolescent (Annex 5) • Enrol in age-appropriate psychosocial support groups • Provide treatment literacy • Provide life skills counselling • Provide adherence counselling • Support appropriate transition into adult HIV treatment and prevention
Prevention of HIV transmission
• Encourage index testing and support for disclosure • Assess for and manage drug and alcohol use • Perform a sexual risk assessment and STI screening and treatment, and linkage of sexual partner to PrEP where applicable (Section 1.3.2) • Assess for and manage IPV/GBV • Provide reproductive health services, including pregnancy screening, pregnancy intention assessment, family planning, and linkage to PMTCT for pregnant adolescents
Referrals, linkages, and support for the continuum of care
• Provide intra-facility and inter-facility referrals as needed for specialized care • Link with youth community groups, targeting youth both in and out of school
Other services: Legal centres, paralegal services, gender-based violence recovery centres, educational institutions, bursary/scholarship programs, income generating activities, constituency development funds, vocational training centres for skills development, etc.

1.5.2 Non-communicable Diseases Screening and Management

Metabolic Disorders

PLHIV are at higher risk for cardiovascular, liver and kidney disease because of the chronic inflammatory state associated with HIV infection itself, and also as a side-effect of some of the ARVs.

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

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

For comprehensive guidelines on prevention, diagnosis and management of diabetes and cardiovascular diseases, refer to Protocols for Management of Selected Non- Communicable Diseases at Primary Care Setting, the Kenya National Clinical Guidelines for the Management of Diabetes and Kenya National Guidelines for Cardiovascular Diseases Management.

Table 1.31: Lifestyle Modifications to Prevent and Manage Cardiovascular Disease in PLHIV

Smoking Cessation

● Smoking cessation has multiple short-term and long-term benefits, including
  ○ Reduced premature aging/wrinkling of skin
  ○ Improved fitness and quicker recovery from common infections
  ○ Reduced risk of respiratory infections and chronic lung disease
  ○ Reduced risk of hypertension, diabetes, kidney disease, heart disease and stroke
  ○ Improved infant outcomes (for pregnant women)
  ○ Reduced risk of cancers: lung, bladder, breast, mouth, throat, oesophagus
  ○ Better response to ART (better viral suppression)
  ○ Reduced risk of developing TB or dying from TB
● Tobacco dependence treatment and cessation programs should combine behavioural/counselling support with pharmacotherapy treatment where necessary and available. For further details on cessation interventions, refer to the Kenya National Guidelines for Tobacco Dependence Treatment

Dietary Changes
● Maintain a healthy BMI (nutritionists to be engaged in patient care) ● Foods from at least four to five food groups should be included in the eating plan each day. Choices within each food group should be varied from day-to-day, depending on what is in season, locally available and affordable ● Limit intake of sugars to 5% of total energy. ● Limit the amount of total fat intake to less than 30% of total energy intake ● Use iodized salt but limit it to less than 5g of salt (equivalent to approximately 1 teaspoon) per day ● Eat a variety of foods from different food groups every day. Include whole or unprocessed starchy foods as part of meals ● Eat lean meat, poultry, insects, eggs, fish or seafood at least twice a week ● Eat plenty of fruits, green leafy vegetables, red and yellow vegetables every day ● Drink plenty of clean safe water every day (At least 2 litres/ 8 glasses of 250ml)
Physical Activity
● Physical activity undertaken throughout life reduces the risk of NCDs, ● The frequency, duration, intensity, type, total amount and benefits of physical activity varies for different age groups.

Screening, diagnosis and Management of Non communicable diseases should be integrated in service delivery within primary healthcare settings.

1.5.2.1 Hypertension

Screening, diagnosis and initial management of hypertension is as described in table 1.32

Table 1.32: Hypertension Screening, Diagnosis, and Initial Management for Adult PLHIV

Hypertension

Screening

PLHIV (18 years of age and above) should be screened for hypertension at every clinical visit. Take 3 measurements at 1 min intervals - use the at average of the last 2 measurements.

Diagnosis of Hypertension

The accurate diagnosis of hypertension depends on the precise measurement of BP. Hypertension is categorised as per the table below:

Grading of Hypertension

Category	Systolic	Diastolic
Optimal	<120	<80
Normal	120-129 and/or	80-84
High Normal	130-139 and/or	85-89
Grade 1 hypertension	140-159 and/or	90-99
Grade 2 hypertension	160-179	100-109
Grade 3 hypertension	≥180	≥110
Isolated systolic hypertension	≥140	90

- BP should be measured and recorded for adults at every visit

- Hypertension requiring intervention is defined as BP ≥ 140/90 mmHg on at least 3 different occasions

Additional Investigations for patients with hypertension

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

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

Refer to Figure 1.5: Management flow chart for NCDs (HTN, DM and CKD)

- If baseline BP is 120-139/80-89 (pre-hypertension): Lifestyle modification, along with monthly BP monitoring
- If baseline BP is 140-159/90-99: Lifestyle modification for up to 3 months, along with monthly BP monitoring
- **If baseline BP ≥ 160/100 mmHg:** Initiate lifestyle modifications and introduce anti-hypertensive medications concurrently
- If does not meet treatment target with lifestyle modifications, then add drugs to lifestyle modification

Note:

Calcium-channel blockers have known drug interactions with PIs and NNRTIs and should be used with caution.

ACE-I and thiazide diuretics do not have significant interactions with ARVs Refer to Annex 31 for Drug-drug interaction

Management of Hypertension among PLHIV

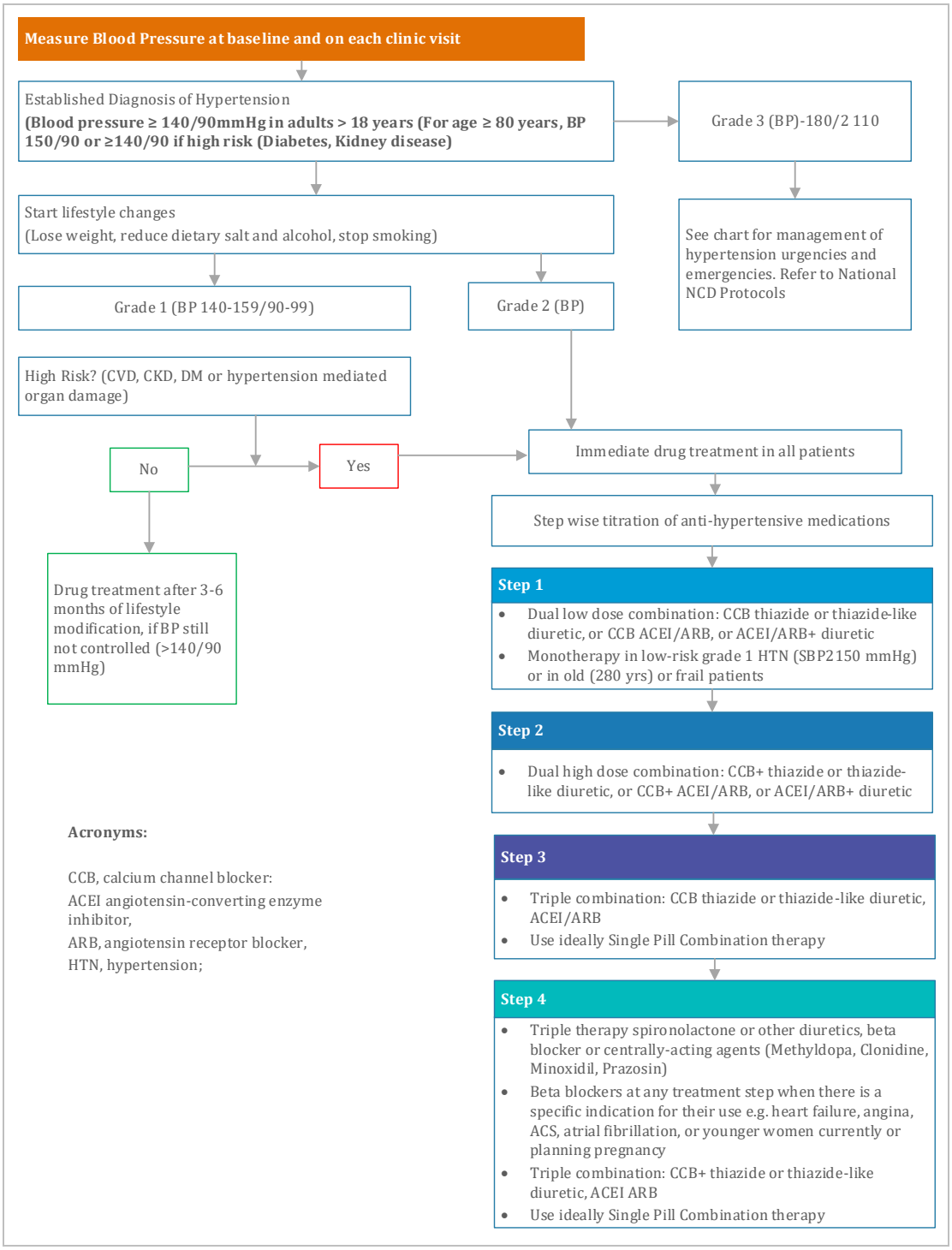


Figure 1.5: Management of Hypertension among PLHIV

1.5.2.2 Diabetes Mellitus

Table 1.33: Type 2 Diabetes Mellitus Screening, Diagnosis, and Initial Management for PLHIV

Diabetes
Blood glucose (fasting or random) should be evaluated at baseline for all PLHIV, then annually. Urine dipstick for protein and glucose can be used if blood glucose testing is not available
• Diabetes Mellitus is defined as fasting blood sugar ≥ 7.0 mmol/L, or random blood sugar ≥ 11.1 mmol/L, or HbA1c > 6.5%, or oral glucose tolerance test ≥ 11.1 mmol/L • Abnormal results should be repeated to confirm the diagnosis
• Management (treatment target is HbA1c ≤ 7.0% or FBS 4-7 mmol/L) • For patients with pre-diabetes • monitor FBS or HbA1c every 3 months and encourage lifestyle modifications • For patients with diabetes: – monitor HbA1c (or FBS if HbA1c is not available) every 3 months – Lifestyle modification for 3-6 months – If it does not meet the treatment target with lifestyle modifications, then add drugs – Metformin o Do NOT use metformin if creatinine clearance < 45 ml/min o Start with low dose (500 mg OD or BD) and titrate up every 1-2 weeks until reaches 1 g BD (or maximum tolerated dose if less than 1 g BD) o **Note:** DTG may increase metformin plasma levels: monitor blood glucose levels; dose reduction of metformin may be required, and maximum daily dose of metformin should be 1g – If does not meet treatment targets with metformin for 3-6 months at maximum tolerated dose then consider adding drug from another class (such as sulfonylureas (gliclazide)) and/or specialist consultation. Some patients may require insulin. – At every visit: A thorough history (to elicit features of hypo glycaemia, other cardiovascular disease risk factors, neuropathy, diabetic foot ulcers) and a physical exam (for BP, neuropathy, foot ulcers) • Additional routine screening for patients with diabetes – Annual ophthalmology examination for diabetic retinopathy – Annual urinalysis: start on an ACE-I/ARB if proteinuria develops (even if BP normal) **Note**: patients with DM are at increased risk of developing TB

Pre-diabetes

Definition: A Health condition characterised by glucose levels higher than normal, regarded as indicative that a person is at risk of progressing to Type 2 diabetes:

Diagnosis:

- HbA1C of 5.7-6.4%,
- FBS levels: 5.6-6.9 mmol/L (100- 124mg/dl) **OR**
- 2-hour plasma glucose during 75g-OGTT: .8-11.0 mmol/L (140- 198mg/dl)

Treatment Goal:

a) Prevent progression to type 2 DM,
b) Avoid non-alcoholic fatty liver disease,
c) Prevent excess weight gain
d) Lower CVD risk.

Treatment:

a) **Lifestyle Interventions:**
   - Smoking Cessation
   - Physical activity (30 minutes 5 times per week)
   - Sleep hygiene
   - Healthy eating habits

b) **Overweight and Obese** patients: advise to lose 5-10% body weight in 12 months. If BMI > 35 kg/m2 or has a history of gestational diabetes, start on Metformin.

c) **Fatty liver present**: Start on pioglitazone, regardless of nutritional status.

Follow up:

- Lifestyle interventions: HbA1c test annually
- Pharmacological treatment: Continue treatment till the HBA1C (tests every 3 months) returns to normal, then continue follow-up at least every 6 months

Screening and Diagnosis of Type 2 DM among PLHIV

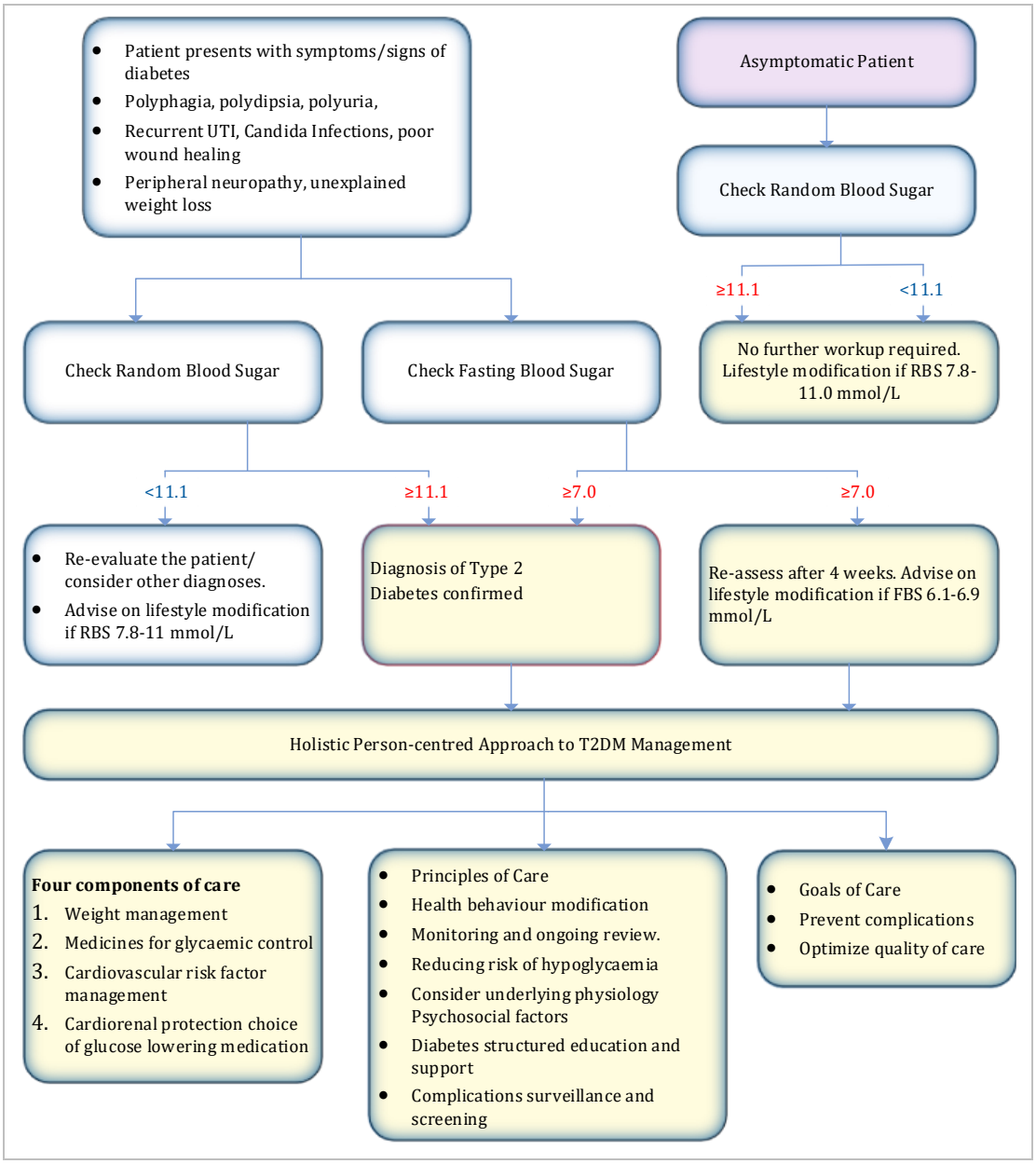
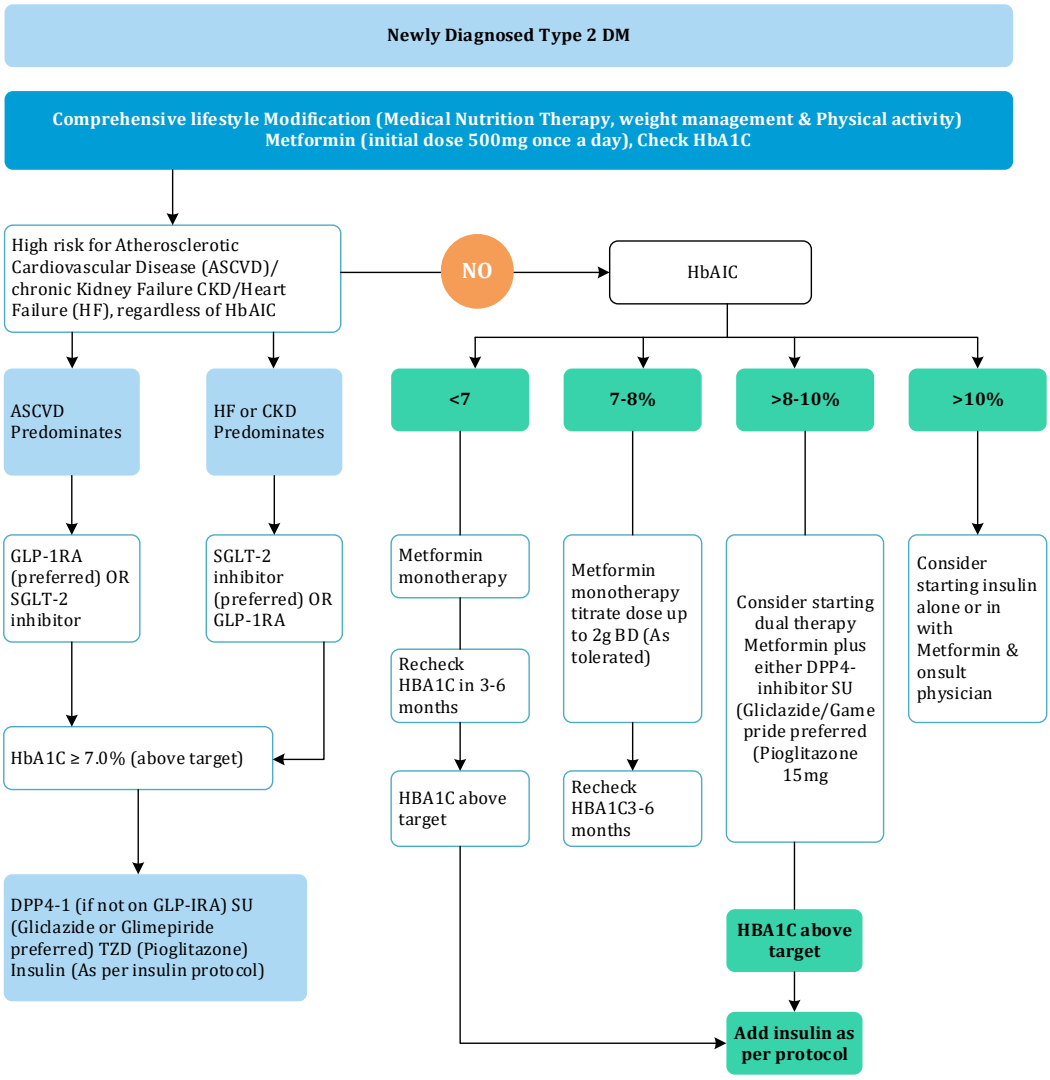


Figure 1.6: Screening and diagnosis of type II diabetes mellitus in PLHIV

Treatment of PLHIV with Type 2 Diabetes Mellitus



Metformin increases the plasma levels of DTG. Start with low dose 500mg OD/BD and titrate every 1-2 weeks to a maximum dose of 1 gm BD

Refer annex 30, 31 and 32 on Drug-to-drug Interaction with ARVs

Figure 1.7: Treatment of PLHIV with Type 2 Diabetes Mellitus

1.5.2.3 Chronic Kidney Disease Screening, Diagnosis, and Initial Management for PLHIV

Prevention, early identification, and management of kidney disease is important to reduce the burden of dialysis and other complications among PLHIV. Acute Kidney Injury (AKI) is a reversible short-term condition commonly caused by massive volume depletion related to HIV-associated gastrointestinal infections. Chronic Kidney Disease refers to longer term disruption of kidney structure and function.

Patients at higher risk for renal disease and TDF-related renal toxicity include those with:

- Pre-existing kidney conditions (IgA nephropathy, Focal Segmental Glomerulosclerosis (FSGS)
- Family History of kidney disease
- Obesity
- Smoking History
- Comorbidities: hypertension, cardiovascular disease, diabetes mellitus, dyslipidaemia
- Severe wasting
- Age over 45 years
- Advanced HIV Disease: WHO stage 3 or 4 and/or CD4 count below 200 cells/mm3
- High HIV viral load
- HIV associated nephropathy (HIVAN)
- Hepatitis B and C coinfection
- Other HIV related conditions such as Immune Reconstitution Inflammatory Syndrome (IRIS)
- Thrombotic Microangiopathy
- Concurrent nephrotoxic agents.

Note: *Glomerular disease, HIV associated Nephropathy is a common cause of CKD among PLHIV*

Key Takeaways for Patients and Clinicians

- Regular monitoring is crucial: This includes checking blood pressure, serum creatinine, and urine albumin-creatinine ratio (UACR)
- Managing modifiable risk factors: hypertension, diabetes, smoking cessation
- Avoid nephrotoxic drugs
- All patients with kidney disease should be co-managed with a nephrologist.

Screening, Diagnosis and Management of CKD

Screening: Urinalysis (for protein) and serum creatinine should be evaluated at baseline for all PLHIV and monitored annually for PLHIV with normal results. Where available, point-of-care-testing should be instituted for screening for serum creatinine and urine albumin-creatinine ratio. Refer to figure 1.8

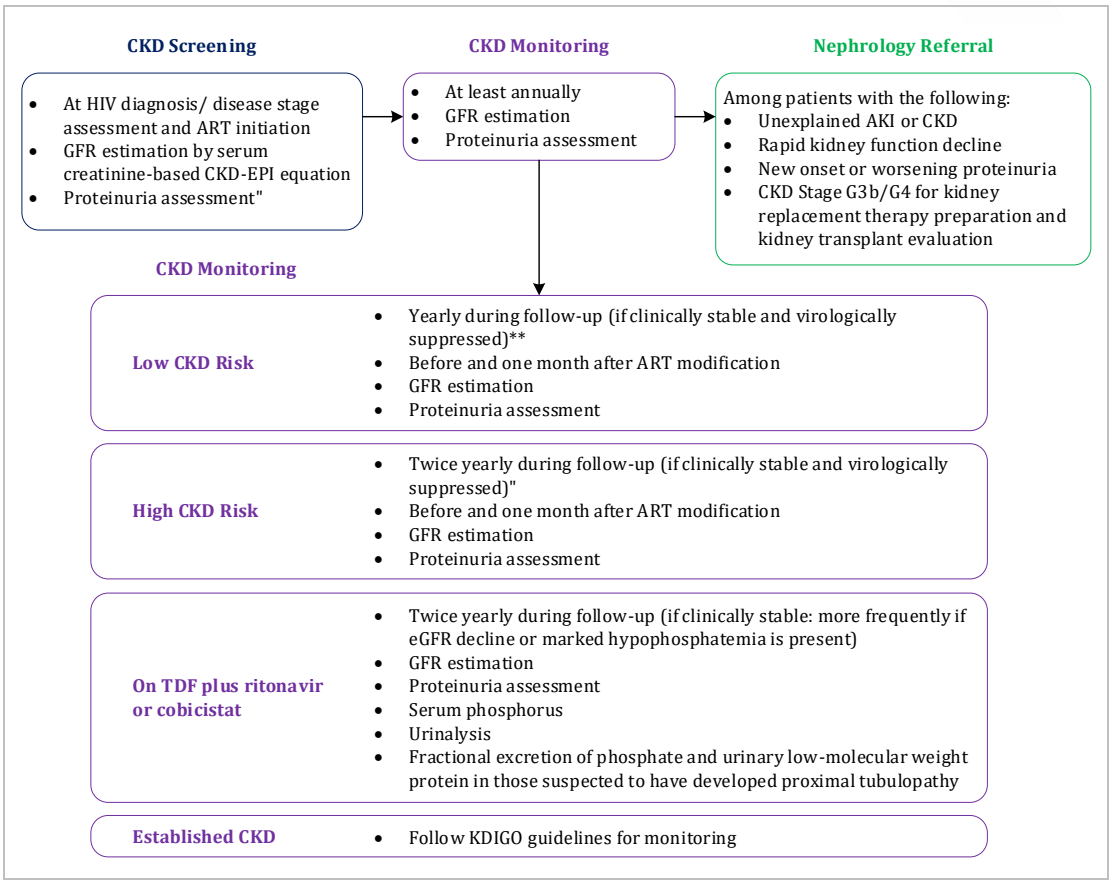


Figure 1.8: Algorithm for Screening and Monitoring Chronic Kidney Disease

Diagnosis:

Chronic kidney disease (CKD) is defined as evidence of kidney damage persisting for three months or longer. In the simplest forms, impaired renal function is characterized by a creatinine clearance less than 90 mL/min or dipstick proteinuria of 1+ or greater ≥ 1. (see Annex 34 for CrCl calculations). Abnormal results should be repeated to confirm diagnosis.

Refer to Annex 38: Risk of renal failure by UACR (Urine albumin to Creatinine Ratio) and eGFR

Management

Antiretroviral therapy

- Effective antiretroviral therapy has led to:
  - decline in the incidence of HIVAN
  - reduced progression of HIVAN to end stage kidney disease
  - reduction in incidence of HIV-associated thrombotic microangiopathy
- Essential to adjust doses of ARVs that are excreted predominantly via the kidneys once renal function begins to decline, as incorrect dosing is associated with higher mortality risk
- Avoid use of fixed dose combinations among PLHIV once eGFR is less than 60ml/min.

Management of TDF-associated nephrotoxicity

- Patients at higher risk for developing TDF-associated renal toxicity include those with:
- pre-existing renal disease
- hypertension
- diabetes mellitus
- severe wasting (weight below 60 kg in adults)
- age > 45 years
- WHO stage 3 or 4
- CD4 < 200 cells/mm3
- high HIV viral load
- concomitant nephrotoxic agents, e.g. acyclovir, NSAIDs and ritonavir
- TDF should generally be avoided if the eGFR is less than 50ml/min per $1.73m^2$
- In PLHIV who experience a more than 25% reduction in eGFR from baseline and an eGFR less than $50ml/min/1.73m^2$ while on TDF, it should be discontinued and substituted with another 'renal-friendly' ARV such as Abacavir

ACE inhibitors or Angiotensin Receptor Blockers (ARBs)

- Use of ACE inhibitors e.g. Enalapril and ARBs such as Losartan and Telmisartan has been associated with reduced progression of chronic kidney disease to end stage kidney disease
- Treatment with one of these agents is recommended in patients with significant albuminuria (>30mg albumin/day in diabetic patients and >300mg/day in nondiabetic patients).

Control of blood pressure

- Blood pressure target among patients with CKD is ≤140/90mmHg
- The BP target is more stringent among CKD patients with moderately to severely increased albuminuria (≤130/80mmHg)
- Several classes of antihypertensive agents can be used to achieve target BP control, including ACE inhibitors/ARBs, calcium channel blockers, thiazide diuretics, beta adrenoceptor blockers, vasodilators such as hydralazine and centrally acting agents such as alpha methyldopa.

Other considerations in management of CKD in PLHIV

- As in the non-HIV CKD population, the following issues must also be addressed among PLHIV with CKD:
- Address other cardiovascular risk factors (hyperlipidaemia, weight loss, smoking cessation)
- Avoidance of nephrotoxins including NSAIDs
- Management of other complications of CKD including anaemia, chronic kidney disease mineral and bone disorders, hyperuricemia and metabolic acidosis.

Vaccination

- PLHIV with CKD should get vaccinated against:
- hepatitis B
- influenza
- pneumococcal
- Immune response to vaccination may be suboptimal due to the double immunosuppression from HIV and CKD

Appropriate drug dosing in PLHIV with CKD

- Drugs that are predominantly excreted via the kidneys must be dose adjusted according to kidney function to avoid accumulation and resultant drug adverse effects
- Apart from Abacavir, other NRTIs will require dose adjustment in patients with chronic kidney disease
- No dose adjustment is required for NNRTIs, protease inhibitors and dolutegravir (see Table 1.34 below)

Table 1.34: Drug dose adjustment for ARVs in adults with CKD

ARV	eGFR				Intermittent Haemodialysis	Peritoneal dialysis
	≥50ml/min	30-49ml/min	10-29ml/min	<10ml/min		
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)						
Abacavir	300mg q12h or 600mgq24h	No dose adjustment required				
Emtricitabine	200mg q24h		200mg q72h	200mg q96h	200mg q24h	No data
Lamivudine	300mg q24h	**300mg q24h****	100mg q24h	25-50mg q24h	25-50mg q24h	25-50mg q24h
Tenofovir Disoproxil Fumarate	300mg q24h	300mg q48h	Not recommended	Not recommended	300mg q7d	No data
			If no alternative: 300mg q72-96h	If no alternative: 300mg q7d		
Tenofovir Alafenamide	25mg q24h			No data	25mg q24h	No data
Zidovudine	300mg q12h			100mg q8h	100mg q8h	No data
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)						
Efavirenz	600mg q24h	No dose adjustment required				
Nevirapine	200mg q12h	No dose adjustment required			Additional 200mg after dialysis	No dose adjustment

Rilpivirine	25mg q24h	No dose adjustment required		
Integrase Strand Transfer Inhibitors (INSTIs)				
Dolutegravir	50mg q24h	No dose adjustment required		
Raltegravir	400mg q12h or 1200mg q24h	No dose adjustment required		
Protease Inhibitors (PIs)				
ATV/r	300/100mg q24h	No dose adjustment required	Not recommended	No dose adjustment
DRV/r	800/100mg q24h 600/100mg q12h	No dose adjustment required		
LPV/r	400/100mg q12h	No dose adjustment required		

****Updated dosing guidance on Lamivudine**: Can be dosed at 300mg every 24 hours even in patients with eGFR 30-49ml/min or lower. Lamivudine is well tolerated with a wide therapeutic window.

1.5.2.4 Dyslipidaemia

Dyslipidaemia

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

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

Management

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

1.5.2.5 Cancer Prevention, Early Detection and Management among PLHIV

PLHIV have a substantially higher risk of developing cancers, mainly due to a weakened immune system which impairs control of oncogenic viral infections and other modifiable risk factors. The common cancers affecting PLHIV are; Kaposi Sarcoma, non-Hodgkin lymphoma, cervical, anal, liver, lung and oral/throat cancers.

Specific Interventions for Cancer Control in PLHIV

Four interventions are important for cancer control among PLHIV:

Achieve viral suppression: Uncontrolled viral replication is a major risk factor for cancer. All PLHIV should initiate ART and be supported and monitored to achieve long- term viral suppression for better treatment outcomes.

Primary prevention

- Avoid modifiable risk factors Refer to Table 1.31 Lifestyle modification to prevent cardiovascular diseases in PLHIV
- Vaccination: vaccination against Human Papillomavirus for girls 9-14 years old is available in Kenya, Hepatitis B Vaccine for newborns and high-risk groups.

Secondary prevention

- Screening and early diagnosis.

Cervical Cancer

All women living with HIV, aged 25 years to 49 years, regardless of when they first contracted HIV, should be screened with the HPV DNA test as the primary method. If HPV DNA is not detected, other methods, including visual inspection with acetic acid (VIA) or a PAP smear, should be used. Frequency of HPV testing is 5-yearly for HIV uninfected women but 3 yearly for HIV infected women. HPV testing is recommended as the primary screening method for women above 30 years of age.

Visual Inspection with Acetic Acid

- Where HPV testing is not yet available, or loss-to-follow-up is a risk, then Visual Inspection with Acetic acid (VIA; Naked or Enhanced) is an acceptable primary screening method.

Cytologic

- Pap smear is recommended as a primary screening method in the following situations:
- For women not eligible for VIA especially where squamocolumnar junction cannot be located.
- As a primary test in women between <30 years of age

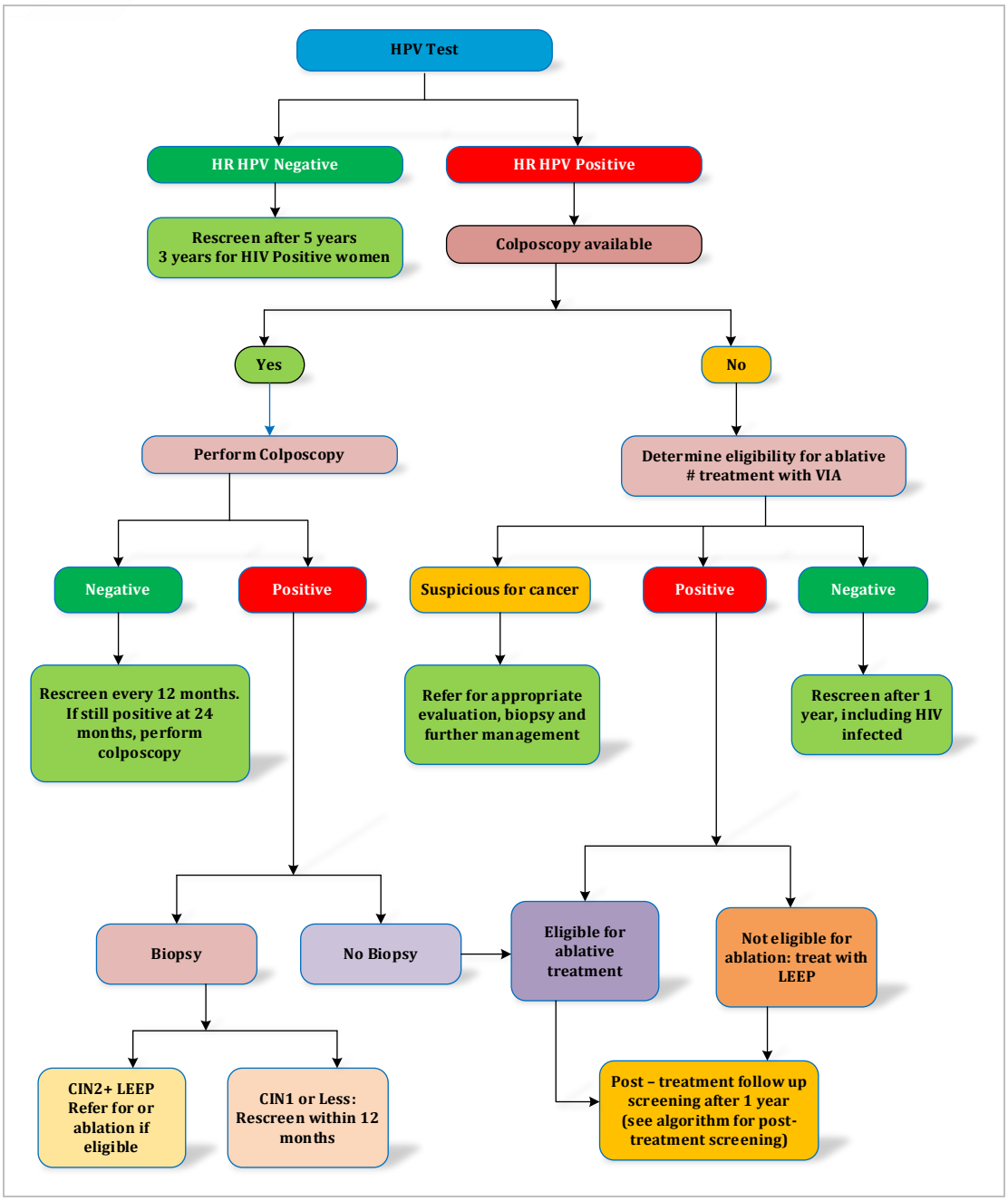


Figure 1.9: Cervical Cancer Screening

Breast cancer:

Breast assessment to be done as per table 1.35

Table 1.35: Breast assessment guide

Age Group	Recommendation	Interval
25 - 34 years	CBE	Every 3 years
35 - 39 years	CBE and Ultrasound	Every 2 years
40 - 55 years	CBE + mammography	Annual
56 - 74 years	CBE + mammography	Every 2 years
75 years older	Consider individual health factors and woman's preference to continue screening	Discuss with patient

Note: Cervical Cancer screening should be integrated with a clinical breast exam (CBE)

Other common cancers cancer

1. **Prostate cancer:** serum prostate-specific antigen (PSA) annually for men 40 years and above; digital rectal examination can be used if PSA is not available, and for all men with urinary symptoms
2. **Colorectal cancer:** Faecal occult blood testing (guaiac or FIT) annually for everyone 45-75 years old, or colonoscopy every 10 years.
3. **Oral cancer:** visual examination on every visit for everyone above 40 years with history of tobacco use, known HPV infection or immunosuppression

Table 1.36: Common cancer symptoms and signs, per organ system

Site of cancer	Common symptoms	Action for healthcare workers
Breast	Lump in the breast, asymmetry, skin retraction, recent nipple retraction, blood stained nipple discharge, eczematous changes in areola	Refer to a surgeon (who can then arrange imaging and biopsy in consultation with a radiologist)
Cervix	Abnormal vaginal bleeding and/or discharge, pelvic pain (Note: early cervical cancer has no symptoms)	Conduct speculum exam, biopsy and refer to gynaecologic oncologist (biopsy can be performed by a well-trained nurse, clinical officer, medical officer or higher).
Colon and rectum	Change in bowel habits, unexplained weight loss, anaemia, blood in the stool	Refer to the appropriate facility for colonoscopy
Oral cavity	White lesions (leukoplakia) or red lesions (erythroplakia), growth or ulceration in mouth; intraoral swellings	Refer to a dentist/ maxillofacial surgeon
Nasopharynx	Nosebleed, permanent blocked nose, deafness, nodes in upper part of the neck	Refer to ENT specialist
Larynx	Persistent hoarseness of voice	Refer to ENT specialist

Site of cancer	Common symptoms	Action for healthcare workers
Stomach	Upper abdominal pain, recent onset of indigestion, weight loss	Evaluate and refer urgently for oesophageal-gastroduodenoscopy (OGD)
Skin melanoma	Brown lesion that is growing with irregular borders or areas of patchy coloration that may itch or bleed	Refer to a dermatologist; or general surgeon if dermatologist is not available
Other skin cancers	Lesion or sore on skin that does not heal	Refer to a dermatologist; or general surgeon if dermatologist is not available
Urinary bladder	Pain, frequent and uneasy urination, blood in urine	Refer to a urologist
Prostate	Difficulty (long time) in urination, frequent nocturnal urination	Refer to a urologist
Testis	Swelling of one testicle (asymmetry)	Refer to a urologist

Tertiary prevention

This entails cancer management, prevention of complications and treatment of side effects and secondary cancers.

1.5.3 Mental Health Screening and Management

People who experience mental health challenges while living with HIV, sexually transmitted infections (STIs), and viral hepatitis share a complex, bidirectional relationship that profoundly affects prevention, diagnosis, treatment adherence, and overall quality of life. Mental illness can predispose individuals to risky behaviors that increase vulnerability to HIV, sexually transmitted infections (STIs), and viral hepatitis. Conversely, living with these infections may elevate the risk of developing mental health disorders, creating a bidirectional relationship between physical and psychological health. Integrating mental health support into HIV, STIs and Viral Hepatitis services is therefore essential.

1.5.3.1 Promotive and Preventive Approaches to Mental Health Care

A comprehensive approach to mental health care includes promotive and preventive strategies such as self-care, psychoeducation, supportive counselling, and enhancing adherence to treatment and prevention of deterioration.

Psychosocial stressors that may not meet diagnostic criteria for mental health disorders can still affect wellbeing and adherence. (Stigma and discrimination, treatment fatigue, financial strain, disclosure concerns, grief and loss, relationship challenges, and workplace stress.)

Self-Care

Practicing self-care regularly can improve emotional resilience, enhance treatment adherence, and support overall quality of life. Below are key self-care strategies to promote mental wellness:

8 DIMENSIONS OF WELLNESS

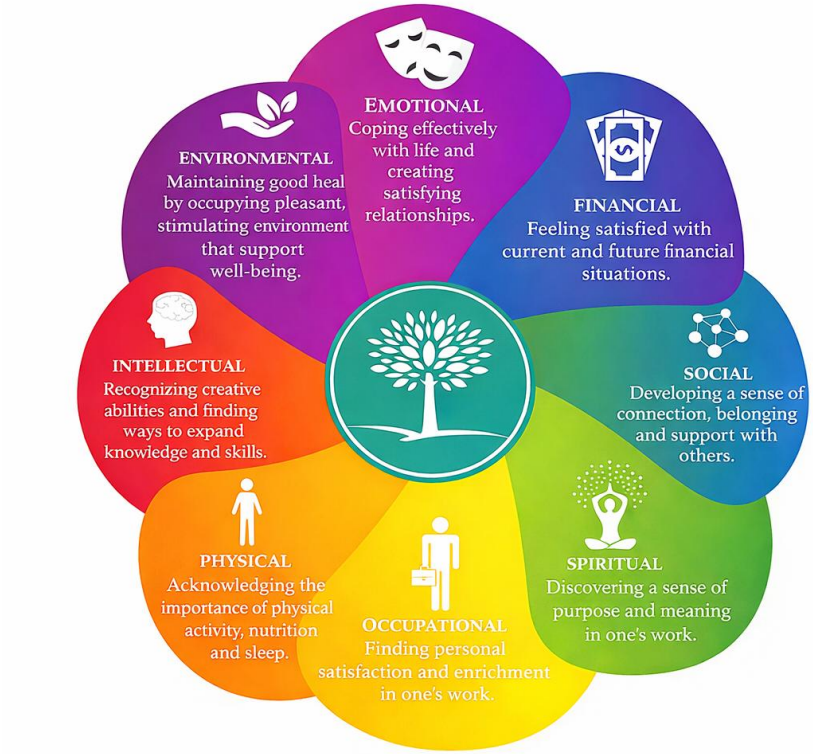


Figure 1.10: Components of Self-care

Psychosocial interventions

1. Supportive Counselling

It focuses on empowering individuals with knowledge about their condition, coping skills, and emotional support to help them manage symptoms, improve their quality of life, and maintain adherence to treatment.

Components of supportive counselling
1. Psycho-education
2. Counselling on self-management
3. Addressing psychosocial stressors
4. Reactivation of or referral to social networks, including peer support groups
5. Regular follow-up until symptoms improve and are stable

2. Brief Intervention (BI) Therapy

This is a solutions-focused, short counselling treatment usually delivered to patients who are not actively seeking help for unhealthy behaviours, addiction, or substance use. This approach helps them recognize the benefits of treatment, improve adherence, and the need for positive behavioural change. Table 1.37 below describes the components of brief intervention therapy.

Table 1.37: Components of brief intervention therapy

Component of BI	Description
1. Screening & Assessment	Identify risk behaviours and determine intervention needs.
2. Providing Feedback	Share findings and raise awareness of associated risks.
3. Advice & Negotiation	Give clear advice and engage the client in exploring options for change.
4. Goal Setting & Strategies	Set achievable goals and outline steps to support change.
5. Referral & Follow-up	Connect clients to additional services and monitor progress.

1.5.3.2 Mental Health Screening

All PLHIV should receive basic mental health screening at enrolment, annually, and whenever clinically indicated. The tools to be used in screening

- PHQ-9 Depression screening tool,
- GAD-7 anxiety screening tool,
- CAGE -AID /CRAFFT tools – Alcohol and Drug Use Disorders.

1.5.3.3 Management of common mental disorders.

Depression

It is a mood disorder that causes persistent feelings of sadness and loss of interest or pleasure in previously rewarding or enjoyable activities and can dramatically affect a person's ability to function and live a rewarding life. Depression can be a significant contributing factor to poor adherence, subsequent HIV treatment failure, and poor control of other comorbidities.

Indications for screening
• Poor adherence • Persistent sadness, anxiety, or mood changes • Feeling of hopelessness, low self-worth, or suicidal thoughts • Major life event such as bereavement, loss of income, or relationship breakdown • Unexplained physical symptoms (e.g., fatigue, insomnia, headaches) • Signs of substance or alcohol use • Social withdrawal, irritability, or behavioural changes • Violence or trauma, such as intimate partner violence or sexual assault • History of mental illness or previously diagnosed psychological conditions • When a caregiver or family member expresses concern about the patient's emotional well-being.

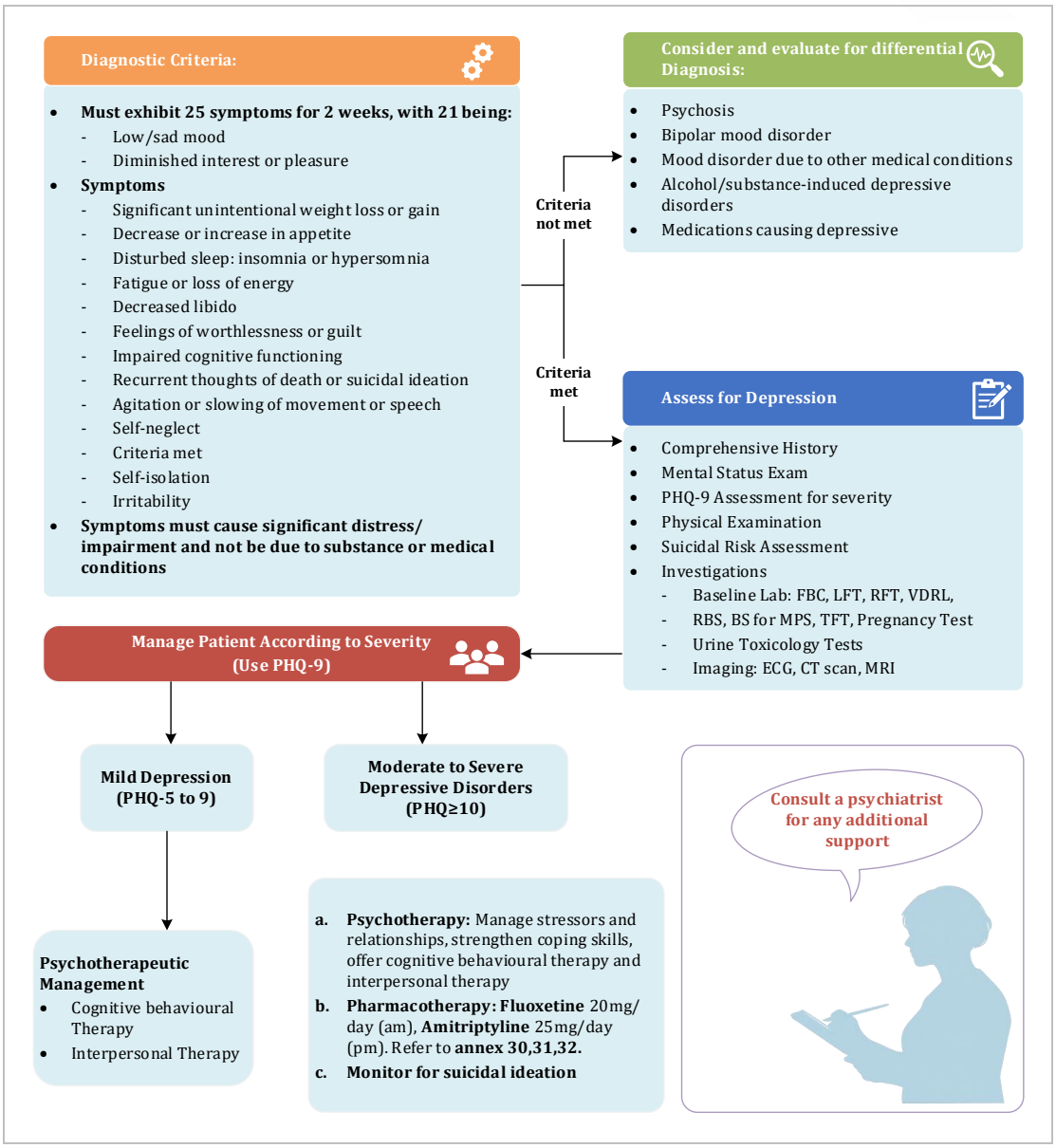


Figure 1.11: Management of depression

Psychosis

Psychotic disorders are conditions characterized by a loss of contact with reality, which manifests as altered thoughts, behaviour, or perceptions and causes significant impairment in various areas of functioning, including work, social relationships, and self-care. Schizophrenia is one of the common Psychotic disorders

Table 1.38: Diagnosis and management of schizophrenia

Diagnostic Criteria:

A. At least two symptoms present for ≥1 month (or less if successfully treated). At least one must be symptoms 1, 2, or 3:
   1) Delusions
   2) Hallucinations
   3) Disorganised speech
   4) Grossly disorganised and catatonic behaviour
   5) Negative Symptoms

B. Presence of symptoms for at least six months (including the 1-month acute phase)

C. Symptoms not due to substance use, medication or other medical condition

Significant social or occupational impairment

Assessment

1) Clinical Evaluation:
   - Comprehensive History
   - Mental Status Examination
   - Physical Examination
   - Suicidal Risk Assessment
2) Laboratory Investigations:
   - Baseline Lab: FBC, LFT, RFT, VDRL, RBS, BS for MPS, TFT, Pregnancy Test
   - Additional: Urine Toxicology Tests
3) Imaging: ECG, CT scan, MRI

Additional tests based on clinical presentation.

Treatment

1) Setting Selection
   - **Outpatient**: Mild to moderate symptoms and good social support
   - **Inpatient**: Severe psychotic symptoms, Aggressive behaviour that puts self or others at risk, persistent symptoms during outpatient care, poor social support and lack of insight
2) Interventions
   - **Psychosocial support**: Psychoeducation, psychotherapy, establishing social support, social skills training, and occupational therapy to improve daily living activities
   - **Pharmacotherapy**: Use of atypical antipsychotics, choose ONE medication and avoid switching: Olanzapine: 5-10 mg OD (max: 20 mg BD), Risperidone: 1 mg OD (max: 6mg OD), Haloperidol 5 mg OD (max: 20mg OD) , Fluoxetine 20mg OD (am)

For other treatment options for Schizophrenia disorders consult a psychiatrist

Referral

- **Population-based**: Children and Adolescents, Pregnant and Breastfeeding mothers, Older persons and patients with multiple medical conditions
- **Symptoms-based**: severe and persistent symptoms, suicidal behavior, risk of harming others
- **Treatment-based**: Poor adherence to antipsychotics, partial or no response to treatment, need for electroconvulsive therapy, need to start clozapine and specific psychological therapies
- **Social support**: Poor social support (homelessness), family needs psychoeducation and vocational rehabilitation

Anxiety Disorders

These are mental health disorders characterized by a feeling of worry or fear that is strong enough to interfere with daily activity.

Types of Anxiety Disorders

- Generalized anxiety disorder
- Panic disorder
- Social anxiety disorder
- Agoraphobia
- Specific phobias
- Separation anxiety disorder
- Selective mutism
- Substance/medication-induced anxiety disorder

In this guideline we shall focus on Generalized Anxiety Disorder (GAD) is characterized by constant persistent and excessive worry about several different daily everyday things when there is no apparent reason for concern.

Generalized Anxiety Disorder

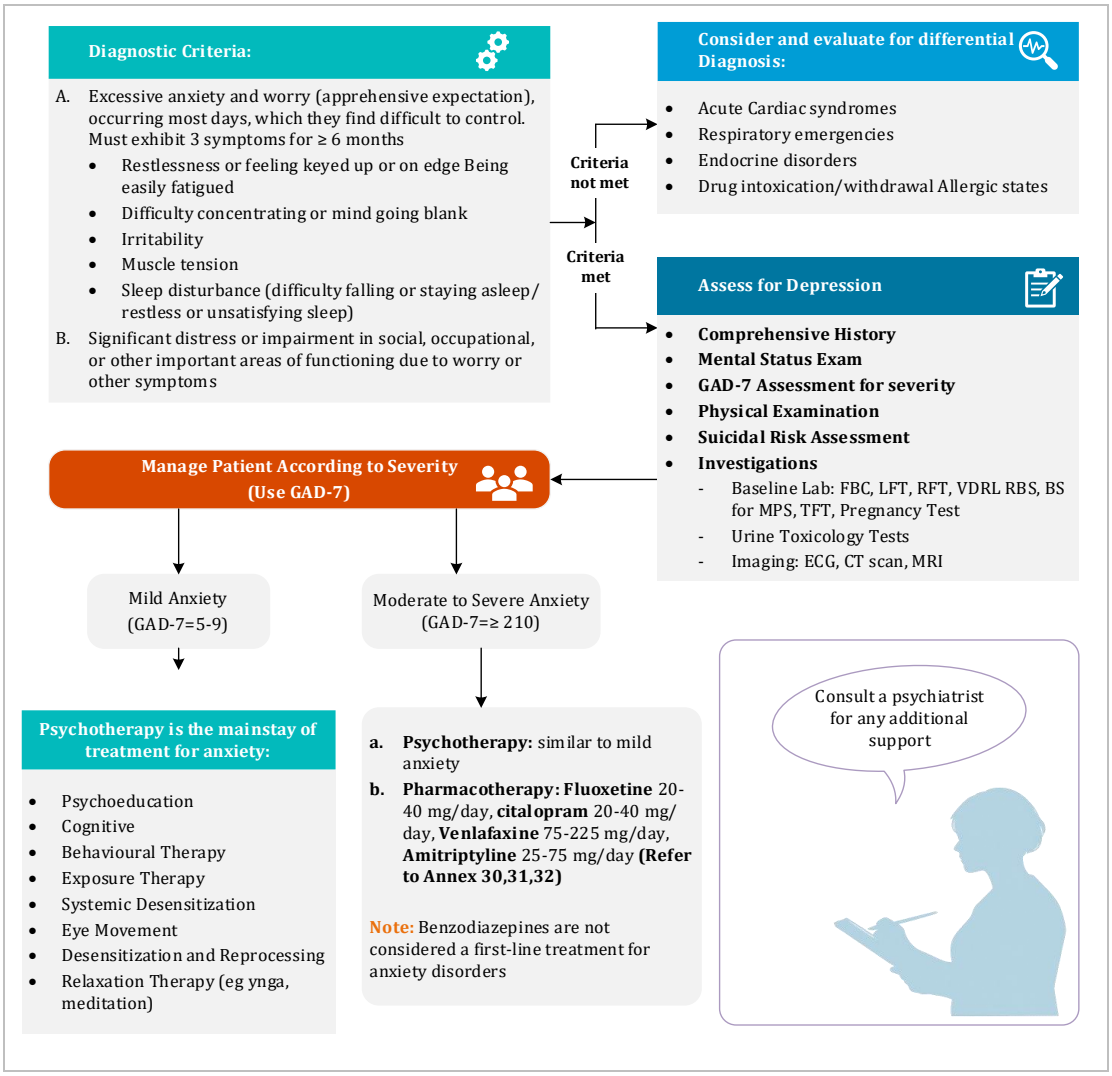


Figure 1.12: Generalized Anxiety Disorder Management Protocol

Post-Traumatic Stress Disorder is a psychiatric disorder that may occur in people

- After Exposure to or witnessing a traumatic event such as natural disaster, serious accident or near-death experience
- In a person threatened with death, sexual violence, or serious injury
- After learning that the traumatic event(s) occurred to a close family member or friend
- After repeated or extreme exposure to aversive details of the traumatic event(s)

This does not apply to exposure through electronic media, television, movies, or pictures, unless this exposure is work related.

Table 1.39: Signs and Symptoms of PTSD

Intrusive	Avoidance	Negative cognition and mood	Arousal /Reactivity
Intrusive thoughts	Avoiding reminders of the event	Blocking Important aspects of the Trauma	Irritability and anger
Nightmares	Avoidance of memories, thoughts and feelings related to the event	Negative thoughts about self and the world	Self-destructive behavior
Flashbacks		Casting blame upon themselves or others	Hyper-vigilance
Marked psychological distress at exposure to similar events		Persistent negative emotional state e.g., guilt, shame, anger, and fear	Exaggerated startle reflexes
Marked physiological reactions to similar cues		Diminished interest in favorite activities	Poor concentration
		Self-isolation and feeling distant	Sleep disturbances
		Difficulty in experiencing positive emotions	

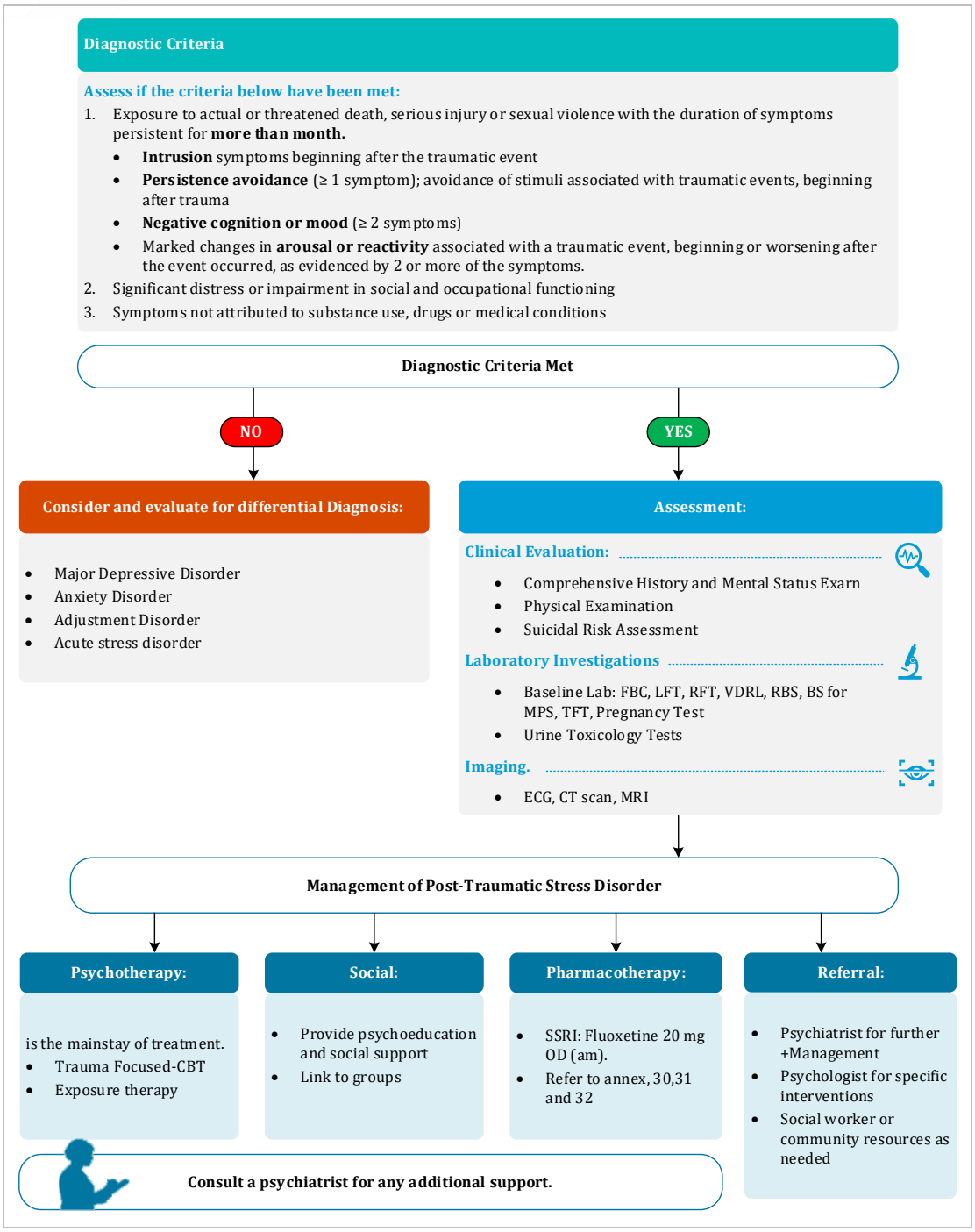


Figure 1.13: Management of Post-Traumatic Stress Disorder

Alcohol and Drug Use/Addiction

Alcohol and other drug use are common among the general population and among PLHIV. Alcohol and drug use can be a significant contributing factor to poor adherence and HIV treatment failure.

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

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

Patients who answer "yes" to any of the questions above, and all patients with a detectable viral load after 3 or more months on ART (whether or not they had achieved viral suppression in the past), should undergo a more thorough screening.

For adolescents, use the CRAFFT screening tool (Table 1.40). For adults, use the CAGE-AID screening tool (Table 1.41). Anyone who screens positive on these tools should have further assessment and management by clinical staff, ideally with experience in managing alcohol and drug use disorders. Table 1.42 gives some general guidance on management of addictions. The National Protocol for Treatment of Substance Use Disorders in Kenya provides more in-depth guidance.

Table 1.40: CRAFFT Screening Interview for Adolescents

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

Table 1.41: CAGE-AID Screening Questions for Adults

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

If referral to the mental health team is not immediately possible for those who screen positive, or as a starting point in supporting a patient while referral is being made, an assessment of whether the patient wants to quit and targeted messages/support based on their stage of quitting may be beneficial. The National Protocol for Treatment of Substance Use Disorders in Kenya provides additional resources for assessments and interventions.

Table 1.42: Addiction Support Based on Stages of Change

Stage of Change	Counselling Approach
Pre-contemplation: not currently considering quitting; no immediate desire to quit	Acknowledge that not everyone is ready to think about quitting Clarify that it is their decision Listen to them describe the benefits they get from their alcohol or drug use (their motivation for continuing to use) Explore why other people might think it is a good idea to quit
Contemplation: not sure if he/she wants to quit, or thinking about quitting but with no immediate plan to quit	Acknowledge that not everyone is ready to quite immediately Clarify that it is their decision Listen to them describe the benefits they get from the alcohol or drug use (their motivation for continuing to use) Listen to them describe the negative effects of their alcohol or drug use (their motivation for considering quitting) Discuss any ideas they have on how they could go about quitting
Preparation: would like to quit within the next month	Congratulate them on their decision to quit Listen to them describe the benefits they expect to get from quitting Discuss any plan they have to try quitting Discuss the challenges they may face with quitting Problem-solve with them on overcoming challenges, including identifying support systems Encourage small steps towards quitting (e.g., avoiding situations that trigger use) Acknowledge that they have the strength to succeed

Action: actively trying to quit, or has recently quit (within past 6 months)	Listen to their experience with quitting Congratulate them on the steps they have taken so far Problem-solve with them on overcoming challenges, including identifying support systems Review the long-term benefits of quitting
Maintenance: has quit (more than 6 months ago) and wants to remain abstinent	Congratulate them on their success so far Discuss potential for relapse and how to deal with it Review the long-term benefits of maintaining abstinence from drug or alcohol use
Relapse	Acknowledge that relapse is common Evaluate what triggered the relapse Reassess motivation to quit and barriers to quitting Problem-solve with them on overcoming challenges and what additional support systems and strategies can be used

As indicated in the introduction of this section on mental health, the following are key areas of concern in mental ill health and there needs to be a high index of suspicion in order to identify these often-debilitating conditions that negatively affect an individual's ability to cope with the tasks of daily living. Importantly, the final two items on table 1.42 in this section emphasize resilience-building, which strengthens mental health, enhances positive engagement with one's environment, and supports living a more meaningful and fulfilling life

Table 1.43: Preferred Pharmacological Treatment Options for Common Mental Disorders

Diagnosis	1st Line Pharmacotherapy	Dosing	Common side effects
Depression and Anxiety Disorders	Fluoxetine	**Initial dose**: 20mg OD in the morning. Gradually increase dose by 20mg weekly Maximum dose :40mg/day Preferred in **hypersomnia**	GI upset, headaches, insomnia, and disturbances of the menstrual cycle (usually resolve after 1-2 weeks of continued use)
	Amitriptyline	**Initial dose:** 25mg OD at night. Titrate dose up by 25mg weekly Maximum dose: 50mg/day Preferred in **insomnia**	Constipation, Dry mouth, Dizziness, Drowsiness, Headache
	Venlafaxine	**Initial dose**: 75mg OD. Increase dose by 75mg weekly. Maximum dose: 150mg OD	Nausea, Sweating, Hot flushes, Dry mouth, Headache, Insomnia
Psychotic Disorders	Olanzapine	**Initial dose:** 5-10 mg OD. Adjust according to response (usual dose 5-20 mg) **Maximum dose**:20 mg BD per day	Drowsiness, Confusion, Blurred vision

	Risperidone	Initial dose: 1mg OD Maximum dose: 6mg per day	Insomnia, Headache, Gynecomastia, Constipation, Nausea, Diarrhoea
	Haloperidol	**Initial dose:** 5 mg OD. Increase by 5mg every two weeks. **Maximum dose**: 20mg per day	Extrapyramidal side effects (prescribe **Benzhexol** alongside Haloperidol to prevent)
PTSD	Fluoxetine	20mg OD in the morning	As above

Treatment options for mental disorders are not limited to the table above.

Information on Drug interactions between ART and other common medication is included in Annexes 32.

1.5.4 Nutrition Services

Optimal nutrition is essential in HIV management as it strengthens immunity, supports ART adherence, reduces infections, and addresses malnutrition including micronutrient deficiencies. In Advanced HIV Disease (AHD), it promotes recovery and reduces mortality.
Nutrition care also helps prevent and manage NCDs by promoting healthy weight, better metabolism, reduced inflammation, and healthier lifestyles. Patient-centred approach leads to improved outcomes and fewer complications.

1.5.4.1 Nutritional Assessment, Counselling and Support (NACS)

All PLHIV should receive nutritional assessment, counselling, and support including:

Nutrition assessment and diagnosis (timed with routine clinic visits preferably monthly for the first year of life, then quarterly up to 14 years old and every 3-6 months aligned with scheduled clinical visits). This should include:

- Anthropometric measures: Table 2.7 provide MUAC interpretation and required actions based on results for children and adults)
- Biochemical investigations as listed in Table 1.22 for baseline and Table 1.26 for follow-up investigations
- Clinical - physical examination
- Dietary assessment (24-hour recall for food type/frequency and household food security assessment) annex 23 household hunger score
- Environmental and psychosocial
- Functional (ability to care for self, bedridden, etc.)

Counselling and education

Counselling and education aim to address the identified nutrition needs during assessment by emphasizing on the utilization of locally available foods and critical nutrition practices (CNPs) as shown in table 1.44.

Table 1.44: Counselling and Education on Nutritional needs

Critical Nutrition Practice (CNP)	Key Messages and Actions
Periodic nutrition assessment	• Conduct Nutrition assessment using a client-centred approach.
Energy intake should be adjusted to fit the unique dietary needs of each PLHIV	• Assess dietary adequacy, food access, and barriers to intake.
Regular drinking of adequate safe and clean water	• Ensure sufficient hydration for digestion, absorption, transport, and metabolism.
Maintain good personal Hygiene, food safety and environmental cleanliness	• Practice regular handwashing with soap, use safe/treated water, wash fruits and vegetables, cook food well, and maintain clean surroundings to prevent infections that worsen malnutrition.
Managing food and drugs interactions	• Use dietary interventions to reduce the severity of drugs related side effects. Drugs can affect appetite, absorption, and cause side effects, while food may alter drug effectiveness. Use dietary adjustments and correct timing of meals/medications to reduce side effects and improve drug efficacy.
Positive living behaviours / Positive Health, Dignity & Prevention	• Discourage risky behaviors (unprotected sex, alcohol, smoking).
	• Encourage condom use or abstinence.
Physical activity	• Improves muscle tone, prevents wasting, boosts appetite, enhances sleep, and stimulates regeneration.
	• Encourage 30 minutes of activity at least 3 days per week.
Seek prompt treatment for all opportunistic infections and manage diet related symptoms	• Timely management of opportunistic infections and nutrition interventions slows disease progression and malnutrition.

Table 1.45: Interpretation of BMI Results for Adults

BMI Level	Classification	Action to Take
< 16	Severe malnutrition	• Refer for facility-based therapeutic intervention; rehabilitation with therapeutic feeds; counselling on intake issues and possible metabolic issues • Screen for TB
16.0–18.4	Mild/moderate malnutrition	• Nutritional counselling and supplementary feeding • Screen for TB
18.5–24.9	Normal/ recommended	• Nutritional counselling, consistent exercise to build muscles
25.0–29.9	Overweight	• Nutritional counselling to reduce energy intake; aerobic physical activity to reduce weight
≥ 30	Obese	• Counselling to change lifestyle and reduce energy intake; aerobic physical activity to reduce weight

Nutrition Support

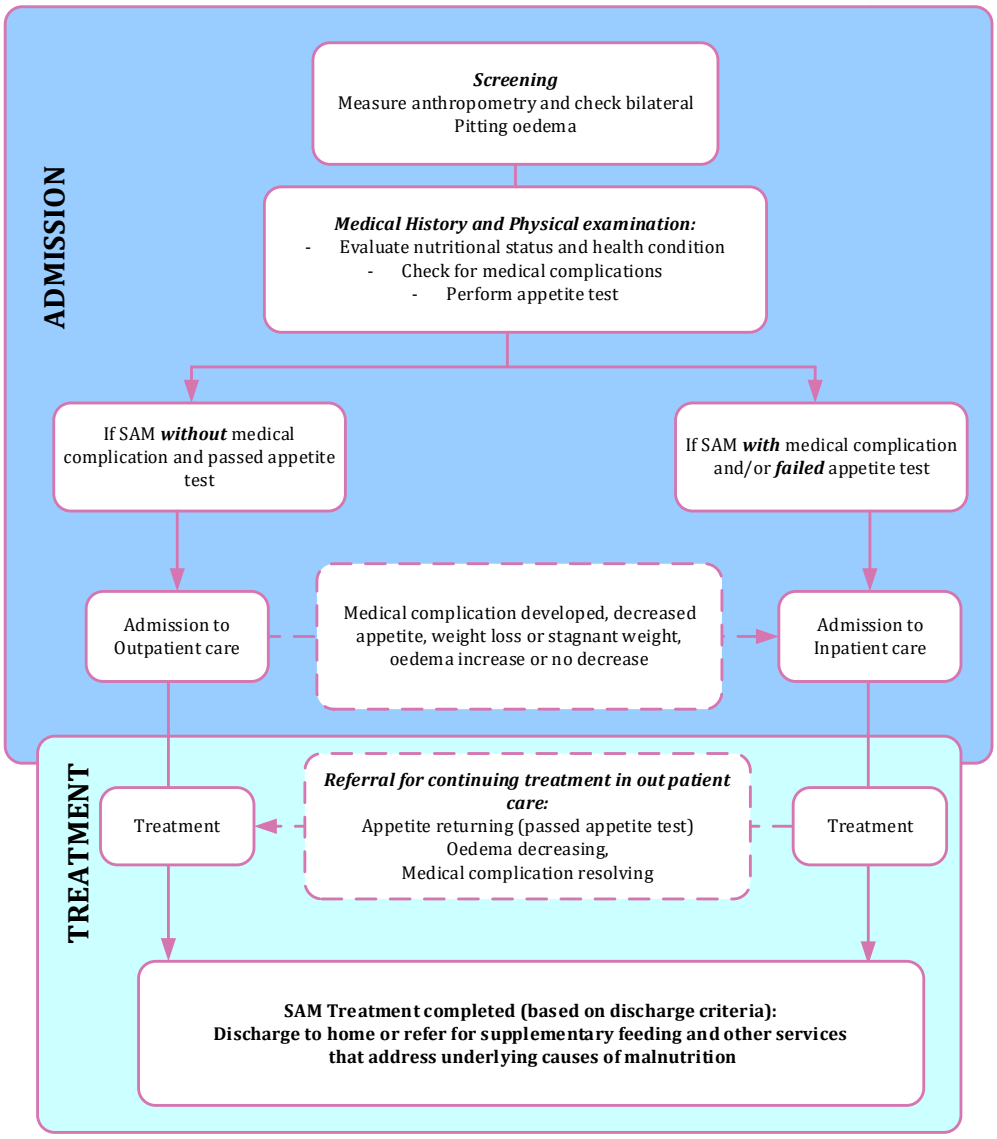
Nutrition Support aims to:

- Rehabilitate and prevent malnutrition.
- Correct nutrient deficiencies and supplement diets to improve energy and nutrient intake.
- Optimize nutrition status, enhance quality of life and reduce mortality.
- Improve adherence to medication and reduce duration of hospital stays, leading to better health outcomes.
- For the diagnosis and management of critically ill PLHIVs, refer to the AHD Operational manual. Nutrition therapy aims to prevent further deterioration, support recovery, and improve response to ART.

Oral or enteral feeding is preferred to maintain gut function and reduce infection risk. However, if the patient cannot tolerate these due to severe gastrointestinal complications, **parenteral nutrition** may be used to meet energy and nutrient requirements. Close monitoring and teamwork among healthcare providers are essential to ensure safe and effective nutrition support.

Screening, Admission, and Treatment Guide for Severe Acute Malnutrition (SAM)

Severe Acute Malnutrition (SAM) is a life-threatening condition requiring prompt identification and treatment. Figure 1-14 provides steps for screening, admission, and management using standard indicators to ensure timely and appropriate care. It aims to support full recovery, prevent complications, and reduce mortality among affected individuals, especially vulnerable groups.



Complications that necessitate hospitalization:

Pitting oedema, poor appetite, Intractable vomiting, Convulsions, Lethargy, Unconsciousness, Lower respiratory tract infection, High fever, Severe dehydration, Severe anaemia, Hypoglycaemia, Hypothermia, Eye signs of vitamin A deficiency, Skin lesions.

Figure 1.14: Screening, admission and treatment guide for Severe Acute Malnutrition

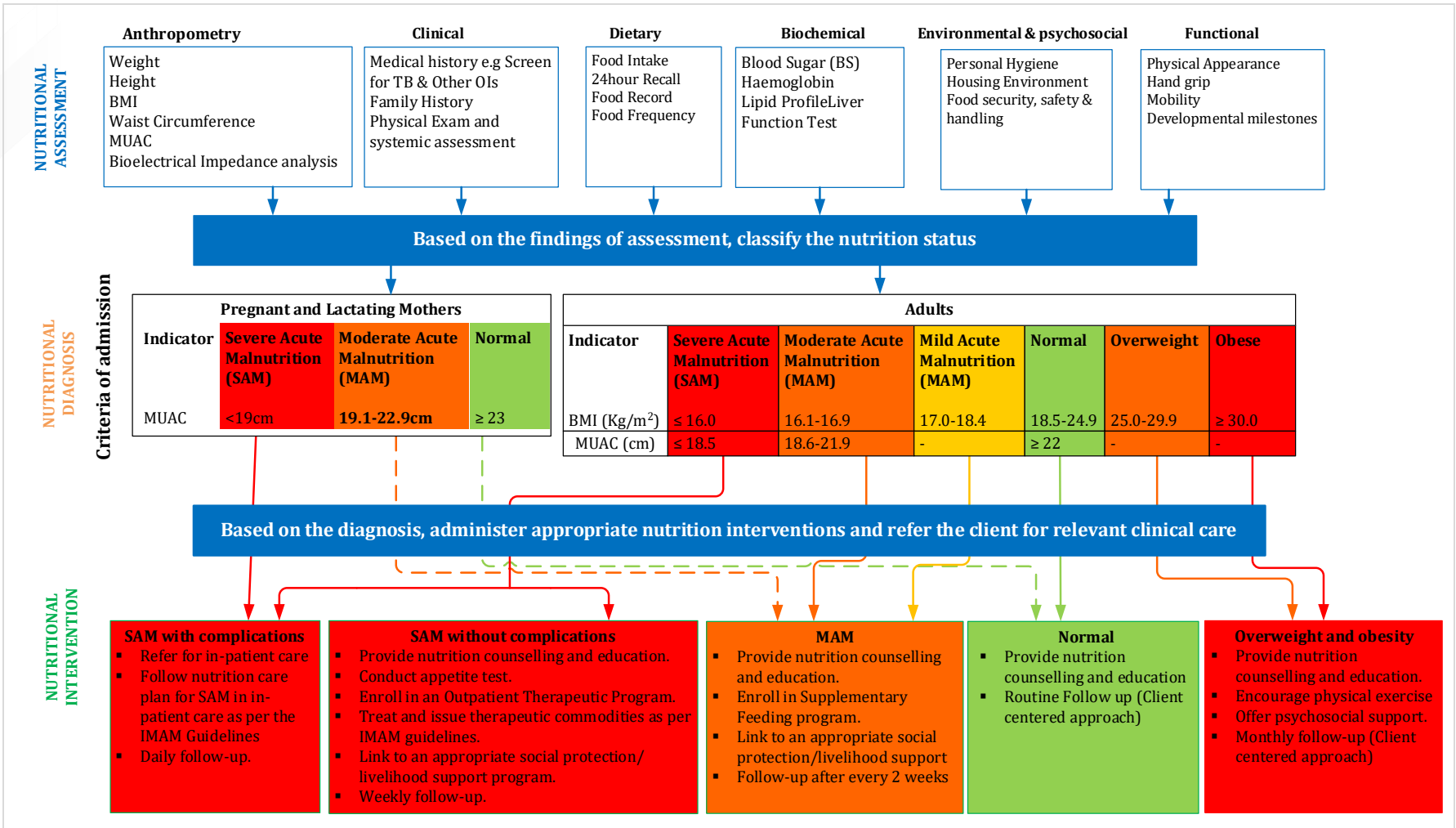


Figure 1.15: Management of Malnutrition in Adults with HIV

1.5.4.2 Nutrition in the elderly PLHIV

The elderly living with HIV have elevated nutritional requirements due to increased metabolic demands associated with HIV infection. Specific nutritional needs for this population include:

- Energy and protein
- Micronutrients
- Calcium and vitamin D

The older PLHIV are prone to NCDs due to age and some ART medication hence need dietary and lifestyle modification.

Nutrition management in critically ill PLHIV

Critically ill PLHIV have increased nutritional needs and are at high risk of malnutrition due to infection and metabolic stress. Nutrition therapy aims to prevent further deterioration, support recovery, and improve response to ART.

Oral or enteral feeding is preferred to maintain gut function and reduce infection risk. However, if the patient cannot tolerate these due to severe gastrointestinal complications, **parenteral nutrition** may be used to meet energy and nutrient requirements. Close monitoring and teamwork among healthcare providers are essential to ensure safe and effective nutrition support.

Enteral and Parenteral Nutrition

Enteral and parenteral nutrition refers to the provision of food and nutrients to the patient when the conventional feeding methods are not adequate or cannot meet nutrition needs. Selection of the mode of feeding is dependent upon several factors. Figure 1.16 below outlines the factors to consider in selection of a feeding method.

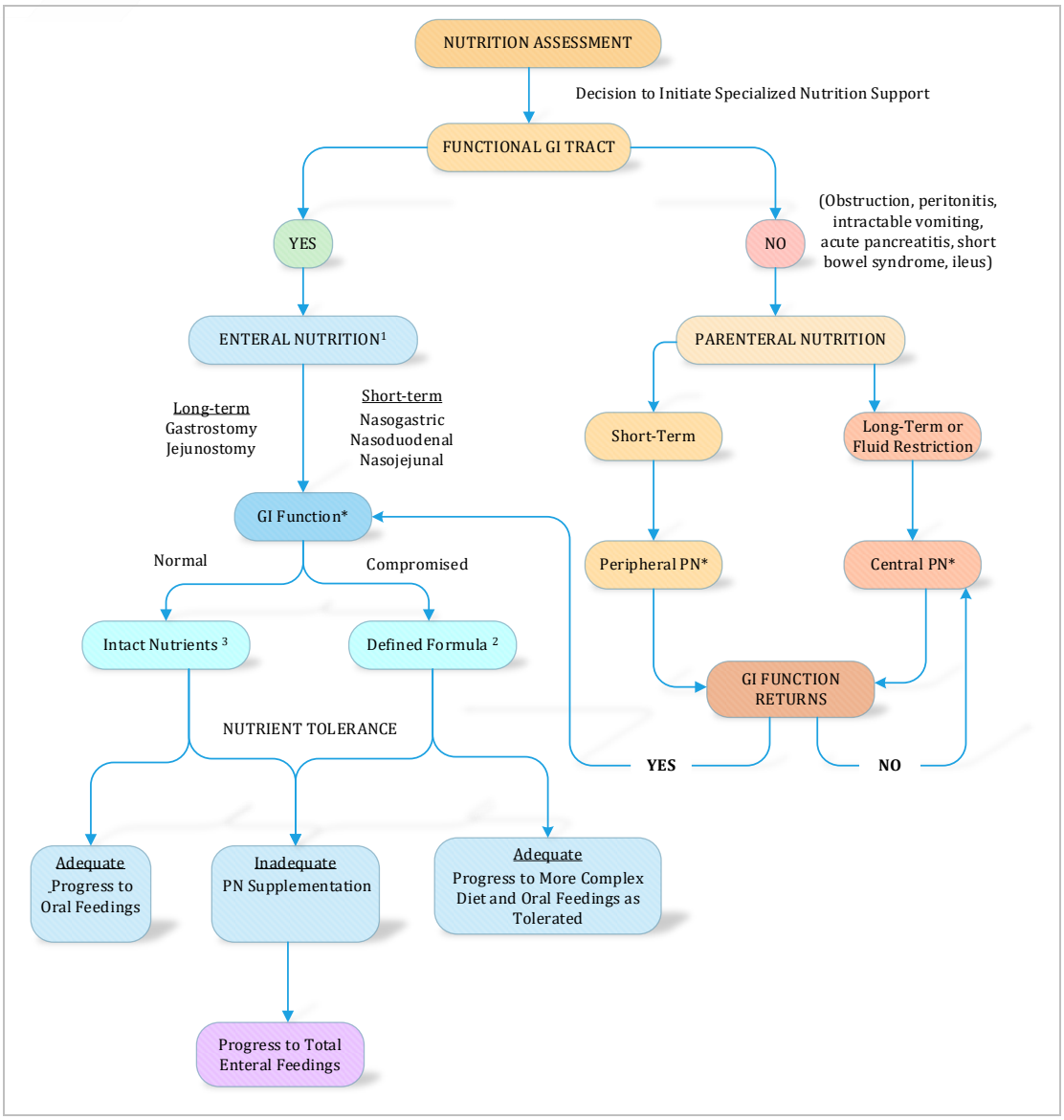


Figure 1.16: Choice of route of nutrition administration (Adapted from JPEN 1993; 17 (4): 1SA)

1.5.5 Prevention of Other Infections

1.5.5.1 Immunizations

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

Table 1.46: Routine Immunization Schedule in Kenya

Contact	Age of Child	Vaccine/Dose	Dosage	Route/Remarks
1	At birth or at first contact (within 2 weeks of life)	BCG[1]	0.05 ml (<1 yr), 0.1 ml (>1 yr)	Intradermal
		OPV birth dose (bivalent)	2 drops	Oral
2	At 6 weeks (or after 6 weeks)	OPV 1	2 drops	Oral
		DPT-HepB+Hib 1	0.5 ml	Intramuscular, left thigh
		PCV10 – 1	0.5 ml	Intramuscular, right thigh
		Rotavirus – 1	0.5 ml (5 drops)	Oral
3	At 10 weeks (or 4 weeks after OPV 1)	OPV 2	2 drops	Oral
		DPT-HepB+Hib 2	0.5 ml	Intramuscular, left thigh
		PCV10 – 2	0.5 ml	Intramuscular, right thigh
		Rotavirus – 2	0.5 ml (5 drops)	Oral
4	At 14 weeks (or 4 weeks after OPV 2)	OPV 3	2 drops	Oral
		DPT-HepB+Hib 3	0.5 ml	Intramuscular, left thigh
		PCV10 – 3	0.5 ml	Intramuscular, right thigh
		IPV	0.5 ml	Intramuscular, right thigh (2.5 cm from PCV site)
		Rotavirus – 3	0.5 ml (5 drops)	Oral
5	At 6 months	Vitamin A	100,000 IU	Oral
		Measles-Rubella[2]	0.5 ml	Subcutaneous, right deltoid
		RTS,S/AS01 (Malaria Vaccine – 1, high-risk counties)[3]	0.5 ml	Intramuscular, left deltoid
6	At 7 months	RTS,S/AS01 (Malaria Vaccine – 2, high-risk counties)	0.5 ml	Intramuscular, left deltoid

Contact	Age of Child	Vaccine/Dose	Dosage	Route/Remarks
7	At 9 months (or after 9 months)	Measles-Rubella 1st dose	0.5 ml	Subcutaneous, right deltoid
		IPV	0.5 ml	Intramuscular, right thigh
		Yellow Fever (high-risk counties)[4]	0.5 ml	Subcutaneous, left deltoid
		RTS,S/AS01 (Malaria Vaccine – 3, high-risk counties)	0.5 ml	Intramuscular, left deltoid
		Typhoid Conjugate Vaccine	0.5 ml	Intramuscular, left upper outer thigh
8	At 12 months	Vitamin A	200,000 IU	Oral
9	At 18 months (or after 18 months)	Measles-Rubella 2nd dose	0.5 ml	Subcutaneous, right deltoid
		Vitamin A	200,000 IU (1 capsule)	Oral
10	At 24 months	RTS,S/AS01 (Malaria Vaccine – 4, high-risk counties)	0.5 ml	Intramuscular, left deltoid
11	At 10 years (girls extend to 14 Years for catch up)	HPV Vaccine 1	0.5 ml	Intramuscular, left deltoid
12	1-2 months after initial dose	HPV Vaccine 2	0.5 ml	Intramuscular, left deltoid
13	At 10 yrs + 6 months (or 6 months after HPV 1)	HPV Vaccine 3	0.5 ml	Intramuscular, left deltoid

Notes:

Infection with HIV is not a contraindication to vaccination. In circumstances where the child's HIV status cannot be established, live vaccines should not be administered to children who are symptomatic for HIV infection

[1]All **asymptomatic** HIV infected children should receive BCG at birth

[2]Asymptomatic Children living with HIV and HIV-exposed Infants should receive Measles/rubella vaccine at 6 months, plus boosters at 9 and 18 months

[3] Children in malaria endemic counties should receive the full course of the Malaria vaccine. 8 malaria endemic counties are Kisumu, Homabay, Siaya, Migori, Vihiga, Kakamega, Busia, Bungoma

[4]Children in yellow fever endemic counties (Baringo, Elgeyo Marakwet, West Pokot and Turkana)

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

Recommended vaccinations for adolescents and adults living with HIV are listed in table 1.47.

Table 1.47: Vaccinations in Adolescents and Adults Living with HIV

Infection	Vaccine	Live (Y/N)	Course	Comments
Hepatitis B	Subunit	N	4 doses (at 0, 1, 2 and 6 months)	Use double dose if non-adjuvanted; use standard dose if adjuvanted
Pneumococcus	Conjugate	N	1 dose (PCV 13)	Preferable to polysaccharide
	Polysaccharide	N	1 dose	Use if >65 years and with comorbidity other than HIV
Human Papillomavirus (HPV)	Virus-like particles	N	3 doses (at months 0, 1-2, and 6)	All girls at 9-14 years old
Influenza	Inactivated	N	1 dose	Annually
Hepatitis A	Inactivated	N	2 - 3 doses	3 doses if CD4 count < 350 cells/mm^3 at 0, 1 and 6 months. If CD4 count > 350 cells/mm^3, give 2 doses at 0 and 6 months. For those at continued risk, one booster dose every 10 years
Additional Vaccines for Special Circumstances				
Yellow fever	Live attenuated	Y	1 dose	Use only in patients <60 yrs of age and CD4 > 200 cells/mm^3
Typhoid	Conjugate	N	1 dose	Provided as 1 dose only up to the age of 65 years
Cholera	Subunit	N	2 doses	As indicated (usually in epidemics). 2 oral doses of the non-replicating vaccine given 1-6 weeks apart with a single booster dose at 2 years from primary vaccination

1.5.5.2 Malaria

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

Recommendations for malaria prevention for PLHIV include:

- Offer cotrimoxazole preventive therapy (CPT) for protection against malaria infection (Annex 41: Co-trimoxazole Preventive therapy)
- In areas of stable malaria transmission, PLHIV should have access to insecticide treated mosquito nets (ITNs) or indoor residual spraying to reduce exposure to mosquito bites and therefore malaria transmission
- PLHIV travelling from non-malarious zones to malaria endemic areas should sleep under ITNs
- Pregnant women with HIV living in areas of stable malaria transmission who cannot take CPT should be given at least three doses of sulfadoxine-pyrimethamine (SP) intermittent preventive treatment for malaria as part of routine antenatal care
- Note: SP should not be given to women who are taking CPT
- PLHIV on CPT who develop fever should not be treated for an unconfirmed presumptive diagnosis of malaria. Laboratory confirmation of malaria should be obtained prior to initiation of anti-malarial therapy
- PLHIV with malaria should receive standard antimalarial therapy according to national guidelines. Those on CPT should not be given sulfa-containing anti-malarial drugs. Patients on ART receiving anti-malarial therapy should be monitored closely for adverse drug reaction.

1.5.5.3 Safe Water, Sanitation and Hygiene

Diarrheal illnesses are common causes of morbidity and mortality among PLHIV.

These diseases are often due to lack of access to safe drinking water, improper disposal of human and animal waste, and poor personal hygiene, leading to contamination of food and water.

Recommendations for prevention of faecal-orally spread illnesses include:

- Offer CPT for protection against some GI infections (Annex 41: Co-trimoxazole Preventive therapy)
- Hand washing with soap and water after handling human or animal faeces, after using the toilet, and before food preparation or eating
- Facilities for proper disposal of human waste.
- Training on household-based water treatment methods and water storage containers that prevent direct hand contact with drinking water

1.6 Adherence Preparation, Support and Monitoring

Effective adherence preparation, monitoring, and support are critical for achieving and maintaining viral suppression in PLHIV and improving treatment outcomes including other co-morbidities.

- Adherence support should begin at the time of HIV diagnosis (during post-test counselling and linkage) and be sustained throughout follow-up.
- Adherence interventions should be planned before ART initiation; client-centred and integrated with other health services to prevent treatment failure.
- Patient preparation and counselling should be collaborative, involving both provider and patient (or caregiver), to support lifelong treatment.

Adherence preparation, monitoring and support for the first 3 months on ART

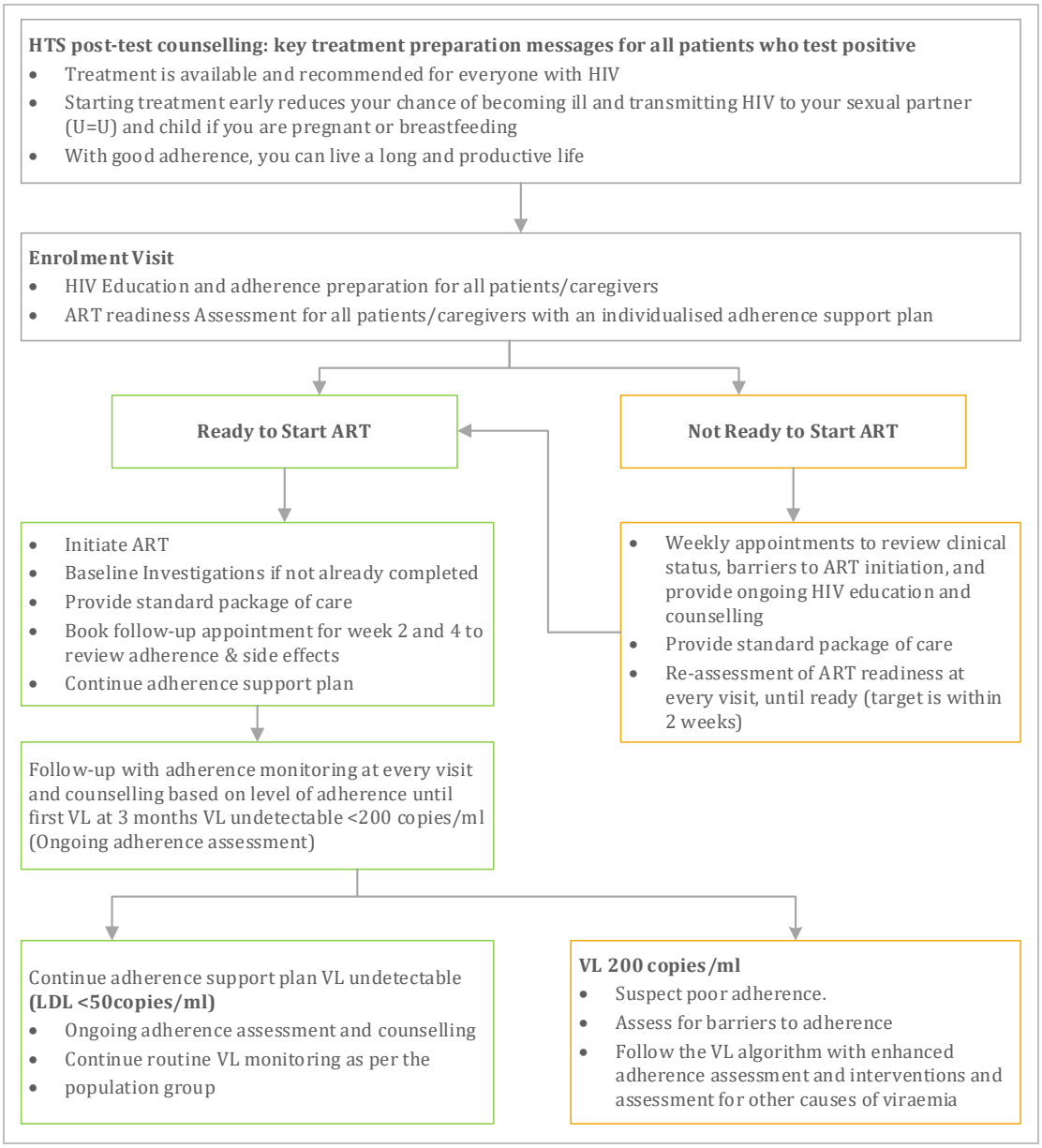


Figure 1.17: Adherence preparation, monitoring and support for the first 3 months of ART

1.6.1 Adherence Preparation Before ART Initiation

At treatment initiation, a readiness assessment should be conducted to identify potential barriers and facilitators of adherence. Special considerations should be made for children, and adolescent and older PLHIV. At treatment initiation, health providers conduct adherence preparation as outlined in Table 1.48.

Table 1.48: Key Components of Adherence Preparation

Component	HIV Focus
Comprehensive counselling and treatment literacy	• Purpose and benefits of ART • Expected side effects and their management • Importance of adherence for viral suppression and prevention of resistance • Provide treatment literacy materials in appropriate formats and language
Readiness assessment using age specific checklists (Annex 7)	• Addressing barriers; stigma, mental illness, substance use, unstable housing, or food insecurity
Treatment supporters	• Identify peers/family for adherence support

1.6.1.1 ART Treatment Preparation

ART treatment preparation is summarized in Table 1.49. The education and counselling sessions should be documented in patient charts.

Table 1.49: Treatment Preparation and Adherence Counselling Guide

HIV Education	
• Ask the patient what they know about HIV • Ask the patient what they know about treatment for HIV • Correct/clarify as needed, ensuring you cover: – Modes of transmission and importance of testing partners/children – HIV effect on the immune system and health – HIV viral load and its relationship to health and to HIV transmission (refer to U=U section 1.6.5) – Goals of ART – Relationship between adherence and viral suppression, treatment failure, and drug resistance – Consequences of drug resistance • Ensure the patient understands by asking them to explain it back to you	
Barriers to Adherence	
• Explore barriers to adherence and clinic attendance while identifying which may be most relevant to the patient.	
• Patient/Other Factors – Side effects (many patients have side effects when they first start their ART, including nausea, headaches, and difficulty sleeping. These side effects almost always resolve with continued use) – Stigma and non-disclosure (having to hide their ARV pill-taking) – Lack of support systems – Alcohol or drug use – Depression or other psychiatric illness	• Provider/System Factors – Pill burden – Poor patient-provider relationship – Inadequate HIV education – Cost of care (direct and indirect) – ARV supply-chain limitations (stock-outs, or low stock levels resulting in small refill quantities)

HIV Education	
– Loss or grief – Cognitive disorders – Chaotic lifestyle/inconsistent daily routine – Forgetting to take pills o Feeling better so does not think the ART is needed any more o Feeling too sick to take ART o Food insecurity ● Age (adolescents - impulsive, more susceptible to social pressure; children – caregiver dependent)	

Individualized Adherence Plan

- Ask the patient what they can do to ensure excellent adherence
- Ensure the adherence plan incorporates details of the patient's specific ART regimen:
  - Number of pills, frequency, food requirements/restrictions
  - Common side effects
  - Important drug interactions
- Work with the patient to make an individualized adherence plan, which may include:
  - Disclosing their HIV status to a trusted friend, family member, partner, teacher etc who can help support their treatment
  - Disclosing their HIV status to household members so they do not have to hide pill-taking
    - Encourage patient to identify a treatment buddy (someone who walks and supports the treatment journey). Bringing them to the clinic or to a session with a counsellor to learn more about HIV is important.
  - Combining pill taking with a consistent activity in their daily routine
  - Keeping the ARVs in a place that they are likely to see every day
  - Setting a daily alarm on their phone/watch/clock
  - Connecting with a support group for additional counselling/education/support
  - Getting treatment for alcohol or drug use, depression or other mental health disorders
- Discuss what to do if:
  - Develops side effects
- Discuss common and serious adverse events for their specific regimen
- Encourage patient to return to clinic for any side effects rather than stopping ART
  - Forgets to take a dose
  - Travels without their ART: go to the nearest health facility or call clinic for guidance
- Ask the patient to summarize their individualized adherence plan

Ongoing Support at Subsequent Visits

- Review the patient's HIV knowledge
- Review the patient's motivation to take ART
- Elicit any concerns the patient may have about their ART, side effects, visit schedule, or health
- Review t

HIV Education
• he ART dosing schedule and ask about any missed pills • Explore barriers to adherence that were previously identified or new ones that have developed • Explore any recent or expected changes in their life or daily routine • Discuss their individualized adherence plan and if any changes are required

1.6.1.2 HIV Education and Counselling

HIV education should be a standard component of the enrolment visit. Prior to ART initiation, all patients/caregivers must be provided with enough information to make an informed choice about ART initiation and adherence. This information can be provided through group or individual counselling. The ART Readiness Assessment and the management plan should be completed for each patient individually as highlighted in table 1.50

Table 1.50: Components of HIV Education

Component	Questions to be Covered
HIV	• What is HIV • How is HIV transmitted • Why should partners and family members be tested for HIV
Viral load	• What is viral load • How often is viral load measured • What do viral load measurements mean, including the goal of achieving viral suppression
CD4 cells	• What are CD4 cells • How are CD4 cells affected by HIV • What happens when CD4 cells decrease • How often is CD4 cell count measured
Antiretroviral therapy (ART)	• What is ART • What are the benefits of ART • When is ART started • Does ART cure HIV • Can you still give HIV to others while taking ART • How long is ART taken
Treatment failure	• What happens if you stop taking ART • What happens if you do not take ART regularly • What happens if the viral load increases • What happens in treatment failure
ART side effects	• What are the side-effects of ART • What should you do if you notice any side effects
Adherence	• What is adherence

Component	Questions to be Covered
	• How should ART be taken • What usually interferes with good adherence • What might make it difficult for you to take your ART as prescribed • What can help you take ART as prescribed • What happens if you miss an appointment
Other medications	• What other medications will you take, in addition to ART (e.g., CPT, TPT)
Nutrition	• Why is nutrition important • What can you do to improve your nutrition
Mental health	• Why is mental health important • What can you do to improve your mental health
Follow-up	• How often will you need to come for clinic visits? • What will we be checking for during your clinic visits

1.6.1.3 ART Readiness Assessment

Before ART initiations, an ART Readiness assessment should be conducted as guided as guided by ART Readiness Assessment Form (Annex 7). However, readiness assessment should not be a barrier to starting ART.

1.6.2 Adherence Support

Individualized patient management plan should include establishing appropriate adherence support interventions (Table 1.51).

Table 1.51: Adherence Support and Retention Interventions

Standard Adherence Support Interventions	
Structural interventions	• Conduct a baseline psychosocial assessment to identify factors influencing adherence (e.g., disclosure, family planning, living circumstances, well-being). • Use a multidisciplinary team (MDT) to develop and implement treatment plans. • Engage peer educators to support HIV education and adherence services. • Assess and prepare patient readiness before and during ART initiation. • Implement a treatment interrupter tracing system to act quickly when appointments are missed. • Link to DSD • Formalize structured health talks and treatment literacy classes. • Link patients to community resources/support systems and other services such as mental health
HIV education and counselling	• Remind patients about HIV disease, how ART works, the importance of excellent adherence, and consequences of poor adherence • Maintain a non-judgmental, trust-building approach, especially with parents/caregivers, and involve children as they mature.

Standard Adherence Support Interventions	
Disclosure and stigma	• Always respect privacy and confidentiality • Discuss with patients the role of disclosure to trusted family/friends in supporting adherence • Offer disclosure support when needed. • For children/adolescents: support age-appropriate, stepwise disclosure with caregivers Younger children should be told incrementally based on maturity Full disclosure should be achieved by 12 years of age Parents/caregivers' HIV status should also be disclosed to school-age children in a phased approach. • Guide disclosure decisions to promote the child's welfare and protect relationships. • Post-disclosure assessment should be conducted (after full disclosure). • Advocate for policies and norms that reduce stigma and discrimination, making disclosure safer and easier. • School-age children - always conduct a stigma assessment and provide support. • Refer to Annex 5: Age-appropriate disclosure for children and adolescents)
Treatment supporter	• Encourage patients to identify a treatment buddy/supporter to give encouragement and reminders. • Invite the supporter to attend at least one adherence counselling session. • Obtain patient consent to contact the supporter if needed.
Support groups	• Link patients to psychosocial support groups and community-based mechanisms (preferably through direct introduction). – Groups provide encouragement, reduce stigma, and support disclosure. – They also allow for experience sharing, counselling, and life skills building. – Some groups include economic empowerment activities. – Support groups can facilitate ART refills for established patients. • Develop population-specific support groups (youth clubs, children's clubs, caregiver groups). • MDT members should act as patrons to ensure alignment with treatment goals.
SMS reminder system	• Enrol patients (with consent) into an automated SMS reminder system. • Review the message type, frequency, and required patient actions. • Ensure confidentiality and privacy in all messages.
Other reminder strategies	• Encourage setting a fixed time daily for ART, linked with routine activities. • Promote use of alarms on phones/watches/clocks as reminders.

1.6.3 Adherence Monitoring

Adherence should be assessed at every clinical encounter using multiple methods described in Table 1.52 below:

Table 1.52: Standardized Adherence Monitoring Strategies

Adherence Monitoring Strategy	Technique	Frequency
Subjective (self-reported adherence)		
Morisky Medication Adherence Scale-4	Use table 1.54 to assess adherence using a standardized questionnaire, and take action as required	Every patient, every visit
Morisky Medication Adherence Scale-8	Use table 1.54 to assess adherence using a standardized questionnaire, and take action as required	Any time a healthcare worker suspects adherence problems (e.g., patients with suspected or confirmed treatment failure; patient who misses an appointment)
Objective		
Pill counts	Ask the patient to bring all their pills with them to follow-up visits. Calculate how many pills should be remaining based on the previous prescription date and amount prescribed and compare to how many pills are actually remaining. Excess pills are assumed to be missed doses. Use Table 1.54 to calculate adherence rate and take action as required	• At every visit until confirmed viral suppression • Any time a healthcare worker suspects adherence problems
Pharmacy refill records	Compare drug pick-up date with expected date of pick-up (based on number of pills dispensed at last visit). If drug pick-up date is later than expected, it is assumed the patient is missing doses equivalent to the number of days late	• At every drug pick-up • Any time a healthcare worker suspects adherence problems
Viral load	Follow the viral load monitoring algorithm (Figure 1.22). Undetectable VL is the best confirmation of adequate adherence	• Age and population based

Table 1.53: Morisky Medication Adherence Scale (MMAS-4)

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

Interpretation of MMAS-4 Score		
MMAS-4 Score	**Adherence Rating**	**Action Required**
0	Good	Continue with routine monitoring, counselling and support
1-2	Inadequate	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 2.39) • Engage treatment supporter in adherence counselling sessions • Follow up in 2-4 weeks
3-4	Poor	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 2.39) • Engage treatment supporter in adherence counselling sessions • Implement DOTs • Follow up in 1-2 weeks

Table 1.54: Morisky Medication Adherence Scale (MMAS-8)

MMAS-8: Ask the patient each question below. Circle the corresponding score for each response. After completion of all questions, add up all the points that you have circled for the total score.		
Question	**Yes**	**No**
1. Do you ever forget to take your medicine?	1	0
2. Are you careless at times about taking your medicine?	1	0
3. Sometimes if you feel worse when you take the medicine, do you stop taking it?	1	0
4. When you feel better do you sometimes stop taking your medicine?	1	0
5. Did you take your medicine yesterday?	0	1
6. When you feel like your symptoms are under control, do you sometimes stop taking your medicine?	1	0

7. Taking medication every day is a real inconvenience for some people. Do you ever feel under pressure about sticking to your treatment plan?	1	0
8. How often do you have difficulty remembering to take all your medications? (Please circle the correct number) _____A. Never/Rarely _____B. Once in a while _____C. Sometimes _____D. Usually _____E. All the time	Points: A. 0 B. ¼ C. ½ D. ¾ E. 1	
Total Score (sum of all items)		

Interpretation of MMAS-8 Score		
MMAS-8 Score	**Adherence Rating**	**Action Required**
0	Good	Continue with routine monitoring, counselling and support
1-2	Inadequate	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 1.59) • Engage treatment supporter in adherence counselling sessions • Follow up in 2-4 weeks
3-8	Poor	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 5.15) • Engage treatment supporter in adherence counselling sessions • Implement DWI • Follow up in 1-2 weeks

Table 1.55: Adherence Rate Based on Pill Counts

Missed Doses per Month		**% of Medications Taken**	**Adherence Rating**	**Action Required (see Table 5.10 for more details)**
For once-daily regimen	**For BD regimen**			
1 dose	1-3 doses	≥ 95%	Good	Continue with routine monitoring, counselling and support
2-4 doses	4-8 doses	85-94%	Inadequate	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 1.57) • Engage treatment supporter in adherence counselling sessions • Follow up in 2-4 weeks

≥ 5 doses	≥ 9 doses	< 85%	Poor	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 1.57) • Engage treatment supporter in adherence counselling sessions • Implement DWI • Follow up in 1-2 weeks

Special Considerations when Counselling Children and Adolescents

Children and adolescents depend on caregivers to support their adherence therefore, all topics covered in the HIV Education and Adherence Counselling sessions (Table 1.56) should be covered with the caregiver, with involvement of the child/adolescent as appropriate based on the stage of disclosure and their developmental stage (Table 1.56).

Table 1.56: Age-appropriate Involvement of Child/Adolescent in HIV Education and Adherence Counselling

Age	Counselling Approach
< 6 years old	The counselling sessions will focus on engaging all of the child's caregivers
6-12 years old	Both the caregiver and the child will be involved. The counselling will focus on the caregiver; younger children can be given a paper and pen and asked to draw their family, school, etc., and talk about their experiences. Disclosure of HIV status to the child should commence by 5 years of age and be completed by 10-12 years of age (Annex 5)
> 12 years old with caregiver present	Most of the counselling can focus on the adolescent, who is often fully responsible for medication administration. However, it is necessary to keep the caregiver coming and involved in supporting the adolescent.
> 12 years old without the caregiver present	Use the HEADSSS tool* to facilitate discussion. Negotiate involvement of a treatment supporter e.g. disclosure to boarding/class teacher to those transitioning to boarding school
* HEADSSS tool assesses: **H**ome; **E**ducation/Employment; **A**ctivities/Hobbies; **D**rugs/Alcohol/Tobacco Use; **S**exuality/Sexual Health; **S**uicide/depression/self-image; **S**afety (Use for all adolescents ≥ 10 years of age **(Refer Annex 6)**	

In addition to the standard HIV Education and Adherence Counselling topics, unique issues need to be addressed for caregivers, children and adolescents (Table 1.57).

Table 1.57: Unique Considerations for Caregivers, Children and Adolescents

Caregiver Barriers to Adherence
• Frequently changing or multiple simultaneous caregivers
• Loss or grief
• Absent or sick caregiver
• Poor understanding of HIV management due to inadequate counselling, advanced age, or illiteracy
• Depression, alcohol and other drug use
• Living far from the health facility
• Economically unstable
• Lack of affection between caregiver and child
• Lack of support systems for the caregiver
Child/Adolescent Barriers to Adherence
• Level of disclosure (is the child/adolescent aware of their HIV status?)
• Lack of understanding of disease/treatment
• Developmental stage and emotional state
• Child refusal to swallow medicine (do not allow refusal to take medicines: all activities should be stopped for the child until the dose is swallowed)
• Stigmatization and discrimination
• Low self-esteem
• Depression
• Defiance related to a troublesome caregiver-child relationship
• Inadequate structures at school (day or boarding) to support adherence
• Lack of support systems for the child/adolescent
Treatment Barriers to Adherence
• Large volumes of syrups
• Bad taste of syrups
• Pill burden
• Confusing regimens combining syrups and tablets
• Side effects
• Dose adjustment requirements as the child grows

Table 1.58: Adherence Preparation, Monitoring, and Support Approaches for Key Populations and Special Groups

Group	Preparation	Monitoring	Support Strategies & Integration Components
People Who Inject Drugs (PWID)	Integration with harm reduction (OST, NSP), hepatitis B/C testing	Regular viral load & retention checks linked to OST services	Peer navigators; OST; needle/syringe programs; linkage to HCV treatment and psychosocial support
Sex Workers	Flexible clinic hours, stigma-free environment, integrated SRH & STI services	Routine adherence & viral load assessments integrated with STI screening	Drop-in centres; community ART refill; condoms/lubricants; linkage to GBV services
Incarcerated Populations	ART initiation on entry, linkage to hepatitis and TB screening	Monthly prison clinic reviews integrating HIV, HBV, TB monitoring	Continuity of care post-release; linkage to community health facilities and social support
Mobile/Migrant Workers	Readiness checks for mobile lifestyles, integration with cross-border care programmes	Appointment tracking; multi-month dispensing	Cross-border ART refill agreements; linkage to mobile outreach and telehealth follow-up
Older PLHIV (>50 years)	Adherence readiness assessment; review of polypharmacy and drug-drug interactions; integration with NCD screening	Routine viral load, renal/hepatic function tests, and NCD monitoring	Simplified regimens; caregiver/family support; linkage to NCD clinics, vision/hearing screening, and social protection programmes
People with Mental Health Needs	Mental health screening at ART initiation; linkage to psychiatric care	Adherence tracking integrated with mental health follow-up	Psychosocial counselling; support groups; coordination between HIV and mental health services

Adherence Monitoring, Counselling and Support for Patients with Viral Load < 200 copies/ml (LDL)

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

- Patient has achieved the treatment goal. Congratulate them.
- Reassure the patient that they will do well if they continue to adhere. However, all patients are at risk of new or worsening barriers to adherence.
- Continue adherence monitoring, counselling and support but at a lower intensity.
- Enrol in less intense DSD models with.
- Assess and address any co-morbid conditions.

All PLHIV with a viral load >200 copies/ml are considered unsuppressed.

Treatment failure is confirmed as per the viral load monitoring algorithm (Figure 1.22).

Poor adherence is often the most common factor in developing treatment failure, though there can be other causes. Adherence must be thoroughly assessed, and all issues must be addressed before switching patients to the next line of ART.

Enhanced Adherence Counselling (EAC) should be initiated in all virally unsuppressed PLHIV.

1.6.4 Enhanced Adherence Counselling

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

- Conduct a thorough assessment of potential barriers to adherence (Table 1.59).
- Develop a plan for addressing barriers to adherence.
- Review VL results and adherence of the caregiver, treatment buddy, and/or spouse/partner if on ART.
- Initiate Enhanced Adherence Counselling (EAC)

The steps to offer Enhanced Adherence Counselling is as outlined in table 1.59

Table 1.59: Components of Enhanced Adherence Counselling Sessions

Enhanced Adherence Counselling Sessions: Overview	
Session 1	• Review understanding of viral load (VL) and discuss why the patient's VL is high • Review common cognitive, behavioural, emotional and socio-economic barriers to adherence – Stigma and non-disclosure – Loss or grief – Treatment literacy – Medications: dosage, timing, storage – Side effects – Discuss risk reduction (e.g., for substance abuse) – Motivation – Mental health screening (screen for depression using PHQ-9, annex 35 – Discuss patient's support systems. • Assist patient to develop adherence plan to address the identified issues
Session 2	• Review adherence plan from the first session and discuss any challenges • Identify other possible gaps and issues emerging • Assist patient to modify the adherence plan to address the identified issues
Session 3	• Review adherence plan from the first and second session and discuss any challenges • Identify other possible gaps and issues emerging • Assist patient to modify the adherence plan to address the identified issues • Decision on repeat VL based on current adherence – If the adherence is good: plan repeat VL testing after three months of good adherence and explain possible ways forward, emphasizing role of the patient and the health facility – If adherence challenges persist: consult with a senior clinician, discuss as an MDT, or consult the Regional or National TWG before repeating the VL

Enhanced Adherence Counselling Sessions: Overview	
Session to Discuss Repeat Viral Load Results	• Discuss result of the second VL test • Plan the way forward: – **If VL now < 200 copies/ml:** continue current regimen with ongoing enhanced adherence; repeat VL as per age/population – **If VL is 200-999 copies/ml:** perform another assessment for causes for viremia and address any issues identified; repeat viral load after an additional 3 months of excellent adherence – **If VL ≥ 1,000:** prepare patient for change of regimen (Table 1.62) to section, Adherence counselling and education for patients preparing to initiate subsequent ART regimens)
Enhanced Adherence Support Interventions for Patients Failing or at High-risk of Failing Treatment (VL ≥ 1,000 copies/mL)	
Case management	• Assign a case manager to all children and adolescents (those not achieving optimum treatment outcomes); pregnant women, orphans, patients with alcohol and substance use disorder, patients with mental illness, patients with suspected or confirmed treatment failure, and any patients who the healthcare team feels has poor adherence or is at high risk of defaulting from care • The case manager is the link between the patient and the MDT • Roles of the case managers include: – Coordinating multidisciplinary management for patients under case management – Following up on appointment-keeping for their patients – Organizing patient reminders (SMS, calling the day before) and other support systems – Ensuring appropriate defaulter tracing – Coordinating home visits to their patients
Home visits	• Observe where and how a patient stores and takes their medications, and assess if they have extra medications because of missed doses • Home visits may also provide a better understanding of a patient's living situation and specific barriers to adherence • Unscheduled home visits may be more revealing, but should only be conducted if the patient consented to home visits previously (preferably at the time of enrolment or initiation)
Monthly "high viral load" clinics	• Patients with suspected treatment failure should be booked for dedicated monthly high viral load clinics • Children and adolescents in school who are unable to attend clinic monthly may attend dedicated monthly clinics during mid-term and school holidays (at least every 6 weeks) • Comprehensive clinical and psychosocial evaluation should be conducted at each visit, appropriate investigations done and any opportunistic infections treated • Enhanced adherence counselling sessions should be conducted at each visit • Support groups for patients with viremia can be timed with "high viral load" clinic days

Enhanced Adherence Counselling Sessions: Overview	
Special support groups	• For health facilities with several patients who are failing treatment or who are on subsequent ART regimens, special support groups can be established so these patients can work through their adherence challenges together • Community support groups can also be engaged and linked to the facility for supporting patients with adherence challenges

Adherence support systems will need to be adapted to patients' specific needs and the context (Table 1.59). Special attention needs to be given to children, adolescents, pregnant and breastfeeding women, patients with mental health disorders and substance users.

1.6.5 Undetectable = Untransmittable (U=U)

Definition: People who maintain a durable undetectable viral load (2 consecutive viral load results of <200 copies/ml six months apart) have minimal HIV virus in their blood and other body fluids secretions that they have "effectively no risk" of passing HIV to others through sex.

1.6.5.1 Benefits of U=U

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

1.6.5.2 Applications of U=U in other settings

Note: U=U messaging is NOT applicable in:

- Pregnant and breastfeeding women LHIV settings. Prophylaxis should be provided to HIV exposed infants during the breastfeeding period as per the guidelines regardless of the viral load status. The goal of PMTCT is to ensure ALL women achieve and sustain LDL.
- People who inject drugs.
- Needle stick injuries.

1.6.6 HIV Re-engagement to Care

Early identification and re-engagement of PLHIV who interrupt treatment is critical to improving individual health outcomes and achieving national HIV epidemic control targets. Treatment interruption of ART can compromise treatment outcomes and contribute to HIV drug resistance, advanced HIV disease, virologic failure and ultimately onward transmission.

- ***Treatment interruption****:* Any PLHIV who has not attended a scheduled clinic visit or collected ART for ≥28 days and is not documented as deceased or transferred out.
- ***Re-engagement to Care****:* The structured, timely process of identifying, tracing, and successfully returning individuals (who have interrupted treatment for ≥28 days) to continuous HIV care, with the goal of achieving and maintaining durable viral suppression.

1.6.6.1 Re-engagement Pathway and Prioritization

Treatment re engagement pathway outlines a clear and responsive process for identifying and returning clients to care (Figure 1.18).

The process includes:

1. Client Identification using appointment registers, electronic medical records (EMRs), and pharmacy dispensing data.
2. Tracing Prioritization for vulnerable and high-risk groups:
    - Newly identified PLHIV
    - People who tested positive and did not initiate ART
    - People in the first 6 months on ART (including those who have re-initiated in the past 6 months)
    - Children and adolescents 0-19 years of age.
    - Pregnant and breastfeeding women
    - People with abnormal lab results e.g. high viral load
    - Clients with advanced HIV disease or recent opportunistic infections
    - Clients with prior treatment interruptions
    - Treatment failure
3. Tracing Timeline
    - **Days 7-14:** Phone tracing (at least 1 successful call) of either the client or the treatment supporter.
    - **From day 14 onwards:** Conduct home visits and/or use peer or community outreach.
    - Provide appointment reminders using SMS (including use of automated client SMS reminders) or calls, especially for high-priority populations

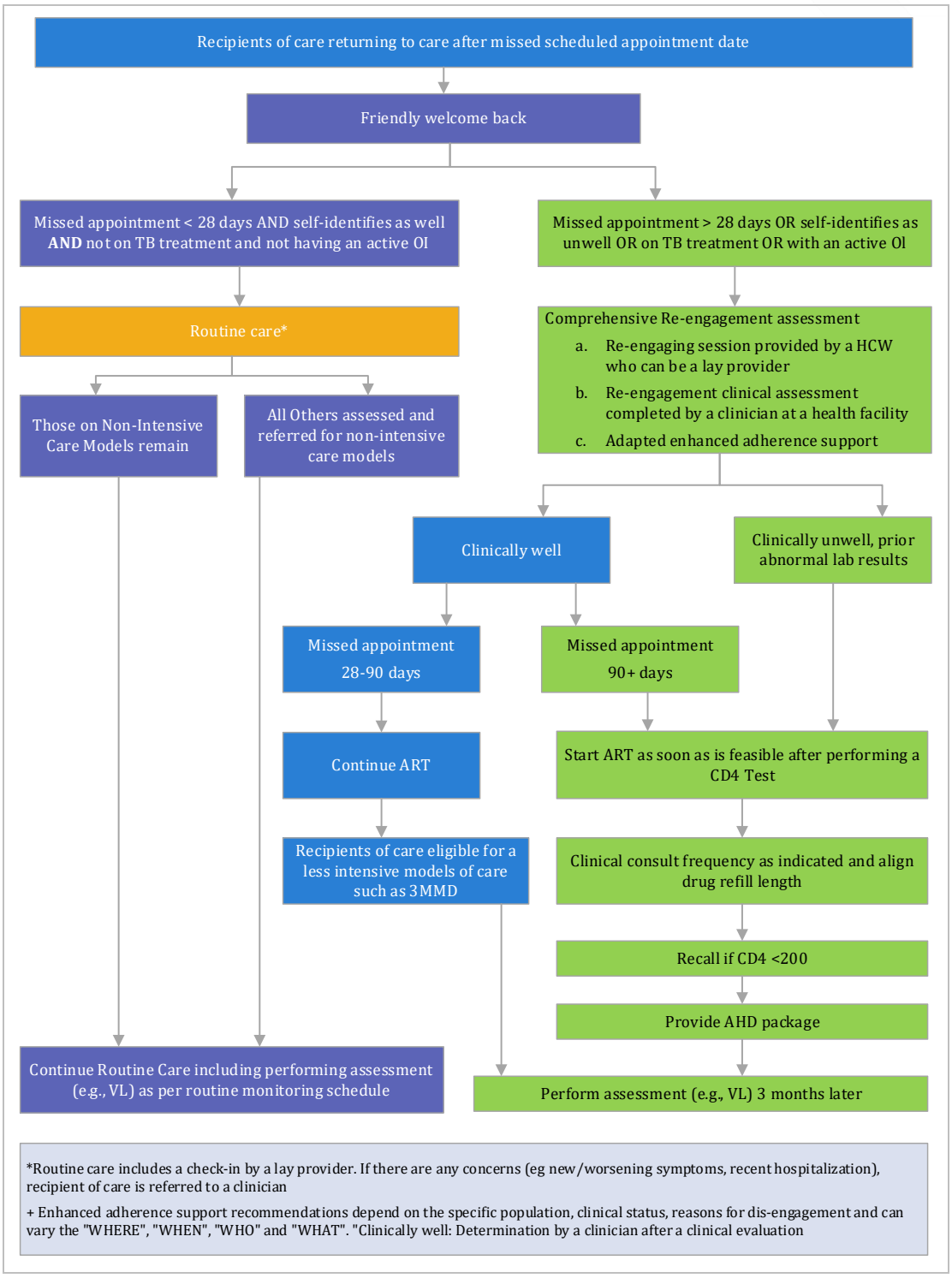


Figure 1.18: Re-engagement to Care after Missed Appointment

1.6.6.2 Package of Care for Re-engaged PLHIV

All recipients of care returning to treatment after interruption should receive a tailored package informed by clinical and psychosocial evaluation. The goal is not only to re-initiate treatment, but to address underlying barriers and support long-term retention.

Package of Care for Re-engaged Clients

- **Friendly welcome back:** a non-judgmental, compassionate approach that reassures the recipient of care they are valued, and that the health facility remains a safe and supportive space for their treatment. Avoid blame or punitive language, and instead express gratitude for the client's return, acknowledge potential challenges they faced, and affirm their commitment to walking the journey to wellness together.
- **Clinical Evaluation:** Conduct physical examination, screen for OI including TB, STIs, and other comorbidities.
- **Psychosocial Assessment:** Explore reasons for interruption (e.g., stigma, mental health, family dynamics, economic barriers).
- **Enhanced Adherence Counselling:** Strengthen treatment literacy, motivation, and planning for continued adherence.
- **CD4 Testing:** Conduct CD4 test if re-engaging after 3 months
- **VL Testing**: Perform a VL 3 months after restarting ART
- **ART Regimen Review:** Assess for potential failure or toxicity; optimize regimen as clinically appropriate.
- **Linkage to Support Systems:** Refer to peer support, community ART groups, or socioeconomic support services as needed.
- **Transition to DSD Models:** After stabilization, offer multi-month dispensing (MMD) or community-based refill models.

1.7 Antiretroviral Therapy in Infants, Children, Adolescents and Adults

The goal of ART is to suppress viral replication with the aim of reducing the patient's VL to undetectable levels. Uninterrupted ART with ongoing strict adherence will help maintain undetectable VL levels thereby preventing damage to the body's immune system, reducing AIDS-related morbidity and mortality and the risk of sexual and vertical transmission of HIV.

1.7.1 Eligibility for ART

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

1.7.2 Timing of ART Initiation

ART should start in all PLHIV as soon as possible, preferably within 2 weeks of confirmation of HIV status, and even on the same day as testing positive for HIV if they are ready. ART Readiness Criteria (Annex 7) can be used to help determine any issues that need to be addressed around the time of ART initiation. Same-day ART initiation has additional benefits for HIV prevention (e.g., for pregnant and breastfeeding women, and the HIV positive partner in a discordant relationship), and is associated with improved retention, viral suppression, and survival. Special considerations for timing of ART initiation are listed in Table 1.60.

Table 1.60: Special Considerations for Timing of ART Initiation

Population	Timing of ART Initiation	Additional Considerations
Infants (<12 months old)	Support ART initiation on the same day as testing positive for HIV after first positive PCR test (do not delay for confirmatory PCR)	Intensive adherence counselling, support and close follow-up required for caregivers. Verify HBV birth-dose completion, give remaining vaccines, align EID with immunization schedule, screen/treat congenital STIs (e.g., syphilis).
All Infants, Children, and Adolescents newly diagnosed with HIV	Support ART initiation on the same day as testing positive for HIV, unless specific opportunistic infections present (e.g. cryptococcal meningitis or TB)	Intensive adherence counselling, support and close follow-up required. Same-day integration: syphilis testing/treatment, HBsAg testing, HBV vaccination if negative, risk-based HCV testing, screen/treat STIs, link SRH/GBV services.
Pregnant and breastfeeding women	Support ART initiation on the same day as testing positive for HIV	Intensive adherence counselling, support and close follow-up required. Triple elimination package: HIV/syphilis/HBsAg testing at first ANC/PNC visit, repeat testing per schedule; link HBsAg-positive women to HBV care; ensure infant HBV birth-dose and Hepatitis B Immunoglobulin are provided IM within 24 hours of life.
Patients with newly diagnosed TB	Start anti-TB treatment immediately and initiate ART as soon as anti-TB medications are tolerated (≤2 weeks) For TB meningitis, delay ART for 4-8 weeks	Monitor closely for IRIS. Screen for and treat STIs; test for HBsAg and vaccinate if negative; manage drug–drug interactions (e.g., rifampicin with DTG).
Patients with cryptococcal meningitis	Defer ART until after completing 5 weeks of CM treatment	Monitor closely for IRIS. During CM treatment, conduct STI screening, HBsAg testing, and vaccinate if eligible; plan ART restart date after antifungal induction.
Patients with high adherence challenges	Start ART as soon as possible with additional support (e.g., enrolment into MAT program, psychiatric care, OVC program)	Assign a case manager. Embed STI services, HBsAg testing/vaccination, mental health and substance use care, GBV/IPV linkage, and family planning in care plan.1.

1.7.3 Initial ART Regimens for Infants, Children, Adolescents and Adults

Nomenclature of Regimens

- **Initial ART regimens;** for ART-naïve individuals or those switching without evidence of treatment failure.
- **Subsequent ART regimens;** for patients experiencing failure with initial regimens or requiring regimen changes due to intolerance or contraindications.

- **Constructive ART regimens** for complex, treatment-experienced cases with multiple drug class failures, where individualized regimens are designed based on drug resistance testing and treatment history.

Refer to Annex 8, *Initial, subsequent, and constructive ART regimens for adults for further description.*

Selecting the right initial ART for infants, children, and adolescents is essential for achieving viral suppression, preserving immunity, and supporting growth. Tables 1.61 and 1.62 present preferred regimens by age and weight band, along with alternatives where DTG is not suitable or available.

Table 1.61: Initial ART Regimens and Dosing for Infants, Children, Adolescents and Adults

Age	Weight	Preferred Regimen	Considerations / Dosing
Pre-term Infants <37 weeks	Any	AZT+3TC+NVP[1]	Refer to weight-based dosing chart[2]
Term infants	<2kgs		
Birth to 4 weeks Term infants ≥37 weeks gestation)	≥ 2kgs	ABC + 3TC + DTG	
> 4 weeks to < 15 years	3 to <24.9 kg	ABC + 3TC + DTG (pALD)	
	≥ 25 kg	TAF + 3TC + DTG[3]	FDC, 25/300/50 mg
≥ 15 years	Any	TDF + 3TC + DTG[4]	FDC, 300/300/50 mg
		Alternative TAF+3TC+DTG	FDC, 25/300/50 mg Population (i) PLHIV new and currently on ART ≥60 years of age (ii) PLHIV currently on ART with comorbidities (diabetes mellitus, hypertension, risk of osteoporosis and chronic renal failure with a creatinine clearance of >30 ml/min)

[1]Infants who initiate ART at less than 37 weeks gestation (premature infants) should initiate on AZT+3TC+NVP irrespective of previous ART exposure; metabolism of other ARVs is not well known for this age group. As soon as these infants become 4 weeks old and >/=37 weeks gestation and attain 3kg they should switch to paediatric ABC+3TC+DTG (pALD 60/30/5 mg; dosing included in Annex 10). Infants on AZT should be monitored for anaemia, neutropenia, lactic acidosis and anaemia of prematurity, consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000, ulizanascop@gmail.com.

[2]Weight-based dosing of all single-drug and fixed-dose combination formulations (Annex 10 &11).

[3]Includes children on ART, newly diagnosed.

[4]Provide TLD for patients ≥ 30 Kgs

Age	Weight	Preferred Regimen	Considerations / Dosing
Additional Notes: • Patients currently on an initial regimen that is not included in the indicated preferred regimens should be considered for regimen optimization • **DTG/3TC dual therapy:** may be considered as an option for HBV-negative patients once fixed-dose combinations are available.			

Table 1.62: Use of Alternative ARVs in Initial Regimens

Age	Weight	Scenario and ARV Affected	Alternative ARV to Use
Pre-term infants,	Any	NVP: Develops hypersensitivity reaction	Use RAL granules if unavailable, consult the RTWG for guidance on ART for the infant
		AZT: Infant Hb < 9.5 g/dL	Consult the RTWG for guidance on ART for the infant
Term infants from birth to < 15 years	< 25 kg	ABC: Develops ABC hypersensitivity reaction[1]	Use AZT (if Hb ≥ 9.5 g/dL); if Hb < 9.5 g/dL consult Regional or National HIV Clinical TWG (call *Uliza* Hotline 0726 460 000; ulizanascop@gmail.com)
		DTG: Unable to tolerate	Use DRV/r at standard weight-based BD dosing, Use LPV/r if weighing below 10kg or younger than 3 years
		DTG: Currently on rifampicin-containing anti-TB medications	Increase DTG dosing frequency to twice daily for duration of rifampicin- containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to once daily dosing[2]
	≥ 30kg	TDF: Impaired renal function (CrCl between 30-60 ml/min)	Use TAF (Only use TAF when the CrCl ≥30cl/min)
		DTG: Unable to tolerate	Use DRV/r
		DTG: Currently on rifampicin-containing anti-TB medications	Give TDF/3TC/DTG FDC morning + DTG 50mg evening for duration of rifampicin- containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to TDF/3TC/DTG OD
≥ 15 years	Any	TDF: Impaired renal function (CrCl ≤ 60 ml/min)	Use ABC or TAF
		DTG: Unable to tolerate	Use DRV/r
		DTG: Currently on rifampicin-containing anti-TB medications	Give TDF/3TC/DTG FDC morning + DTG 50mg evening for duration of rifampicin- containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to TDF/3TC/DTG OD

Age	Weight	Scenario and ARV Affected	Alternative ARV to Use

[1]ABC hypersensitivity reaction (AHR) is rare in the Kenyan population. For diagnosis and management of AHR, see table 1.64.

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

- For other scenarios that are not covered in this table, discuss as Multidisciplinary team and consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform)
- **Always discuss the possibility of new side effects when changing to a new ARV,** particularly side effects common to all ARVs (headache, nausea, diarrhoea) and any side effects specific to the new ARV. Reassure patients that most side effects resolve with continued use after 1-2 weeks
- Conduct a VL 3 months after single ART switch

Paediatric Abacavir/Lamivudine/Dolutegravir (pALD) Fixed Dose Combination

Paediatric Abacavir (ABC) 60mg + Lamivudine (3TC) 30mg + Dolutegravir (DTG) 5mg (pALD) is a new strawberry-flavoured dispersible fixed-dose combination available for use among children who are **term (37 weeks and above) and** at **least 4 weeks of age**. It should be administered to children who are on ABC+3TC+DTG and weigh at least 3kg to 24.9kg. The FDC is not scored and therefore should not be swallowed whole, split, or crushed. The required number of tablets, dosed by weight band, are dispersed in water and administered to the child. Refer to Annex 12b for administration instructions.

Paediatric ALD provides a complete regimen in an FDC that will ease administration and reduce dosing errors. Table 1.63 below provides dosing guidance for pALD.

Table 1.63: pALD Dosing chart

Weight	Tabs	
3 - 5.9 Kg	1	
6 - 9.9 Kg	3	
10 - 19.9 Kg	5	
20 - 24.9 Kg	6	

1.7.4 Monitoring and Changing ART

1.7.4.1 Changing ARVs Due to Adverse Drug Reactions

Educate patients at ART initiation (and after changes) about possible side effects of ART and other prescribed medicines. Adverse drug reactions (ADRs) can undermine adherence - identify early and manage decisively. Always review co-medications (including over the counter and herbal medicines) at every visit. Many common agents can interact with ART and may require dose adjustment or substitution of the ARV or the co-medication.

Annexes 30, 31 and 32 list frequent ART drug-drug interactions (DDIs) and management actions. Check for DDIs whenever any new drug is started.

Report all suspected ADRs to the Pharmacy and Poisons Board using the national pharmacovigilance tools at http://www.pv.pharmacyboardkenya.org/. Post-marketing PV is essential because rare ADRs may emerge in routine care that were not detected in clinical trials. Table 1.64 summarizes significant ARV-associated ADRs that may warrant drug substitution.

Table 1.64: Common Significant Adverse Drug Reactions

ARV Agent	Adverse Drug Reaction	High Risk Situations/Comments
NRTIs		
ABC	ABC hypersensitivity reaction	Do not re-challenge
AZT	Anaemia, neutropenia	Risk factors: CD4 count < 200 cells/mm^3; BMI < 18.5 (or body weight < 50 kg); anaemia at baseline; concurrent use of other drugs with similar ADR (cotrimoxazole, ganciclovir, ribavirin)
	Lactic acidosis	Risk factors: Pregnancy; obesity
	Lipoatrophy	Risk factors: Low CD4 count
TDF	Renal dysfunction	Risk factors: Underlying renal disease; age > 60 years; BMI < 18.5 (or body weight < 50 kg); diabetes; hypertension; concomitant PI use or nephrotoxic drug Avoid in patients with CrCl<60ml/minute unless no suitable alternative such as required to treat HIV/HBV co- infection if TAF is not available
	Loss of bone mineral density	Risk factors: Advanced age, menopause
TAF	Weight gain	Risk factors: women; concomitant use of INSTIs Provide advice on healthy eating and physical activity to maintain a healthy weight
NNRTIs		
All NNRTIs	Rash	Manage rash based on severity
EFV	CNS side-effects	Risk factors: Pre-existing psychiatric disorder
	Gynaecomastia	Switch from EFV to an alternative, and consult if gynecomastia does not improve
NVP	Hepatotoxicity	Manage as outlined in Table 1.67
PIs		
All PIs boosted with RTV	GI intolerance (LPV/r>ATV/r>DRV/r)	Consult for recommendation on alternative regimen (R-TWG or Uliza Hotline 0726 460 000, https://nhcsc.nascop.org/clinicalform)
	Dyslipidaemia (LPV/r>DRV/r>ATV/r)	Risk factors: Obesity; sedentary lifestyle; diet high in saturated fats and cholesterol

ARV Agent	Adverse Drug Reaction	High Risk Situations/Comments
ATV/r	Hyperbilirubinemia	This only requires drug substitution if cosmetic effect of jaundice is likely to interfere with patient adherence
DRV/r	Rash/hypersensitivity	Risk factors: sulfa allergy
INSTIs		
All INSTIs	Weight gain	Risk factors: women; concomitant use of TAF Provide advice on healthy eating and physical activity to maintain a healthy weight
	Rash/hypersensitivity	Consult (Uliza Hotline 0726 460 000, https://nhcsc.nascop.org/clinicalform)
DTG	Insomnia	Give in the morning, if no improvement then try giving with low fat meal or on empty stomach

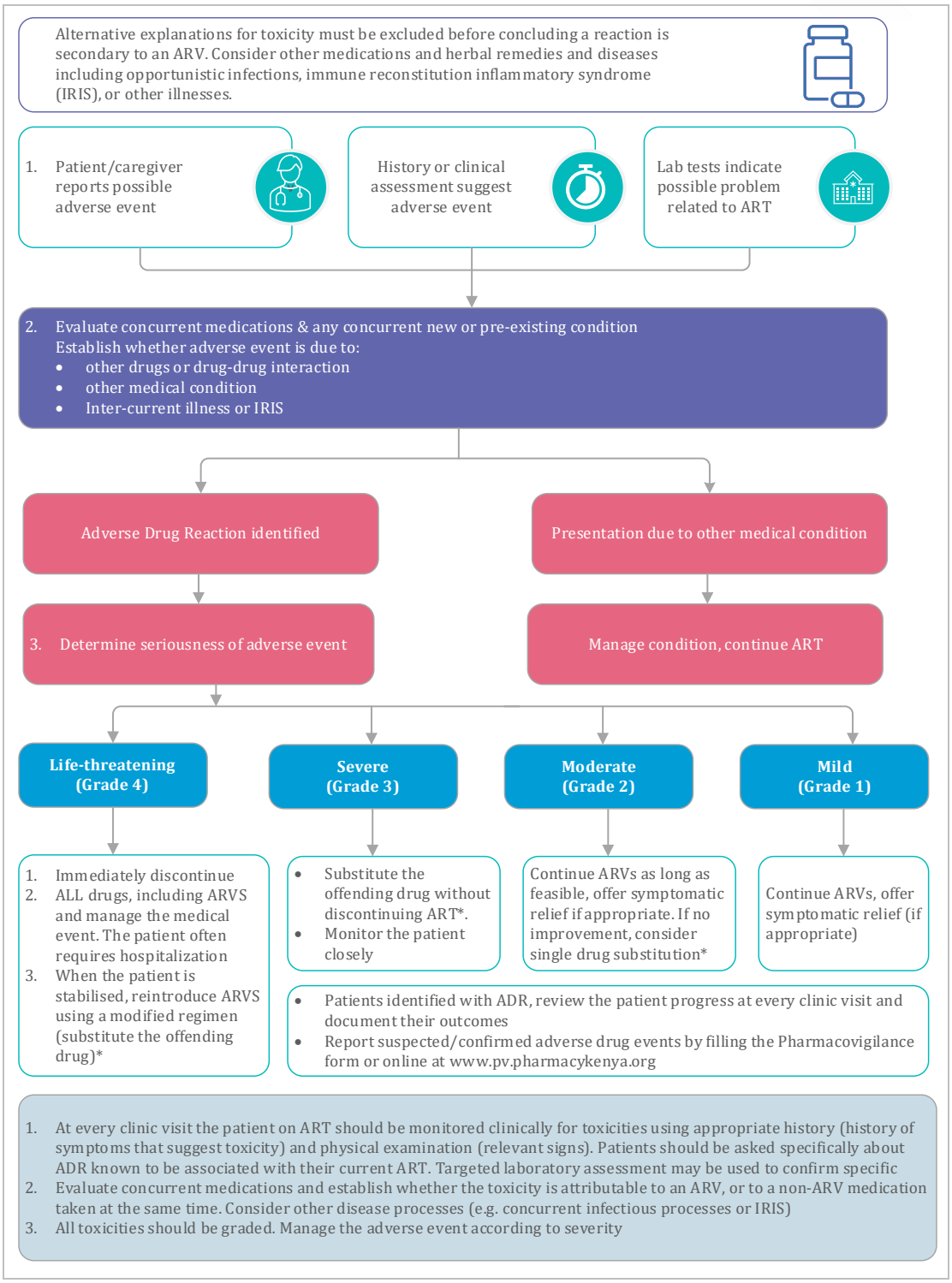


Figure 1.19: General Principles for Managing Adverse Drug Reactions

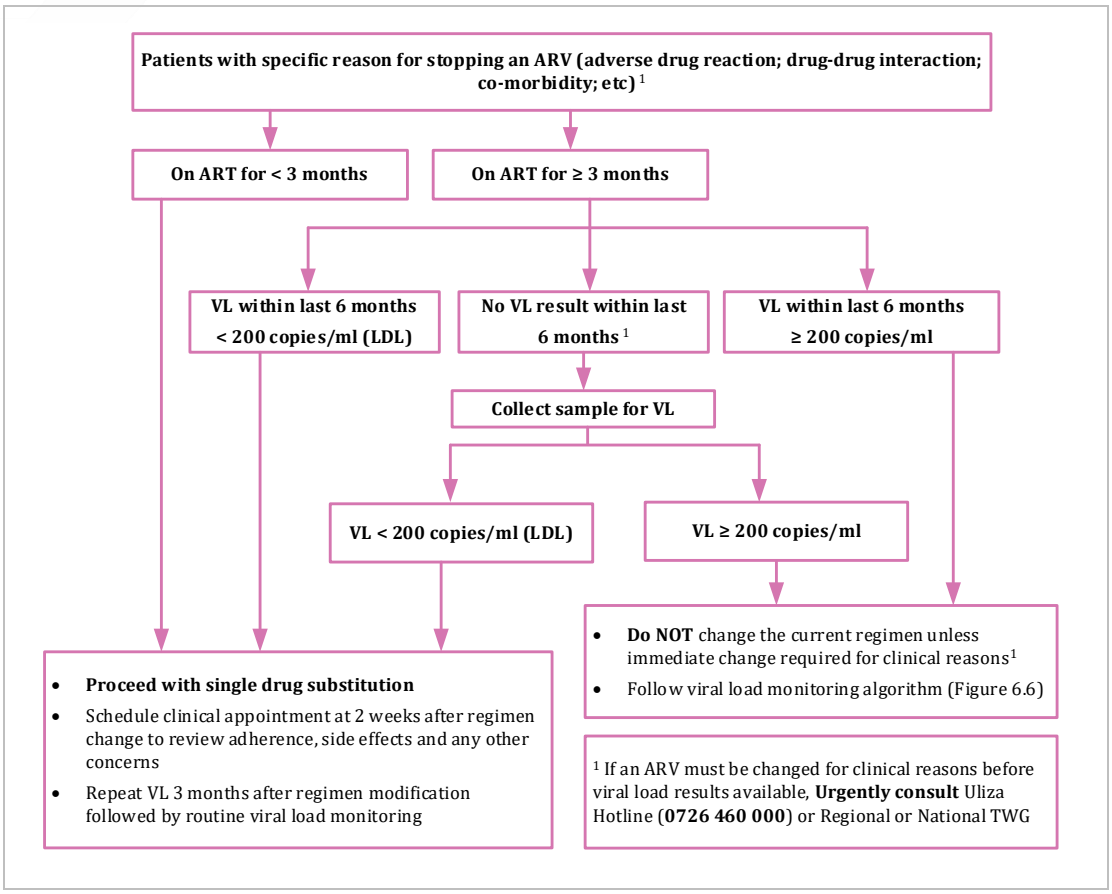


Figure 1.20: Managing single drug substitution

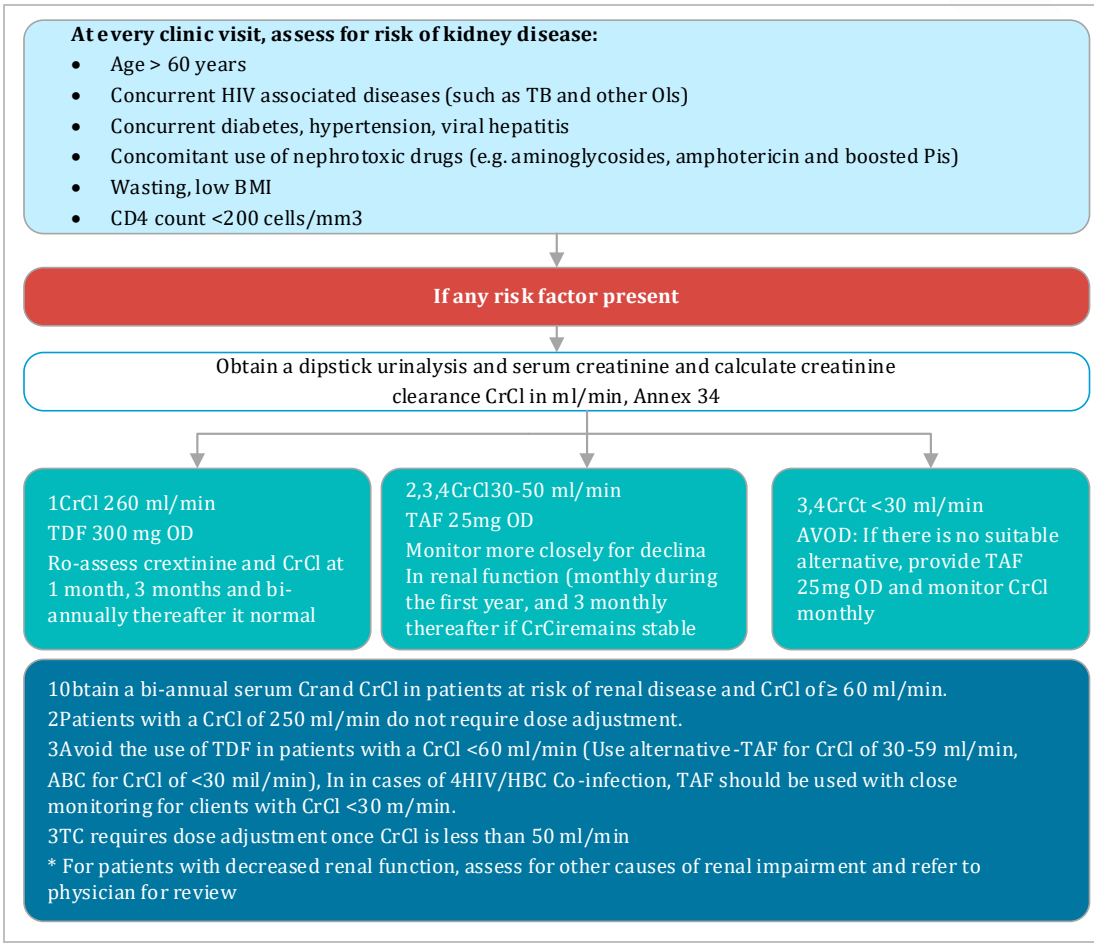


Figure 1.21: Managing TDF associated renal toxicity

Table 1.65: Diagnosis and Management of Abacavir Hypersensitivity Reaction (AHR)

Diagnosis
Within 3 weeks of initiating an ABC-containing regimen, patient develops any 2 of the following symptom groups concurrently • Fever • Erythematous and/or pruritic rash • Respiratory symptoms (shortness of breath and/or sore throat and/or cough) • GI symptoms: nausea and/or vomiting and/or diarrhoea • Extreme fatigue and/or body pain preventing normal activities AND: there is not a more likely alternative explanation for the symptoms
Management
• Stop ABC immediately and substitute with an alternative ARV • Patient must NEVER be re-challenged with ABC – a single dose could result in a fatal hypersensitivity reaction • Clearly mark file and educate patient about avoiding ABC in future • Issue an Adverse Event alert card

Note:

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

Table 1.66: ARV, CTX and Fluconazole Adjustments in Renal and Hepatic Impairment

Drug	CrCl (ml/min)		Haemodialysis	Liver impairment
	30 – 60	15 - 29.9		
ABC	No change			Reduce adult dose to 200 mg BD for moderate to severe liver impairment. AVOID in severe hepatic impairment
AZT	No change	300 mg/day	300 mg/day	Reduce dose by 50% or administer on alternate days in moderate to severe impairment
TDF[2]	AVOID	AVOID	AVOID	No change
TAF	No change	AVOID unless HBV+2	No dose adjustment- Administer after dialysis	No change
3TC	150 mg OD	150 mg OD	75 mg OD	No change
PIs (LPV, RTV, ATV, DRV)	No change			No change, use with caution in moderate to severe impairment
RAL	No change			No change in mild to moderate impairment. Use with caution in severe impairment
DTG				
EFV	No change			Use with caution in mild to moderate liver impairment. AVOID in severe impairment
NVP	No change			AVOID
ETR	No change			Use with caution in severe liver impairment
CTX	If CrCl > 30 ml/min then no dose adjustment required; if 15-30 ml/min then use 50% of normal recommended dose; if CrCl < 15 ml/min then CTX should be avoided			Use with caution in mild to moderate liver impairment. AVOID in severe impairment
Fluconazole	If CrCl ≤ 50 ml/min then use 50% of normal recommended dose (no dose adjustment required for CrCl > 50 ml/min)			Use with caution

1. Patients with evidence of renal or hepatic impairment should have access to regular monitoring of renal and liver function.
2. TDF and renal impairment: replace TDF with TAF in patients with renal disease
   - Avoid the use of TDF in patients with CrCl < 60ml/min. For patients with CrCl between 30 - 60ml/min use TAF-LD. For PLHIV with CrCl <30ml/min or on dialysis, use TAF/FTC 25/200 +DTG 50mg, or ABC 600 + 3TC Renal dose + DTG 50mg
   - For patients with HBV co-infection, the benefit of TAF for treating HBV often outweighs the risks of renal impairment, so TAF can be tolerated in more severe levels of renal impairment.

If HBV is negative and on initial ART regimen, substitute TDF with ABC, TAF or DTG + 3TC dual therapy, following the single drug substitution algorithm (Figure 1.20). If prior ART treatment failure or any other scenario, consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform)

Table 1.67: Management of Drug-Related Hepatotoxicity

ALT	<2.5 x Upper Limit of Normal (ULN)	2.5 – 5 x ULN	> 5 x ULN
Action	Retain regimen, repeat in 2 weeks	Retain regimen, repeat in 1 week	Discontinue offending drug/s Consult senior clinician for next step
Note: All patients with acute increase in liver enzymes should be evaluated for other likely causes of hepatitis/hepatotoxicity and managed appropriately			

Table 1.68: Management of AZT-Associated Bone Marrow Suppression

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

Note:

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

1.7.4.2 Changing ARVs Due to Drug-Drug Interactions

Patients must be asked about other medications (including non-prescription and herbal medicine) they are taking at every visit. Some common drugs have specific drug-drug interactions that may require dose adjustment or substitution of the ARV or the other interacting

drugs. Common medications that interact with specific ARVs include: rifampicin, rifabutin, antacids, multivitamin/mineral supplements, methadone, several anti-fungal, anti-convulsant, calcium-channel blockers, some anti-depressants, some statins, and some anti-malarial.

Annexes 30, 31 and 32 provide common drug-drug interactions and management recommendations. It is recommended practice to check for interactions whenever a new medicine is started.

1.7.4.3 Changing ARVs Due to Treatment Failure

Viral load is the gold standard for monitoring response to ART and identifying treatment failure. Treatment failure should be suspected when a new or recurrent HIV-associated condition indicating severe immunodeficiency (WHO stage III or IV condition) develops after at least 6 months on ART.

Treatment failure should always be confirmed with VL testing.

Frequency of routine VL monitoring for specific populations:

- **For PCR positive HEIs:** baseline at the time of ART initiation, at month 3 then every 6 months.
- **Age 0-24 years old:** at 3 months after ART initiation and then every 6 months
- **Age ≥ 25 years old:** at 3 months after ART initiation, then at month 12 and then annually
- **Pregnant or breastfeeding:**
  - If already on ART: At confirmation of pregnancy regardless of when the last VL was done, then 6 monthly until complete cessation of breastfeeding
  - Newly diagnosed HIV: before initiation of ART then after 3 months then every 6 monthly until complete cessation of breastfeeding (Baseline VL testing for newly HIV diagnosed pregnant and breastfeeding women)
- Before making any drug substitution (if no VL results from the last 6 months)
- Three months after any regimen modification (including single-drug substitutions), and then as per population group
- For any patient with a detectable VL follow the viral load monitoring algorithm (Figure 1.22)

1.7.4.4 Interpreting Viral Load Results and Defining Treatment Failure

- **Treatment Goal:** Sustained viral suppression defined as below the Lower Detection Limit (LDL), < 50 copies/ml.
- **Viral suppression:** Viral load < 200 copies/mL.
- **Persistent low-level viremia (PLLV) is defined as having between 200-999 copies/ml on two consecutive measures.** These patients are at increased risk of progression to treatment failure, development of resistance and death and therefore require a similar case management approach as patients with VL ≥ 1,000 copies/ml, and consultation with the Regional or National HIV Clinical TWG (*Uliza* Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform).
- **Treatment failure is suspected when a patient has a high VL ≥ 1,000 copies/ml after at least 3 months of using ART.** Treatment failure is only confirmed when VL is ≥ 1,000 copies/ml after assessing for and addressing poor adherence or other reasons for high VL and then repeating VL after at least 3 months of enhanced adherence to allow for viral re-suppression.

The interventions for the levels of viral load are summarized in table 1.69 and figure 1.22 below

Table 1.69: Interventions for various levels of viral load for clients on ART

Clinical Definition	Category	Lab Value	Management
Suppressed	Suppressed	• <200 Copies/ml • Treatment goal <50 Copies/mL (LDL)	• Continue management • Remind client of treatment goal • Enrol in DSD • Routine VL • Messaging on U=U
Unsuppressed	LLV	• 200 - 999 Copies/ml	• Discuss patient in multi-disciplinary team (MDT) • Assign a case manager • Assess for & address likely causes of non-adherence • Provide enhanced adherence support/intervention as appropriate • Assess for other causes of viremia and manage appropriately • After 3 months of excellent adherence, repeat VL • Follow VL algorithm (Figure 1-22)
	Suspected Treatment Failure	• ≥1000 Copies/ml	

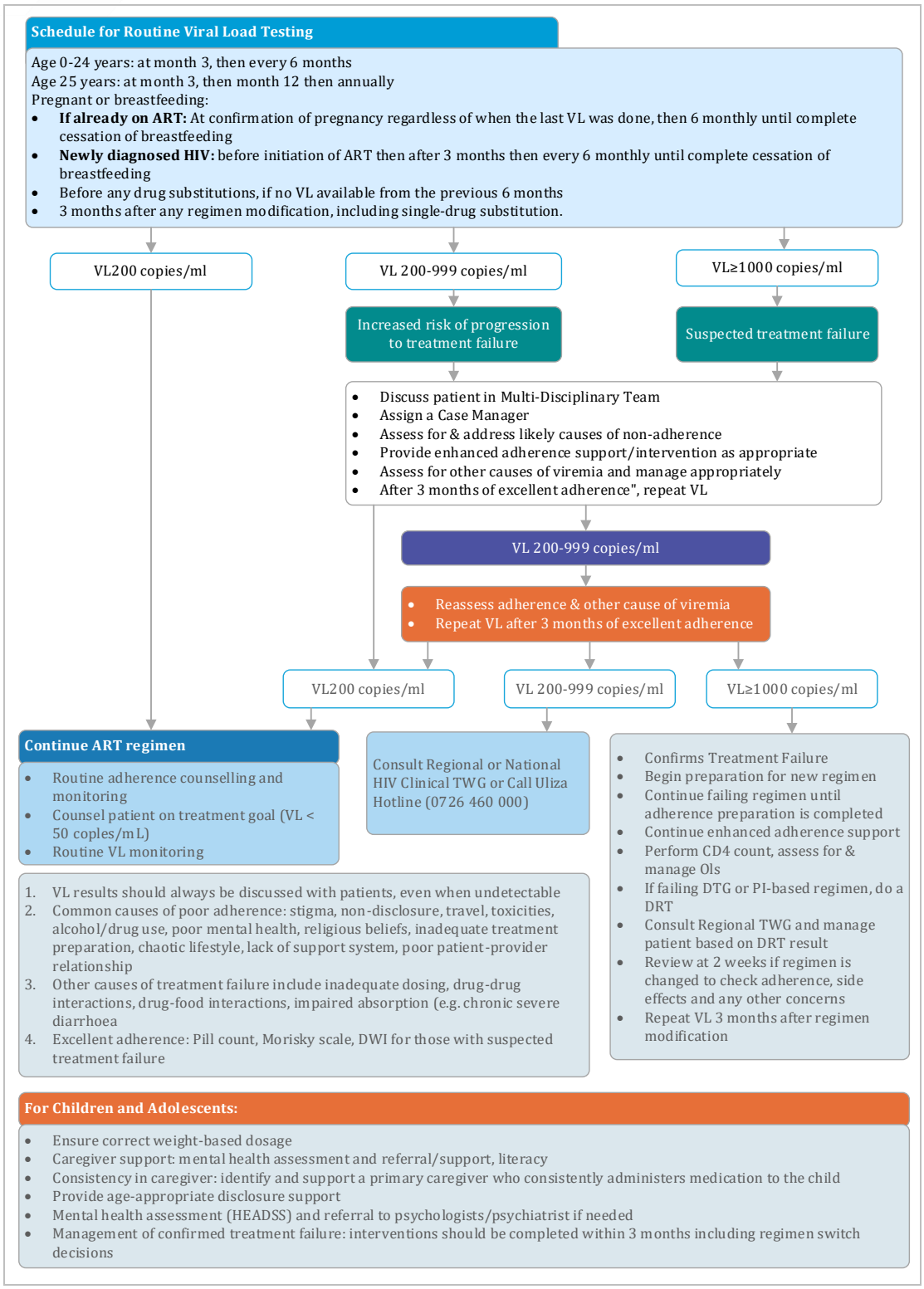


Figure 1.22: Viral Load Monitoring and Management of Viremia for Patients on ART

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

Daily witnessed ingestion by a treatment buddy or healthcare worker is recommended to confirm excellent adherence before repeating the VL. All adherence issues must be resolved before switching to a new regimen otherwise the patient will quickly fail the new regimen as well and soon run out of viable ART options. **An exception to this may be when the regimen itself is the primary cause of poor adherence** (e.g., side effects from one of the ARVs are not manageable such as severe diarrhoea with DTG or DRV/r that does not improve with symptom management), in which case the regimen may need to be modified to allow for perfect adherence. This should be done in consultation with the Regional or National HIV Clinical TWG.

1.7.5 Subsequent ART Regimens in Infants, Children, Adolescents and Adults

When initial ART regimens fail, timely transition to an effective subsequent regimen is critical to maintain viral suppression and prevent disease progression. Table 1.70 outlines recommended subsequent regimens by weight and clinical scenario.

Table 1.70: Recommendations for Change to Subsequent ART Regimens excluding TB/HIV co-infection

Weight/Scenario	Initial Regimen	Subsequent Regimen
< 25 Kgs	ABC + 3TC + DTG	DRT-based switch
≥ 25 Kgs	TAF+3TC+DTG	DRT-based switch
≥ 15 years old	TDF + 3TC + DTG	DRT-based switch
HIV/HBV Co-Infection	Always maintain TDF or TAF in order to treat the HBV as well as HIV	
TB/HIV Co-Infection	Refer to Table 1.82 Recommended ART regimens for patients who develop TB while **failing** initial ART regimen	

NOTES:

1. A switch to a subsequent regimen should only be made after consultation with the Regional TWG/Uliza NASCOP.
2. The DRT results will be used to determine if there is presence of DTG or PI drug resistance mutations or if there is an underlying problem with non-adherence. Daily witnessed ingestion is recommended prior to performing DRT.
3. Options may include PI-based regimens, with the preferred PI being Darunavir boosted with Ritonavir, in the setting of major DTG mutations.
4. DRV/r FDC 400/50mg can only be used for individuals who are ≥12 years of age and ≥ 40 kgs; for children ≥ 3kg and ≥ 10kg requiring DRV, use 75mg or 150mg boosted with ritonavir.
5. ABC or TDF/TAF is the preferred option in subsequent regimens (even if ABC or AZT previously used)

Important Considerations for Initial Regimen Failure in Children

- Children requiring subsequent ART regimens, and their caregivers should undergo thorough clinical and psychosocial assessment to rule out intercurrent illness or non-adherence as the reason for a high viral load

- All children failing an initial regimen should be discussed in the MDT and preferably with an experienced ART provider prior to change of ART to a subsequent regimen. However, this should not cause undue delay in switching to a failing regimen
- The choices for infants and children who are highly treatment-experienced are limited and will need to be discussed with the Regional or National HIV Clinical TWG.

Table 1.71: Possible Constructive ART regimens in Children, Adolescents and Adult

Category	Possible Constructive Regimen	Comment
Children	DTG + 3TC + DRV/r	Individualized/Constructive ART selection is based on DRT results Regional or National HIV Clinical TWG may recommend re-using some of the ARVs the patient has already failed, even when resistance is present The protease inhibitor (PI)-based regimen used in constructive ART regimens for treatment failure is Darunavir/Ritonavir (DRV/r) 600/100 mg for adults
	DTG + AZT + 3TC + DRV/r	
	DTG + ABC (or TDF) + 3TC + DRV/r	
	ETR + 3TC + DRV/r	
Adults	DTG + 3TC + DRV/r	
	DTG + AZT + 3TC + DRV/r	
	DTG + TDF + 3TC + DRV/r	
	DTG + TDF (or AZT) + 3TC	
	ETR + 3TC + DRV/r	

1.8 Advanced HIV Disease (AHD) and HIV Related Co-Infections

Advanced HIV Disease (AHD) is defined as:

- Adults, adolescents, and children five years and older presenting with a CD4 cell ≤200 cells/mm3 or WHO clinical stage 3 or 4 disease.
- All children younger than five years living with HIV are considered to have advanced HIV disease (Although children on ART for more than 1 year and are clinically stable and virally suppressed are not considered to have AHD)

Patients with AHD are more likely to have an opportunistic infection (OI), are more likely to need consultation or referral for complicated clinical issues, and are more likely to develop immune reconstitution inflammatory syndrome (IRIS) upon starting ART.

To promptly identify AHD, a CD4 test should be conducted in the following PLHIV:

a. Newly diagnosed with HIV
b. Returning to care after treatment interruption of ≥ 3 months
c. With treatment failure
d. Hospitalised or seriously ill or clinically unstable

1.8.1 Comprehensive Management of Advanced HIV Disease

This section includes management of opportunistic infections, psychosocial and adherence support, and integrated services for STIs, hepatitis B, reproductive health, and gender-based violence (GBV). Table 1.72 describes the comprehensive management of advanced HIV disease.

Table 1.72: Comprehensive Management of Advanced HIV Disease

Care Element	Description for Clients with Advanced HIV Disease (AHD)
Package of Care	• Standard HIV care package plus intensified clinical, nutritional and psychosocial support • Screen and manage opportunistic infections (TB, cryptococcal disease, PCP, severe bacterial infections) – TB: WHO recommended molecular test, mWRDs (GeneXpert Ultra, TrueNaat, TB Lamp), LF-LAM for all presumptive TB – Blood Cryptococcal Antigen (bCrAg) testing if CD4 ≤200 – Provide Cotrimoxazole Preventive Therapy (CPT) and TB Preventive Therapy (TPT) – Initiate ART promptly unless TB or cryptococcal meningitis is suspected • Screen and treat STIs clinically or etiologically based on capacity • Conduct HBsAg testing; link HBV-positive to care and vaccinate if unexposed • Assess reproductive health needs: pregnancy testing, contraception, safer conception • Screen for GBV/IPV and refer to support services • Monitor closely for Immune Reconstitution Inflammatory Syndrome (IRIS)
Focus on ART Counselling	• Emphasize urgency of ART to prevent further immune deterioration • Address OI risks, medication side effects, and co-infection management • Provide counselling on reproductive goals and GBV disclosure support • Educate on STI/HBV prevention and treatment
Management of Cryptococcal Disease (CM)	• Cryptococcal meningitis is a leading cause of mortality among individuals with AHD. • Screen adolescents and adults with CD4 ≤200 cells/mm^3 using CrAg testing. • Promptly initiate antifungal treatment for confirmed cases. • Maintain a high index of suspicion for symptoms of meningitis in AHD clients. • Refer to full guidance on CM diagnosis, treatment, and prevention.
Management of Tuberculosis (TB)	• TB is the most frequent and fatal opportunistic infection in PLHIV with AHD. • Conduct TB screening for all clients at each visit using ICF (WHO 4 Symptom TB Screening Tool, W4SS), mWRDs, and LF-LAM as applicable. • Initiate TB treatment promptly if TB is diagnosed. • Provide TB preventive therapy (TPT) to eligible PLHIV after active TB is ruled out • Provide TPT after completion of TB treatment for those who have never used TPT before. • Refer to detailed TB prevention, diagnosis, and management protocols.
Follow-Up Frequency	• Weekly until ART initiation • At week 2 and 4 post-ART, then monthly until CD4 >200 with viral suppression • Integrate STI and HBV management into follow-up • Adjust schedule based on psychosocial, reproductive, or GBV-related needs

1.8.2 Screening, diagnosis and prevention components of the package of care for children and adolescents with AHD

The STOP approach should be used for management of children and adolescents with AHD.

- **Screen:** TB, Cryptococcal meningitis (10+), malnutrition
- **Treat:** TB, severe pneumonia, severe bacterial infections, cryptococcal meningitis and severe acute malnutrition
- **Optimize:** Rapid ART start (within 7 days) with optimal regimen
- **Prevent:** Bacterial infections and PJP - Cotrimoxazole, TB - TB preventive therapy, Cryptococcal meningitis - fluconazole pre-emptive therapy, Vaccination: Pneumococcal, HPV, Measles, BCG, Rotavirus.

The **STOP AIDS** approach in children and adolescent with AHD is described in detail in table 1.73

Table 1.73: Package of care for children and adolescents with AHD

Intervention	Component	<5 years	5-9 years	10-19 years
Screen	Screen for TB using clinical algorithm followed by X-ray when indicated and available Ultra Xpert MTB/RIF assay as the first test (Induced or expectorated) sputum, gastric aspirate, stool or nasopharyngeal aspirate or other extrapulmonary specimens	Yes	Yes	Yes
	LF-LAM assay	Yes	Yes	Yes
	Cryptococcal antigen screening (Specimen: Serum, plasma or whole blood). If cryptococcal antigen positive or symptomatic, lumbar puncture	No	No	Yes
	Malnutrition - Weight for Height, Height for age, MUAC			
Treat	TB, Severe Pneumonia, Severe Bacterial Infections, Cryptococcal meningitis, Severe Acute Malnutrition	Refer to OI manual, Kenya Basic Paediatrics Protocol, National TB guidelines		
Optimize	Rapid antiretroviral therapy start – within 7 days with optimal regimen	Yes	Yes	Yes
Prevent	Pneumococcal Conjugate Vaccine	Yes	No	No
	Cotrimoxazole	Yes	Yes	Yes
	TB Preventive therapy	Yes	Yes	Yes
	Fluconazole pre-emptive therapy for cryptococcal antigen positive without evidence of meningitis	N/A	N/A	Yes
	HPV (As per national guidelines)	No	No	Yes

1.8.3 TB/HIV Co-infection

Tuberculosis remains the leading cause of morbidity and mortality among PLHIV in Kenya. Kenya is among the high TB/HIV burden countries, with TB accounting for a significant proportion of deaths among PLHIV. HIV increases the risk of progression from latent TB infection to active TB disease, while TB accelerates HIV disease progression. The dual epidemic poses unique diagnostic, treatment, and prevention challenges, necessitating an integrated approach in line with national and WHO guidelines.

1.8.3.1 TB/HIV Co-infection Screening and Diagnosis

Diagnosis of Pulmonary TB in Children Aged ≤15 years

Figure 1-24: Summarizes TB/HIV co-infection screening and diagnosis

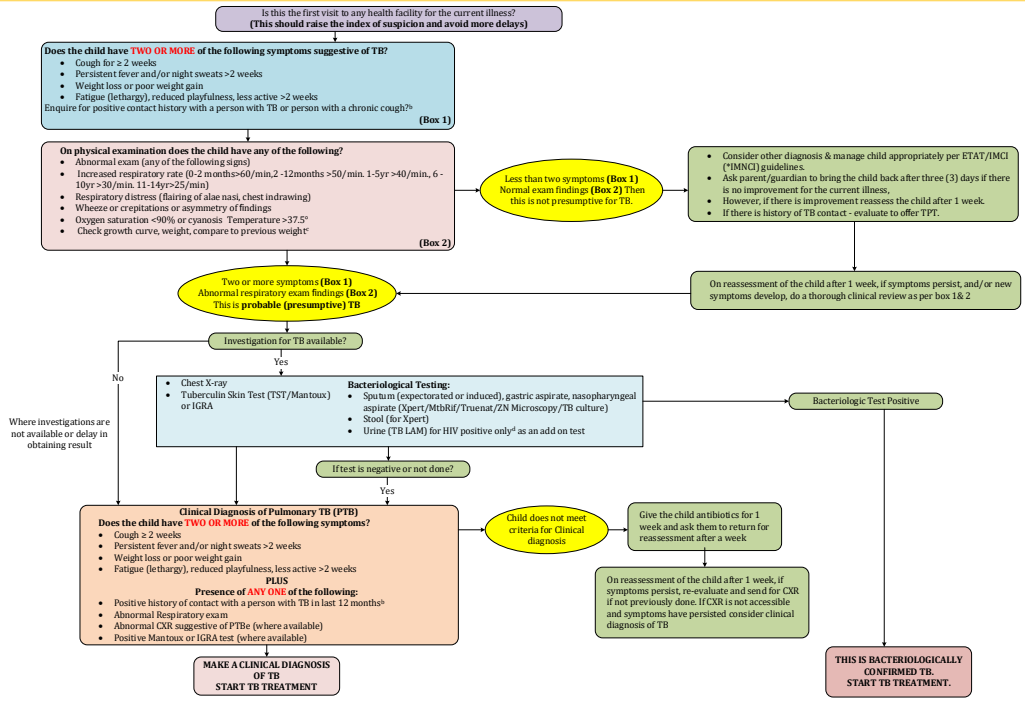
REPUBLIC OF KENYA

MINISTRY OF HEALTH

MINISTRY OF HEALTH

SIMPLIFIED ALGORITHM FOR THE DIAGNOSIS OF PULMONARY TUBERCULOSIS IN CHILDREN (AGED BELOW 15 YEARS)

National Tuberculosis, Leprosy and Lung Diseases Program



Addtional Information

*** Respiratory symptoms suggestive of TB include**

All ages: Cough > 2 weeks

Younger children:

- Cough
- Or breathing faster than usual
- Or wheeze not responding to salbutamol

NB/all children started on TB treatment should have their HIV status known

*** History of contact – ask if there is an individual with known TB or chronic cough who:**

- Currently they live in the same household as child (*80% of children have no household contact) or
- Who has visited the home and spent time in the home in contact with child in the preceding 12 months (e.g. relative, maid, driver, worker) or
- For school going children – individual in the same school classroom or dormitory with TB or chronic cough or
- Pre-school children – if they spend time in a day care centre within community or
- All children - if they have spent significant time in a hospital / health facility setting in the preceding months (high risk of exposure to patients with TB in hospital months setting)

Diagnosing DR TB - Clinical considerations

- Diagnosis in children is largely based on clinical and radiological diagnosis
- Consider DR TB diagnosis in a child with a TB diagnosis and contact history as above
- Bacteriologic diagnosis should always be attempted; however, this should not delay treatment initiation

*** Check weight / poor weight gain includes:**

- Weight loss or
- Weight for age Z-score (WAZ) or weight for height z-score (WHZ) below -2. or
- Poor weight gain: -flattening of growth curve (chart) or documented crossing of percentile preceding months or
- Older children (or parents) report they have noticed that they (their child) have lost weight /become thinner in recent weeks to months.

* TB LF-LAM Indications

A rapid point-of-care urine dip-stick test

LF-LAM SHOULD NOT be used as an alternative test to mWRD but as an adjunct test to help diagnose TB while waiting for mWRD results.

Indications include.

- PLHIV adults, adolescents and Children ≥5 years with advanced HIV disease (CD4 cell count <200 cells/mm3 or WHO stage 3 and 4 disease.
- All CLHIV Less than 5 Years

*** Abnormalities on Chest X-ray that are suggestive of PTB include:**

- Enlarged perihilar or paratracheal lymph nodes (+/- narrowing of airways due to compression by lymph nodes)
- Miliary opacification (diffuse micronodules in lung fields)
- Pleural effusion
- Opacification of a lobe or segment of a lobe
- Cavitation (more frequent in teenagers).
- PLHIV that have danger signs or severe illness (RR.30BPM, Temp>39°c, Heart rate >120BPM, confusion or disorientation, unable to walk unaided)
- PLHIV is currently admitted in Hospital and has signs and symptoms of PTB
- PLHIV with signs and symptoms of TB (presumptive TB) in outpatient setting

Drug Sensitive Tuberculosis (DSTB) Treatment Regimens for Kenya for Children 10 Years and Below
Note: All children less than 1 year of age will require the 6-month regimen

	Eligibility for 4-month regimen	Eligibility for 6-month regimen	Eligibility for 12 months
Age	>1 year to 10 years	All infants (<12 months) Above 10 years (11 to <15 years)	
Type of TB **Indicators of severity**	Non-severe Pulmonary TB Stable enough to be managed as an outpatient at the point of diagnosis No danger signs TB cervical lymph nodes	• Severe Pulmonary TB • All hospitalized patients at point of diagnosis • Severely ill at diagnosis with any danger sign such as. Difficulty in breathing with associated central cyanosis, Grunting, Oxygen saturation <90%, ; Increased respiratory rate (age 0-2months >60/min; 2-12months >50/min; 1-5yr >40/min; 6-10yr >30/min) ; unable to drink/breastfeed; Weak or absent pulse; Coma/convulsing /confusion; Not responding to pain or unresponsive • Extra Pulmonary TB	TB Meningitis & Ostoearticular TB
Immune status	• HIV negative, No severe acute malnutrition • No other immunosuppressive condition	• HIV positive • Severe acute malnutrition (SAM) • Any immunosuppressed child	
Bacteriologic status	• Bacteriologically negative • Bacteriologically confirmed	• Clinically diagnosed	
Treatment regimen	4 months - 2RHZE / 2RH	6 months - 2RHZE / 4RH	12 months- 2RHZE / 10RH

Childhood Drug Resistant TB (DRTB) Treatment Regimen

Resistance pattern	Target group	Regimen (Child friendly formulations)
1. Isoniazid Mono-resistant TB	Children <25 kgs	6RHZE/LFX
2. Poly-drug resistance (PDR) TB	Children <25 kgs	9RHZE/LFX
3. MDR/RR TB	<15 years Non severe dx	6Bdq/Lzd/Lfx/Cs/Cfz 3Lfx/Cs/Cfz
	<15 years Severe dx	6Bdq/Lzd/Lfx/Cs/Cfz 6Lfx/Cs/Cfz
4. Pre-XDR (FQ Res.) TB	<15 years (Children)	6Bdq/Dlm/Cfz/Cs/Lzd 3Dlm/Cfz/Cs
5. XDR TB		Consult national clinical review team
Any Difficult to manage child (DS or DR TB)		Consult sub county and county clinical review teams

MOH/DNTLDP/CPTBDXALG/01

Figure 1.23: Simplified algorithm for diagnosis of PULMONARY TB in children aged < 15 years of age

MINISTRY OF HEALTH
REPUBLIC OF KENYA

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SIMPLIFIED ALGORITHM FOR THE DIAGNOSIS OF EXTRA PULMONARY TUBERCULOSIS IN CHILDREN (AGED BELOW 15 YEARS)

National Tuberculosis, Leprosy and Lung Diseases Program

Presence of TWO OR MORE of the following symptoms lasting > 2 weeks
- SYMPTOM ARISING FROM AFFECTED ORGAN (see table)
- Weight loss or poor weight gain
- Persistent fever and/or night sweats
- Fatigue, reduced playfulness, less active

PLUS

Presence of ONE OR MORE of the following:
- Positive contact history
- Abnormal sign arising from the AFFECTED ORGAN (see table)
- Investigation relevant to AFFECTED ORGAN is positive (where available)
- Positive mantoux or IGRA test (where available)

↓

MAKE A CLINICAL DIAGNOSIS OF EXTRA PULMONARY TB
START TB TREATMENT

EXTRA PULMONARY TUBERCULOSIS IN CHILDREN – SYMPTOMS, SIGNS & INVESTIGATIONS

(In addition to the clinical features due to EPTB listed below, the child may have one or more of the classic non-specific signs: persistent fever, poor weight gain/ weight loss and lethargy/ reduced activity, lasting >2 weeks)

Site of EPTB	Symptoms and Signs for EPTB specific to the affected site	Investigation
TB lymphadenitis (cervical, axillary or inguinal LN)	• Lymph node enlargement for more than one month. • Painless, non-tender • Often asymmetrical • +/- caseous (cheese like) discharge • Most commonly in neck area	**Fine needle aspiration (FNA) for:** • Xpert, culture • Microscopy – predominance of lymphocytes, AFB **Lymph node biopsy - Histology**
Pleural TB)	• +/- Chest pain is often one-sided. • +/- Cough • Large effusion - fast breathing, breathlessness • Dullness on percussion, reduced breath sounds on affected side	• CXR • Chest ultrasound • Pleural tap1
TB meningitis	Persistent CNS symptoms: • Early signs – Persistent headache, irritability/abnormal behaviour, one-sided weakness, changing gait, blurred vision, squint (signs progressively worsening over weeks) • Late (severe) signs - reduced level of consciousness, convulsions, neck stiffness bulging fontanelle, cranial nerve palsies.	• Lumbar puncture – CSF1 • CT scan brain with contrast • Cranial ultrasound in infants <6 months with open anterior fontanelle
Miliary TB	• Non-specific signs: persisting fever, weight loss/poor weight gain, lethargy. • Often have respiratory symptoms & signs (fast breathing, +/- cough, wheeze, respiratory distress)	• CXR – diffuse miliary opacities (micronodules) • Fundoscopy – see micro-nodules on retina • High risk for other extra pulmonary sites. Look for other lesions.
Abdominal TB	• Abdominal pain >2 weeks • Progressive swelling of abdomen over several weeks. • Exam: Abdominal swelling, ascites (shifting dullness, fluid thrill.	• Ascitic tap1 • Abdominal ultra-sound2
Spinal TB	• Persisting pain in focal point in the back. • Early sign: Tender / pain when apply pressure at part of spine, loss of lordosis / reduced curvature in lower back if located in lumbar vertebrae. • Advanced disease: Deformity of spine• Progressive lower limb weakness	• X-ray of affected spine – lateral and antero-posterior views
Pericardial TB	• Breathless with minimal exertion, palpitations (feeling of rapid heartbeat), cough may be present • Cardiac failure (tachycardia, pedal oedema, infants – periorbital puffiness • Distant heart sounds • Apex beat difficult to palpate	• CXR – global enlargement of heart. • Echocardiogram (Cardiac ultrasound). Pericardial tap

1. Cerebrospinal fluid (CSF), pleural fluid, ascitic fluid specimens, joint fluid - the following findings are suggestive of TB: Colour – clear or light yellow colour. Biochemistry – high protein and low glucose Microscopy - increased white cell counts, predominantly lymphocytes. (note that bacteriologic tests rarely detect MTb from these body fluids).
2. Abdominal ultra-sound shows ascites +/- septation, enlarged abdominal lymph nodes. All specimens (FNA, CSF, aspirates etc.) may be sent for bacteriologic tests such as GeneXpert, AFB microscopy or TB culture as appropriate, however detection rate is lower than sputum

Drug Sensitive Tuberculosis (DSTB) Treatment Regimens for Kenya for Children 10 Years and Below
Note: All children less than 1 year of age will require the 6-month regimen

	Eligibility for 4-month regimen	Eligibility for 6-month regimen	Eligibility for 12 months
Age	>1 year to 10 years	All infants (<12 months) Above 10 years (11 to <15 years)	
Type of TB **Indicators of severity**	Non-severe Pulmonary TB Stable enough to be managed as an outpatient at the point of diagnosis No danger signs TB cervical lymph nodes	• Severe Pulmonary TB • All hospitalized patients at point of diagnosis • Severely ill at diagnosis with any danger sign such as. Difficulty in breathing with associated central cyanosis, Grunting, Oxygen saturation <90%, ; Increased respiratory rate (age 0-2months >60/min; 2-12months >50/min; 1-5yr >40/min; 6-10yr >30/min) ; unable to drink/breastfeed; Weak or absent pulse; Coma/convulsing /confusion; Not responding to pain or unresponsive • Extra Pulmonary TB	TB Meningitis & Ostoearticular TB
Immune status	• HIV negative, No severe acute malnutrition • No other immunosuppressive condition	• HIV positive • Severe acute malnutrition (SAM) • Any immunosuppressed child	
Bacteriologic status	• Bacteriologically negative • Bacteriologically confirmed	• Clinically diagnosed	
Treatment regimen	4 months - 2RHZE / 2RH	6 months - 2RHZE / 4RH	12 months- 2RHZE / 10RH

* If the child has known contact with a person with drug-resistant TB, this table does not apply, start the child on treatment as per the drug-resistant TB guidelines

Childhood Drug Resistant TB (DRTB) Treatment Regimen

Resistance pattern	Target group	Regimen (Child friendly formulations)
1. Isoniazid Mono-resistant TB	Children <25 kgs	6RHZE/LFX
2. Poly-drug resistance (PDR) TB	Children <25 kgs	9RHZE/LFX
3. MDR/RR TB	<15 years Non severe dx	6Bdq/Lzd/Lfx/Cs/Cfz 3Lfx/Cs/Cfz
	<15 years Severe dx	6Bdq/Lzd/Lfx/Cs/Cfz 6Lfx/Cs/Cfz
4. Pre-XDR (FQ Res.) TB	<15 years (Children)	6Bdq/Dlm/Cfz/Cs/Lzd 3Dlm/Cfz/Cs
5. XDR TB		Consult national clinical review team
Any Difficult to manage child (DS or DR TB)		Consult sub county and county clinical review teams

*Children (15 years) weighing above 25 Kgs with INH mono resistance or poly drug resistance should be put on the adult dose

MOH/DNTLDP/CPTBDXALG/01

Figure 1.24: Simplified algorithm for diagnosis of EXTRA-PULMONARY TB in children aged < 15 years of age

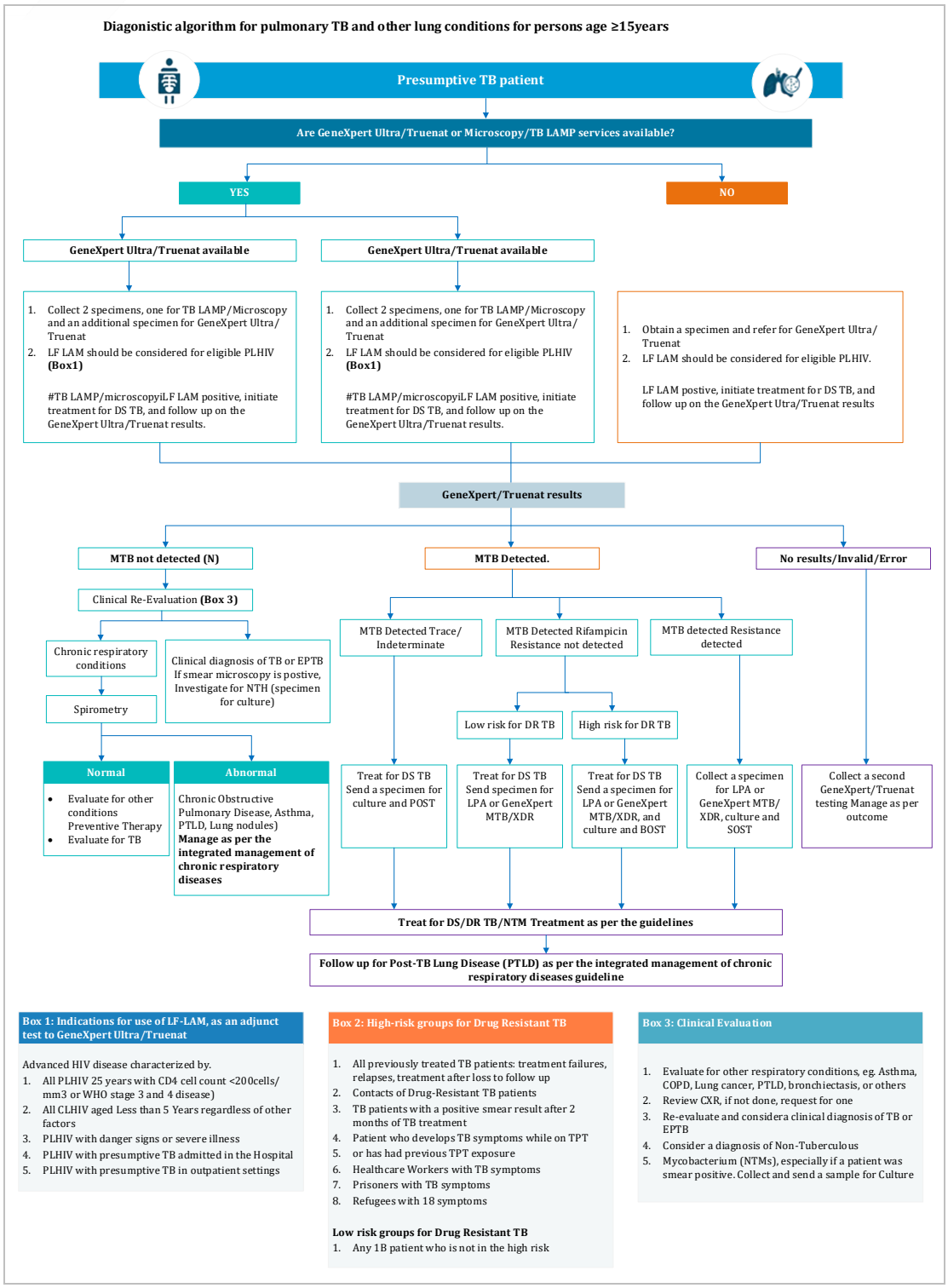


Figure 1.25: TB diagnostic algorithm above 15 years

TB/HIV co-infection screening, diagnosis, treatment and prevention is summarized in Table 1.74

Table 1.74: TB/HIV Co-Infection Screening, Diagnosis, Treatment and Prevention

Component	Key Actions / Recommendations	Considerations
Screening – Intensified Case Finding (ICF)	Symptom screen for all PLHIV at every clinical visit using ICF tool: ● Cough of any duration ● Fever ● Noticeable weight loss/ Failure to thrive/ Poor weight gain ● Night sweats ● Reduced playfulness/ lethargy / irritability (child) ● Contact with a TB case	"Yes" to any → detailed history, exam, sputum (smear/GeneXpert); "No" → assess for TPT eligibility; Q5–Q6 apply only to children
Screening - Active Case Finding (ACF)	Systematic efforts beyond routine facility-based screening to reach underserved or high-risk populations with TB screening and testing services	Conducted by NTP or partners in community settings; targets may include prisoners, people in informal settlements, hard-to-reach rural communities, healthcare facility staff, and other high-risk groups
Diagnosis	**Primary test:** GeneXpert (preferred for presumptive TB) Specimen for children where possible - gastric aspirate, or stool or nasopharyngeal aspirate **Adjunct test:** LF-LAM for PLHIV with AHD (CD4 <200, WHO stage 3/4), danger signs, severe illness, inpatient admission, or presumptive TB in outpatient settings **Children:** Clinical diagnosis symptoms/ signs and CXR mainstay of diagnosis in children.	LF-LAM +ve → start TB treatment immediately, investigate for TB/HIV-related diseases; LF-LAM –ve but suspicion remains → await GeneXpert, manage per clinical response; LF-LAM cannot detect rifampicin resistance. Children: *Absence of bacteriologic confirmation SHOULD NOT BE USED TO DELAY TREATMENT DECISIONS FOR CHILDREN.*
Chest X-ray (CXR)	Perform a baseline chest X-ray for all PLHIV. Use digital CXR where available. Repeat CXR as clinically indicated, based on symptoms or diagnostic need.	Supports TB diagnosis in symptomatic individuals; not a substitute for bacteriological confirmation; can help detect subclinical or extra-pulmonary TB features.
Drug-susceptible TB treatment **OR** **Clinically diagnosed TB**	All forms of pulmonary TB, cervical lymph node TB give 6-month treatment: Intensive: 2 months RHZE; Continuation: 4 months RH TB meningitis/bone TB give 12 months treatment: Intensive: 2 months RHZE; Continuation: 10 months RH	Give pyridoxine with isoniazid; Severely ill children (severe respiratory disease, TB meningitis, pericardial TB) give oral prednisolone for the first 2 weeks until stable.

Component	Key Actions / Recommendations	Considerations
in children, treatment.		Follow Programmatic Management of Drug-Resistant TB (PMDT) guidance for RR-TB/DR-TB.
Follow-up and monitoring response to Treatment		Follow-up smears at months 2, 5, 6 for bacteriologically confirmed pulmonary TB. Children do clinical monitoring of response – symptom resolution and weight/growth. Do monthly weighing and dose adjustment with weight change.
Drug-resistant TB	Refer to DR-TB clinical team for individualized regimen	Follow national PMDT guidelines
TPT Eligibility	PLHIV ≥12 months (including pregnant/breastfeeding); all household contacts of bacteriologically confirmed TB; healthcare workers; prisoners/staff; other risk groups; neonates exposed to TB after disease exclusion	Contraindicated in: active TB, active hepatitis, chronic alcohol abuse, symptomatic peripheral neuropathy
TPT Regimens	Preferred: 3HP – Rifapentine + Isoniazid, once weekly × 12 doses (Paediatric formulations when available this will be preferred for children below 15 years) Alternative: 6H - Isoniazid once daily × 6 months	Avoid 3RH in PLHIV due to drug–drug interactions; pyridoxine supplementation with all TPT regimens; adjust for children and pregnant women. Paediatric dispersible tablet formulations for children weighing <30 kg that are unable to swallow whole tablets. (INH 100mg DT; Rifapentine 150mg scored DT).
Follow-up for TPT	Monthly clinic visits: TB symptom screening, adherence reinforcement, ADR monitoring, documentation in ICF/TPT register; harmonize with routine clinic appointments	Stop TPT if TB develops during course; provide/update TPT appointment card
Management of ADRs	Peripheral neuropathy (INH): Increase pyridoxine to 100 mg/day (double weight-based for children), assess for other causes; consider analgesics, amitriptyline, carbamazepine if symptomatic Drug-induced liver injury (H, P, R): Screen for symptoms (jaundice, abdominal pain, N/V, hepatomegaly); check LFTs if symptomatic; stop offending drug, investigate other causes; do not reintroduce until LFTs normalize	Expert consultation recommended for severe cases; symptoms may persist after stopping TPT

Use of LF-LAM in TB Diagnosis Among PLHIV

The lateral flow urine lipoarabinomannan assay (LF-LAM) is a rapid, point-of-care diagnostic test for tuberculosis (TB) that detects mycobacterial antigens in urine. It is particularly useful in people living with HIV (PLHIV) with advanced disease or severe illness, where conventional sputum-based tests may be challenging. LF-LAM is recommended as an adjunct to WHO-endorsed molecular tests (e.g., GeneXpert MTB/RIF) and can expedite TB diagnosis and treatment initiation, especially in inpatient and high-mortality risk settings. Figure 2.24 describes the use of LF-LAM for Diagnosis of TB among PLHIV.

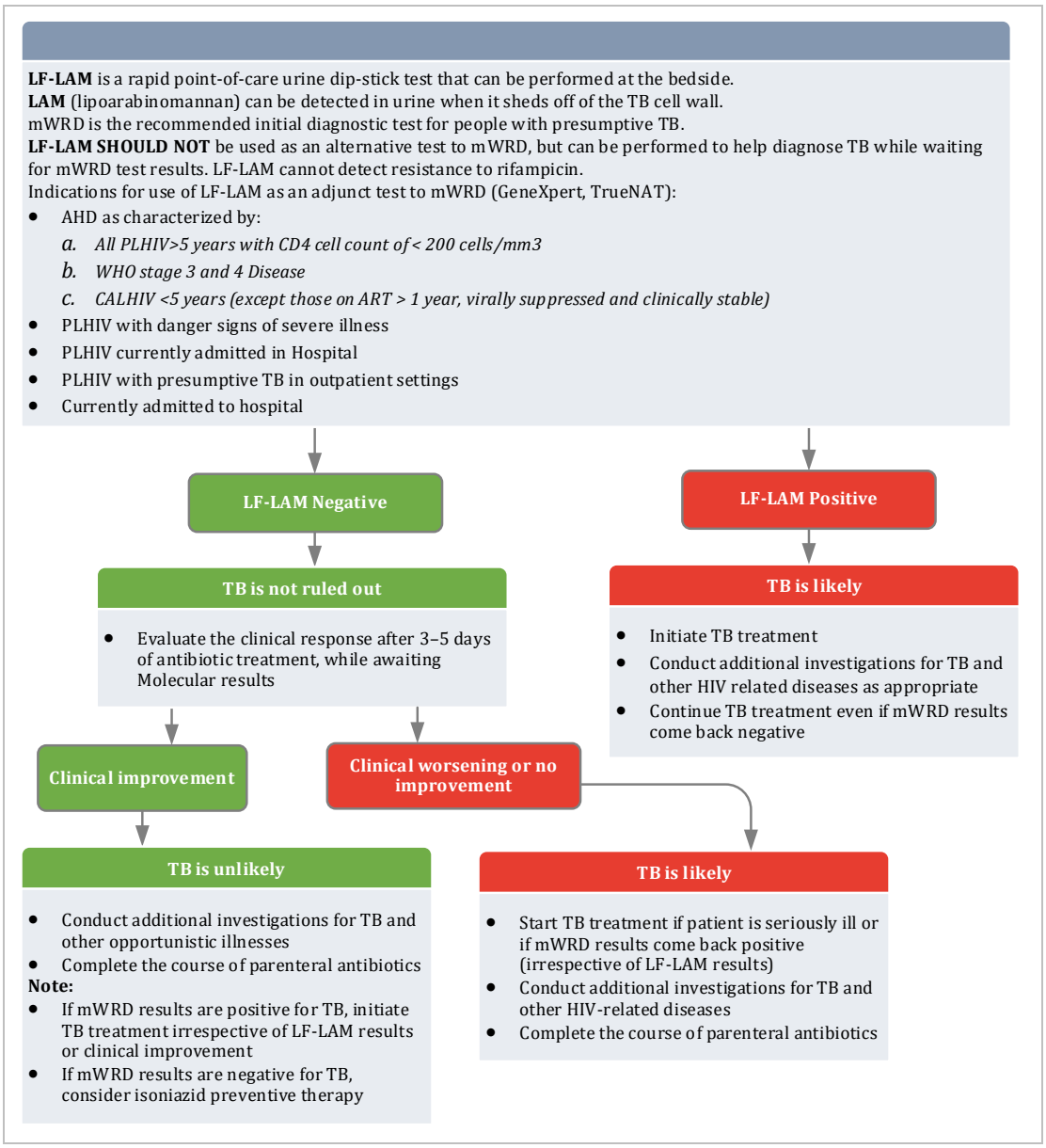


Figure 1.26: Use of LF-LAM for Diagnosis of TB among PLHIV

1.8.3.2 Drug Susceptible TB Treatment Regimen for Children, Adolescents and Adults

Tuberculosis treatment regimens for drug-susceptible TB are standardized to ensure effective cure, prevent relapse, and minimize the development of drug resistance. The choice of regimen and duration depends on the disease site and severity. Children and adolescents with clinically diagnosed TB (no drug susceptibility test done) are assumed to have drug-susceptible TB unless there is a clear close contact with confirmed DR-TB.

Table 1.75 presents the recommended intensive and continuation phase regimens for children, adolescents, and adults.

Table 1.75: Drug Susceptible TB Treatment Regimen for Children, Adolescents and Adults

TB disease category	Recommended regimen	
	Intensive phase	Continuation phase
All forms of Pulmonary TB Cervical lymph node TB (6-months treatment)	2 RHZE	4 RH
TB meningitis or Osteoarticular TB (12-months treatment)	2 RHZE	10 RH
Drug resistant TB	Refer to clinical guidelines.	

- Follow up smears should be done for all bacteriologically confirmed pulmonary TB cases at end of month 2, 5 and 6 of TB treatment using smear microscopy
- Follow up of Rifampicin Resistant (RR) TB and DR TB should be done as per PMDT guidelines\Patients taking isoniazid containing regimen should also be given Pyridoxine (Vitamin B6) daily for the duration of treatment to reduce the risk of developing peripheral neuropathy
- Once TB treatment is started it should be completed; unless another definitive diagnosis (like lung cancer) is established and TB is ruled out.

1.8.3.3 TB Preventive Therapy (TPT)

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

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

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

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

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

Summary of recommendations for TPT among the PLHIV

- PLHIV are at a much higher risk of getting TB disease compared to the general population
- TB preventive therapy should be given to all PLHIV above 12 months of age who do not have active TB disease. This should be done irrespective of immune status, ART status, previous history of TB and pregnancy status.
- Children aged <12 months living with HIV who are household contacts of a person with bacteriologically confirmed pulmonary TB, and whom active TB has been ruled out should receive TB preventive therapy.
- TPT may be given immediately following successful completion of TB treatment among the PLHIV.
- Repeat TPT is not recommended among PLHIV except if a PLHIV becomes a household contact of a person with bacteriologically confirmed pulmonary TB
- PLHIV aged 15 years and above should be provided with 3 months of weekly Rifapentine and Isoniazid (3HP),
- PLHIV aged less than 15 years are given 6 months of daily INH (6H).
- 3HP regimen may be considered (Age ≥2 years)
- In PLHIV on PI/r-based ART, pregnant women and those who do not tolerate 3HP should be given six months of daily INH (6H)

For eligible patients previously treated for TB, initiate TPT upon completion of their TB treatment.

Recommended TPT Regimens for PLHIV

The choice of TPT regimen depends on age, concomitant medications, pregnancy status, and potential drug–drug interactions with antiretroviral therapy. Table 1.76 outlines the recommended TPT regimens for different PLHIV populations.

Table 1.76: Recommended TPT Regimens for PLHIV

Target populations	TPT Regimen
Children, Adolescents and Adult PLHIV excluding patients on PI/r-based ARV regimens	**Preferred:** Rifapentine and Isoniazid (3HP) Once weekly for three months *(12 doses)*
• Adult PLHIV on PI/r-based ARV regimens • Any patient with intolerance or contraindication to 3HP • Pregnant women	Isoniazid (6H) Once daily for 6 months
• The 3RH (rifampicin and isoniazid) regimen is not recommended for PLHIV due to drug- drug interactions • All TPT regimens should be given with Vitamin B6 (pyridoxine), if available, to reduce the risk of developing peripheral neuropathy • Comprehensive health education and adherence counselling should be conducted prior to initiation of TPT	
Notes • Children should be weighed at each visit and correct weight-based dosing confirmed. • Clients on 3HP should receive weekly dose of pyridoxine. • 3RH is used in HIV negative populations. Not recommended for PLHIV due to drug-drug interactions. • TPT is recommended for DR and MDR TB contacts (Consult for appropriate regimens).	

Follow-Up for Patients on Tuberculosis Preventive Treatment (TPT).

Table 1.77: Follow-Up for Patients on Tuberculosis Preventive Treatment (TPT)

Action/ Clinical Step	Frequency	What to Look For	Management	Clinical Notes
Symptom screening for active TB	Monthly	Cough ≥2 weeks, fever, night sweats, weight loss, TB contact history	If TB positive → stop TPT, initiate TB treatment	Harmonize with other clinic schedules; can be in-person or remote
Assess and reinforce adherence	Monthly	Missed doses, barriers, patient concerns	Provide adherence counselling; address side effects or barriers	Use motivational interviewing; link with peer support
Assess for adverse drug reactions (ADRs)	Monthly	See ADR section	Manage per ADR protocol	Monthly AE monitoring
Provide/update TPT appointment card	Monthly	-	Maintain synchronized visits with other chronic care appointments	Helps avoid missed visits
Update recording and reporting tools	Monthly	ICF/TPT cards, Contact Management/TPT register	Document all visits, changes, outcomes	Keep EMR updated
Document TPT outcome	Completion or early stop	Completion, discontinuation, lost to follow-up	Record in EMR and national TB/TPT register	Supports national program monitoring
Baseline LFTs (if indicated)	At initiation (risk-based)	Older age, alcohol use, chronic hepatitis, hepatotoxic drugs	-	WHO: not mandatory unless high-risk
Pyridoxine supplementation	At initiation & ongoing (at-risk)	PLHIV, malnourished, alcohol use, pregnant, diabetics, renal failure	INH regimen → give pyridoxine	Prevents peripheral neuropathy

Adverse Drug Reaction (ADR) Management for Patients on Tuberculosis Preventive Treatment (TPT)

Table 1.78: Adverse Drug Reaction (ADR) Management for Patients on TPT

Adverse Reaction	Suspected Drug(s)	Diagnosis	Management	Notes
Peripheral Neuropathy	Isoniazid (INH)	Burning, numbness, tingling (feet, bilateral); ↓ sensation; weakness; risk ↑ with alcohol, diabetes, malnutrition, other neurotoxic drugs	Pyridoxine 100 mg/day (children: double weight-based dose); assess for other causes (diabetes, thyroid, B12 deficiency, syphilis); analgesics, tricyclic antidepressants, anticonvulsants; stop TPT if no improvement/worsening	Usually mild, reversible; prevention with B6
Drug-Induced Liver Inj1ry (DILI)	INH, Rifapentine (P), Rifampicin (R)	Jaundice, abdominal pain, nausea, vomiting, anorexia, hepatomegaly, abnormal LFTs; onset often in first weeks	See DILI grading below; symptomatic patients → assess LFTs, stop drugs if severe; screen for viral hepatitis; do not restart after severe/life-threatening DILI	Routine LFT monitoring not required unless symptomatic
Rash	Isoniazid (H), Rifapentine (P), Rifampicin (R)	Maculopapular rash with/without pruritus; onset usually within a few days of TPT initiation; may be mild and self-limiting; severe cases: exfoliation, mucosal involvement, Stevens–Johnson syndrome	**Mild (<50% BSA):** Continue TPT; close monitoring; treat with antihistamines ± topical steroids (no oral steroids). **Moderate (≥50% BSA):** Stop TPT; treat with antihistamines ± topical steroids; consider desensitization after complete resolution. **Severe (mucosal involvement, blistering, fever):** Stop TPT; hospital admission for IV fluids, wound care, pain control, infection prevention; **never re-challenge**; report AE and issue alert card	Always assess severity before deciding to stop TPT

Drug-Induced Liver Injury (DILI)

Drug-Induced Liver Injury refers to liver damage caused by medications used in Tuberculosis Preventive Treatment (TPT), most commonly isoniazid (INH), rifapentine (P), and rifampicin (R). It may present symptoms such as jaundice, abdominal pain, nausea, vomiting, and anorexia, and is typically associated with abnormal liver enzyme levels. DILI often develops within the first few weeks of treatment and may range from mild asymptomatic enzyme elevation to life-threatening liver failure. Prompt recognition, appropriate grading, and timely management are critical to preventing severe outcomes. Table 1.79 presents grading and management of DILI.

Table 1.79: Grading and Management of DILI

	Grade 1: Mild	Grade 2: Moderate	Grade 3: Severe	Grade 4: Life threatening
ALT (SGPT)	**1.25 – 2.5 x ULN**	**2.6 – 5.0 x ULN**	**5.1 – 10.0 x ULN**	**> 10.0 x ULN**
AST (SGOT)	**1.25 – 2.5 x ULN**	**2.6 – 5.0 x ULN**	**5.1 – 10.0 x ULN**	**> 10.0 x ULN**
ACTION	Continue treatment regimen; patients should have weekly followed up until resolution (return to baseline) or stabilization of AST/ALT elevation	Continue treatment regimen; patients should have weekly followed up until resolution (return to baseline) or stabilization of AST/ALT elevation	Stop all drugs, including TPT drugs; measure LFTs weekly; TPT **should not** be reintroduced after severe DILI	Stop all drugs, including TPT drugs; measure LFTs weekly. TPT **should not** be reintroduced after life threatening DILI
PLHIV who develop DILI during treatment of active TB disease, may have anti-TBs reintroduced after toxicity is resolved in consultation with a senior clinician. Risk factors for DILI: Older than 35 years, female gender, alcohol use, viral hepatitis, pre-existing renal disease, extensive TB disease, malnutrition (hypoalbuminemia).				

1.8.3.4 ART for TB/HIV Co-infection

All PLHIV who are diagnosed with TB/HIV co-infection should receive ART and cotrimoxazole preventive therapy (CPT) as part of comprehensive HIV care. For patients not yet on ART, TB treatment should be started immediately, followed by ART initiation as soon as anti-TB medications are tolerated preferably within two weeks. In cases of TB meningitis, ART should be delayed for 4–8 weeks to reduce the risk of severe immune reconstitution inflammatory syndrome (IRIS), with close clinical monitoring. Patients already on ART should begin TB treatment without delay while continuing ART, with careful assessment for treatment failure and adjustments to the regimen where necessary to address potential drug–drug interactions. All individuals receiving concurrent TB and HIV treatment require close monitoring for toxicity and IRIS. Management of multidrug-resistant TB (MDR-TB) in HIV-positive patients should take place in settings with experienced clinicians or multidisciplinary teams capable of close follow-up. Table 1.80 preferred art regimens for TB/HIV co-infection for patients starting initial art regimen.

Table 1.80: Preferred ART Regimens for TB/HIV Co-infection for Patients Starting Initial ART Regimen

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

1. Refer to Annex 10 for weight-based ARV dosing
2. TAF/3TC/DTG: Do not initiate TAF-LD in ART-naïve patients who are on Anti TB. Use other options which include; ABC/3TC/DTG plus DTG 50mg until 2 weeks after completion of Rifampicin based TB treatment; re-enforce adherence interventions

Table 1.81: Preferred ART Regimens for Patients who Develop TB while Virally Suppressed on current ART Regimen

Current Regimen	Age Category	Recommended Substitution
PI/r-based	All ages	**Patients <30kg: Consult regional/national TWG** **Patients ≥ 30kg:** should be switched to EFV-based ART and maintained on EFV-based ART after completion of TB treatment If illegible to use EFV due to prior treatment failure, Consult regional/national TWG
DTG-based	All ages	Administer the double-dose of DTG (i.e., the standard weight-based dose of DTG given twice daily) while taking rifampicin containing TB treatment. Two weeks after completion of TB treatment revert to the recommended DTG dose once daily.
TAF-based		Switch to ABC/3TC/DTG plus DTG 50mg until 2 weeks after completion of Rifampicin based TB treatment then revert back to TAF-based regimen

- Always assess for HIV treatment failure in patients who develop TB after being on ART for ≥ 6 months. Patients failing Initial ART Regimen who develop TB refer to Table 1.82 for recommended Subsequent ART regimens
- Patients on subsequent ART regimens, or nonstandard drugs who require regimen change because of TB treatment, consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform)

The recommended ART regimens for patients who develop TB while failing initial ART regimen as described in Table 1.82

Table 1.82: Recommended ART Regimens for Patients who Develop TB while Failing Current Regimen

Age/ Scenario	Initial ART	Subsequent ART
< 30 kg body weight	ABC (or AZT) + 3TC + DTG	• Start anti-TB immediately • Urgently consult regional/National TWG meanwhile increase DTG dosing frequency to twice daily
≥ 30 kg or ≥ 15 years Old	TDF (or TAF or ABC or AZT) + 3TC + DTG	**Case scenario 1:** DTG Failure without confirmed resistance: Start anti-TB immediately • Consult regional/National TWG meanwhile increase DTG dosing frequency to twice daily • (a) TLD; start anti-TB immediately, consult regional/national TWG; meanwhile use TLD plus DTG 50mg; re-enforce adherence interventions- plan for DRT if re-suppression is not achieved. b) TAF-LD; start anti-TB immediately, consult regional/national TWG, meanwhile switch to ABC+3TC+DTG plus DTG 50mg, re-enforce adherence interventions- plan for DRT if re-suppression not achieved **Case scenario 2:** With confirmed INSTI Resistance- Consult regional/national TWG
	PI/r- based regimen	• Start anti-TB immediately • Urgently consult regional/national TWG for way forward.
Pregnant or Breastfeeding	Follow the same recommendations as for ≥ 30 kg or ≥ 15 years old.	
HIV/HBV Co-infection	Always maintain TDF or TAF in subsequent regimens instead of switching to a different NRTI	

1. Always assess HIV treatment failure in patients who develop TB after being on ART for ≥ 6 months.
2. For patients on subsequent ART or nonstandard drugs who require regimen change because of TB treatment, consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform)
3. NRTIs in the patient's current regimen do not require any adjustments with anti-TB treatment
4. Use "super-boosted" LPV/r by adding additional ritonavir to manage the drug interaction between LPV/r and rifampicin (see Annex 16 for dosing recommendations)
5. Follow the viral load monitoring algorithm, assess and address reasons for treatment failure, and collect DRT samples. Consult the Regional or National TWG to constitute ART based on DRT results
6. Special Populations: Infants, children with co-morbidities, and pregnant adolescents should have regimen switches guided by a multidisciplinary team (MDT).

1.8.4 Management of Cryptococcal Meningitis (CM)

Cryptococcal meningitis is a leading cause of mortality among PLHIV, particularly those with advanced immunosuppression. Early detection through targeted screening and prompt treatment significantly improves survival.

1.8.4.1 Screening and Diagnosis of Cryptococcal meningitis

All adults and adolescents with a baseline CD4 count ≤ 200 cells/mm^3, or those with WHO Stage 3 or 4 disease, should undergo routine cryptococcal antigen (CrAg) screening. Screening should ideally be a reflex laboratory test triggered by a low CD4 result, rather than requiring a separate clinician request.

CrAg screening is indicated for PLHIV, including children and adolescents, when cryptococcal disease is clinically suspected. Patients who test positive for blood CrAg should undergo lumbar puncture (LP) for cerebrospinal fluid (CSF) CrAg testing to determine the presence of meningitis. Symptomatic patients with negative blood CrAg should be evaluated for alternative causes of sub-acute meningitis, such as TB meningitis.

Where possible, additional tests such as CSF GeneXpert for TB and urine LF-LAM should be performed concurrently. Special considerations apply to pregnant women, as fluconazole use in the first trimester is associated with teratogenic risk. In such cases, management should be adapted in consultation with expert guidance.

The algorithm in figure 1-27 outlines the stepwise approach to routine CM screening, diagnosis, and treatment in HIV-infected adults and adolescents.

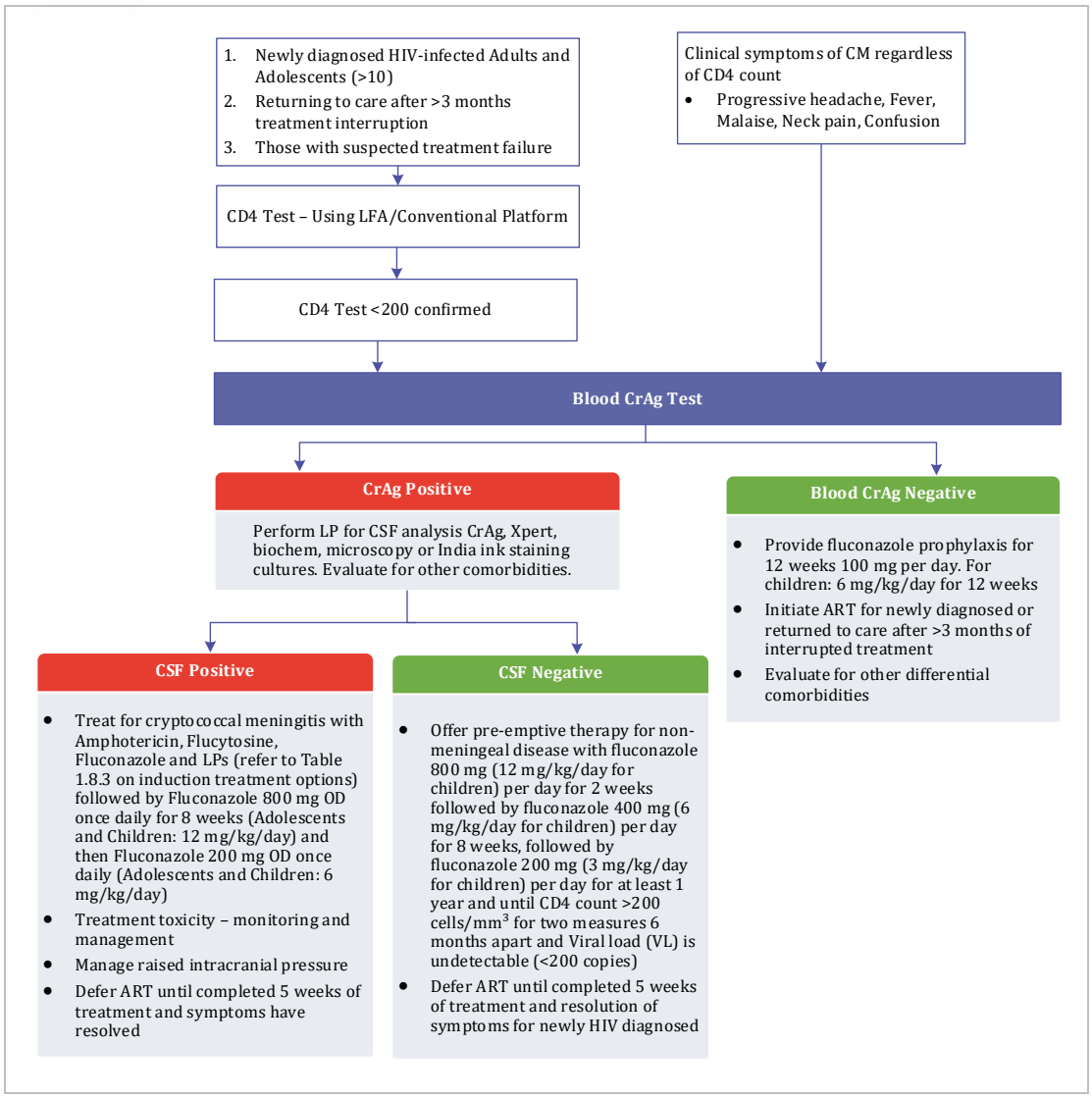


Figure 1.27: Routine Screening for Cryptococcal Meningitis for HIV-infected Adults and Adolescents

1.8.4.2 Primary Prophylaxis of Cryptococcal Meningitis

Consider primary fluconazole prophylaxis for PLHIV with a CD4 <200 and a negative blood CrAg. Rapid initiation of ART and immune reconstitution is the most effective way to prevent cryptococcal meningitis. Provide:

- **Adults:** Fluconazole 100 mg once daily for 12 weeks
- **Children:** 6mg/kg daily for 12 weeks

Pre-emptive Therapy

Offer pre-emptive therapy for non-meningeal disease (bCrAg positive with CSF negative):

- **Induction:** fluconazole 800 mg (12mg/kg per day for children) per day for 2 weeks
- **Consolidation:** fluconazole 400 mg daily (6mg/kg for children) for 8 weeks
- **Maintenance:** fluconazole 200 mg daily (6mg/kg for children) for at least 1 year and until CD4 count >200 cells/mm3 for two measures 6 months apart and VL is undetectable.

Defer ART initiation, resumption or switch to new regimen until 5 weeks of treatment and symptom resolution.

1.8.4.3 Treatment of Cryptococcal Meningitis

Components:

- Antifungal treatment
- Management of treatment toxicity
- Management of raised intracranial pressures

The treatment of cryptococcal meningitis is as described in Table 1.83

Table 1.83: Treatment of Cryptococcal Meningitis

1. Induction Phase	
Preferred regimen: Liposomal amphotericin B stat *PLUS* Flucytosine PLUS Fluconazole	• Liposomal amphotericin B: **Single dose** 10 mg/kg **+** • Flucytosine: 100 mg/kg/day divided into 4 doses **for 14 days** **+** • Fluconazole: 1200 mg daily (adults); 12 mg/kg/day (children/adolescents, max 800 mg daily) **for 14 days**
Alternative 1 Amphotericin B deoxycholate *PLUS* Flucytosine followed by Fluconazole	• Amphotericin B deoxycholate: 1 mg/kg/day **for 7 Days** **+** • Flucytosine: 100 mg/kg/day divided into 4 doses for **7 days** **THEN** • Fluconazole: 1200 mg daily (adults); 12 mg/kg/day (children/adolescents, max 800 mg daily) **for 7 days**
Alternative 2 Fluconazole *PLUS* Flucytosine	• Fluconazole: 1200 mg daily (adults); 12 mg/kg/day (children/adolescents) **for 14 Days** **+** • Flucytosine: 100 mg/kg/day divided into 4 doses **for 14 days**
Alternative 3 Liposomal amphotericin B *PLUS* Fluconazole	• Liposomal amphotericin B: 3–4 mg/kg/day **for 14 Days** **+** • Fluconazole: 1200 mg daily (adults); 12 mg/kg/day (children/adolescents, max 800 mg daily) **for 14 days**
Alternative 4 Amphotericin B deoxycholate *PLUS* Fluconazole	• Amphotericin B deoxycholate: 1 mg/kg/day **for 14 Days** **+** • Fluconazole: 1200 mg daily (adults); 12 mg/kg/day (children/adolescents, max 800 mg daily) **for 14 days**

2. Consolidation Phase	
Fluconazole	Fluconazole: • Adults: 800 mg daily for 8 weeks • **Children/adolescents:** 6 -12 mg/kg/day, max 800 mg daily) **for 8 weeks**
3. Maintenance Phase (Secondary Prophylaxis)	
Fluconazole	• Fluconazole: 200 mg daily (adults); 6 mg/kg/day (children/adolescents) • Continue at least for 1 year **AND** CD4 > 200 cells/mm^3, two measures 6 months apart **AND** viral loads is LDL
Treatment of Pregnant Women	• Both Fluconazole and Flucytosine are contraindicated in pregnancy. • Amphotericin (liposomal or deoxycholate) can be used • **Consult** regional/national TWG for all pregnant women with cryptococcal meningitis
Notes: • Fluconazole requires a dose adjustment for impaired renal function; when CrCl ≤ 50 ml/min use 50% of the standard recommended dose • Fluconazole should not be used with rifabutin-based TB treatment • When using high-dose fluconazole check ALT after one week of treatment and based on symptoms thereafter	

The management of cryptococcal meningitis in individuals on ART and supportive care is described in table 1.84

Table 1.84: Management of Cryptococcal Meningitis (CM) in Clients on ART and Supportive Care

Component	Scenario / Intervention	Recommendation
Amphotericin B Therapy	Adults	**Pre-infusion:** 1 L normal saline + 20 mmol KCl over 2–4 hrs; Amphotericin B in 1 L 5% dextrose; 8 mEq KCl orally twice daily (increase in 2nd week if needed); magnesium 250 mg twice daily (or magnesium chloride 4 mEq twice daily)
	Adolescents & Children	**Pre-infusion:** 1 L normal saline + 20 mmol KCl over 2–4 hrs; Darrow's or Ringer's may be used
	Caution	Avoid KCl in patients with renal impairment or hyperkalaemia
Adverse Effect Management	Hypokalaemia (K < 3.3 mmol/L)	Give 1 L normal saline + 40 mmol KCl OR 8 mEq KCl orally every 8 hrs; add magnesium; monitor potassium daily
	Raised creatinine (> 2× baseline)	Omit Amphotericin B; increase hydration to 1 L every 8 hrs; if improved, restart at 0.7 mg/kg/day alternate days; if no improvement, stop Amphotericin B and switch to fluconazole 1,600 mg/day to complete induction; monitor creatinine daily

Component	Scenario / Intervention	Recommendation
Therapeutic Lumbar Punctures (LPs)	Indication	All patients with symptomatic CM
	If opening pressure ≤ 40 cm	Remove CSF to reduce pressure to 20 cm
	If opening pressure > 40 cm	Remove CSF to reduce pressure by 50%
	Frequency	Daily LPs until pressure normal for 3 consecutive days; restart if symptoms return
	If ICP measurement not possible	Daily LPs until severe headache subsides; remove 10–20 ml CSF each time

Table 1.85: Simplified chart for CM induction therapy using preferred regimen

Management of Cryptococcal Meningitis with Single high-dose Liposomal Amphotericin B, Flucytosine and Fluconazole														
Pre-emptive hydration and electrolyte supplementation														
DAY	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
1 Litre normal saline solution with 20mEq KCl over 2 to 4 hours before each controlled infusion	X													
2 times 8-mEq KCl tablet (twice daily)	X	X	X											
Magnesium supplementation (if available)	X	X	X											
Drug administration – Liposomal Amphotericin B, Flucytosine and Fluconazole														
DAY	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Liposomal Amphotericin B (10 mg/kg)	X													
Flucytosine (5FC) (100 mg/kg/day in 4 divided doses)	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Fluconazole (1200 mg/day)	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Monitoring Treatment-related Toxicity														
DAY	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Serum Potassium	X		X											
Serum Creatinine	X		X											
Haemoglobin	X						X							X
Therapeutic Lumbar Puncture														

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Lumbar Puncture	X		X		X		X		X		X		X	
Adapted from WHO Cryptococcal Meningitis Guidelines 2022														

Timing of ART in Cryptococcal meningitis treatment

- **On ART < 14 days:** Stop ART; restart after completing 5 weeks of CM treatment
- **Treatment interruption:** Do not start ART until after 5 weeks of CM treatment
- **Treatment failure:** Continue ART with CM treatment; do not switch regimen until after 5 weeks

1.8.4.4 Considerations for discharge from AHD care

- Clinically stable on ART with no active OIs
- Viral load <200 copies/mL for 2 consecutive results
- Completed OI and co-infection prophylaxis or treatment
- Psychosocially stable and adherent to care plan

Note:

Follow up CD4 is only recommended for the following:

- Cryptococcal meningitis treatment (when to discontinue secondary fluconazole prophylaxis)
- CNS toxoplasmosis and PCP (when to discontinue cotrimoxazole prophylaxis

ELIMINATION OF VERTICAL TRANSMISSION OF HIV, SYPHILIS, AND HEPATITIS B VIRUS

Prevention of vertical transmission of HIV, syphilis, and hepatitis B should be offered as part of a comprehensive package of fully integrated, routine maternal and child health services. The elimination of vertical transmission is anchored on comprehensive testing, prevention and treatment services, assessment of pregnancy intentions, and the provision of family planning options for women. These services should be patient-centred, promoting equity and ensuring that structural barriers that may hinder health service access are addressed.

All women of reproductive age (15-49 years) should be offered HIV testing and those living with HIV initiated on treatment and supported to achieve viral suppression (VL <50 copies/ml)

2.1 Package of Services for Pregnant and Breastfeeding Women

Table 2.1 Essential Package of Services for Triple Elimination of Vertical Transmission of HIV, Syphilis and Hepatitis B

MCH	Package of Care for Women of Reproductive Age	Implementation considerations
Preconception	1. Comprehensive medical history that includes knowledge of HIV status for the client and their sexual partners 2. Detailed physical examination. 3. Investigations: Full blood count, random blood sugar, syphilis test, HIV test, blood group and rhesus, urinalysis. Additional investigations based on history and examination 4. Cervical cancer screening 5. Interventions: a. Pregnancy intention assessment b. HIV risk assessment and linkage to appropriate prevention, including PrEP c. Family planning counselling and service provision d. Adolescent girls and young women: i. Provide age-appropriate SRH information ii. Provide Life skills and education e. Initiate treatment for women living with HIV, Syphilis and HBV f. Screen for sexual and gender-based violence g. Nutrition assessment, counselling, and support	1. Healthcare worker capacity building 2. Service integration 3. AYP-friendly services 4. Healthcare financing: social health insurance 5. Health products (laboratory and therapeutic) availability

MCH	Package of Care for Women of Reproductive Age	Implementation considerations
	6. Adherence support for women living with HIV and HBV	
1st ANC	**Minimum of 8 ANC Contacts recommended**	
	1. Physical Examination: vital signs, anthropometric measurements 2. Baseline investigations on 1st visit: – Full blood count and blood group – Urinalysis – Random blood glucose – HIV, Syphilis and Hepatitis B testing* 3. Counselling for HIV and STI prevention, PrEP eligibility screening 4. TB screening 5. Early obstetric ultrasound 6. Nutrition assessment, counselling, and support 7. Nutritional supplementation: Folic acid, Iron and calcium 8. Risk assessment and categorization for Vertical transmission of HIV 9. Screen for Violence/IPV, mental health 10. Screen and treat other STIs 11. Discuss pregnancy danger signs and refer as appropriate 12. Adherence support for women living with HIV and HBV 13. Cotrimoxazole Prevention therapy for Women living with HIV	
Other ANC Contacta	1. Standard package of obstetric services (refer to the current National Guideline on Quality Obstetric and Perinatal Care) 2. Adherence support for women living with HIV and HBV 3. Counselling for HIV and STI prevention, PrEP eligibility screening 4. Nutrition assessment, counselling, and support	
3rd-Trimester ANC, Labour and Delivery	1. HIV and Syphilis re-testing (and initial testing if this is the 1st visit)* 2. Hepatitis B testing (if not tested at 1st ANC) 3. Risk categorization and provision of infant prophylaxis based on risk (Refer to Figures 2.1 and 2.2) 4. Comprehensive obstetric care (refer to the National Guideline on Quality Obstetric and Perinatal care) a. Early Infant Diagnosis for HEI (refer to Figure 1.3 EID algorithm) 5. Nutrition assessment, counselling, and support	
PNC		

MCH	Package of Care for Women of Reproductive Age	Implementation considerations
6 weeks	1. HIV re-testing or testing if 1st test 2. Early Infant Diagnosis for HEI (refer to Figure 1. 3 EID algorithm) 3. HIV and STI prevention messaging, including PrEP eligibility assessment 4. Comprehensive postnatal care (refer to the current National Guideline on Quality Obstetric and Perinatal Care) 5. Nutrition assessment, counselling, and support	
Every 6 months until complete cessation of breastfeeding	1. 6-monthly HIV testing and risk categorization 2. HIV and STI prevention messaging, including PrEP eligibility assessment 3. Adherence support and viral load testing for breastfeeding women living with HIV 4. Early Infant Diagnosis for HEI (refer to Figure 1. 3 EID algorithm) 5. Nutrition assessment, counselling, and support 6. Infant feeding counselling and support 7. Mental health assessment and support	
*All mothers who test positive for syphilis, should have titres done in settings where this is possible. The titres are used to monitor response to treatment. *For mothers who tested positive for syphilis previously and were treated, the current titres if lower would make them not eligible for treatment despite a positive treponemal/nontreponemal test result. *For settings where titres are not done provide treatment as per guidelines.		

2.1.1 HIV Risk Stratification for Women of Reproductive Age

Assessment and determination of HIV infection risk ensures that women of reproductive age receive targeted client-centred interventions for HIV and STI prevention.

Risk stratification and Management for HIV Negative Women in MNCH settings:

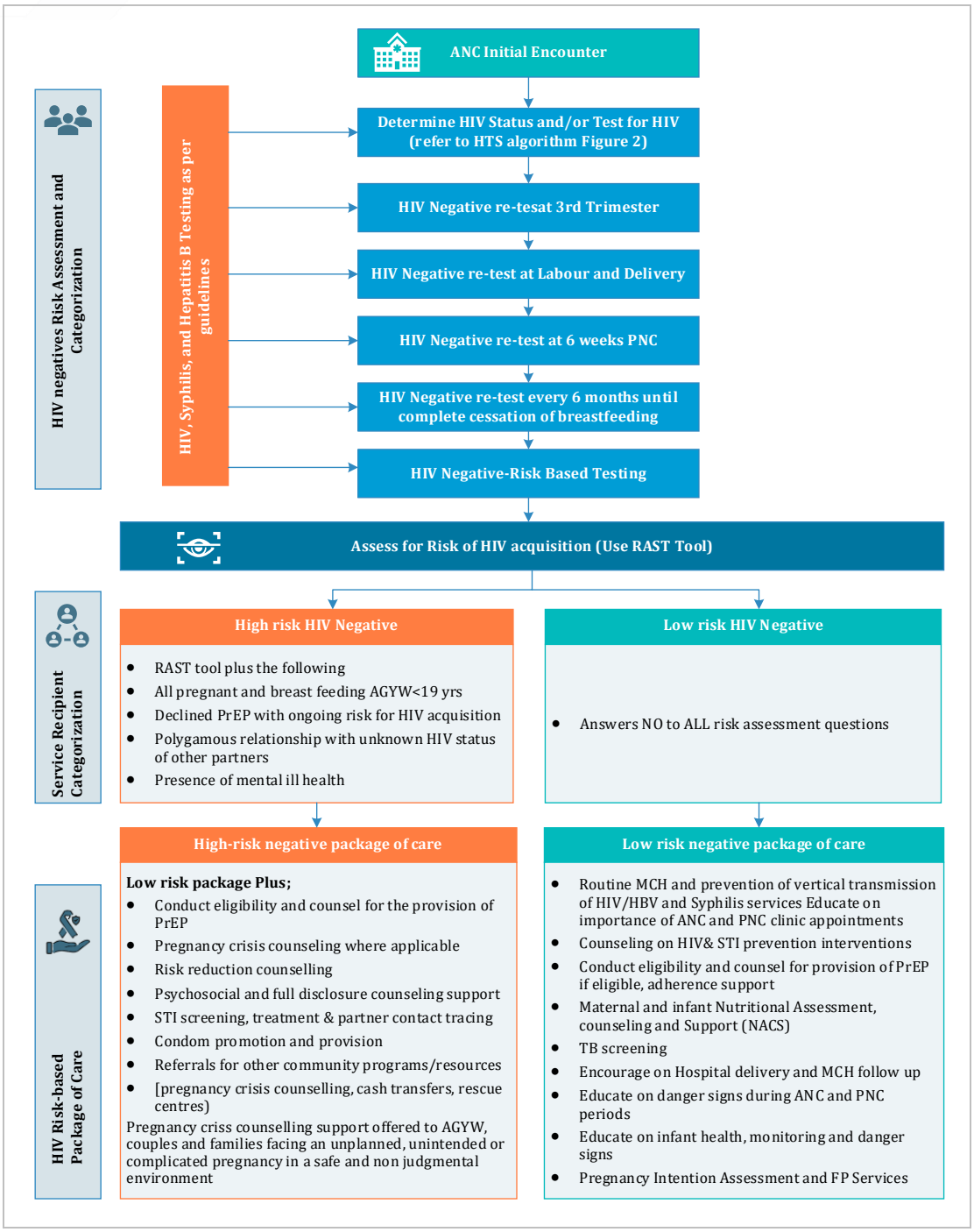


Figure 2.1: Risk stratification and Management for HIV Negative Women in MNCH

2.1.2 Risk Categorization for PBFW Living with HIV

Risk categorization for PBFW living with HIV is a key approach to identify PBFW at increased risk of vertical transmission and provide targeted interventions to reduce transmission as described in figure 2.1.

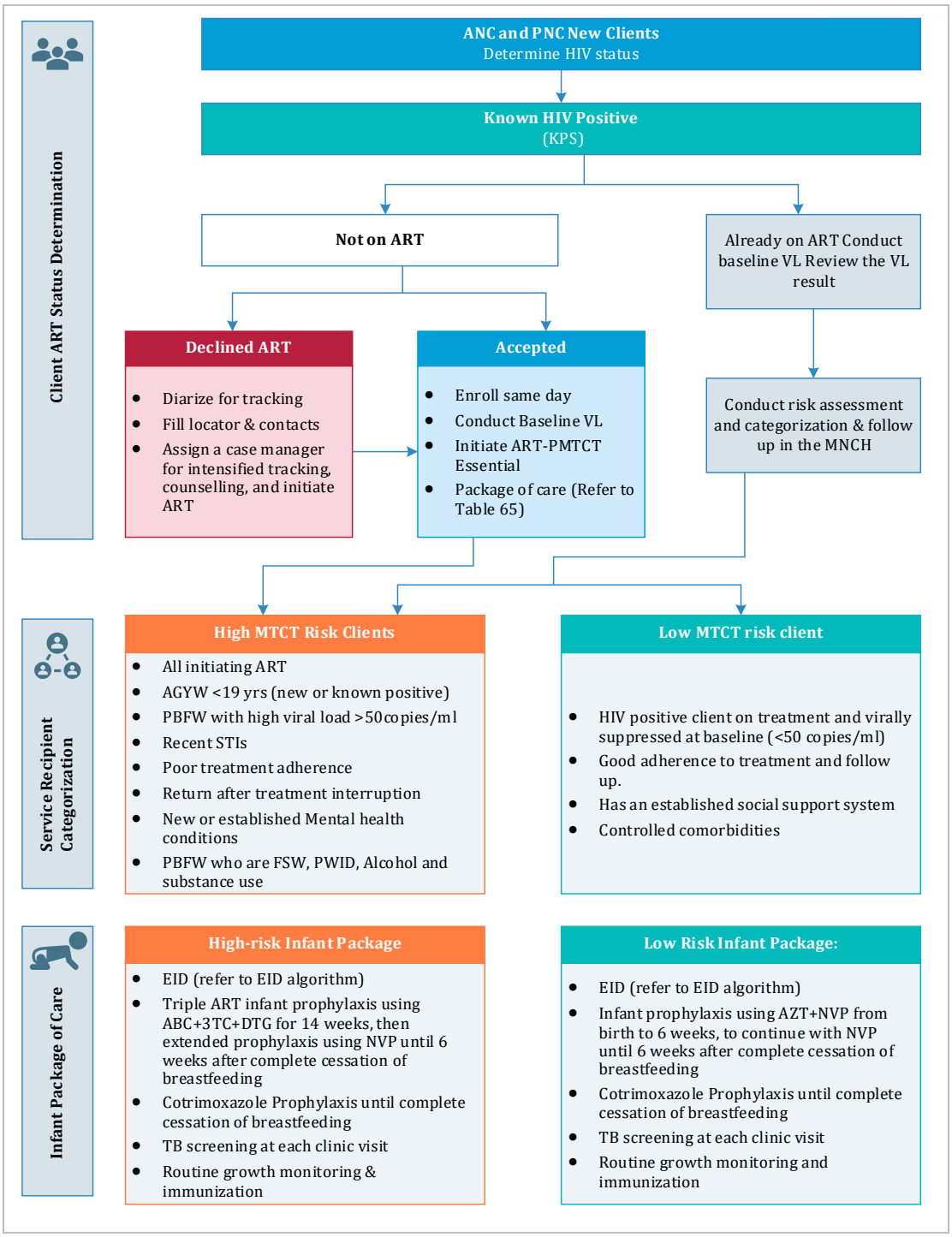


Figure 2.2: Vertical HIV Transmission risk categorization and package of care for women who are known positive and breastfeeding in MNCH settings

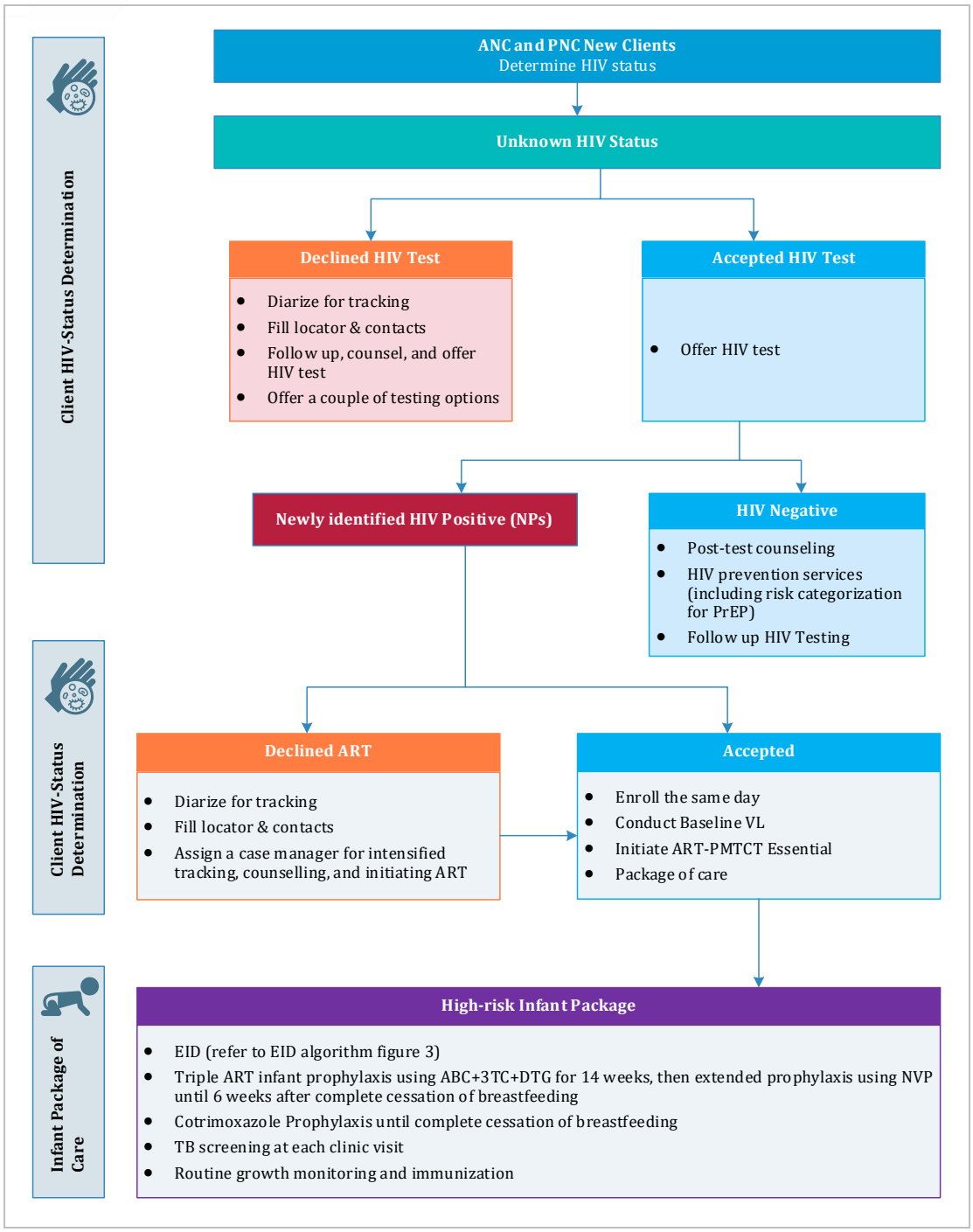


Figure 2.3: Enhanced Package of care for infants at high risk of vertical transmission among newly diagnosed pregnant and breastfeeding women in MNCH settings

2.1.3 Antiretroviral Therapy for HIV-positive Pregnant and Breastfeeding Women

The goal of ART for pregnant and breastfeeding women living with HIV is two-fold: to restore and maintain maternal immune function and therefore general health, and secondly, to prevent transmission of HIV in utero, at labour and delivery, and during breastfeeding. To achieve these goals, the mother must take effective antiretroviral therapy to achieve viral suppression.

Table 2.2 Summary of recommendations for the use of ART for Pregnant and Breastfeeding Women Living with HIV

Overall Recommendations	
When to start	ART should be initiated for all newly diagnosed PBFW
What to start	Preferred: TDF+3TC+DTG Alternative: TAF+3TC+DTG (Refer to table 4.9 for priority groups for initiation/transition to TAF)
Monitoring	• Conduct Baseline viral load: – Known positive on ART – Known positive not on ART – Newly diagnosed pregnant and breastfeeding women. • For known positive, follow-up viral load will be conducted 6-monthly, after baseline VL, until complete cessation of breastfeeding. • For newly diagnosed PBFW and known positives newly initiated on ART, conduct VL 3 months post ART initiation after baseline VL, then every 6 months until complete cessation of breastfeeding.

2.1.4 Approach to Triple Elimination of Vertical Transmission of HIV, Syphilis & Hepatitis B

The country has adopted triple elimination of HIV, Syphilis, and Hepatitis B among pregnant and breastfeeding women. It is recommended that screening be conducted for all three diseases and management provided as appropriate.

Table 2.3: Approach to Triple Elimination of Vertical Transmission of HIV, Syphilis, and Hepatitis B

Triple Elimination of HIV, Syphilis and Hepatitis B Approach		
Infant Scenario	**Infant Prophylaxis**	
HIV-Exposed Infant	Infants at High risk of HIV acquisition[1](refer to risk categorization algorithm Figures 2.1 and 2.2	Infants at low risk of HIV Acquisition[1]
	ABC+3TC+DTG[2,3] for 14 weeks, then extended prophylaxis using NVP until 6 weeks after complete cessation of breastfeeding	AZT+NVP for 6 weeks then NVP continued until 6 weeks after complete cessation of breatfeeding

<table>
<tr><th colspan="2">Triple Elimination of HIV, Syphilis and Hepatitis B Approach</th></tr>
<tr><td>Confirmed/highly probable congenital syphilis</td><td>
Definition:
● Abnormal signs and symptoms
● Mother with reactive treponemal and non-treponemal test during pregnancy and a reactive non-treponemal serologic test at delivery
Management:
<table>
<tr><th>Infant Management</th><th>Maternal management for women with positive serologic tests</th></tr>
<tr><td>Aqueous crystalline penicillin G 100,000–150,000 units/kg/day, administered as 50,000 units/kg/dose IV every 12 hours during the first 7 days of life and every 8 hours thereafter for a total of 10 days;
OR
Procaine penicillin G 50,000 units/kg body weight/dose IM in a single daily dose for 10 days[5]</td><td>Benzathine penicillin 2.4MU IM stat
OR
Ceftriaxone IM 1g OD for 10-14 days in case of penicillin allergy</td></tr>
</table>
</td></tr>
<tr><td>Possible Congenital Syphilis:</td><td>
Definitions:
Asymptomatic infant (with serum quantitative nontreponemal serologic titre equal or less than fourfold of the maternal titre at delivery[6])
● The mother not treated, inadequately treated, or has no documentation of having received treatment.
● The mother was treated with erythromycin or a non-penicillin G regimen)
● The mother received the recommended regimen but treatment was initiated <30 days before delivery.
Management:
Preferred - Aqueous crystalline penicillin G 100,000–150,000 units/kg/day, administered as 50,000 units/kg/dose IV BD during the first 7 days of life and TID thereafter for a total of 10 days;
Alternatives:
Procaine penicillin G 50,000 units/kg body weight/dose IM in a single daily dose for 10 days
OR,
Benzathine penicillin G 50,000 units/kg body weight/dose IM in a single dose [8]
</td></tr>
<tr><td>Congenital syphilis Less likely or unlikely</td><td>
Definitions:
Less likely
Asymptomatic infant (with serum quantitative nontreponemal serologic titre equal or less than fourfold of the maternal titre at delivery[6])
● Mother treated during pregnancy and has no evidence of reinfection or relapse
● Treatment was appropriate for the infection stage, and
● Treatment regimen initiated ≥30 days before delivery
</td></tr>
</table>

<table>
<tr><th colspan="2">Triple Elimination of HIV, Syphilis and Hepatitis B Approach</th></tr>
<tr><td></td><td>Management:
Benzathine penicillin G 50,000 units/kg body weight/dose IM in a single dose, particularly if follow-up is uncertain and the neonate has a reactive nontreponemal test
Unlikely
● Asymptomatic infant
● Mother treated adequately before pregnancy
● Mother's nontreponemal serologic titer4 remained low and stable before and during pregnancy and at delivery (e.g., VDRL ≤1:2 or RPR ≤1:4)
Management: No treatment is required</td></tr>
<tr><td>Infant whose mother is HBsAg test positive</td><td>
<table>
<tr><th>Infant Management</th><th colspan="2">Maternal management</th></tr>
<tr><td>Hepatitis B vaccine birth dose at 0.5ml and, Hepatitis B Immunoglobulin 0.5ml[7] IM within 24 hours of birth
Hepatitis B vaccination provided at 6, 10, and 14 weeks postnatally (per regular EPI schedule)</td><td>HIV-negative pregnant women
Start TDF+FTC or TDF+3TC prophylaxis as early as possible, or at least from second trimester of pregnancy until at least after delivery, or completion of the infant HBV vaccination series)
Long-term treatment is based on treatment eligibility criteria (Figure 2.4:)</td><td>PBFW living with HIV
Should be on an ART regimen that contains TAF+3TC or TDF+3TC
Treatment is lifelong</td></tr>
</table>
</td></tr>
</table>

[1] Newly identified HEI will be risk-categorized and provided infant prophylaxis based on risk

[2]Enhanced infant prophylaxis with ABC+3TC + DTG should be provided for infants of women with inconclusive HIV results and continued until mother is confirmed PCR negative

[3]ABC/3TC/DTG cannot be used in infants <37 weeks. Use AZT/3TC/ NVP for post-natal infant prophylaxis for preterm infants at high risk of HIV infection

[4]Implementation Considerations will be guided by the National Program. NVP intolerance or TB co-infection use DTG for Infant prophylaxis (provide an additional pDTG dose in TB co-infection)

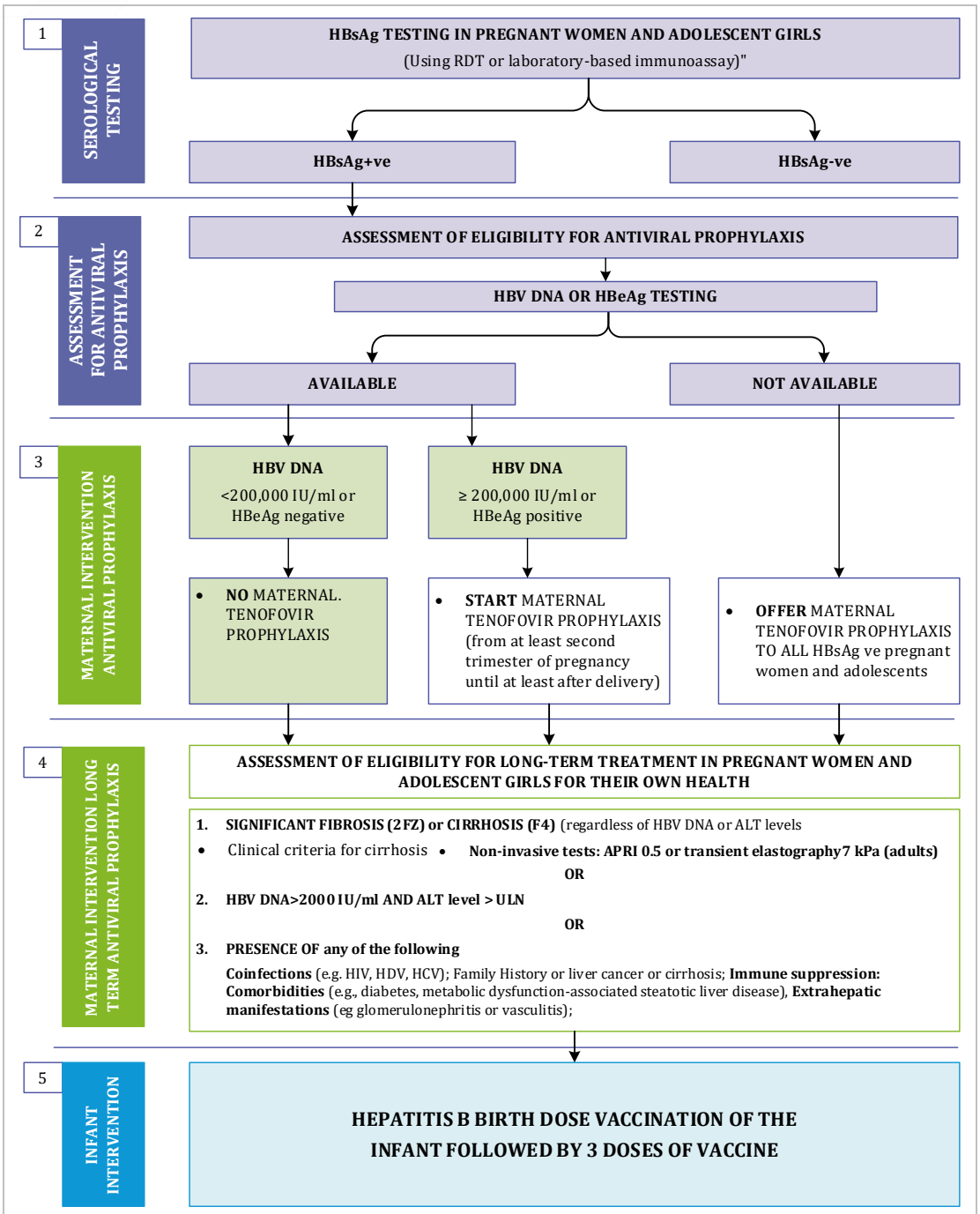
[5] Where serologic test titres are available

[6] If more than 1-day dose is missed before completion of 10 days, treatment should be restarted

[7]Hep B vaccine and HEPBIG administered on separate thighs

[8] Before using single dose Benzathine penicillin regimen the recommended evaluation include CSF analysis, long bone radiography and complete blood count with platelets should be normal and follow up should be certain. If not normal or not done a ten day course of recommended crystalline penicillin G should be provided

Figures 2-4 and 2-5 below provide further guidance for maternal antiviral prophylaxis and management of the HBV-exposed infant.



[a] At least once and as early as possible in the pregnancy.

[b] Hepatitis B timely (within 24 hours) birth dose vaccination of the infant followed by 2 or 3 doses of hepatitis B vaccine should be given regardless of HBsAg status of the pregnant mother. HBIG (if available) is also provided

Figure 2.4: Algorithm on using antiviral prophylaxis for preventing vertical transmission and eligibility for antiviral therapy for pregnant adults and adolescents

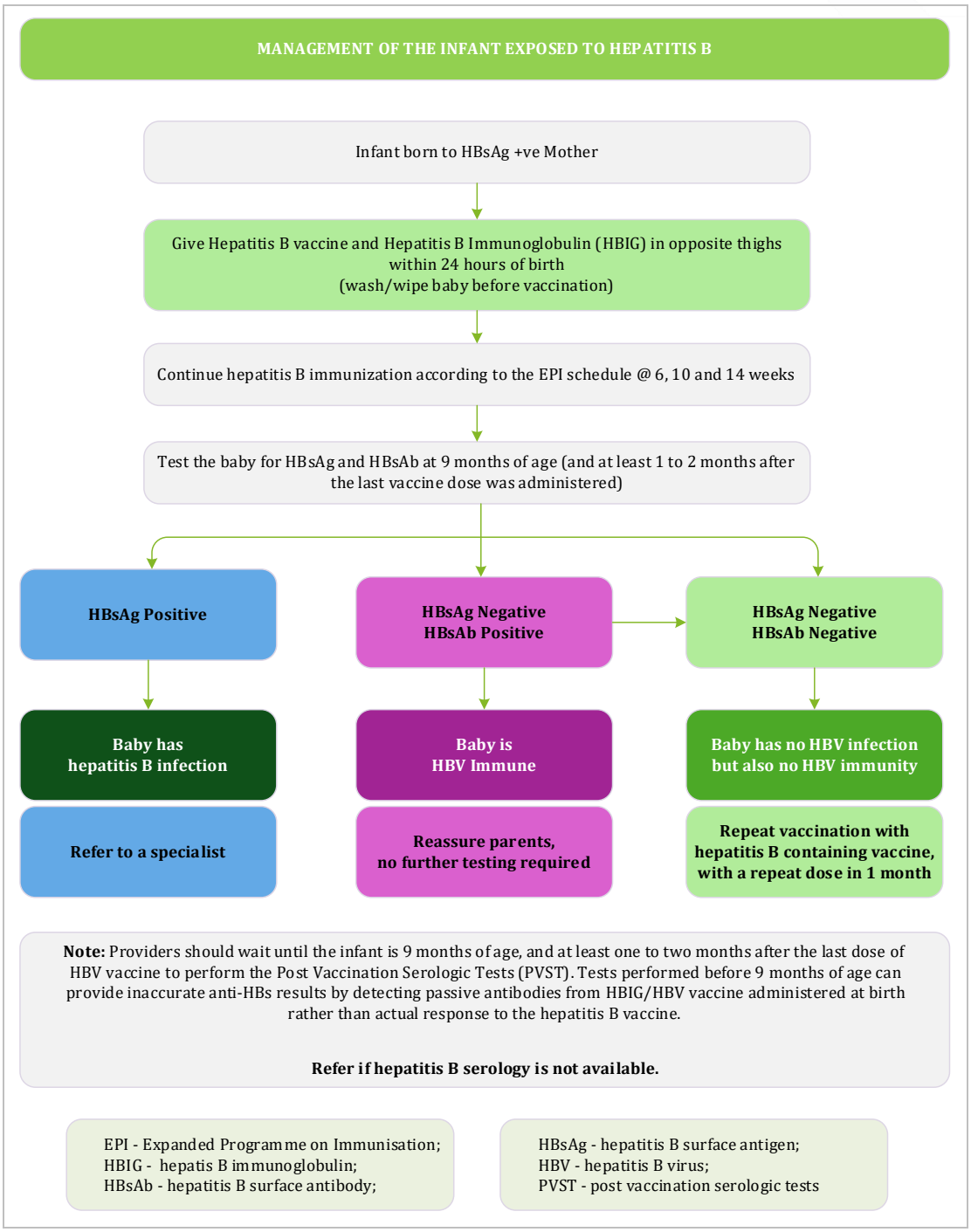


Figure 2.5: Algorithm for management of infants exposed to HBV

2.1.5 Postnatal Infant Prophylaxis Dosing for Infants at High and Low Risk of Vertical Transmission of HIV

Infants should receive antiretroviral prophylaxis according to their HIV acquisition risk category (refer to figures 2-1 and 2-2)

- **Low-risk infants** receive AZT+NVP for 6 weeks then NVP continued until 6 weeks after complete cessation of breastfeeding, with dosing based on age or birth weight.
- **High-risk infants** complete a 14-week course of triple ART (ABC+3TC+DTG) and continue NVP until 6 weeks after the complete cessation of breastfeeding.

Infants who present late in care or those who are identified late should be assessed for risk of vertical transmission, categorized, and provided post-natal infant prophylaxis based on risk (14 weeks ABC+3TC+DTG for infants at high risk, followed by extended NVP prophylaxis, and AZT+NVP for 6 weeks followed by NVP until 6 weeks after complete cessation of breastfeeding, for infants at low risk). Refer to tables 2.4 and 2.5 for dosing charts

Table 2.4: Nevirapine and Zidovudine (Birth to 6 weeks) and Extended Nevirapine Prophylaxis for Infants at Low Risk of Vertical Transmission of HIV, and Infants Continuing Infant Prophylaxis

Infant Age/Weight (kg)	Nevirapine Once Daily Dose (10 mg/ml)	Zidovudine Twice Daily Dosing (10mg/ml)
Birth to 6 weeks		
≤ 2.0 kg	2mg/kg/dose	4mg/kg/dose
2.0 – 2.49	10mg (1 ml)	10mg (1ml)
>2.5	15mg (1.5 ml)	15mg (1.5ml)
6 – 12 weeks	20mg (2 ml)	-
12 weeks – 6 months	20mg (2ml)	-
6 – 9 months	30mg (3ml)	-
9 – 24 months	40mg (4ml)	-

2.1.6 Infant Prophylaxis Dosing: ABC+3TC+DTG 14 week -Regimen for Infants at High Risk of Vertical Transmission of HIV

Table 2.5: Infant Prophylaxis Dosing: ABC+3TC+ DTG Regimen for Infants at High Risk of HIV Acquisition

Dosing For Term Infants <4 weeks of age and >2kg[1]		
Age in Weeks	**Drug Strength of Pediatric Formulation**	
	ABC/3TC Double-scored tablet (dispersible) 120mg/60mg	DTG[2] Tablet (dispersible) 10mg
< 2 weeks	¼ (On alternate days)	½ (On alternate days)
2 - < 4weeks	¼ (Daily)	½ (Daily)

For infants aged 4 weeks and above, and ≥ 3kg – To Use Paediatric FDC ABC/3TC/DTG (60mg/30mg/5mg)			
> 4 weeks[3]	3 – 5.9kg	6 – 9.9kg	10 – 13.9kg
	1 Daily	3 Daily	4 Daily

[1]For infants <4 weeks of age and >2kg, use ABC/3TC (120mg/60mg) and pDTG (10mg) as per the dosages and schedule of administration as shown above

[2]DTG should not be administered to infants <37 weeks of gestation. For pre-term infants <37 weeks gestation use AZT/3TC and NVP

[3]For infants age 4 weeks and above, and ≥ 3kg, use paediatric FDC **ABC/3TC/DTG** (60mg/30mg/5mg) as per the dosing chart above

Infants at high risk of HIV acquisition should receive triple infant prophylaxis with ABC+3TC+DTG for 14 weeks, after which they should continue with NVP prophylaxis until 6 weeks after complete cessation of breastfeeding

2.1.7 Maternal, Infant, Young Child & Adolescent Nutrition (MIYCAN) in the Context of HIV

Introduction

Maternal, Infant and Young Child Nutrition (MIYCAN) in the context of HIV aims to improve health outcomes and prevent vertical transmission. Preventing vertical transmission is the first step in safeguarding the nutritional status of children at risk of HIV. Infants born to HIV-positive mothers face elevated risks of morbidity and mortality, extending beyond potential HIV acquisition during pregnancy, delivery, or breastfeeding, underscoring the need for vigilant care. HIV-positive mothers require optimal nutrition during pregnancy and lactation to support their health, enhance immunity, and reduce transmission risk. However, many face challenges in meeting their nutrient needs, calling for regular assessment and support from health workers. Adherence to ART is vital for maintaining viral suppression and preventing transmission during pregnancy, delivery, and breastfeeding. For infants and young children, exclusive breastfeeding for the first six months of life and continued breastfeeding for 24 months or beyond with appropriate complementary feeding are key to growth and survival, in line with national and WHO recommendations. Nutrition interventions should also extend to adolescents, who require adequate nutrition to support growth, immunity, and ART adherence, ensuring lifelong health and resilience.

Breastfeeding Key Recommendations.

- **Exclusive breastfeeding:** Give only breast milk for the first 6 months of life; medicines or supplements allowed if prescribed.
- **Mixed feeding:** Avoid mixed feeding in infants under 6 months due to increased risk of HIV transmission and illness.
- **Breastfeeding duration:** All infants should be exclusively breastfed for 6 months, with appropriate complementary foods introduced thereafter, and continued breastfeeding to 24 months or beyond.
- **Maintaining breastfeeding:** Support mothers to sustain exclusive breastfeeding, including expressing milk if separated from their infants.

- **New HIV diagnosis while breastfeeding:** Start maternal ART immediately, give infant ARV prophylaxis, and conduct infant PCR testing.
- **Breastfeeding cessation:** Do so gradually within 1 month only when a safe, adequate diet is available; HIV-positive mothers and infants remain on ART. The baby should continue preventive medicine (prophylaxis) for six weeks after stopping breastfeeding.
- **Non-breastfeeding situations:** Follow the current MIYCN Policy and Breast Milk Substitute (BMS) Regulation and Control Act.
- **Complementary feeding:** Begin at 6 months while continuing breastfeeding; aim for at least 5 of these 8 food groups — breast milk, flesh foods (meat, poultry, fish, etc.), dairy, eggs, legumes, nuts, vitamin A-rich fruits/vegetables, other fruits/vegetables, and grains/roots/tubers.

Breastfeeding Recommendations in other Conditions

Table 2.6: Breast feeding recommendation in other conditions

Disease	Breastfeeding Recommendation
HIV	Exclusive Breastfeeding for 6 months (180 days); timely introduction of appropriate age specific complementary feeds alongside breastfeeding up to 2 years or beyond.
Tuberculosis	If mother has bacteriologically confirmed TB: feed expressed breastmilk by cup, avoid rooming-in, and mother should wear a facemask when feeding.
Herpes Simplex	Avoid breastfeeding from affected breast until lesions heal; express and discard milk from the infected breast, feed from the healthy breast.
Syphilis	If infectious lesions present, avoid breastfeeding from that breast until treatment is completed and lesions heal; feed from unaffected breast. Express and discard milk from the infected breast
Hepatitis B	Same as HIV exclusive breastfeeding for 6 months; continue with complementary feeding up to 2 years or beyond.
Other breast conditions recommendations Breastfeeding should continue unless the mother has breast conditions that significantly increase the risk of HIV transmission, such as cracked or bleeding nipples, breast abscess, or mastitis. In such cases, the affected breast should be rested, and expressed milk from that breast should be discarded until healing occurs. The infant can continue feeding from the unaffected breast. Prompt assessment, treatment, and counselling should be provided to support continued optimal feeding and prevent transmission.	

Complementary feeding for children 6-24 months old is described on figure 2-6 below:

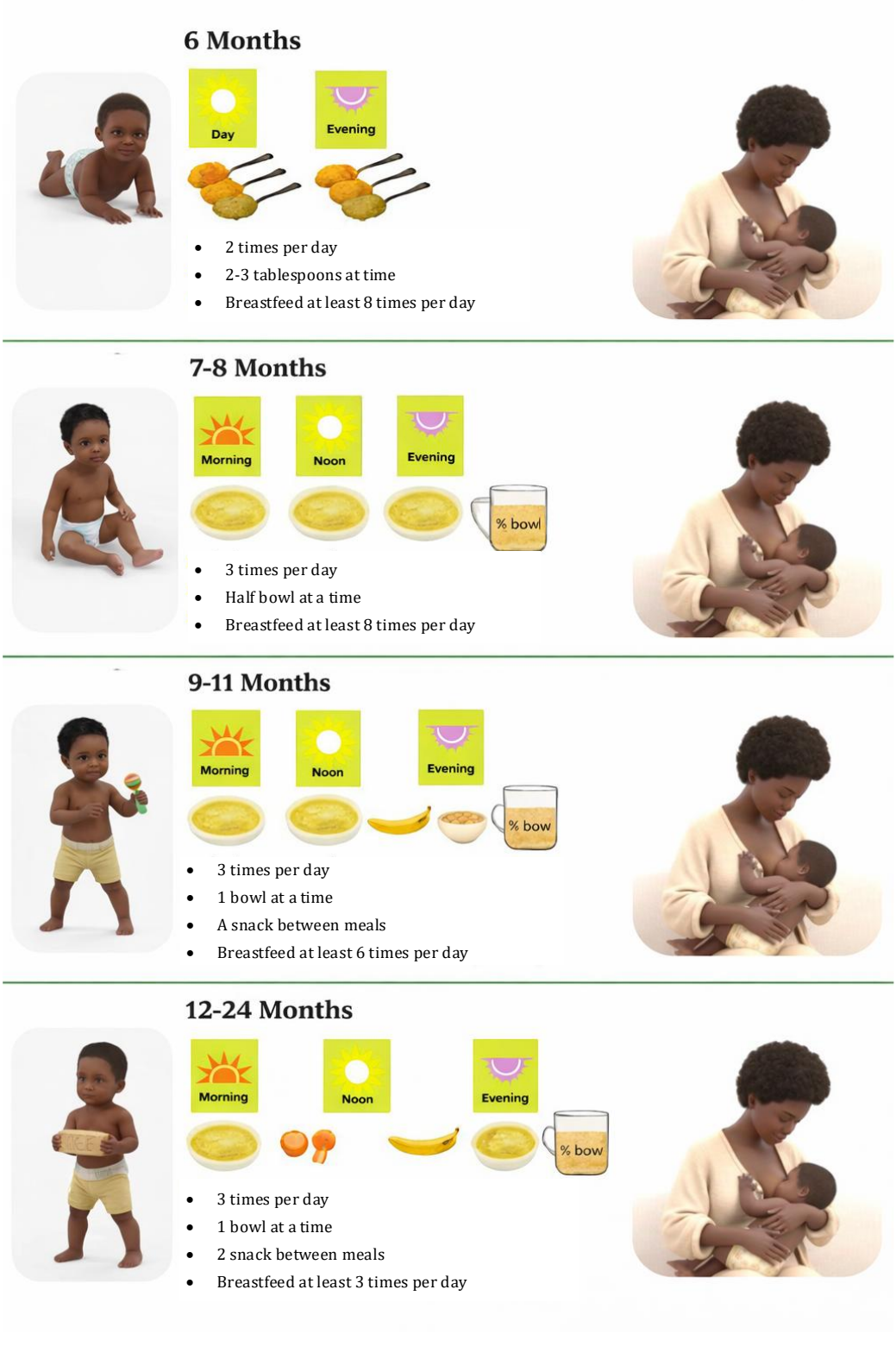


Figure 2.6: Complementary feeding recommendations for children aged 6-24 months

Interpretation of Weight-for-Height and MUAC Measurements in MIYCAN

Weight-for-Height (WFH) and Mid-Upper Arm Circumference (MUAC) are essential components of Nutrition Assessment within the Maternal, Infant, Young Child, Adolescent and Nutrition (MIYCAN) framework. They provide objective measures for identifying and managing malnutrition across different life stages, forming the foundation for effective Nutrition Assessment, Counselling and Support (NACS).

WFH is primarily used for infants and young children under five years to determine whether their body weight is appropriate for their height or length. It helps detect acute malnutrition (wasting) or overweight, guiding classification using Z-scores or percentiles and informing appropriate nutrition interventions.

MUAC is a simple, quick, and reliable tool used for pregnant and lactating women to assess body fat and muscle reserves. It identifies women at risk of undernutrition and related complications such as low birth weight, poor maternal recovery or inadequate milk production.

Together, WFH and MUAC strengthen nutrition assessment under MIYCAN by enabling early detection, classification, and management of malnutrition. These measures support targeted counselling, supplementation and follow-up ensuring improved growth, health and well-being for mothers, infants, young children and adolescents.

Table 2.7: Interpretation of MUAC Results for Children and Pregnant/Lactating Women

MUAC Level by Age (cm)				Classification	Action to Take
6-59 months	5-9 yrs	10-17 yrs.	Pregnant &Breastfeeding Women		
< 11.5	< 13.5	< 14.5 cm	<19	Severe acute malnutrition	Irrespective of clinical signs, admission (referral) for stabilization/therapeutic rehabilitation
11.5–12.4	13.5-14.4	14.5-18.5	19.1-22.9	Moderate acute malnutrition	Admission for supplementary feeding is recommended
12.5–13.4	_	_	-	Mild acute malnutrition	Nutritional education and counselling
> 13.5	≥ 14.5	≥ 18.5	≥ 23	Normal	Education and counselling of caregivers

Table 2.8: Interpretation of Weight for Height Z-scores for Children

Z- score	Severity	Action to take
< - 3	Severe	SAM with complications to be managed within inpatient settings, while SAM without complications is managed in outpatient settings using therapeutic feeds
- 3 to <- 2	Moderate	Manage using supplemental feeds
- 2 to <- 1	Mild	Nutrition counselling and education
-1SD to 1SD	Normal	Monitor to maintain optimal nutrition status

MANAGEMENT AND CONTROL OF SEXUALLY TRANSMITTED INFECTIONS

Overview

Sexually transmitted infections (STIs) remain a significant public health burden, contributing to reproductive health complications, adverse pregnancy outcomes, and increased risk of HIV transmission. Effective prevention, diagnosis, and management of STIs are essential components of comprehensive sexual and reproductive health services. Untreated or poorly managed infections can lead to serious health consequences such as infertility, chronic pelvic pain, pregnancy complications, and heightened vulnerability to HIV infection. Table 3.1 summarizes the major STI-related complications.

Table 3.1: STI-Related Complications

Population Group	Morbidity
Women	• Pelvic inflammatory disease • Chronic pelvic pain • Ectopic pregnancy • Infertility • Cervical cancer • Pregnancy complications: abortions, preterm labour and chorioamnionitis
Men	• Epididymitis • Infertility • Urethral strictures • Prostatitis
Newborns/Infants	• Congenital syphilis • Stillbirth • Neonatal death • Prematurity and low birth weight • Neonatal conjunctivitis • Sepsis and pneumonia
General Population	• Increase risk for HIV infection and progression • Mental and psychological issues • Stigma and social exclusion

3.1 Prevention of STIs

There are four prevention approaches whose interventions are as summarized in table 3.2

Table 3.2: Approaches and Key Interventions for STI Prevention

Prevention Approaches	Key Interventions
Primary Prevention Approaches	
Comprehensive sexual health education	Implement age-appropriate, evidence-based sexual health education in schools and communities, covering topics such as STIs, contraception, and healthy relationships.
Community engagement	Engage Community Health Promoters (CHPs), parents, Community Own Resource Persons (CORPS), and communities through gender transformative approaches in discussions to enhance awareness and reduce stigma associated with
Promotion of safe sex practices	Promote consistent and correct condom use; ensure accessibility and affordability of condoms.
Behavioural interventions	Encourage limiting the number of sexual partners and promote mutual monogamy as well as encourage safe sexual practices.
Biomedical approaches	These include products and medical technologies in the prevention and management of STIs. These include; **Vaccination Programs:** advocate for vaccination against HPV and other vaccine preventable STIs to reduce the incidence of these infections and their associated complications, such as cervical cancer. **STI PrEP and PEP:** Adopt and scale up novel approaches for prevention of STIs among target populations based on global recommendations, local adoptions and rapid advice
Access to healthcare services	Facilitate regular screening and testing for STIs, especially for high-risk groups. This includes offering services in various settings, such as schools and community centres. Ensure STI prevention and treatment services are integrated into primary healthcare to increase accessibility.
Community-based interventions	Leverage CORPS to disseminate information and promote healthy behaviours within their communities. Also implement outreach programs targeting key and vulnerable populations, such as sex workers and men who have sex with men, fisher folks, AGYW, to provide information and resources.
Secondary Prevention Approaches	
Regular screening and testing	Conduct regular STI screening for KVPs and other high-risk populations and integrate it into general healthcare, family planning, and antenatal services to facilitate early detection.
Early diagnosis and treatment	Utilize point-of-care (POC) testing and rapid diagnostic tests (RDTs) to enable early, quick diagnosis and immediate treatment. Ensure that effective treatment options are readily available and affordable.

Prevention Approaches	Key Interventions
Encourage partner notification	Implement strategies to encourage individuals diagnosed with STIs to inform their sexual partners. This can include using partner notification services or providing tools for self-notification. Ensure that partners of diagnosed individuals receive appropriate testing and treatment to reduce the risk of re-infection and further transmission. Provide options for expedited partner treatment
Monitoring and follow-up	Establish systems for follow-up care after diagnosis and treatment to ensure successful outcomes, monitor for potential reinfection and prevent AMR. Provide appropriate care for complications arising from untreated STIs, such as PID or infertility.
Tertiary Prevention Approaches	
Comprehensive clinical care	Deliver integrated physical and psychological care, including counselling and management of complications like infertility and chronic pain.
Long-term follow-up and support	Provide long-term follow-up to manage recurrent infections or complications. Offer counselling and support groups for individuals affected by STIs to address mental health issues, stigma, and relationship concern.
Education and awareness for patients	Provide information on managing STIs, understanding treatment regimens, and preventing future infections. This includes lifestyle modifications and safer sexual practices. Equip patients with the knowledge to communicate effectively with healthcare workers and partners about their condition.
Research, Innovation, Policy and development	Support research into new treatment modalities and rehabilitation strategies for STIs, particularly for those that may result in chronic health issues. Promote ongoing research to understand the long-term impacts of STIs and evaluate the effectiveness of tertiary prevention strategies.
Primordial Prevention of STIs	
Protective laws and policies	Enact and enforce laws and policies that protect human rights, prevent sexual violence, and support access to STI and reproductive health services.
Universal education	Promote equal access to education for all that empower individuals to make informed health decisions.
Stigma and discrimination reduction	Implement public campaigns and training to reduce stigma and discrimination associated with STIs and marginalized populations.
Poverty alleviation and socioeconomic improvements	Invest in social protection programs and economic empowerment initiatives that reduce vulnerability to STIs.
School and adolescent health policies	Develop age-appropriate school health programs that support adolescent sexual and reproductive health through education, access to services, and safe environments/spaces.
Health insurance and social health access schemes	Expand health insurance coverage and include STI prevention, diagnosis, and treatment under universal health benefit packages.

3.2 Control of STIs

The control of STIs involves the identification of risk factors, prompt and timely screening, management, proper communication and messaging as well as advocacy for prevention, and management.

3.2.1 Risk Factors for STI's Acquisition and Transmission

There are several risk factors associated with STI acquisition and transmission summarized in 3.3.

Table 3.3: Risk Factors for STI Acquisition and Transmission

Risk Factor Category	Description
Unprotected sexual activity	Engaging in unprotected vaginal, penile, oral, or anal sex where no condom or dental dam used
Sexual practices	Inconsistent use of condoms, Genital-to-genital contact and high-risk practices like oral sex and receptive anal intercourse. Higher number of partners increases exposure risk.
Previous STI history	Having a prior STI increases susceptibility to new infections.
Non-barrier contraceptives	Use of spermicides like nonoxynol-9 can damage genital epithelium.
Substance use	Alcohol and drug use impair decision-making in the ability to practice safe sex.
PrEP Use	May lead to lower condom use, increasing STI risk.
Family planning methods	IUD insertion process can temporarily introduce bacteria into the uterus (particularly leading to infections in the first 20 days) and/or destabilize the vaginal normal microbiome, which could indirectly contribute to infections.
Sexual coercion	SGBV and non-consensual sex increase STI risk.
Age and cultural practices	(younger people, especially those below 25 years, are at higher risk due to factors like risky sexual behaviour, biological susceptibility and cultural practices such as early marriage)

3.2.2 Screening for STI's

Screening plays a vital role in the control and prevention of STIs and should be prioritized for all sexually active individuals. The HCWs should take a detailed history and carry out a careful physical examination to detect the presence of infections. The physical examination should focus on potential anatomical areas including oropharynx, anorectal and urogenital regions. A speculum examination should be performed for clients with a history of vaginal intercourse, a proctoscopy for those with a history of receptive anal intercourse, and an oral examination for clients reporting oral sex.

The 5 P' s critical during STI screening help the HCW assess risk of STI in the client include as outlined in table 3.4

Table 3.4: The 5 Ps of Taking a Sexual History

P	Description	
Partners	Ask about the number and gender(s) of sexual partners. This helps assess exposure risk and guide further testing or prevention efforts.	Do you have sex with men, women, or both?" "In the past 3 months, how many partners have you had sex with?" __ "In the past 12 months, how many partners have you had sex with?" __
Practices	Discuss types of sexual practices (oral, anal, vaginal) to identify potential sites for STI testing and tailor risk-reduction counselling.	"To understand your STI risk, I need to understand the kind of sex you had recently." "Have you had vaginal sex?" Yes/No "If yes, do you use condoms?" Never/Sometimes/Always "Have you had anal sex?" Yes/No "If yes, do you use condoms?" Never/Sometimes/Always For condom answers, if never, "Why don't you use condoms?" "If sometimes in what situations/ with whom do you not use condoms?" "Have you had oral sex?" Yes/No
Protection	Inquire about condom or barrier use and how consistently they are used to evaluate protection level against STIs.	"What do you do to protect yourself from STIs (sexually transmitted infections) or HIV?"
Past STIs	Assess history of previous STIs, treatments received, and whether the individual or any partners have had recurrent infections.	"Have you ever had a sexually transmitted infection?" Yes/No Name of infection(s):
Prevention	Explore knowledge and use of preventive methods, including PrEP, regular testing, and vaccinations (e.g., HPV, Hepatitis).	Which STI prevention options do you know What are the risks and benefits of each?

There are several barriers to the uptake of these services as shown in table 3.5

Table 3.5: Barriers, Consequences and Solutions to Uptake of STI Screening Services

Barrier	Consequence	Potential Solution
Culture & religion	Avoidance of care, misinformation	Community engagement, culturally sensitive messaging
Age and consent	Legal access restricted	Policy reform, adolescent rights education
Asymptomatic STIs	Delayed testing, hidden transmission	Routine screening, opportunistic testing

Limited STI information	Low awareness, risky behaviour	Peer education, social media campaigns
Stigma	Avoidance of testing & disclosure	Normalize STI care, provider sensitivity training
Partner notification fear	Continued transmission	Anonymous notification services
No youth-friendly centres	Youth avoid healthcare settings	Youth-focused clinic models, peer support
Confidentiality concerns	Fear of being outed	Strong privacy policies, self-testing
Commodity shortages	Interrupted care	Improved supply chains, national investment

3.2.3 Advocacy for Prevention, Management and Control of STIs

Advocacy is seeking public support for or recommendation of a particular cause or policy on STIs prevention. It is critical to fighting the stigma associated with STIs and their symptoms, to normalize conversations about sexual intercourse and sexual health, and to frame STI services as what they are: essential components of routine primary health care. Advocacy efforts can foster the political will and commitments required to scale up existing prevention services and develop new prevention tools. Special attention is needed to reducing stigma among AYP and other KVPs, such as MSM, FSW and PWID. To be effective, advocacy should target various population groups as laid out in the advocacy matrix below:

Table 3.6: Advocacy matrix

Target Population	Media	Key Message
Kenya National Assembly (Health Committee, Senate)	Fact sheets Policy briefs	Prioritization for the allocation of funds for STI prevention, management and surveillance at national level with emphasis on diagnostics equipment's and HPT
County Assemblies Health Committees	Fact sheets Policy briefs	Prioritization for the allocation of funds for STIs at county level, Human Resources for Health
MOH	Standard Operating Procedures National Guidelines Policies and regulations, Job aids for health care providers, Conferences	Quality Management of STIs
Professional medical bodies	Conferences Dissemination of SOPs, Newsletters	Policy direction with regards towards the Regulation/limit antibiotics.
CSOs to lobby	Fact sheets Newsletters	Stigma reduction and advocacy, community mobilization and sensitization

Target Population	Media	Key Message
Community (Chief's barazas and targeted outreaches)	Pamphlets Posters Flip Charts	Stigma reduction and advocacy, community mobilization and sensitization
Youth groups	Awareness creation Social Media campaigns, infographics, Champions of STIs, influencers. Leveraging on and expanding existing hotlines, chatbots, websites, USSD.	Stigma reduction and advocacy, community mobilization and sensitization
Media	Improving the public's perception of prevention, control and care related to STIs. Helping to mobilize political good will Helping to diminish stigmatization in society and communities Communicating prevention messages and raising awareness about the devastating consequences of STIs other reproductive tract infections. Engaging bloggers on websites and platforms for key and vulnerable populations to dis- disseminate STI prevention and treatment messages Leveraging on and expanding existing hotlines, chatbots, websites, USSD.	Creating awareness Advocacy Stigma reduction Mobilization and sensitization
Churches, Mosques, other places of religious worship	Fact sheets Newsletters	Creating awareness Advocacy Stigma reduction Mobilization and sensitization

3.3 Management of STI

3.3.1 Aetiological STI Case Management

The aetiological approach involves diagnosing and treating STIs based on laboratory-confirmed identification of the specific causative pathogen. It is considered the gold standard in STI care because of its high specificity, accuracy, and ability to guide targeted treatment with the added advantage of detecting asymptomatic infections, identifying co-infections, and supporting public health surveillance and clinical decision-making.

This method minimizes the risk of misdiagnosis, overtreatment, or missed infections as well as combating antimicrobial resistance (AMR). With increased availability and access to laboratory testing, aetiological management is the preferred approach to management of STIs in the country.

3.3.2 Clinical STI Case Management

The clinical approach to STI management is used in settings where laboratory diagnostic support is either unavailable, not feasible, not practical or not applicable. The clinical approach has diagnosis based on a combination of patient reported symptoms and findings from physical examination, without laboratory confirmation. Even though this approach enables timely treatment, it is inherently less precise than the etiological approach and carries a greater risk of misdiagnosis or missed infections. Its effectiveness relies heavily on the clinical competence and experience of the healthcare provider.

To enhance diagnostic accuracy and move toward national goals of evidence-based STI care, it is strongly recommended that point-of-care (POC) rapid diagnostic tests (RDTs) be introduced and utilized where laboratory support is minimal. When available, these tests support a shift from a purely clinical to aetiological management, enabling more accurate diagnosis, appropriate treatment, and reduced AMR. The use of RDTs such as those for syphilis, TV, CT and NG should be integrated into routine practice wherever possible at all levels of care. Facilities implementing clinical management must also be supported with regular training, supervision, and quality assurance systems to ensure safe and effective STI care. The package of care for individuals with STI is outlined on table 3.6

Table 3.7: Package of Care for Clients with STI

#	Package	Description
1.	**Consent and confidentiality**	Obtain informed consent for examination, treatment, and partner notification while ensuring confidentiality and privacy throughout care.
2.	**History taking and risk assessment**	Gather sexual history and assess risk behaviours using the 5 Ps: partners, practices, protection, past STIs, and prevention.
3.	**Clinical examination**	Conduct genital, anorectal, and oropharyngeal examinations. For women, include speculum and bimanual exams if indicated; use proctoscopy if anal symptoms are present.
4.	**Laboratory testing**	Perform tests such as NAATs, serology, microscopy, culture and point-of-care diagnostics to confirm infection.
5.	**Diagnosis and treatment**	Make a laboratory confirmed diagnosis except in level 2 facilities without laboratory capability and initiate appropriate treatment.
6.	**Counselling and health Education**	Provide tailored counselling on STI prevention, treatment adherence, risk reduction, and safe sex practices.
7.	**Partner notification and contact tracing**	Encourage and assist with partner notification through patient referral, provider referral, or expedited partner therapy.
8.	**Condom promotion and provision**	Demonstrate correct and consistent condom use and provide condoms to reduce reinfection and prevent transmission.
9.	**Linkage to other services**	Clients diagnosed with an STI who present with other medical conditions such as HIV, TB, or non-communicable diseases should be referred to and linked to appropriate services for comprehensive care. This includes facilitating HIV testing, cervical cancer screening, PrEP initiation, mental

#	Package	Description
		health support, chronic disease management, and ensuring timely follow-up where needed.
10.	**Follow-up and connection to ongoing care**	Schedule follow-up visits to assess treatment success, perform test-of-cure where needed, and retest for reinfection.

3.3.3 Laboratory Diagnostic Tests for STIs

Laboratory diagnosis is essential for accurate and effective case management of STIs. It enables identification of the causative pathogen, ensures appropriate treatment, reduces overtreatment, and supports surveillance of AMR. Kenya prioritizes etiologic diagnosis using validated laboratory methods. Laboratory testing should be conducted at the point of care.

The primary diagnostic methods include:

- **Serologic Tests**: These tests detect antibodies or antigens and are commonly used for infections like syphilis and HIV. RDTs for serology can be used at the point of care and are particularly valuable in settings with limited laboratory infrastructure.
- **Microscopy**: Direct examination of clinical specimens under a light microscope can aid in the identification of certain pathogens, such as *Candida* species and *Trichomonas vaginalis*. It is useful for supporting clinical diagnosis in settings with basic lab capability.
- **Nucleic Acid Amplification Tests (NAATs)**: NAATs are molecular tests that detect the genetic material of pathogens and are highly sensitive and specific. They are the recommended first-line test for many STIs, including *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. Some NAATs are available as rapid molecular tests suitable for use at point of care.
- **Culture**: Culture involves growing the organism in specialized media for identification and antimicrobial susceptibility testing. It remains important for diagnosing *Neisseria gonorrhoeae*, particularly in the context of resistance monitoring, and for *Trichomonas vaginalis* where NAATs are unavailable.

Where possible, laboratory services should be supported through integrated sample referral systems that allow for timely specimen transport, testing, and feedback of results to the point of care. This ensures equitable access to diagnostic services across all levels of the health system.

3.4 Diseases Characterized by Genital, Anal, or Perianal Ulcers

More than one aetiologic agent (e.g., herpes and syphilis) can be present in genital, anal, or perianal ulcer. Less common infectious causes of genital, anal, or perianal ulcers include chancroid, Lymphogranuloma Venereum (LGV), and granuloma inguinale (donovanosis). Genital Ulcer Diseases (GUDs) e.g., syphilis, herpes, and LGV might also present as oral ulcers. Genital, anal, or perianal lesions can also be associated with infectious and non-infectious conditions that are not sexually transmitted (e.g., yeast, trauma, carcinoma, aphthae or Behcet's disease, fixed drug eruption, or psoriasis). Table 3.7 summarizes Signs, symptoms, Diagnosis and Treatment of Diseases characterized by Genital, Anal, or Perianal ulcers.

Table 3.8: Signs, symptoms, Diagnosis and Treatment of Diseases characterized by Genital, Anal, or Perianal ulcers

STI	Signs & Symptoms	Diagnosis	Treatment
Chancroid ***(H. ducreyi)***	Painful, soft genital ulcers. Tender, suppurative inguinal lymphadenopathy (buboes).	**Primarily Clinical + exclusion of syphilis & HSV** Culture/NAAT – definitive but rarely available and testing is very rarely done due to the fastidiousness of the organism	Azithromycin 1 g PO STAT **OR** Ceftriaxone 1 g IM STAT **OR** Erythromycin base 500 mg PO TID for 7 days
	Management: Re-examine after 3–7 days. Treat partners. Biopsy non-healing ulcers.		
Genital Herpes ***(Herpes Simplex Virus, HSV-1 or HSV-2)***	Painful vesicles/ulcers, itching, burning, dysuria, recurrent outbreaks, systemic symptoms in first episode (fever, malaise)	**PCR/NAAT (vesicle or ulcer swab)** HSV type-specific serology (documents exposure, not diagnostic) Viral culture (specific but only done in reference/research laboratories)	**First Episode:** Acyclovir 400 mg PO TID for 7–10 days **OR** Famciclovir 250 mg PO TID for 7–10 days **OR** Valacyclovir 1 g PO BD for 7–10 days
			Recurrent Episode[a]: Acyclovir 400 mg PO TID for 5 days **OR** Famciclovir 250 mg PO BD for 5 days **OR** Valacyclovir 500mg PO OD for 3 days
			Episodic Therapy Acyclovir 800 mg PO BD for 5 days or 800 mg PO TID for 2 days **OR** Famciclovir 1 g PO BD for 1 day or 500 mg PO OD, followed by 250 mg BD for 2 days or 125 mg PO BD for 5 days **OR**

STI	Signs & Symptoms	Diagnosis	Treatment
			Valacyclovir 500 mg PO BD for 3 days OR 1 g PO OD for 5 days
			People living with HIV and immunocompromised persons Acyclovir 400 mg PO TID for 5 days **OR** Valaciclovir 500 mg PO BD for 5 days **OR** Famciclovir 500 mg PO BD for 5 days
			Severe Disease (Disseminated infection, Meningitis, encephalitis, pneumonitis, hepatitis) Intravenous (IV) acyclovir therapy (5–10 mg/kg body weight IV TID)
Note:[a] Suppressive treatment for recurrent genital herpes should be tailored to response to treatment and patient preference; it can last as long as 6 – 12 months or even longer. If genital ulcers persist, despite ongoing suppressive therapy, refer for specialist care			
Granuloma Inguinale ***(K granulomatis)***	Painless, beefy red ulcers on genitals /perineum; bleeds easily; no lymphadenopathy may form pseudo-buboes or extend internally	**Tissue biopsy, crush preparation or smear showing Donovan bodies** **Clinical diagnosis**	Azithromycin 1 g PO once/week or 500 mg PO daily for >3 weeks OR Doxycycline 100 mg PO BD for at least 3 weeks OR Erythromycin 500 mg PO QID for >3 weeks OR Trimethoprim-sulfamethoxazole one double-strength (160 mg/800 mg) tablet PO BD for >3 weeks

STI	Signs & Symptoms	Diagnosis	Treatment
Lymphogranuloma Venereum (LGV) (*Chlamydia trachomatis L1–L3)*	Tender inguinal/femoral lymphadenopathy (often unilateral), rectal pain/discharge	**NAAT for *C. trachomatis* (genital, rectal swab or bubo aspirate)** **Clinical diagnosis** LGV-specific PCR (not routinely available);	Doxycycline 100 mg PO BD for 21 days OR Azithromycin 1 g PO once weekly for 3 weeks OR Erythromycin base 500 mg PO QID for 21 days
Management Start presumptive treatment. Drain buboes if needed. Follow up. Test partners.			
Stage	**Signs & Symptoms**	**Diagnosis**	**Treatment**
Primary Syphilis ~3 weeks after exposure	Painless chancre at site of inoculation (genital, anal, or oral) Non-tender, often bilateral lymphadenopathy	DEFINITIVE: **Darkfield microscopy or PCR from lesion exudate** PRESUMPTIVE: **Serological testing** **<u>Screening:</u> Nontreponemal tests (RPR/VDRL)*** **<u>Confirmation</u>: Treponemal tests(TP-PA, EIA or CIA)*** Note: Serologic tests may be negative early and may persist after treatment- see Figure 3-1 for interpretation.	Benzathine Penicillin 2.4MU IM STAT OR Doxycycline 100mg PO BD for14 days (Not recommended in pregnancy) OR Erythromycin 500mg QID PO for 14 days OR Ceftriaxone 1g IM OD for 10-14 Days
Secondary Syphilis ~6–8 weeks after chancre appears; systemic dissemination	Skin rash, especially on palms and soles Mucosal ulcers, generalized lymphadenopathy - Fever, malaise, sore throat - Rash and symptoms resolve with or without treatment	Same as primary	Same as primary

STI	Signs & Symptoms	Diagnosis	Treatment
Latent Syphilis: Asymptomatic phase after secondary symptoms resolve	No clinical signs, Persistent seropositivity Classified as early latent (≤1 year) or late latent (>1 year or unknown duration)	**Serologic testing** (no lesions for direct tests) Clinical history helps stage latency (early vs. late)	Benzathine Penicillin 2.4 MU IM Weekly for 3 weeks OR Procaine Penicillin 1.2 MU IM OD for 20 days OR Doxycycline 100mg PO BD for 30 days (Not recommended in pregnancy)
Tertiary Syphilis: Can occur up to 20 years after untreated infection	**Cardiovascular:** aortitis, aneurysms, Gummatous lesions, **Ocular syphilis:** vision changes or blindness	**Serologic tests** remain reactive Imaging (e.g., MRI, CT) may assist in evaluation	Benzathine Penicillin 2.4 MU IM Weekly for 3 weeks OR Procaine Penicillin 1.2 MU IM OD for 20 days OR Doxycycline 100mg PO BD x 30 days (Not recommended in pregnancy)
Neurosyphilis	**Neurosyphilis:** headache, ataxia, paralysis	**Serologic tests** **CSF analysis** (VDRL, protein, WBCs) for neurosyphilis **Imaging** (e.g., MRI, CT) may assist in evaluation	Aqueous crystalline penicillin G, 18-24 MU daily administered as 3-4 MU IV every 4 hours for 10-14 days
Early Congenital Syphilis (birth–2 yrs)	Snuffles (nasal discharge), rash on palms/soles, hepatosplenomegaly, jaundice, anaemia, bone changes (osteochondritis, periostitis)	**Dark-field microscopy or PCR** from lesions, nasal discharge or placenta **Serological tests-** quantitative comparison of infant vs maternal RPR/VDRL **Clinical Signs**	See Table 3.8
Late Congenital Syphilis (>2 yrs)	Hutchinson's triad (teeth, keratitis, deafness), frontal bossing, saddle nose, saber shins, Clutton's joints	**Serological testing** (screening then confirmatory)	See Table 3.8
*All individuals who test positive for syphilis, should have titres done in settings where this is possible. The titres are used to monitor response to treatment. *For individuals who tested positive for syphilis previously and were treated, the current titres if lower would make them not eligible for treatment despite a positive treponemal/nontreponemal test result. *For settings where titres are not done provide treatment as per guidelines.			

Table 3.9: Clinical Classifications and Treatment regimens for Congenital syphilis

Clinical classification	Recommended regimen
Confirmed or highly probable congenital syphilis	Aqueous crystalline penicillin G 100,000–150,000 units/kg/day, administered as 50,000 units/kg/dose IV BD during the first 7 days of life and every 8 hours thereafter for a total of 10 days; OR Procaine penicillin G 50,000 units/kg/dose IM in a single daily dose for 10 days.
Possible congenital syphilis	Aqueous crystalline penicillin G 100,000–150,000 units/kg/day, administered as 50,000 units/kg/dose IV BD during the first 7 days of life TID thereafter for a total of 10 days; OR Procaine penicillin G 50,000 units/kg/dose IM OD for 10 days; OR Benzathine penicillin G 50,000 units/kg/dose IM STAT.
Congenital syphilis Less likely	Benzathine penicillin G 50,000 units/kg/dose IM STAT
Congenital syphilis unlikely	No treatment is required

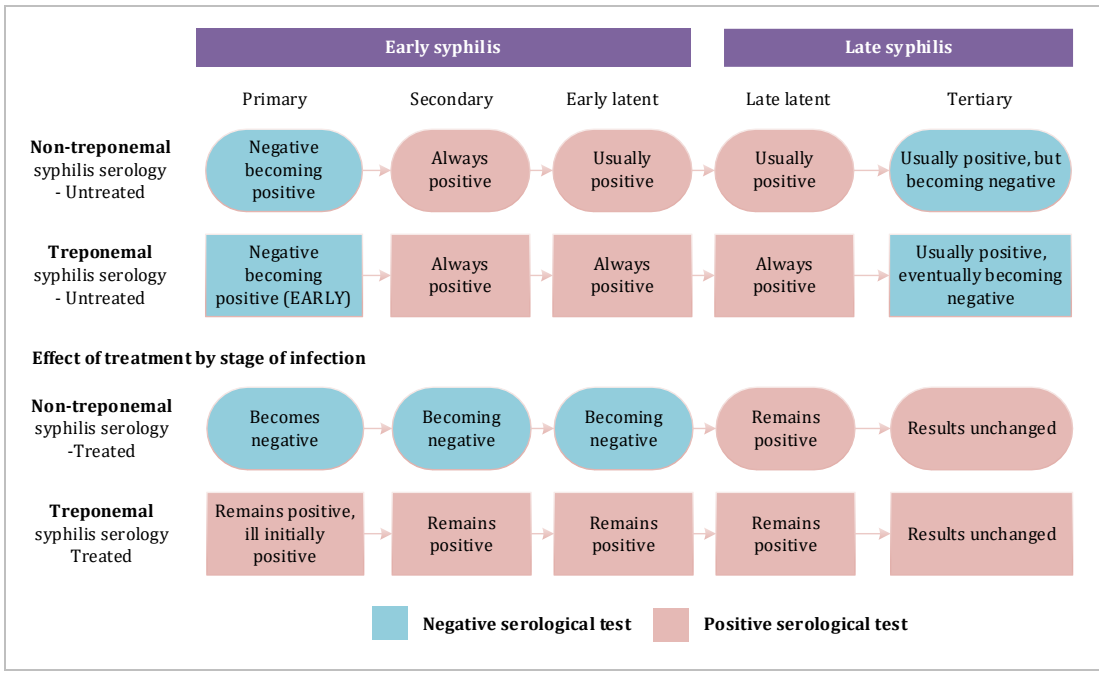
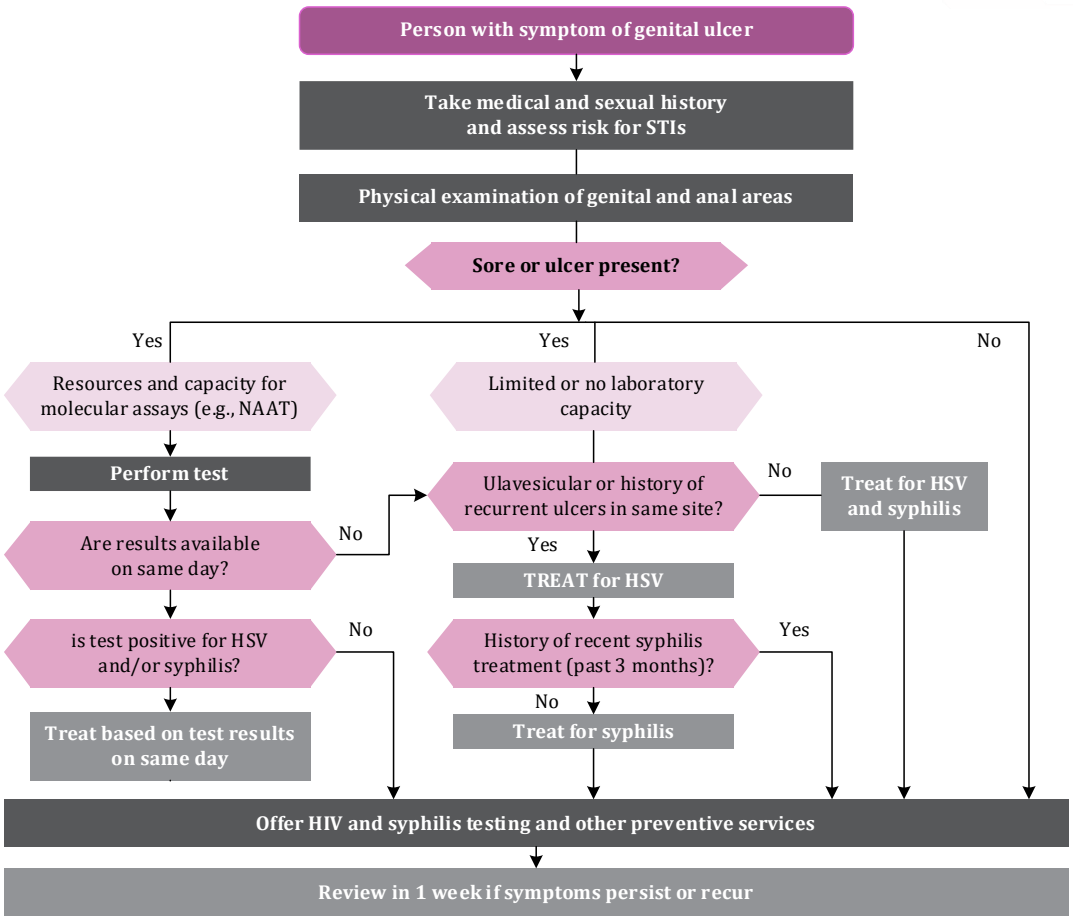


Figure 3.1: Reactivity of serological tests by stage of syphilis & effect of treatment (adopted from WHO)



HS, herpes simplex virus

* If molecular assay was performed and results were not available on same day, revise the clinical management initially provided according to the test results when available

Figure 3.2: Management of patient with anogenital ulcers

3.5 Diseases Characterized by Urethritis/Vaginitis and Cervicitis

Urethritis/ Vaginitis is characterized by urethral/vaginal inflammation. Symptoms, include dysuria, urethral or vaginal pruritis, and mucoid, mucopurulent, or purulent discharge. Signs of urethral or vaginal discharge on examination can also be present among persons without symptoms.

Urethritis/vaginitis is generally classified based on the aetiology:

- Gonococcal urethritis (GU), caused by *Neisseria gonorrhoea* (NG)
- Non-gonococcal urethritis (NGU), commonly caused by *Chlamydia trachomatis* (CT), *Mycoplasma genitalium* (MG), *Trichomonas vaginalis* (TV) amongst other organisms.

Cervicitis is frequently asymptomatic. When symptomatic, it is characterized by either or both of the following two signs:

i. A purulent or mucopurulent endocervical exudate visible in the endocervical canal or on an endocervical swab specimen
ii. Sustained endocervical bleeding is easily induced by gentle passage of a cotton swab through the cervical os.

Certain women might report an abnormal vaginal discharge and intermenstrual vaginal bleeding especially after sexual intercourse.

Diagnosis

Molecular testing, microscopy and culture are the preferred diagnostic techniques.

3.5.1 Chlamydia

Chlamydial infection, caused by Chlamydia trachomatis, is the most common bacterial sexually transmitted and results in substantial morbidity and economic cost worldwide. Genital infections due to C. trachomatis are asymptomatic in approximately 70% of women and 50% of men. Symptoms of uncomplicated chlamydial infection in women include abnormal vaginal discharge, dysuria, and post-coital and intermenstrual bleeding. Common clinical signs on speculum examination include cervical friability and discharge. Symptomatic men usually present with urethral discharge and dysuria, sometimes accompanied by testicular pain. If left untreated, most genital infections will resolve spontaneously with no sequelae but they may result in severe complications, mainly in young women. Infection can ascend to the upper reproductive tract and can cause PID, ectopic pregnancy, salpingitis and tubal factor infertility in women and epididymitis in men. The risk of complications may increase with repeated infection.

3.5.2 Gonorrhoea

Gonorrhoea, caused by Neisseria gonorrhoeae, is the second most common bacterial sexually transmitted infection (STI) and results in substantial morbidity and economic cost worldwide. Uncomplicated gonococcal infection commonly manifests as urethritis in men with symptoms of urethral discharge and dysuria. On examination, the urethral discharge may range from scanty and mucoid to copious and purulent. Gonorrhoea is often asymptomatic in women; less than half of infected women complain of non-specific symptoms such as abnormal vaginal discharge, dysuria, lower abdominal discomfort and dyspareunia. The most common clinical signs are vaginal discharge and cervical friability due to mucopurulent cervicitis. Rectal infections in men and women are largely asymptomatic; occasionally patients complain of rectal and anal pain or discharge. Pharyngeal infections are mainly asymptomatic, but mild sore throat and pharyngitis may occur. In most women with gonorrhoea, the lack of discernible symptoms results in unrecognized and untreated infections which can resolve simultaneously but may lead to serious complications such as PID, this includes endometritis, salpingitis and tubo-ovarian abscess, which can lead to ectopic pregnancy and infertility. Untreated urethral infection in men can lead to epididymitis, urethral stricture and infertility. The risk of complications increases with repeated infection. Infants of mothers with gonococcal infection can be infected at delivery, resulting in neonatal conjunctivitis manifesting as purulent ocular discharge and swollen eyelids. Untreated conjunctivitis may lead to scarring and blindness.

3.5.3 Mycoplasma Genitalium

M. genitalium is a sexually transmitted bacterium with a characteristic flask shape on electron microscopy. It has the smallest known genome capable of self-replication. Infections with *M. genitalium* in men are usually asymptomatic and there are limited data on the natural history of infection with *M. genitalium*. Estimations from existing data suggest that about 5% of men infected with *M. genitalium* will develop non-gonococcal urethritis. However, asymptomatic infections are common, having a similar frequency to that of chlamydial infections. In some men with acute epididymitis, the presence of *M. genitalium* has been identified as the cause. In women, vaginal discharge and lower abdominal pain due to PID have been associated with *M. genitalium.*

3.5.4 Bacterial Vaginosis

Bacterial vaginosis (BV) is the most common cause of vaginal discharge among women of childbearing age. It is not STI but a polymicrobial disorder of the vaginal microbiome. The condition is characterized by low concentrations or an absence of lactobacilli and a florid presence of anaerobic flora. BV has been linked to several adverse outcomes, including adverse outcomes of pregnancy and an increased risk of STIs, including HIV, PID and tubal factor infertility. About 90% of symptomatic women have a white vaginal discharge, which can be seen on the vulva, and an abnormal vaginal odour. On external visual examination and digital examination of the vagina, the thin, white, homogenous discharge may be observed externally on the posterior fourchette of the vulva or the labia. If speculum examination is feasible, homogeneous discharge may be observed to be adherent to the vaginal wall, and the cervix is usually normal in appearance.

3.5.5 Trichomoniasis

T. vaginalis is a sexually transmitted protozoan that infects the vagina, the urethra and paraurethral glands in women and the urethra and the sub preputial sac in men. About 50–85% of women with *T. vaginalis* infection may be asymptomatic. Among these asymptomatic women, 30–50% will develop symptoms within the subsequent six months. For symptomatic women, the primary concern is usually an abnormal vaginal discharge. Half of symptomatic women also report vulval itching. Vulval erythema and oedema may be noted on examination. On speculum examination, a vaginal discharge, classically described as yellow or greenish, sometimes with a frothy appearance, may be seen. There may be vaginitis as shown by erythema of the vaginal mucosa. The cervix may have punctate haemorrhages, known as the “strawberry cervix”. The visualization of a “strawberry cervix”, albeit uncommon, is highly indicative of *T. vaginalis* infection.

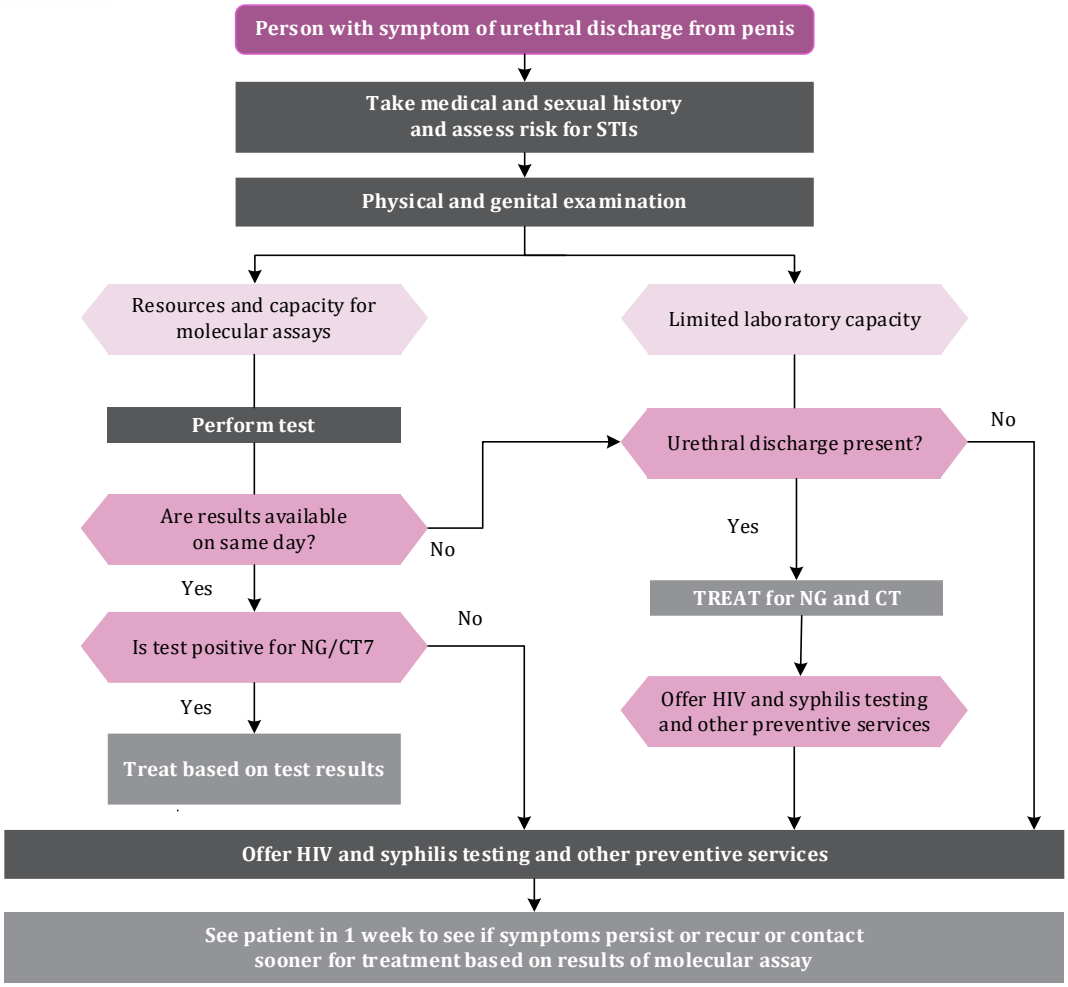
3.5.6 Candidiasis

Candida yeasts are commensals of the vaginal microbiome in many healthy women and typically do not cause any problem, but they can lead to symptomatic yeast infections when the microbial balance or host defences are altered. It is therefore not an STI but gains importance as a differential diagnosis. Vulvovaginal candidiasis is caused by *C. albicans* in about 90% of cases. The non-albicans species cause the rest of vulvovaginal candidiasis – *C. glabrata* in about 8% of cases, and the other non-albicans species, such as *C. tropicalis*, *C. krusei* and *C. parapsilosis* cause most of the remainder. Candidiasis presents with pruritus or a burning sensation of the vulva and vaginal soreness or irritation. Other clinical manifestations include dyspareunia and dysuria. If there is discharge, it characteristically is curdy, white or creamy and thick but can vary from watery to homogeneously thick. On examination, the vulva may be swollen and erythematous with excoriation and occasionally peripheral pustulopapular. Speculum examination shows the vaginal wall to be erythematous, and an adherent discharge may be seen, either curd-like or homogeneously white. The cervix looks normal.

Although men can be colonized with *Candida* species and the male sex partners of women with candidiasis are transiently colonized, candida balanitis and balanoposthitis among men are not recognized as STIs. Signs, symptoms, diagnosis and treatment of urethritis, Vaginitis and cervicitis are as shown in table 3.9.

Table 3.10: Signs symptoms diagnosis and treatment of urethritis, vaginitis and cervicitis

STI	Signs & Symptoms	Diagnosis	Treatment
Chlamydia **Chlamydia trachomatis**	Urethral/vaginal discharge, dysuria, and post-coital and intermenstrual bleeding	NAAT for C. trachomatis	Azithromycin 1G, PO STAT OR Doxycycline 100 mg, PO BD for 7 days
Gonorrhoea **Neisseria gonorrhoeae**	Urethral/vaginal discharge, dysuria, and post-coital and intermenstrual bleeding	NAAT for N. Gonorrhoeae	• Cefixime 800 mg PO STAT **AND** Azithromycin 2 g PO STAT • OR • Ceftriaxone 1G If cephalosporins cannot be used (resistance, allergy or no access) • Gentamicin 240mg IM + Azithromycin 2 gram, PO STAT • Spectinomycin 2gm IM + Azithromycin 2 g PO STAT
Mycoplasma Genitalium	usually asymptomatic Can present with non-gonococcal urethritis or acute epididymitis in men Can present with vaginal discharge and lower abdominal pain due to PID in women	NAAT for M. genitalium	Doxycycline 100 mg PO BD for 7 days to reduce bacterial load **FOLLOWED** by Azithromycin 1 g PO OD for 1 STAT (initial dose) then 500 mg OD for 3 days OR Doxycycline 100 mg PO BD for 7 days to reduce the bacterial load, **FOLLOWED** by Moxifloxacin 400 mg PO OD for 7 days.
Bacterial Vaginosis	white vaginal discharge on the vulva, and abnormal vaginal odour	Amsel criteria or Nugent Score	Tinidazole 2 g PO STAT (except during pregnancy) OR Metronidazole 2g PO STAT OR Secnidazole 2g PO STAT
Trichomoniasis **Trichomonas vaginalis**	may be asymptomatic vulval itching yellow or greenish vaginal discharge	wet mount smear microscopy, antigen detection assays, culture and NAATs	Tinidazole 2 g PO OD for 2 days (except during pregnancy) OR Metronidazole 400 mg PO BD for 7 days OR Secnidazole 2g PO OD for 2days
Candidiasis **Candida Albicans**	external dysuria and vulvar pruritus, pain, swelling, and redness	Vaginal PH and Gram stain Candida culture	Fluconazole 150–200 mg PO STAT



NG, *N.gonorrhoeae*; CT, *C. trachomatis*.

* If molecular assay was performed and results were not available on same day, revise the syndromic treatment initially provided according to the test results when available

If test is negative but urethral discharge is present, treat for non-gonococcal/non-chlamydial urethritis (such as *M. genitalium*,

T. vaginalis or herpes simplex virus)

Figure 3.3: Management of Patients with Urethritis flow chart

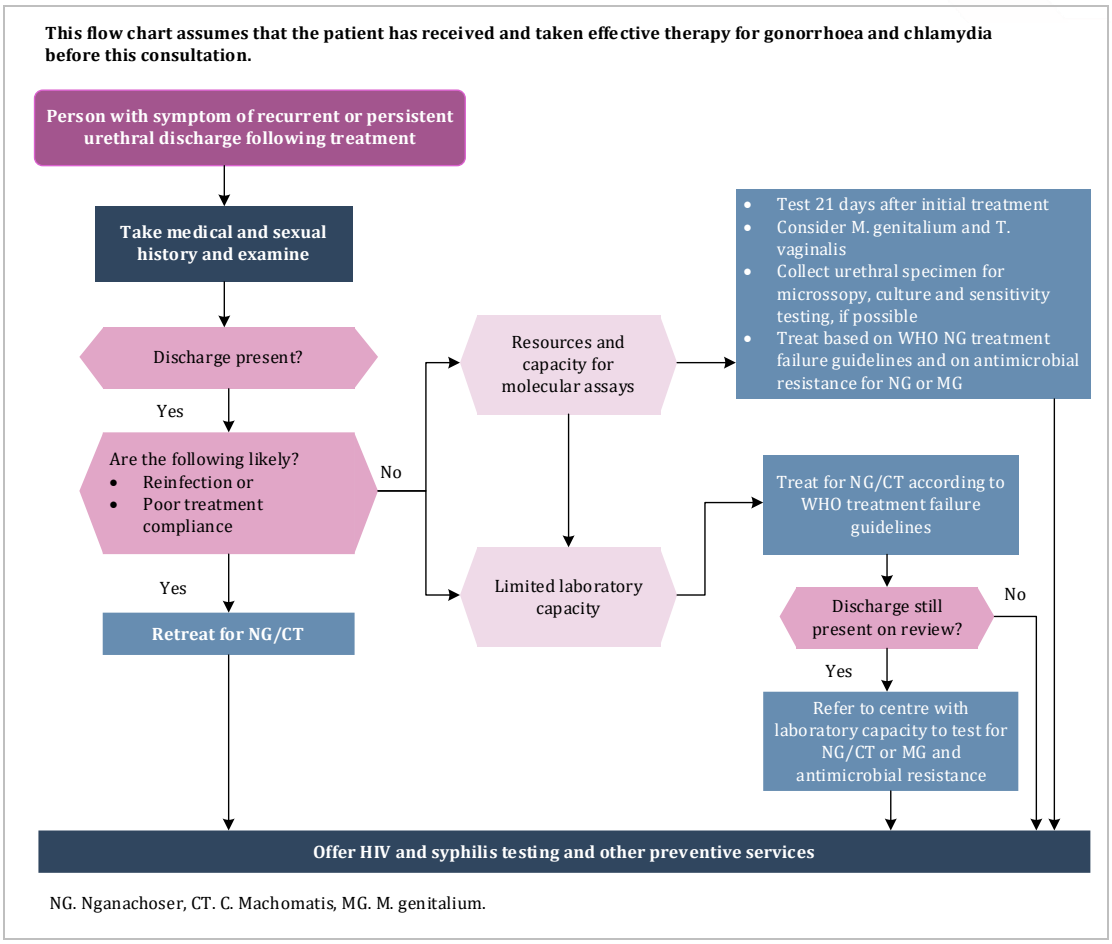
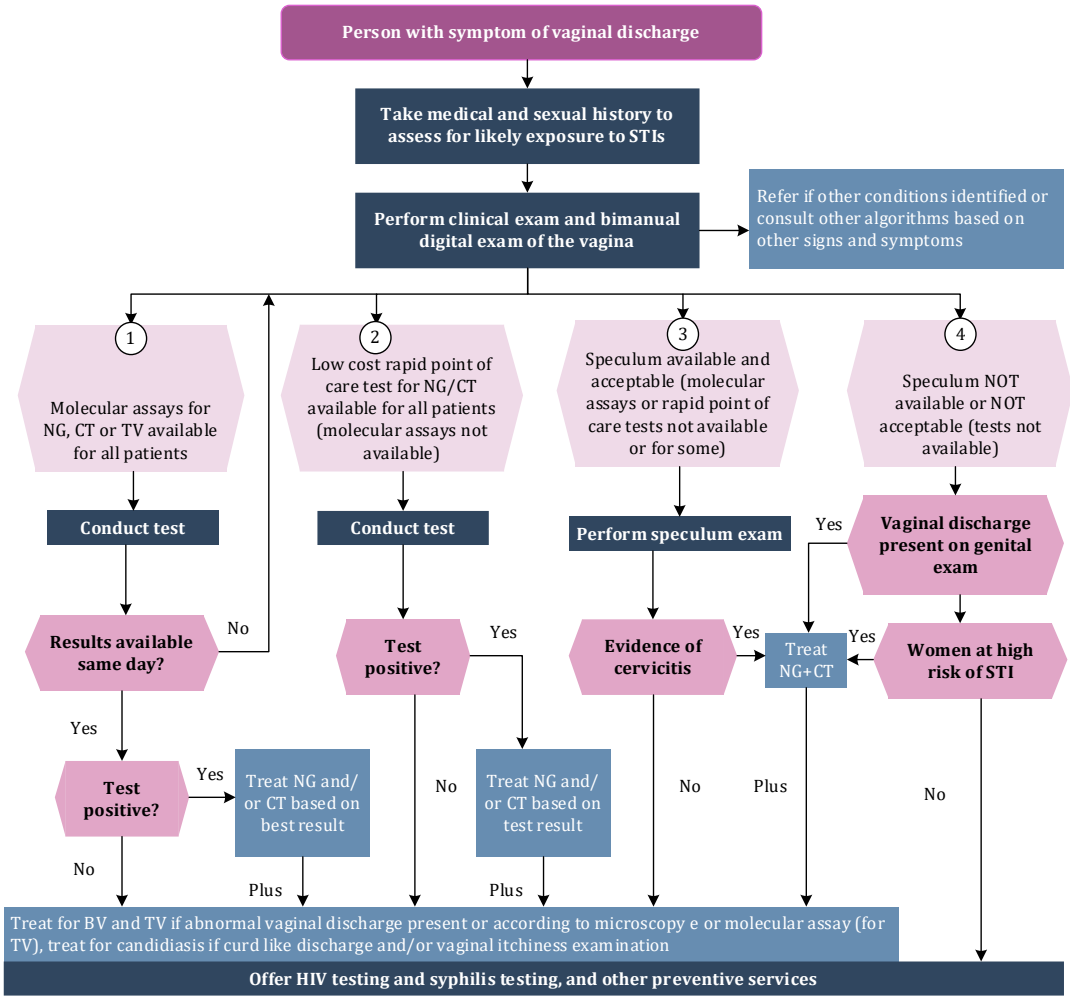


Figure 3.4: Management of Patients with persistent/ recurrent Urethritis flow chart



NG, N. gonoceree: CT, C. trachomtis, TVC vagilais, 1. vaglais, sexually transmitted infection

NG, *N. gonorrhoeae;* CT, *Chlamydia trachomatis*; TV, *Trichomonas vaginalis*; BV, bacterial vaginosis.

a If molecular assay was performed and results were not available on same day, revise the clinical management initially provided according to the test results when available

b perform rapid point of care test or molecular assay if available to confirm NG/CT and treat if positive; if negative do not treat and ask woman to return if symptoms recur

c if woman complains of recurrent or persistent discharge refer to a centre with laboratory capacity

Figure 3.5: Management of Patients with Vaginitis flow chart

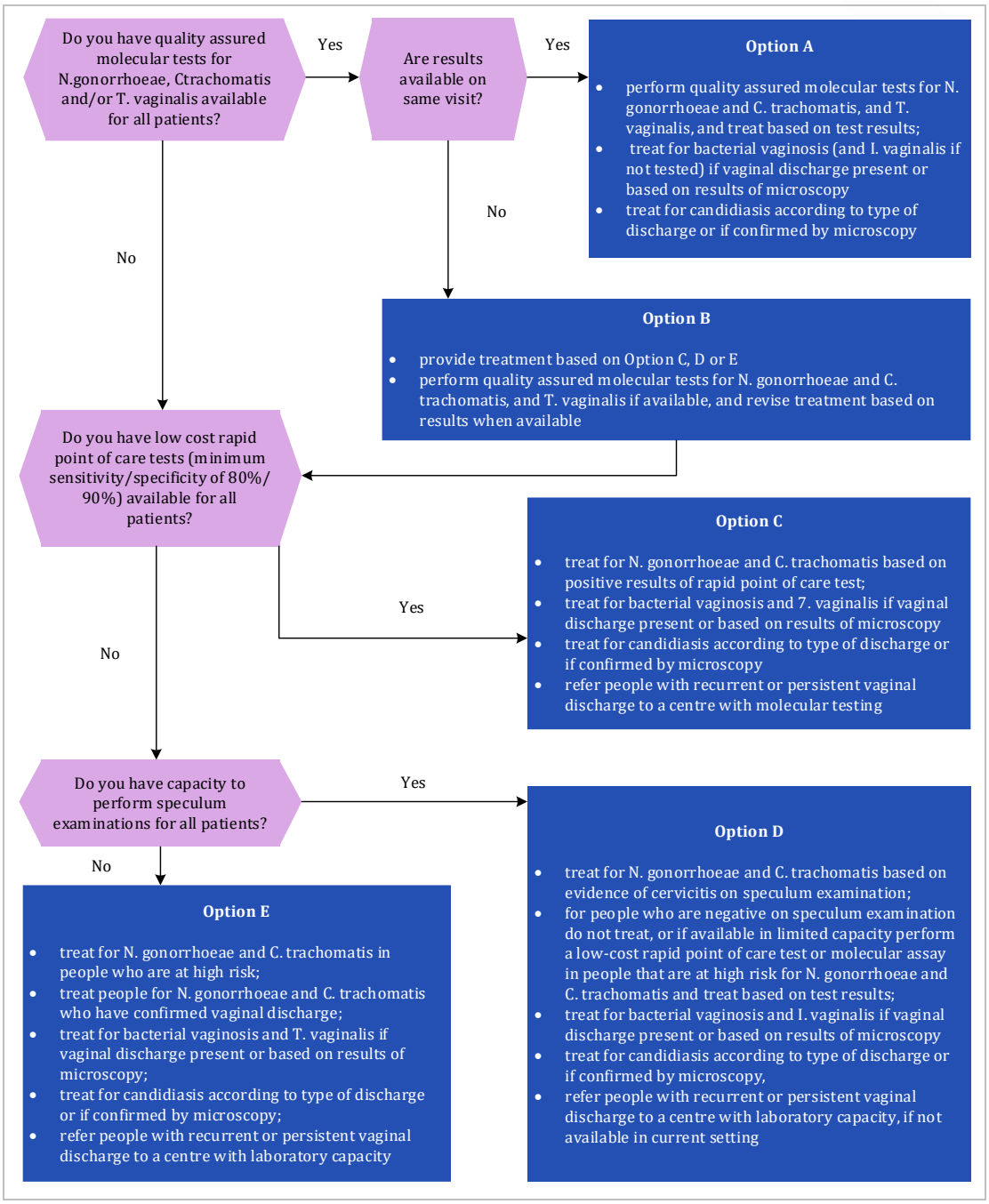


Figure 3.6: Management Options for Patients with Vaginitis flow chart

3.5.7 Pelvic Inflammatory Disease (PID)

PID comprises a spectrum of inflammatory disorders of the upper female genital tract, including any combination of endometritis, salpingitis, tubo-ovarian abscess, and pelvic peritonitis and is commonly caused by untreated sexually transmitted organisms including CT, NG, TV, MG.

Acute PID is difficult to diagnose because of the considerable variation in symptoms and signs associated with this condition. Women with PID often have subtle or nonspecific symptoms or are asymptomatic. Delay in diagnosis and treatment contributes to inflammatory sequelae in the upper genital tract.

Diagnosis of PID is clinical based on pelvic or abdominal pain with cervical, uterine, or adnexal tenderness. Additional criteria that may increase diagnostic accuracy are fever, purulent vaginal discharge, elevated C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), and confirmation of *Neisseria gonorrhoeae* or *Chlamydia trachomatis* cervicitis in the laboratory, or a wet mount preparation showing many white blood cells (WBCs). Specificity in diagnosis is enhanced by endometritis on histology from curettage specimen, sonographic findings of hydrosalpinxes; fluid in the Pouch of Douglas (POD) and laparoscopic features of PID (adhesions) though this misses early PID. Following initiation of empiric outpatient treatment, all women with PID should be closely monitored to ensure clinical improvement within 48–72 hours.

Referral for inpatient care or surgical evaluation should be considered in the following situations:

- Severe clinical illness, including high fever (>38°C), severe pelvic pain, or signs of sepsis
- Suspected or confirmed tubo-ovarian abscess, particularly if large, ruptured, or with signs of peritonitis
- Lack of clinical improvement within 48–72 hours of initiating outpatient antibiotics
- Inability to tolerate or adhere to oral medications or outpatient follow-up
- Uncertain diagnosis requiring exclusion of other surgical emergencies such as ectopic pregnancy or appendicitis
- Pregnancy, due to increased risk of complications; inpatient management is required
- HIV-positive or immunocompromised patients, who may require closer monitoring and broader-spectrum antibiotics
- Clinical signs of peritonitis or acute abdomen, such as guarding, rebound tenderness, or paralytic ileus, requiring urgent surgical evaluation

Table 3.11: Signs, symptoms, diagnosis and treatment of PID

Aetiology	Signs & Symptoms	Diagnosis	Treatment
Chlamydia trachomatis Neisseria Gonorrhoea Trichomonas Vaginalis Mycoplasma Genitalium	Fever, vaginal discharge, lower abdominal pain and tenderness of pelvic organs	NAAT for C. trachomatis, N Gonorrhoea, T. Vaginalis and M. Genitalium	Cefixime 800 mg STAT **AND** Doxycycline 100 mg PO BD for 14 days **AND** Metronidazole 400 mg PO TDS for 14 days OR Ceftriaxone 1 g IM STAT **AND** doxycycline 100 mg PO BD for 14 days **AND** Metronidazole 400 mg PO TDS for 14 days OR IM Gentamicin 240 mg STAT **AND** doxycycline 100 mg PO BD for 14 days **AND** Metronidazole 400 mg PO TDS for 14 days

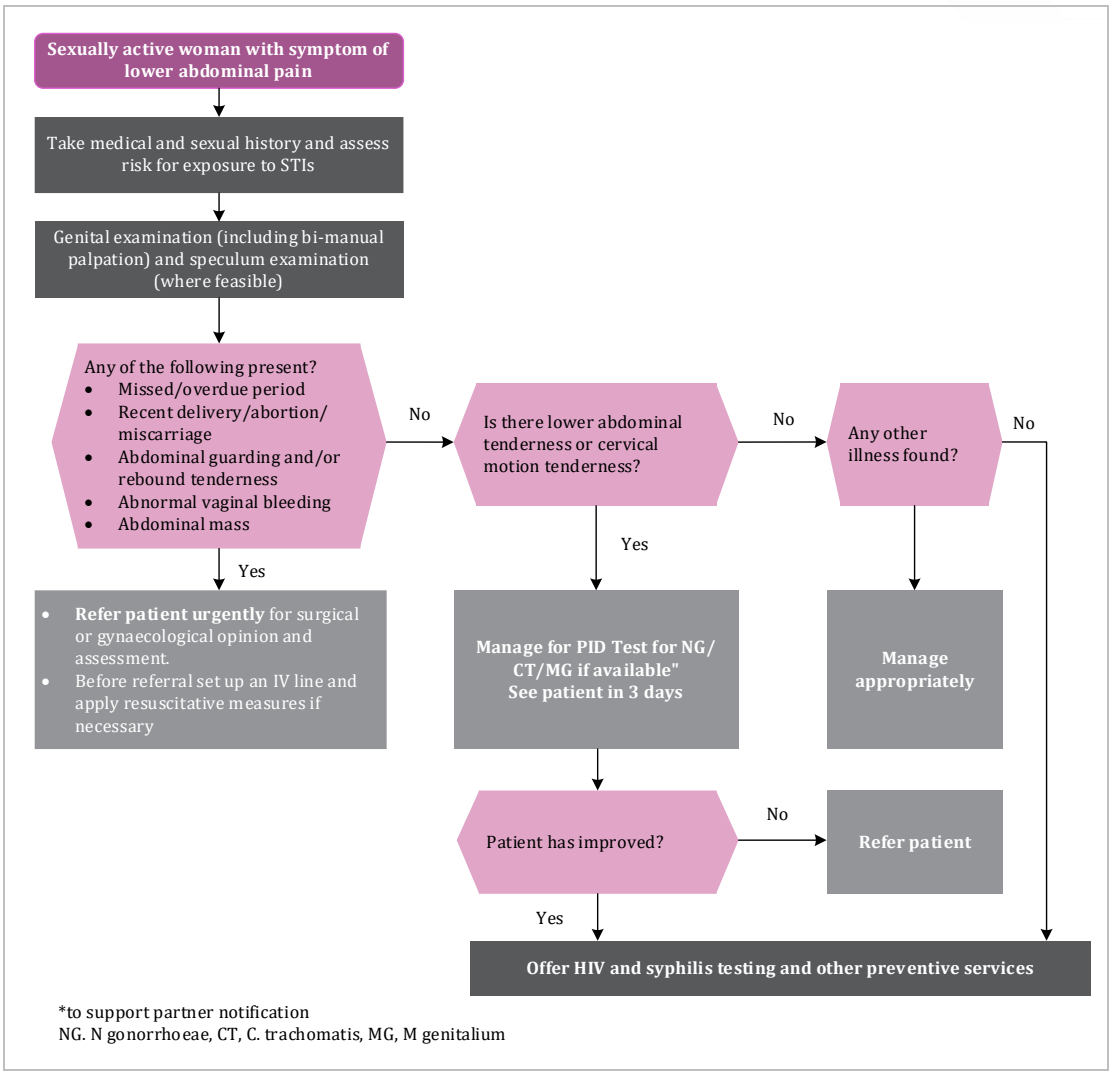


Figure 3.7: Examination and management of sexually active woman with lower abdominal pain

3.5.8 Epididymitis

Acute epididymitis is a clinical condition characterized by pain, swelling, and inflammation of the epididymis, typically lasting less than six weeks. If the condition persists for more than six weeks, it is classified as chronic epididymitis. In some cases, the testicle may also be involved, resulting in a condition known as epididymo-orchitis.

Acute epididymitis can be caused by STIs, most commonly *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Mycoplasma genitalium*. It may also be caused by enteric organisms such as *Escherichia coli*, particularly among individuals who engage in anal intercourse.

When the cause is STI, urethritis is often present, although it may be asymptomatic.

Table 3.12: Aetiology, Signs & symptoms, Diagnosis and Treatment of Epididymitis

Aetiology	Signs & Symptoms	Diagnosis	Treatment
Chlamydia trachomatis *Neisseria gonorrhoea* *Mycoplasma genitalium* enteric organisms (i.e., *Escherichia coli*)	Epididymal and/or testicular pain Tenderness and swelling of epididymis, testis and/or scrotum Symptoms of urinary tract infection or urethritis Fever	NAAT for C. trachomatis, N gonorrhoea, M. genitalium and enteric organisms	Empirical treatment should cover Chlamydia trachomatis, Neisseria gonorrhoeae, and Mycoplasma genitalium. If the patient reports anal sex, additional coverage should be provided for enteric pathogens, particularly *Escherichia coli*.

Clinical Case Management of Diseases Characterized by Testicular Pain

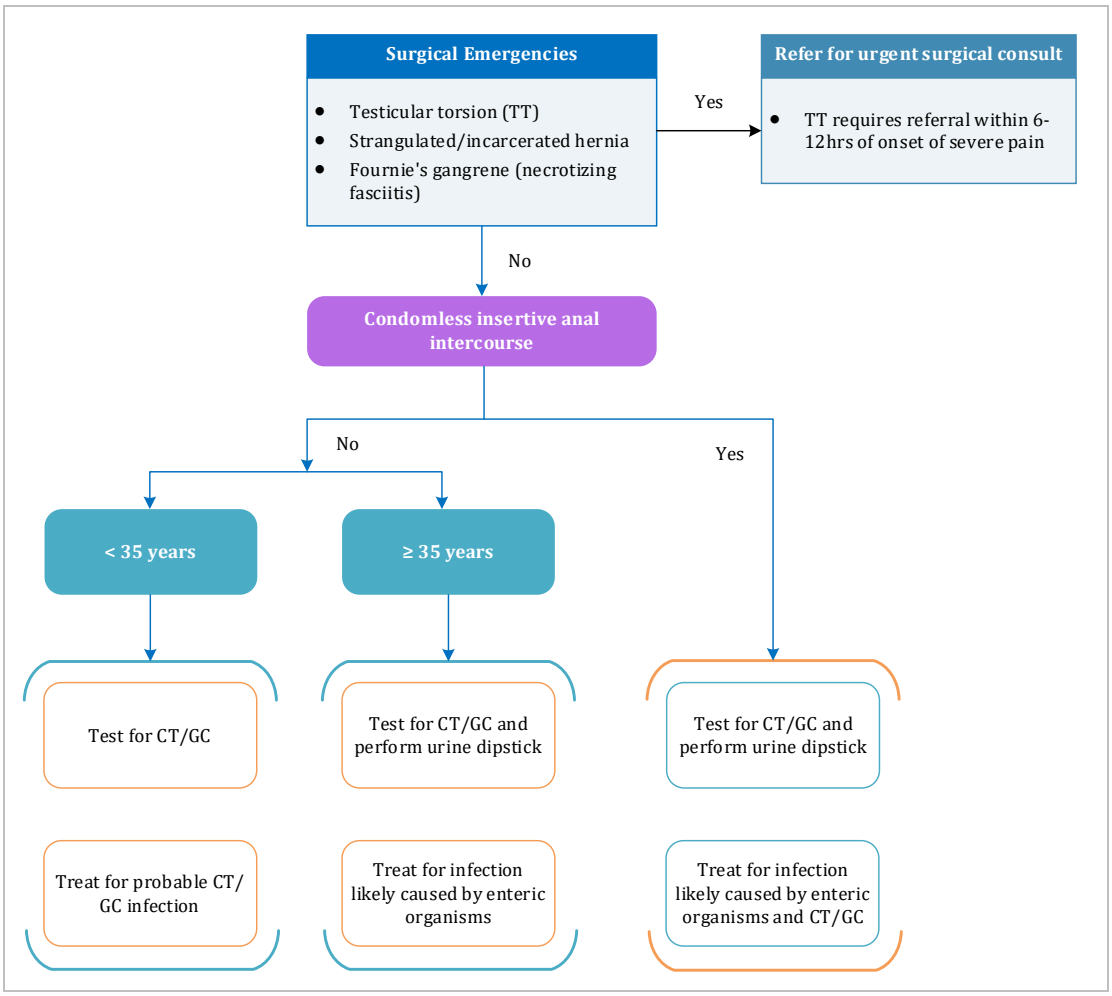


Figure 3.8: Testicular Pain Management

3.5.9 Proctitis, Proctocolitis, and Enteritis

Sexually transmitted gastrointestinal syndromes include proctitis, proctocolitis, and enteritis. Evaluation for these syndromes should include recommended diagnostic procedures, including anoscopy or sigmoidoscopy, stool examination for WBCs, and a comprehensive microbiologic workup which should include testing for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma genitalium*, *Lymphogranuloma venereum*, *Herpes simplex virus type 2*, and *Treponema pallidum*.

Proctitis is inflammation of the rectum that can be associated with anorectal pain, tenesmus, or rectal discharge and commonly occurs among persons who have receptive anal exposures. Proctocolitis is associated with symptoms of proctitis, diarrhoea or abdominal cramps, and inflammation of the colonic mucosa. Proctocolitis can be acquired through receptive anal intercourse or by oral-anal contact, depending on the pathogen. Enteritis usually results in diarrhoea and abdominal cramping without signs of proctitis or proctocolitis.

Treatment should be directed to the specific enteric pathogen and where aetiological diagnosis is not possible, coverage should be provided for the most common pathogens.

Table 3.13: Signs, symptoms, diagnosis and treatment of Proctitis, Proctocolitis and Enteritis

Aetiology	Signs and Symptoms	Diagnosis	Treatment
Chlamydia trachomatis *Neisseria Gonorrhoea* Treponema pallidum, Lymphogranuloma venereum *Mycoplasma Genitalium* enteric organisms (i.e., *Escherichia coli*)	anorectal pain, tenesmus, or rectal discharge diarrhoea or abdominal cramps, and inflammation of the colonic mucosa	NAAT for *C. trachomatis, N Gonorrhoea, M. Genitalium and enteric organisms* *T. pallidum serological testing*	Empirical treatment should cover *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, Treponema pallidum, Lymphogranuloma venereum and *Mycoplasma genitalium*. If the patient reports receptive anal sex, additional coverage should be provided for enteric pathogens, particularly *Escherichia coli*.

3.5.10 Anogenital Warts

Warts in the anogenital region are largely caused by Human papilloma virus genotypes 6 and 11. The warts may be on the penis, vulvar, or at the anal opening. In some cases, the warts are visible while in other cases they may be internal in the vagina or the anal canal making them not easily visible.

Diagnosis requires detailed history-taking and a physical examination to rule out other causes of growths in the region such as haemorrhoids, and malignancy. Sexual partners should be examined carefully for evidence of warts. Patients with anogenital warts should be made aware that they are highly infectious to their sexual partners and should use condoms to help reduce the risk of transmission of infection to them. Subclinical genital HPV infection typically clears spontaneously; therefore, specific antiviral therapy is not recommended to eradicate HPV infection. It is recommended that biopsy and histology of anogenital warts is taken to rule out malignancy. The quadrivalent or nonvalent HPV vaccine is highly effective for preventing anogenital warts. A summary of the signs, symptoms, diagnosis and treatment of warts are shown in table 3.13.

Table 3.14: Signs, symptoms, diagnosis and treatment of warts

Aetiology	Signs & Symptoms	Diagnosis	Treatment
Anogenital Warts Human Papilloma Virus	Benign exophytic, papular or flat growths that may occur anywhere in the anogenital region	Medical examination for warts NAAT for HPV	Warts small in size or number <3 Podophyllin 10-25% weekly application until warts fall off. Vaginal or the anal canal warts Podophyllin applied with use of speculum or proctoscope and allowed to dry before removing appliance. OR Imiquimod 5% cream applied by patient with finger/cotton swab at bedtime, left on overnight, 3 times a week **OR** every other day for 16 weeks Large or many warts >3 Refer patients for physical ablation and histological examination.

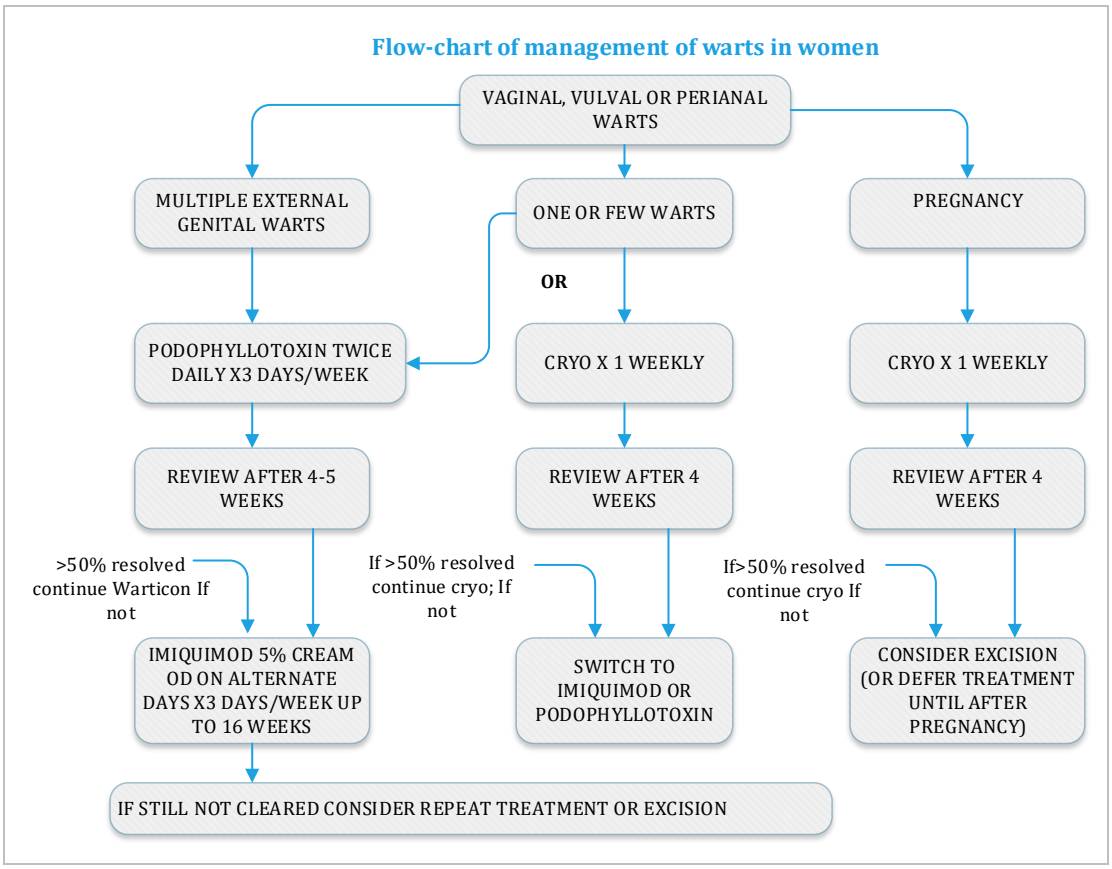


Figure 3.9: Management of warts in women

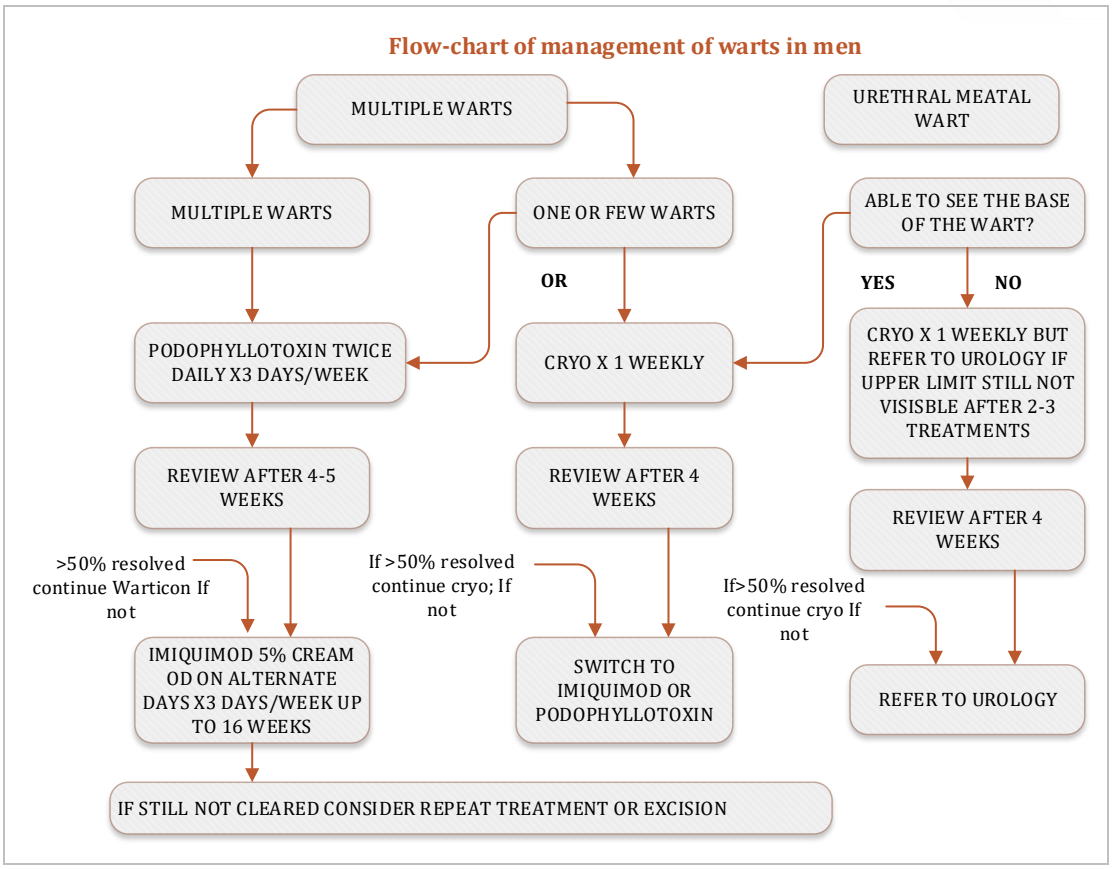


Figure 3.10: Management of warts in men

3.6 Ectoparasitic Infections

3.6.1 Pediculosis Pubis

Pediculosis pubis is caused by the parasite *Phthirus pubis* and is usually transmitted by sexual contact The clinical diagnosis is based on typical symptoms of itching in the pubic region, lice and nits can be observed on pubic hair.

Recommended Regimens for Pediculosis Pubis includes:

Permethrin 1% cream rinse applied to affected areas and washed off after 10 minutes

OR

Pyrethrin with piperonyl butoxide applied to the affected area and washed off after 10 minutes

OR

Malathion 0.5% lotion applied to affected areas and washed off after 8–12 hours

OR

Ivermectin 250 µg/kg body weight PO, repeated in 7–14 days

3.6.2 Scabies

Scabies is a skin infestation caused by the mite *Sarcoptes scabiei*, which causes pruritus. Sensitization to *S. scabiei* occurs before pruritus begins. The first time a person is infested with *S. scabiei*, sensitization takes weeks to develop. However, pruritus might occur <24 hours after a subsequent reinfestation. Scabies among adults is frequently sexually acquired, although scabies among children usually is not. Scabies diagnosis is made by identifying burrows, mites, eggs, or the mites' faeces from affected areas.

Recommended Regimens for Scabies include:

Permethrin 5% cream applied to all areas of the body from the neck down and washed off after 8–14 hours

OR

Ivermectin 200 ug/kg body weight orally, repeated in 14 days*

OR

Ivermectin 1% lotion applied to all areas of the body from the neck down and washed off after 8–14 hours; repeat treatment in 1 week if symptoms persist

* Oral ivermectin has limited ovicidal activity; a second dose is required for eradication.

3.7 Neonatal Conjunctivitis (Ophthalmia Neonatorum- ON)

Neonatal conjunctivitis of the newborn appears as ocular redness, swelling and draining which is sometimes purulent and occurs within the first month of life. This condition is referred to as ophthalmia neonatorum (ON). All newborn babies, regardless of maternal signs or symptoms of infection, should receive prophylaxis against ophthalmia neonatorum due to gonorrhoea or chlamydial infection. Neonatal conjunctivitis is caused by a bacterial infection, acquired by the baby during passage through an infected birth canal. The most common bacterial agent is *Neisseria gonorrhoea*, with the second most common to be *Chlamydia trachomatis*.

The incubation period is usually as follows:

- *trachomatis*: 5-14 days
- *N. gonorrhoea*: 3-5 days

Other bacteria that cause ON include *Haemophilus, Streptococcus, Staphylococcus and Pseudomonas.* Viral infections causing ON are less common and include *Herpes simplex virus, adenovirus or enterovirus*. The neonatal conjunctiva is particularly vulnerable to infection because of the lack of immunity and the absence of local lymphoid tissue at birth.

It is recommended to use one of the following options for topical application to both eyes immediately after birth or within one hour of birth:

Tetracycline hydrochloride 1% eye ointment (Single application)

OR

Silver nitrate 1% solution (Single application)

OR

Chloramphenicol 1% eye ointment (Single application)

Specific Treatments by Pathogen should be initiated as needed:

- **Gonococcal Conjunctivitis**: Intramuscular ceftriaxone is the first-line treatment. The infant requires hospitalization and close monitoring for systemic infection.
- **Chlamydial Conjunctivitis**: Requires systemic antibiotics, typically oral azithromycin. Topical treatment alone is ineffective and can lead to pneumonia.
- **Herpetic Conjunctivitis**: Treated with systemic acyclovir and antiviral eye drops. This is a serious condition that requires prompt antiviral treatment to prevent neurological damage.
- Other Bacterial Conjunctivitis: May be treated with topical ointments containing antibiotics like polymyxin and bacitracin, or erythromycin or tetracycline.

3.8 Diseases Characterised by Oropharyngitis

Oropharyngeal gonorrhoea and chlamydia have become more frequent as a result of engaging in oral sex. Of particular concern is the development of AMR by *N. gonorrhoeae* isolated from the throat. Patients presenting with oropharyngitis give a history of having engaged in oral sex recently and usually suffer from symptoms of a sore throat and loss of voice or a hoarse voice. Therefore, history and physical examination is crucial. An examination of the back of the throat for inflammation and presence of a discharge is required. Treatment should focus on the specific pathogen and where aetiological diagnosis is not possible, coverage should be provided for the most common pathogens causing oropharyngitis including *N. gonorrhoea* and *C. trachomatis*.

3.9 Diseases Following Sexual Assault

Survivors of sexual assault should receive immediate, survivor-centred, trauma-informed care, with presumptive STI treatment provided without delay and not conditional on police reporting. For adolescent and adult women, empiric treatment should cover chlamydia, gonorrhoea, trichomonas, and syphilis while for adolescent and adult men, empiric treatment should cover chlamydia, gonorrhoea, and syphilis as below. All eligible survivors should be offered HIV PEP, hepatitis B vaccination, and, for women, emergency contraception. Baseline testing for HIV, syphilis, pregnancy, and site-specific STIs should be done, if possible, but should not delay presumptive treatment. Survivors should receive counselling on medication adherence, STI symptoms, and abstinence or condom use until treatment is complete. Follow-up visits are essential to review injuries, completion of STI presumptive treatment, HIV PEP, repeat HIV testing, and completion of hepatitis vaccination.

Recommended Regimens for STI Presumptive Treatment Following Assault
Presumptive STI treatment for Female sexual assault survivors
Ceftriaxone 1 g IM STAT
Azithromycin 2 g PO STAT **OR** Doxycycline 100 mg PO BD for 7 days
Metronidazole 400 mg PO TID for 7 days OR Tinidazole 2 g PO OD for 2 days OR Secnidazole 2 g PO OD for 2 days.
Presumptive STI treatment for Male sexual assault survivors
Ceftriaxone 1 g IM STAT
Azithromycin 2 g PO STAT **OR** Doxycycline 100 mg PO BD for 7 days

CONTROL AND MANAGEMENT OF VIRAL HEPATITIS

Overview

Hepatitis refers to liver inflammation as evidenced by the elevation of hepatic transaminase enzymes ALT and AST. While hepatitis can result from various causes including alcohol use, drugs (e.g., isoniazid, paracetamol overdose), non-alcoholic fatty liver disease (NAFLD), autoimmune conditions, and infections like cytomegalovirus, Lyme disease, leptospirosis, malaria, or yellow fever the most common and clinically significant form is caused by hepatitis viruses.

4.1 Hepatotropic Viruses

There are five common types of hepatotropic viruses: Hepatitis A, B, C, D and E. Which are either ribonucleic acid (RNA) (hepatitis A, C, D and E), or deoxyribonucleic acid (DNA) viruses (hepatitis B). These viruses are broadly classified into two groups namely, enteric and parenteral. Currently effective and licensed vaccines are available for the prevention of HAV and HBV. Furthermore, HDV can be prevented as HBV immunization is protective against HDV.

- **The enteric viruses (HAV and HEV):** typically transmitted via the faecal-oral route, often through contaminated food or water. Although sexual transmission has been reported where sexual practices facilitate the faecal-oral exposure (e.g. oral-anal contact) this this contributes little to the overall burden. These forms of hepatitis are acute, self-limiting and do not lead to chronic liver disease.

The parenterally transmitted viruses (B, C and D): Are primarily transmitted via exposure to infected blood and body fluids. Common routes of transmission include vertical transmission (MTCT), sexual transmission, blood/blood product transfusions and percutaneous exposure (needlestick injuries, body piercing/traditional scarification, unsafe injection practices and inadequately sterilized medical equipment). Hepatitis B, C and D have the potential to become chronic, leading to Chronic viral hepatitis (CVH) which increases the risk of cirrhosis and hepatocellular carcinoma. Hepatitis D is unique in that it is an incomplete virus that can only infect individuals already infected with Hepatitis B, as it requires the Hepatitis B virus for replication. Hepatitis D co-infection or superinfection with HBV accelerates the progression of chronic liver disease.

While acknowledging the importance of hepatitis A and E, both of which cause acute viral hepatitis, this guideline primarily focuses on chronic hepatitis B and C. This aligns with the WHO global elimination agenda which has a strategic focus on HBV and HCV as these account for 96% of all viral hepatitis mortality.

Key features of different hepatitis viruses is summarized in Table 4.1

Table 4.1: Summary of key feature of different hepatitis viruses

Virus	Mode of Transmission	Course of Illness	Chronic Infection
Hepatitis A Virus (HAV)	Faecal-oral (contaminated food/water)	Acute, self-limiting	No
Hepatitis B Virus (HBV)	Blood, body fluid sexual, perinatal, certain medical procedures	Acute or chronic	Yes
Hepatitis C Virus (HCV)	Blood (primarily injection)	Acute or chronic	Yes (~70–85%)
Hepatitis D Virus (HDV)	Requires HBV co-infection	Chronic co-infection	Yes
Hepatitis E Virus (HEV)	Faecal-oral (especially in outbreaks)	Acute; severe in pregnancy	No

4.2 Acute Viral Hepatitis

Most patients with acute viral hepatitis have a subclinical or asymptomatic infections, when symptomatic the following are features in the clinical presentation which typically may be in phases:

- **Prodromal phase**: general malaise, fever, arthro-myalgias
- **Icteric phase**: anorexia, nausea and vomiting, jaundice, pale stools, dark urine, pruritus, hepatomegaly.
- **Recovery Phase**: Jaundice and other symptoms resolve. Jaundice may take up to 6 weeks or more to resolve.

4.3 Chronic Viral Hepatitis

If chronicity is established after acute infection, then individuals will be asymptomatic until the manifestations of CVH complications such as cirrhosis, hepatocellular carcinoma, etc. arise later in life.

4.4 Prevention of Viral Hepatitis

A comprehensive prevention strategy for viral hepatitis includes vaccination, harm reduction, safe healthcare practices, and public health education. The prevention framework consists of four levels:

i. Primary Prevention (before infection)

ii. Secondary Prevention (early detection and transmission interruption)

iii. Tertiary Prevention (reduction of complications and long-term impact)

iv. Primordial Prevention (structural and policy interventions)

Table 4.2: CVH Prevention Approaches and Key Interventions

Prevention Approaches	Key Interventions
Primary Prevention	
Vaccination	Hepatitis B birth dose and routine immunization;
Infection control in healthcare	Sterilization of equipment, safe blood handling, use of gloves, hand hygiene, sharps disposal
Harm reduction programs	Needle and syringe programs (NSPs), opioid substitution therapy (OST), education on safe injections
Secondary Prevention	
Screening and early diagnosis	HBV and HCV testing in high-risk groups (pregnant women, PLHIV, PWID)
Surveillance and monitoring	Outbreak detection, lab strengthening, data systems, seroprevalence surveys
Treatment and care	Linkage to care for and access to antivirals for both HBV and HCV as indicated.
Tertiary Prevention	
Clinical management and treatment	Antiviral therapy for HBV and Direct-Acting Antivirals (DAAs) for HCV, liver function monitoring, follow-up and screening for early detection of HCC and other complications.
Patient counselling and support services	Adherence support, co-infection management, psychosocial care
Primordial Prevention	
Health education and policy development	Public awareness campaigns, stigma reduction, legislation on safe healthcare practices

4.5 Diagnosis of Viral Hepatitis

The approach for diagnosing viral hepatitis infection includes:

- Clinical assessment – to recognize clinical features of VH
- Laboratory evaluation to assess for liver injury and

Serological and molecular tests that identify the causative virus as well as whether the patient has acute vs. chronic infection.**Clinical features of Viral Hepatitis**:

- Low grade Fever
- Yellowing of the skin and eyes (jaundice)
- Dark-coloured urine
- Fatigue
- Loss of appetite
- Nausea and vomiting
- Abdominal pain
- Bleeding or easy bruising
- Itching
- Liver failure, ascites and liver cancer
- Impaired mental function (Encephalopathy

4.5.1 Laboratory testing for screening and diagnosis of viral hepatitis

Viral Hepatitis can be tested by either serological or molecular techniques

4.5.2 Serological Tests

This is the first line assay in screening for exposure to the hepatitis virus. They are used to identify all individuals who might be infected with viral hepatitis. Serological assays detect the host immune response (anti-HBc, antibodies to HCV) or a viral antigen (e.g. HBsAg, HCVAg). These are available inform of rapid diagnostic tests (RDTs) or laboratory-based enzyme immunoassays (EIAs).

4.5.3 Molecular Tests

These are confirmatory tests as they detect the presence of viral nucleic acid (DNA or RNA) in plasma, serum or dried blood spot.

Table 4.3 below summarizes the essential laboratory tests for screening and diagnosis of viral hepatitis.

Table 4.3: Summary of essential Laboratory test for screening and diagnosis of viral hepatitis

Virus	Specimen	Type of test	Purpose
Hepatitis A	*Plasma or Serum*	Serological Assay for the detection of HAV-specific Immunoglobulin (IgM) antibodies,	Screening
	Plasma/Serum/Stool	Virological assay to detect PCR viral RNA. Stool sample can also be used to detect the genetical materials (RNA)	Confirmatory. Usually, a positive anti-HAV IgM is sufficient
Hepatitis B	Serum/Plasma,	Serological assay to detect HBsAg; antibodies to HBs and HBc to check for current/past infection or immunity	Screening
	Serum/Plasma	Virological assay to detect PCR viral DNA for active virus	Confirmatory
Hepatitis C	Serum/Plasma	Serological assay to detect anti -HCV	Screening
	Serum/Plasma	Virological assay to detect PCR viral RNA for active and chronic infection	Confirmatory
Hepatitis D	Serum/Plasma	Serological assay to detect Immunoglobulin G (IgG) anti-HDV	Screening
	Serum/Plasma	Virological Assay to detect PCR viral RNA	Confirmatory
Hepatitis E	Serum/Plasma	Serological assay to detect specific IgM antibodies (HEV)	Screening
	Serum/Plasma/Stool	Virological assay to detect PCR viral RNA for HEV. Stool sample can also be used to detect the genetical materials (RNA)	Confirmatory

4.6 Hepatitis B Virus (HBV)

4.6.1 Epidemiology and Basic Information Hepatitis B Virus (HBV)

Hepatitis B infection is caused by the hepatitis B virus (HBV), an enveloped DNA virus.

Transmission is parenteral and as HBV is highly infectious, 100 times more than HIV and remains stable in the environment (outside the body) for extended periods this increases the risk of transmission

The subsequent clinical manifestations of acute HBV infection are variable. About 30-50% of adults will be symptomatic to some degree, while infants and children are frequently asymptomatic. Acute hepatitis B is typically a self-limiting illness with a case fatality rate of less than 1%.

Chronicity is more common following acquisition in childhood. where more than 90% of infants exposed to HBV develop chronic infection, compared to less than 5% of individuals infected during adulthood. Chronic Hepatitis B (CHB) is defined by the presence of detectable HBsAg in the blood or serum for 6 months or longer.

The natural course of CHB infection involves different phases, with individuals moving between phases depending on their age, immune status, viral activity, and other factors.

Each phase has specific clinical and virological features that guide patient monitoring and treatment decisions. Importantly, not all individuals experience every phase, and some may remain in one phase for extended periods.

The typical progression of HBV infection, including possible long-term complications such as cirrhosis and hepatocellular carcinoma (HCC) has been outlined in Table 4.4

Table 4.4: Natural History of Hepatitis B Virus Infection, Key features and possible outcomes

Stage	Clinical Phase	Description	Possible Outcomes
Acute HBV Infection	Acute Phase	Within first 6 months of infection; may be asymptomatic or symptomatic.	Spontaneous recovery (anti-HBs) or progression to chronic infection
Chronic HBV Infection	Immune-Tolerant Phase	Seen mostly in early-life infection; high viral replication but little liver damage.	May remain stable or progress to immune active
	Immune-Active Phase (HBeAg-positive)	Active inflammation with high replication; Liver damage may occur.	HBeAg Seroconversion or progression to fibrosis
	HBeAg Seroconversion	Transition to lower replication and inflammation.	May lead to inactive carrier phase
	Inactive Carrier Phase (Immune Control)	Low viral load and liver inflammation. Often stable.	Stable phase or reactivation (immune escape)
	HBeAg-negative CHB (Immune Escape Phase)	Reactivation phase with ongoing liver damage despite HBeAg negativity.	Risk of fibrosis and HCC

Stage	Clinical Phase	Description	Possible Outcomes
	HBsAg Seroconversion	Functional cure with viral clearance. Rare spontaneous event.	Long-term resolution
Long-Term Outcomes	Cirrhosis (Compensated)	Advanced liver scarring with preserved function.	Risk of decompensation or HCC
	Decompensated Cirrhosis	Liver function fails; clinical complications present.	Requires urgent care or transplant evaluation
	Hepatocellular Carcinoma (HCC)	Primary liver cancer. Cirrhosis can occur with or without chronic HBV.	High mortality if not detected early

4.6.2 HBV Transmission and high-risk groups

Hepatitis B is transmitted horizontally through exposures to infected blood or other body fluids, primarily via sexual contact, sharing needles, occupational exposure (like needle stick injuries), and vertically from an infected mother to her infant during birth.

Table 4.5 summarizes the transmission and respective high-risk groups.

Table 4.5: HBV Transmission and high-risk groups

Transmission Route	Description	Examples	Risk Groups
Perinatal transmission	Vertical transmission	In utero, labour and breastfeeding	Children born of HBsAg-positive Mothers with high VL (≥200,000 IU/mL) in absence of prophylaxis
Horizontal Child to Child	Nonsexual transmission among children especially in high-prevalence areas	Close contact with open wounds or sores	Children in households with an infected person, in institutions, informal settlements, conflict zones or refugee camps and unvaccinated children
Parenteral (blood Exposure)	Exposure to infected blood or blood products including health care associated, occupational exposure	Blood transfusion, unsafe sharing of needles and syringes, re-use of unsterilized equipment, accidental needle stick injuries, Unsafe medical procedures	People who inject drugs (PWID), recipients of unsafe medical or dental procedures, blood transfusion recipients (especially before screening), HCW, people undergoing haemodialysis, People in correctional facilities and PLHIV
Sexual	Unprotected sexual contact	Unprotected vaginal, oral or anal sexual contact	MSM, FSW and individuals having unprotected sex with multiple partners.
Household contact/ exposure	Sharing personal items that may be contaminated with blood	Razors, toothbrush and nail clippers	Sexual partners of the infected person, children under 5 years old living with an infected person, unvaccinated household members and People providing medical care in the home.

Transmission Route	Description	Examples	Risk Groups
Certain Traditional Practices	Cultural or traditional procedures involving skin penetration	Scarification, tattooing, circumcision with unsterile tools	Practitioners of scarification, tattooing, tooth extraction, circumcisers, traditional birth practices, body piercing and cupping therapy

4.6.3 Testing for HBV

Who to test:

In view of the asymptomatic nature of CVH it is recommended that all individuals have an HBV test at least once in their lifetime. A targeted approach that considers a context specific risk profiling can be used to prioritize testing and determine special populations who may need further preventive measures (for the negatives) with, counselling, care, and treatment for those who test positive. Table 4.6 summarizes testing frequencies for different populations

Table 4.6: HBV Testing and Re-testing Recommendations for Different Populations

Testing approach and population	Recommendations
Infants born to known HBsAg positive mothers	• Screen Baby for HBV with HBsAg **AND** Anti- HBs antibody at **9-12 months- Baby completes Vaccine schedule**
Infants and children whose mother's HBsAg status is unknown	• Screen Baby for HBV with HBsAg **AND** Anti- HBs antibody at **9-12 months- Baby completes Vaccine schedule**
Adolescents and young people (10–17 years)	• Offer HBsAg serological testing to adolescent and young people (at least once a lifetime) • Retesting based on exposure
General population adults aged ≥18 years	• Offer HBsAg serological testing (at least once a life-time) • Birth cohort testing among identified age or demographic groups (i.e. specific "birth cohorts") known to have high viral hepatitis prevalence due to past generalized exposures that have since been identified and removed. • Retest any time if there is a new risk exposure, except those vaccinated against Hepatitis B make use of existing community- or health facility-based testing opportunities or programmes such as at antenatal clinics, HIV or TB clinics.
Pregnant and breastfeeding women	• Test at first ANC/contact visit for HIV, HBsAg, and syphilis with • Retest per recommendation in the VTP Section 2.1 of this guideline • Couples and partners in antenatal care settings should be offered HBV testing services. • Follow specific population retesting guidelines.
Close contacts and household members of HBsAg positive person	• Offer HBsAg serological testing to detect past or present HBV infection with linkage to prevention, care and treatment services

Testing approach and population	Recommendations
Key and vulnerable populations	• Offer HBsAg serological testing at first contact irrespective of reason for visit, • Retest HBsAg -negative individuals every 12 months. (Once a year) except those vaccinated against Hepatitis B
Patients with STI	• Offer HBsAg serological testing at initial presentation; • Re-test based on population typology.
PLHIV	• Offer HBsAg serological testing as part of baseline test for prior to initiation of ART
Prior to PrEP initiation	• Offer HBsAg serological testing as part of baseline screening for person being evaluated for prior to initiation of PrEP
Blood Donors	• Offer HBsAg serological testing prior to blood donation
Other Risk Groups	Mandatory HBsAg serological testing for the following individuals: • Clinical suspicion of chronic viral hepatitis (symptoms, signs, laboratory markers); • Chronic renal disease, on dialysis • Tuberculosis, • HBV endemic regions • Sicklers who have received multiple blood transfusions • Diabetes mellitus. Health-care workers: in all settings except those vaccinated against Hepatitis B

N/B: Anyone who require Hepatitis Vaccine must be screened for HBsAg

4.6.4 Diagnosis of HBV

A diagnosis of Hepatitis B infection relies on a positive HBsAg test. However, there are other tests that are important to assess disease phase and guide treatment decisions. These are represented in Table 4.7.

Table 4.7: HBV Diagnostic Markers of Clinical Importance

Marker	Interpretation
Hepatitis B surface antigen (HBsAg)	• Indicates Presence of infection. • First appearing 1-3 weeks before onset of symptoms. • CHB defined as Presence of HBsAg on at least one occasion for adults and persistence of HBsAg for six months or more.
Hepatitis B e antigen (HBeAg)	• Is usually a marker of high levels of viral replication and infectivity, independent of disease phase (Acute/Chronic)
Hepatitis B surface antibody (anti-HBs)	• Appears 1-3 months after HBV vaccination or during recovery from acute HBV infection. It denotes recovery infection and immunity
Anti-HBe	• Detected among people with lower levels of HBV replication but also in HBeAg-negative disease (HBV that does not express HBeAg)
Hepatitis B core antibody (Anti- HBc Total)	• Anti-HBc appears at the onset of symptoms in acute hepatitis B and persists for life after infection. Indicates exposure to HBV (past or current). • Measures both IgM and IgG) • Individuals with immunity to hepatitis B from vaccination do not develop anti-HBc.
IgM anti-HBc	• Detected during Acute Hepatitis B and a flare or reactivation of CHB. IgM anti-HBc positivity indicates recent infection with HBV. Present during first 6 months. • Its presence indicates acute infection and should be ordered only when acute HBV infection is a concern.
HBV DNA PCR (quantitative)	• Quantifies the amount of virus in the blood (viral load) for treatment and monitoring.

4.6.5 Initial Evaluation /Assessment of Treatment Eligibility

Antiviral therapy is not indicated for Acute HBV. In addition, it is estimated that only a small proportion of individuals with CHB require treatment, determining eligibility for treatment is therefore a critical component of care. All individuals newly diagnosed with HBsAg must undergo initial evaluation for treatment eligibility. This process uses both clinical assessment and laboratory or imaging tests as follows:

- Assess the severity of liver disease using non-invasive tests. (APRI* Score or Transient elastography)
- ALT** **and** HBV DNA PCR (viral load)
- **Medical history**: Screening for presence of coinfections (e.g. HIV, HDV or HCV), comorbidities (e.g. diabetes, steatotic liver disease) immune suppression (e.g. long-term steroids, transplant), extrahepatic manifestations (e.g. glomerulonephritis, vasculitis), or family history of liver cancer or cirrhosis

* APRI: aspartate aminotransferase-to-platelet ratio index.

**ALT: alanine aminotransferase,

All assessments must be client-centred, confidential, and culturally sensitive, with linkage to prevention, treatment, and psychosocial services for those who are eligible.

Table 4.8 outlines assessment of treatment eligibility for HBsAg positive patients among the general population and assessment

Table 4.8: Assessment of Treatment eligibility for patients who are HBsAg-positive

Assessment of treatment eligibility for General Population aged ≥12 years
1. Patient diagnosed to have **severe liver disease** ● Non-invasive tests (APRI>0.5 or transient elastography>7kPa) ● Liver cirrhosis (per clinical criteria) OR 2. Patient with HBV DNA >2,000IU/mL **AND** ALT level>ULN OR **3. Medical History: PRESENCE OF any of following** (regardless of APRI score, HBV DNA or increased ALT) ● Coinfection (e.g. HIV, HDV, HCV) ● **Family history** of liver cancer or cirrhosis ● Immune suppression ● **Comorbidities** (e.g. diabetes, metabolic dysfunction-associated steatotic liver disease) ● **Extrahepatic manifestations** (e.g. glomerulonephritis or vasculitis)

While transient elastography(fibroscan) is considered the non-invasive gold standard for liver staging, the APRI score provides an acceptable validated estimate where elastography is not available. Laboratory based nucleic acid amplification is still the gold standard to quantify HBV DNA for treatment eligibility and monitoring.

4.6.6 General Care measures

General Care measures should be prioritized for all HBsAg positives regardless of treatment eligibility threshold. These measures include;

- **Counselling on lifestyle** e.g., healthy diet and physical activity
- **Protection from additional liver insults** e.g. avoidance of alcohol, HAV vaccination if non-immune
- **Preventive measures:** Screening and HBV vaccination for family, household members and sexual contacts of infected persons.

4.6.7 Treatment for persons with Chronic Hepatitis B (CHB) infection

Once treatment eligibility is established it is recommended that the patient is prepared to start treatment by providing adherence support, establishing risk factors for renal dysfunction and baseline renal function and HIV test. (as indicated). Tables 4.9., 4.10 and 4.11

Table 4.9: Preferred and Alternative First-line Antiviral Regimes

Population	Preferred first line	Alternative	Special Considerations
Adults	Tenofovir, Entecavir (ETV)	TDF + 3TC TDF + FTC (where TDF monotherapy is not available)	ETV or TAF for people with osteoporosis and/or impaired kidney function
Adolescents (12–17 years)	Tenofovir, Entecavir	TDF + 3TC TDF + FTC TAF (where TDF monotherapy is not available)	
Children (2–11 years)	Tenofovir*, Entecavir	—	
*Low dose formulations of TDF may not be widely available ETV is not an appropriate option for people with both HIV and HBV unless combined with a fully suppressive ART regimen.			

Dosing of Antivirals in Children and Adolescents

Table 4.10: Dosing of Antivirals in Children and Adolescents

Drug	Patient Group	Dose	Notes
ETV[a]	Weight <30 kg	0.015 mg/kg once daily (maximum 0.5 mg daily)	a ETV: approved for children aged two years or older and is not appropriate for HIV/HBV co-infected b TDF: Approved for children two years or older and weighing at least 10 kg c TAF: approved for children six years and older and weighing more than 25 kg and for children 12 years and older with compensated liver disease
	Weight >30 kg	0.5 mg once daily	
TDF[b]	Age >2 years	8 mg/kg once daily (maximum 300 mg daily)	
	Age >12 years	300 mg daily	
TAF[c]	Age >12 years	25 mg once daily	

Entecavir Oral Solution Dosing in Children ≥12 Years

Entecavir is recommended for children aged 2 years and older who weigh at least 10 kg. The dose of oral solution should be based on body weight and whether the child is lamivudine-naïve or lamivudine-experienced.

Table 4.11: Entecavir Oral Solution Dosing in Children ≥12 Years

Body Weight (Kg)	10-11	>11-14	>14-17	>17-20	>20-23	>23-26	>26-30	≥30
Lamivudine Naïve (once daily)	3 ml	4 ml	5 ml	6 ml	7 ml	8 ml	9 ml	10 ml
Lamivudine Experienced (once daily)	6 ml	8 ml	10 ml	12 ml	14 ml	16 ml	18 ml	20 ml
• 10 ml oral solution = 0.5 mg oral tablet. • TAF may replace TDF • Entecavir is not recommended in HIV co-infected children.								

4.6.8 Monitoring Treatment for persons with Chronic Hepatitis B (CHB) infection

Monitoring for people not yet receiving treatment

People who do not currently meet the criteria for antiviral therapy or who have expressed a desire to defer treatment should be monitored **annually** for disease progression with ALT, HBV DNA levels (if HBV DNA testing is available) and APRI score

Monitoring for people receiving treatment:

HBV DNA PCR (quantitative) should be performed 6 months after initiating treatment and annually thereafter to assess treatment response.

In addition, the following should be monitored at least annually:

- Non-invasive tests (APRI score or transient elastography) to assess stage of disease and progression of fibrosis or cirrhosis; and
- ALT levels[a], HBsAg[b] and HBeAg/anti-HBe[c]
- HCC screening - See section 4.5

Visits should be scheduled every 3-6months and treatment adherence should be regularly assessed at each visit.

[a]ALT levels fluctuate among people with CHB, and longitudinal monitoring is required to determine the trend. The ULN for ALT has been defined as below 30 U/L for men and boys and 19 U/L for women and girls. For people not yet on treatment: persistently abnormal or normal may be defined as two ALT determinations above or below the ULN during a 6- to 12-month period.

[b]Among people receiving treatment, monitor for HBsAg loss (although this occurs rarely) and for seroreversion to HBsAg positivity after discontinuing treatment. Quantitative HBsAg, if available, can be used to determine whether HBsAg concentrations are declining.

[c]Monitoring of HBeAg and anti-HBe mainly applies to those who are initially HBeAg positive. However, those who have already achieved HBeAg seroconversion and are HBeAg negative and anti-HBe positive may subsequently serorevert.

4.6.9 Treatment Duration

4.6.9.1 Patients with Cirrhosis

Patients with cirrhosis (APRI >1 or transient elastography >12.5 Kpa or Metavir score F4) should not stop HBV treatment as viral reactivation can trigger life-threatening hepatitis flares which in these patients with poor functional reserve can lead to decompensation, liver failure and death. Therefore, **lifelong suppressive therapy is strongly recommended**.

4.6.9.2 Patient without Cirrhosis.

In patients without cirrhosis long term HBV therapy can sometimes be discontinued once sustained immune control of the virus is achieved to minimize cost, drug toxicity and lifelong adherence burden. This should only be considered under careful specialist supervision and after meeting strict criteria. If any of these criteria (Table 4.12), is not met antiviral therapy should continue.

Table 4.12: Managing HBV Patients without Cirrhosis

1.No evidence of Cirrhosis

AND

2.Close monitoring can be guaranteed in the short and long-term (with necessary tests)

AND

3.Evidence of HBeAg seroconversion (i.e. HBeAg negative and anti-HBe positive for people initially HBeAg-positive)

AND

> 12 months of undetectable HBV DNA

AND

5. Persistently normal ALT (at least two tests 6 months apart)

Everyone who stops treatment should be closely monitored with the ALT + HBV DNA every 3 months for the first 12 months, then every 6 months for the next 12 months and annually thereafter. The aim is to detect early biochemical or virological relapse, and the first-year post-discontinuation bears the highest risk of relapse.

Table 4.13: Definition of HBV Relapse

Type of Relapse	Definition	Action
Virological	HBV DNA > 2000 IU/mL after being undetectable	Intensify monitoring
Biochemical	ALT > x2 ULN with HBV DNA > 2000 IU/mL	Restart antiviral therapy
Clinical	Symptoms + jaundice + ALT flare with detectable HBV DNA	Urgent retreatment- restart antiviral therapy

4.6.10 Retreatment

Relapse is common after stopping therapy. Retreatment is recommended if there are consistent signs of reactivation: HBsAg or HBeAg becomes positive, ALT levels increase, or HBV DNA becomes detectable again (if HBV DNA testing is available).

4.6.11 Hepatocellular Carcinoma (HCC)Surveillance

Ongoing HCC surveillance prioritises the patients with the highest risk. Abdominal ultrasound and alpha-fetoprotein level every 6 months is recommended in the following situations:

- CHB with liver cirrhosis
- Non cirrhotic CHB with high risk (men >30years and women > 40yrears with perinatal infection, HIV/HDV coinfection, alcohol or family history of HCC)

Any patient who screens positive should have an urgent referral to a facility with oncology services.

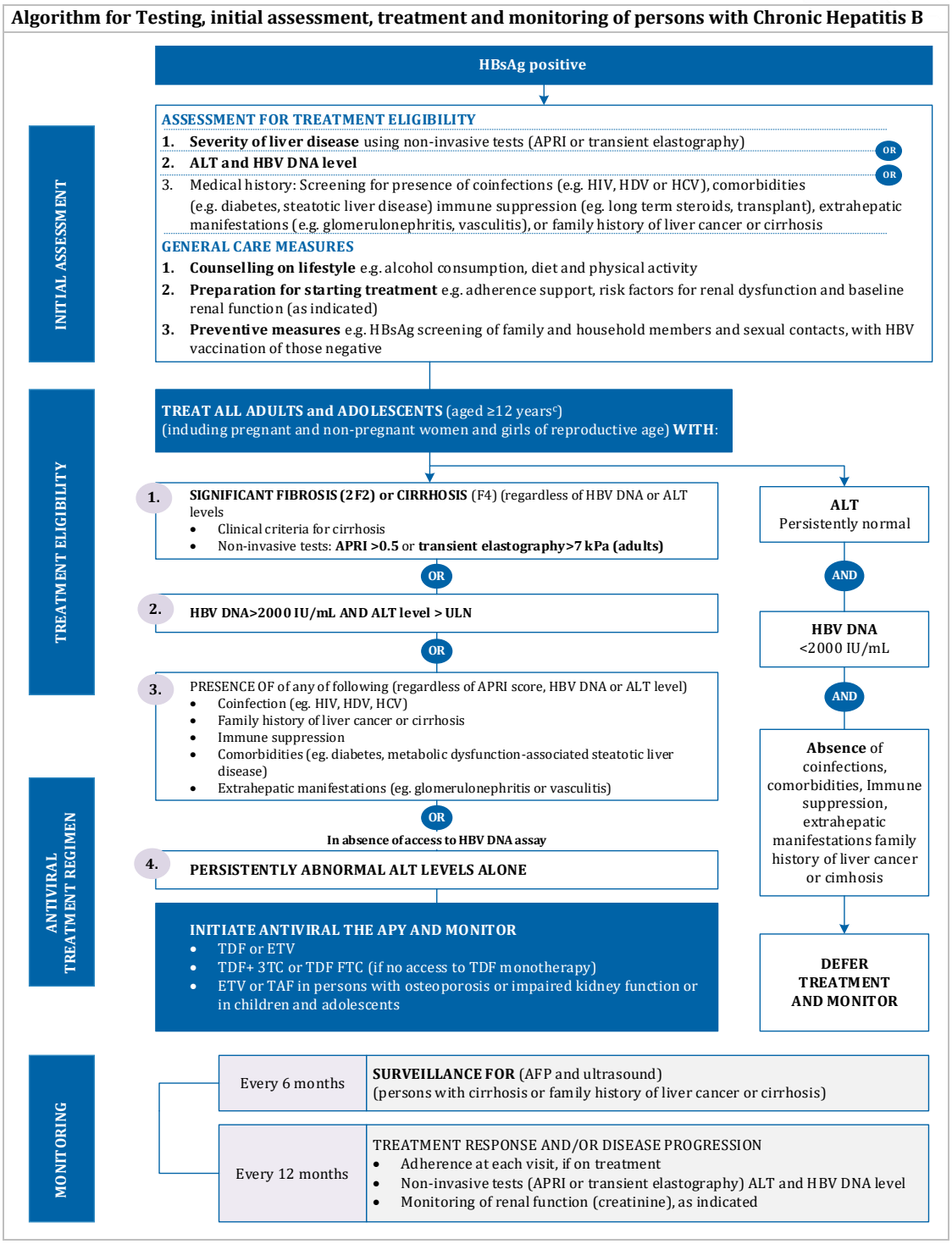


Figure 4.1: Algorithm for Testing, initial assessment, treatment and monitoring of persons with CHB (adopted from WHO)

Footnotes for figure 4-1: Algorithms for Testing, initial assessment, treatment and monitoring of persons with CHB (adopted from WHO)

ALT: alanine aminotransferase, APRI: aspartate aminotransferase-to-platelet ratio index

a. Defined as the presence of persistence HBsAg for six months or more

b. Before initiation, consider assessing renal function: serum creatinine level, estimated glomerular filtration rate, urine dipsticks for proteinuria and glycosuria and risk factors for renal dysfunction (decompensated cirrhosis, creatinine clearance <50 mL/min, poorly controlled hypertension, proteinuria, uncontrolled diabetes, active glomerulonephritis, solid organ transplantation, older age, BMI <18.5 kg/m2 (or body weight <50 kg), concomitant use of nephrotoxic drugs or a boosted protease inhibitor for HIV). Monitoring should be more frequent for those at higher risk of renal dysfunction.

c. Age groups: these guidelines use the following definitions for the purpose of implementing treatment recommendations for adolescents and children aged two years and older. An adult is a person aged 18 years or older; an adolescent 12–17 years old inclusive; and a child is 2–11 years old. Countries may have other definitions under national laws.

d. Clinical features of decompensated cirrhosis: portal hypertension (ascites, variceal haemorrhage and hepatic encephalopathy), coagulopathy or liver insufficiency (jaundice). Other clinical features of advanced liver disease and cirrhosis may include: hepatomegaly, splenomegaly, pruritus, fatigue, arthralgia, palmar erythema and oedema.

e. Non-invasive test cut-offs for APRI and transient elastography have not yet been validated for children and adolescents.

f. The ULN for ALT has been defined as <30 U/L for men and boys and <19 U/L for women and girls. Persistently normal or abnormal may be defined as two ALT values below or above the ULN at unspecified intervals during a 6- to 12-month period. ALT levels fluctuate with CHB and require longitudinal monitoring to determine the trend.

g. Raised ALT may normalize in pregnancy and is therefore not a good marker for deciding about long-term treatment in pregnancy.

h. Pregnant women should be reassessed after delivery.

All people with CHB should be monitored regularly for disease activity and progression and surveillance for HCC and after stopping treatment for evidence of reactivation. More frequent monitoring may be required for those with more advanced liver disease, during the first year of treatment or if adherence is a concern.

Table 4.14: Selected non-invasive tests to assess liver fibrosis

Tests	Components	Requirement	Online calculator
APRI	AST, platelets	Simple blood tests	https://www.hepatitisc.uw.edu/page/clinical-calculators/apri.
FIB-4	Age, AST, ALT, platelets	Simple blood tests	http://www.hepatitisc.uw.edu/page/clinical calculators/fib-4.
FibroScan®	Transient elastography	Dedicated equipment	-

APRI and FIB-4 Calculations interpretations

FIB-4	
$\text{FIB-4} = \dfrac{\text{Age (years)} \times \text{AST (U/L)}}{\text{Platelet Count } (10^9/\text{L}) \times \sqrt{\text{ALT (U/L)}}}$	• A FIB-4 score of < 1.45 has a negative predictive value of 90% for advanced fibrosis • A FIB-4 score of >3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis
• AST/ALT upper limit of normal: use 40 IU/L if none specified • Platelet count: expressed in terms of X1000/microLitre	

AST-to-platelet ratio index (APRI)	
$\text{APRI} = \dfrac{\dfrac{\text{AST Level}}{\text{AST (Upper Limit of Normal)}}}{\text{Platelet Count } (10^9/\text{L})} \times 100$	• The lower the APRI score < 0.5, the greater the negative predictive value (the ability to rule out cirrhosis)(No Fibrosis) • The higher the value >1.0, the greater the positive predictive value (ability to rule in cirrhosis)
• AST upper limit of normal: Use 40 IU/L if none specified • Platelet count: expressed in terms of X1000/microlitre	

4.7 Hepatitis C Virus (HCV)

Epidemiology and Basic Information Hepatitis C Virus (HCV)

HCV infection causes both acute and chronic hepatitis. Most acute infections are asymptomatic with spontaneous clearance occurring in 25-30% and about 70% developing chronic infection. Chronic HCV infection carries a higher risk than CHB of progression to cirrhosis which ranges from 15% to 30% after about 20 years of infection with HCV. Annually, approximately 1–3% of persons with cirrhosis progress to HCC. The risk of progression to cirrhosis and HCC varies according to both host and virological factors. Age of acquisition, alcohol use, HBV or HIV coinfection and immunosuppression due to any cause increase the risk of developing cirrhosis or HCC.

In Kenya the prevalence of HCV is 1-2% among the general population with higher HCV antibody prevalence among the PWID of 13-22% antibody reported in Nairobi and Coastal regions respectively.

4.7.1 HCV Transmission and high-risk groups

Table 4.15: HCV Transmission and high-risk groups

Mode of Transmission	Groups at Risk
Injection drug use	• People who inject drugs (PWID), or history of sharing injection or non-injection drug use equipment (needle, syringes, water, intranasal straw) • Prison populations due to unsafe injection practices
Sexual transmission	• Men who have sex with men • Unprotected sex with an infected person
Unsafe medical procedures	• People undergoing tattooing, body piercing or scarification procedures done where infection control practices are substandard • People who undergo medical injections or dental treatment in unregulated health-care provider • Haemodialysis patients who may be exposed through improperly sterilized dialysis equipment
Blood transfusions and organ transplants	• Recipients of infected blood and blood products particularly before 1990, when screening for HCV was not widely implemented
Perinatal transmission	• Children from infected mothers
Occupational exposure	• Healthcare workers, particularly sharps and blood specimen handlers
Others	• People living with HIV, as co-infection

Sexual transmission of HCV occurs infrequently in heterosexual couples. It is more frequent in men who have sex with men and PWID. Transmission among HIV-negative men who have sex with men is increasing.

4.7.2 Prevention of HCV

There is no vaccine is available for HCV, prevention efforts must focus on harm reduction, infection control, and creating public awareness.

4.7.3 Diagnosis of HCV

HCV diagnosis is based on serological and molecular testing, including:

- **Anti-HCV antibody test:** Detects prior or current infection. A positive result requires confirmatory testing.
- **HCV RNA PCR test:** Confirms active infection and quantifies viral load.
- **HCV genotype testing:** Determines treatment regimen, as some genotypes respond better to specific DAAs.
    - **Genotypic testing is recommended:** only for genotypic dependent DAAs (Kenya has pan genotypic DAAS hence not mandatory)

Table 4.16: Recommendations for Hepatitis C screening among adults

Population	Recommendations
Persons with recognized risk /exposure	One-time Anti HCV testing for ● Persons with HIV ● PWID ● Abnormal ALT ● Tattoo in unregulated settings ● Occupational exposure (HCV contaminated sharps) ● Children born to HCV-infected women ● Prior recipients of blood products or organs prior to July 1992, including persons who received clotting factor concentrates prior to 1987 ● Ever incarcerated
Routine /periodic testing for persons with ongoing risk factors	**Annual Anti-HCV testing** ● PWID ● Maintenance haemodialysis **Bi-annual RNA testing** ● Those who achieved SVR with ongoing risk should be retested using RNA testing, as the antibody remains positive
Birth cohort testing	Specific identified birth cohorts of persons with identified shared risk

N/B: Any person who requests for HCV test should receive it regardless of disclosure of risk because many persons may be reluctant to disclose stigmatizing risks

4.7.4 Treatment of HCV

All patients with a diagnosis of chronic HCV infection are eligible for treatment. Pan genotypic directly acting antivirals (DAA) regimens are available for all adults, adolescents and children aged 3 years and above with chronic HCV infection, regardless of stage of disease. DAAs offer high cure rates with relatively short treatment durations.

Most children with HCV infection acquire it vertically and should be referred for close follow up with a paediatrician. The same pan genotypic DAA regimens recommended in adults (sofosbuvir/daclatasvir, sofosbuvir/velpatasvir, glecaprevir/pibrentasvir) can be used in children >3 years. Treatment during childhood achieves comparable response rates to adults and adverse effects are more frequent. In view of the slow progression deferring treatment until the child is older is a valid option for most paediatric patients. Special considerations should be made for certain conditions where drug-drug interactions or insufficient safety data may play a role in decision-making:

Table 4.17: Recommended DAA Regimens and Duration for Hepatitis C Treatment for adults, adolescents and children >3 years

Recommended Pan genotypic DAA Regimens			Non-Pan genotypic DAA Regimen (in minimal GT3 infection settings)
Sofosbuvir/ daclatasvir* (SOF/DCV)	**Sofosbuvir/ velpatasvir** (SOF/VEL)**	**Glecaprevir/ pibrentasvir (G/P)**	**Sofosbuvir/ ledipasvir** (SOF/LED)**
12 weeks	12 weeks	8 weeks	12 weeks
Adults (>18 years): Adolescents (12–17 years): Older children (6–11 years); Younger children (3–5 years) *In patients without cirrhosis treatment duration is 12 weeks. *Patients with compensated cirrhosis and treatment experienced patients' duration is for 24 weeks. ** For use in those with genotype 1, 4, 5, or 6 infections.			

Table 4.18: Recommended DAA Regimens and Duration for Hepatitis C Treatment for Children

Recommended Pan genotypic DAA Regimens			Non-Pangenotypic DAA Regimen (in minimal GT3 infection settings)**
Sofosbuvir/ daclatasvir* (SOF/DCV)	Sofosbuvir/ velpatasvir (SOF/VEL)	Glecaprevir/pibrentasvir** (G/P)	Sofosbuvir/ ledipasvir*** (SOF/LED)
>26 kg 400/60 mg OD (film-coated tablets)	>30 kg 400/100 mg OD (FDC tablet)	>45 kg 300/120 mg OD (FDC tablet/6 packets of oral pellets)	≥35 kg 90/400 mg OD (FDC tablet)
14–25 kg 200 mg/30 mg* (as single tablets, sofosbuvir preferred as smaller 100 mg tablet)	17–29 kg 200/50 mg OD (FDC tablet or granules)	30–<45 kg 250/100 mg od (5 packets oral pellets) 20–<30 kg 200/80 mg od (4 packets oral pellets)	17–35 kg 45/200 mg (tablet)
	<17 kg 150/37.5 mg OD (coated granules)	<20 kg 150/60 mg od (3 packets oral pellets)	<17kg 33.75/150 mg OD (FDC granule packets)
FDC = fixed-dose combination * Dosing based on population pharmacokinetic modelling studies **Available as FDC 100/40 mg tablets or oral pellets 50/20 mg *** For use in those with genotype 1, 4, 5, or 6 infection or where genotype 3 infection is uncommon. Not recommended as initial therapy without genotype subtyping. Efficacy is lower in non-GT1 infections (e.g., GT3), especially in sub-Saharan Africa.			

4.7.5 Drug Interactions in treatment of HCV

Active tuberculosis:

Some medications used to treat active tuberculosis, such as rifampin, a first-line TB medication, interact with first-line DAAs. Such cases should be discussed by the TB and VH national program for regimen formulation. Consideration should be made to treat TB first because active TB is a public health risk and can progress quickly, requiring immediate and effective treatment.

Epilepsy:

Co-administration DAAs with certain anti-epileptics is contraindicated due to concerns of subtherapeutic DAA levels that can lead to treatment failure and viral resistance.

For conditions where drug interactions exist, consult a specialist. Checking drug interaction prior to HCV treatment should be done using the following tool: https://www.hep-druginteractions.org/checker

Pregnancy:

Pregnancy may represent a unique opportunity to identify and treat those with chronic HCV infection, particularly for those who otherwise do not regularly engage in healthcare. Further, achievement of HCV cure either during pregnancy or in the post-partum period will help to eliminate risk of current and future mother-to-child transmission. Current guidance does not endorse routine treatment of HCV during pregnancy, but it can be considered on a case-by-case basis in consultation with a specialist.

Table 4.19: Potentially significant drug interactions of sofosbuvir

Drug Name	Effects on concentration	Clinical comment
Anticonvulsants: carbamazepine, phenytoin, Phenobarbital, oxcarbazepine	↓ sofosbuvir	Co administration is not recommended. Change anticonvulsant therapy
Antimycobacterials: rifabutin, rifampicin, rifapentine	↓ sofosbuvir	Co administration is not recommended. Change anticonvulsant therapy
HIV Protease Inhibitors (e.g. atazanavir, lopinavir, darunavir, ritonavir)	↓ sofosbuvir	Sofosbuvir alone is safe with HIV protease inhibitors. But Co-administration is contraindicated when sofosbuvir is combined with velpatasvir.

Table 4.20: Potentially significant drug interactions of daclatasvir

Drug Name	Effects on concentration	Clinical comment
NNRTIs: Efavirenz, Nevirapine	↓ Daclatasvir	The dose of daclatasvir should be increased to 90mg if administered with efavirenz or nevirapine
HIV Protease Inhibitors: Atazanavir, Ritonavir, Saquinavir, Tipranavir, Indinavir, Fosamprenavir	↑ Daclatasvir	The dose of daclatasvir should be reduced to 30mg
HIV Protease Inhibitors: Darunavir/ ritonavir Lopinavir/ritonavir	(potentially ↑ Daclatasvir)	No dose modification
Antifungals: Ketoconazole	↑ daclatasvir	The dose of daclatasvir should be reduced to 30mg
Anticonvulsants: carbamazepine, phenytoin, Phenobarbital, oxcarbazepine	↓ daclatasvir	Co-administration is contraindicated Change anticonvulsant therapy

4.7.6 Monitoring of Hepatitis C Treatment

Patients enrolled into treatment should have HCV viral load done at baseline and 12 weeks after completion of treatment. Treatment success, or HCV cure, is reflected in a sustained virological response (undetectable viral load) at 12 weeks after treatment - SVR12.

Note: If a loss to follow up is anticipated, virological response can be assessed at 4 weeks after treatment as an undetectable viral load -SVR4 has been shown to correlate well with SVR12 in >99% of the patients without cirrhosis or prior DAA exposure.

4.7.7 Retreatment Following Treatment failure

Sofosbuvir/velpatasvir/voxilaprevir is generally considered for use in the retreatment of HCV-infected persons who previously failed a DAA regimen. Where not available, it is recommended the regimen should be constructed in consultation with an infectious disease specialist or hepatologist.

For those who do not have viral suppression 12 weeks after treatment, it is recommended to perform drug resistant testing. The regimen should be constructed based on the resistant pattern in consultation with a specialist.

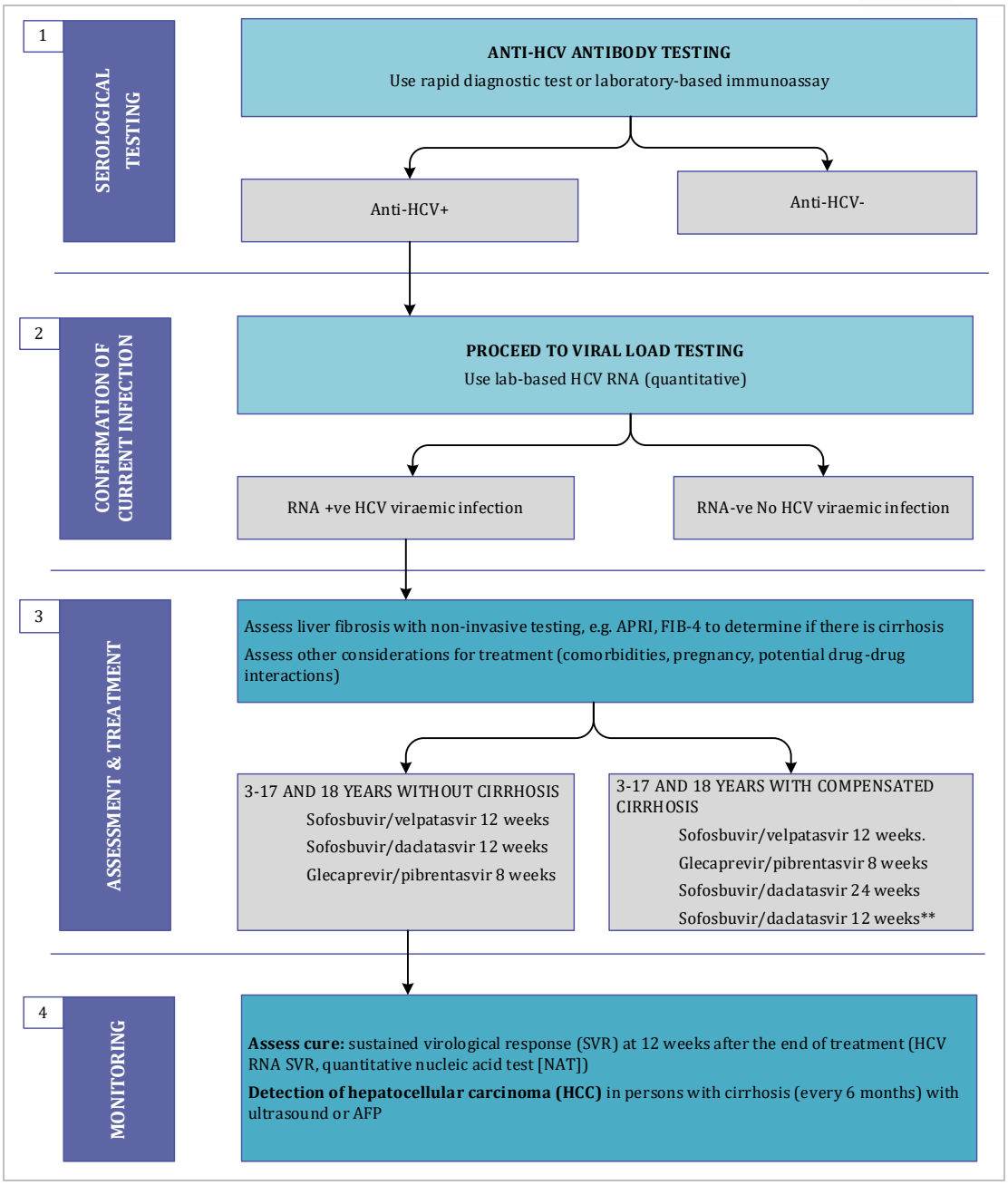


Figure 4.2: Algorithm for diagnosis, treatment and monitoring HCV infection in adults, adolescents and children >3years

4.8 Hepatitis D Virus (HDV)

Hepatitis D virus (HDV) is a ribonucleic acid (RNA) virus that requires hepatitis B virus (HBV) for its replication and therefore occurs simultaneously or as super-infection in individuals with HBV infection.

In Kenya, the true burden of HDV remains unknown due to limited surveillance data and may be underdiagnosed among individuals with chronic HBV infection HBV immunization programs have resulted in a decline in hepatitis D incidence worldwide

4.8.1 Clinical Course, Diagnosis and Management of Hepatitis D Virus (HDV) Infection

Table 4.21: Clinical Course, Diagnosis Course, Diagnosis and Management of Hepatitis D

Category	Description	Key Clinical Actions
Diagnosis	All HBsAg-positive individuals should be screened for anti-HDV IgM/IgG. Positive antibody tests should be confirmed with HDV RNA PCR to assess active infection.	Refer samples to central labs; ensure pre- and post-test counselling.
Monitoring and Surveillance	Chronic HDV requires lifelong follow-up. Cirrhotic patients need HCC screening every 6 months (ultrasound ± AFP).	Integrate HDV care with HBV programs; include in cancer surveillance.
Treatment Options	Pegylated Interferon-α (PEG-IFNα): Only approved antiviral for HDV, with modest response rates. Nucleotide analogues (e.g., tenofovir, entecavir): Used to suppress HBV but do not directly affect HDV. ***Emerging therapies:*** Bulevirtide (entry inhibitor) is approved in some countries and shows promising efficacy. ***Liver transplantation:*** Considered for patients with decompensated cirrhosis or end-stage liver disease.	Consider PEG-IFNα in eligible patients with careful monitoring. Continue HBV antiviral therapy to control co-infection. Refer to national referral centres for emerging therapies or transplant evaluation.

SPECIAL POPULATIONS

5.1 Key and Vulnerable Populations (KVPs)

Key populations are groups at increased risk of HIV, Hepatitis B and C, and sexually transmitted infections (STIs) due to higher-risk behaviours and legal or social barriers that limit access to health services leading to delayed diagnosis and treatment. Vulnerable populations face heightened risk mainly due to social, structural, or economic factors.

Table 5.1: Key and vulnerable populations in Kenya

Key Populations	Vulnerable population
• Men who have sex with men (MSM) • Sex workers (FSW AND MSW) • People who inject drugs (PWID) • Transgender people	• Truck drivers, • Fisher forks • People in prison setting • Discordant Couples (DC)

Implementation Strategies for KVP Programming

KVP programming strategies include the following:

- **Hotspot Mapping and Size Estimation:** Identify locations where key populations gather, estimate their numbers, and use this data to plan targeted services.
- **Needs Assessment:** Engage KPs at mapped sites to identify their needs and inform program design, conducted annually using a standard tool.
- **Peer Education:** Train and support community members to promote healthy behaviours among their peers.
- **Outreach and Microplanning:** Deliver targeted services, including HIV, sexually transmitted infections (STIs), and Hepatitis screening, through structured outreach to improve access and health outcomes.
- **Community lead monitoring**

Service Delivery Approach For KVP

Every contact with a KVP is an opportunity to screen and link to prevention and treatment services. It's recommended that HIV, viral hepatitis, and STIs services be delivered through tailored, stigma-free, and integrated models to reduce disparities in health outcomes. Evidence-based interventions should be provided as comprehensive packages with strong referral and linkage systems in place. Integrated programmatic priorities for KVPs are as described in table 5.2.

Table 5.2: Integrated programmatic priorities for KVPs

Integrated Programmatic Priorities	Implementation Strategies	Rationale
Differentiated Service Delivery (DSD)	Provide services via outpatient integration model, co-location of services, health workforce integrated models, outreach clinics, mobile units, outreach peer-led models, stand-alone health facility based models, drop-in centres, and community sites; guided by hotspot mapping and microplanning.	Increases access, reduces travel barriers, and brings services closer to KVPs in underserved or high-burden areas.
Combination Prevention	Offer condoms, PrEP, PEP, PMTCT, male circumcision, vaccinations (Hepatitis B vaccine, HPV vaccine), needle/syringe programs, health education, and psychosocial support.	Reduces new infections through layered, comprehensive prevention
Service Integration	Provide HIV, hepatitis, and STIs services at one point, alongside ART, MAT, STIs treatment, and family planning.	Improves early detection, continuity, efficiency, and uptake of care
Peer Navigation and Support	Engage trained peer educators and navigators to build trust, improve service uptake, support adherence to ART, viral hepatitis therapy, and STIs treatment, and enhance retention and re-engagement in care.	Improves adherence and health outcomes through community trust and peer-led support.
Structural Interventions	Address stigma, discrimination, and legal barriers through community sensitization, healthcare worker training, legal reform, economic empowerment, and violence prevention, discrimination of oppressive laws, Program sustainability	Promotes dignity, reduces access barriers, and supports sustainable engagement with health services.
Community Engagement	Ensure KVP-led organizations are actively involved in planning, implementing, and evaluating programs.	Enhances trust, accountability, and sustainability of interventions tailored to KVP needs.

Interventions for Key and Vulnerable Populations should focus on biomedical, behavioural and structural areas. The table below describes each in detail.

Table 5.3: Interventions for Key and Vulnerable Populations

Interventions for Key and Vulnerable Populations	
Biomedical Interventions	• HIV Testing services (HTS) • Post-Exposure Prophylaxis (PEP) • Pre-Exposure Prophylaxis (PrEP) • STI screening and treatment • TB screening, referral and treatment • HIV care and treatment • Drug related referral for detoxification and treatment, • Screening, referral and treatment for hepatitis • Reproductive health services (family planning, and cervical cancer Screening) • Prevention of vertical transmission (PMTCT) • Male and female condoms and lubricants • Vaccination, diagnosis and treatment of viral hepatitis • Mental Health and Psychosocial Support • Needle and syringe programs (NSPs)
Behavioural interventions	• Peer education and outreach • Health Education • Social and behaviour change communication (SBCC) • Evidence-based behaviour changes interventions • Risk assessment, risk reduction counselling and skills building to negotiate for safer sex. • Mental Health education and referrals
Structural interventions	• Reduction of stigma and discrimination • Advocacy interventions for policy/program/service changes • Promotion of social cohesion and development of leadership skills • Economic empowerment • Stakeholder engagement • Prevention and response to Violence and police harassment

Comprehensive Packages for HIV Prevention and Treatment among Key and Vulnerable Populations

Table 5.4: Comprehensive Packages for HIV Prevention and Treatment among KVPs

Intervention	Recommendations
HIV testing services	• Offer HIV testing services and link to appropriate HIV services depending on the test outcomes. • Retest KP every 3 months • Retest VP every 6 months • Integrate HIV self-testing at every service delivery point
Correct and effective messaging	• Offer targeted SBCC for each respective sub-population typology
Safer sex practices and SRH services	• Counsel on correct and consistent use of condoms including use of condom-compatible lubricants and contraceptives to prevent unintended pregnancies • Offer condoms and lubricants • Offer additional contraceptives as appropriate
Prevention and treatment of sexually transmitted infections	• Offer routine Screening, diagnosis, treatment, and prevention of STIs as part of comprehensive HIV prevention and care for KVPs. • HIV Prevention technologies such as DVR, CAB -LA and LEN
Prevention, diagnosis, and treatment of TB	• Screened for TB at every contact • Offer TPT to those eligible • Offer treatment to KVP with active TB
Prevention, vaccination, diagnosis, and treatment for viral hepatitis among the PWIDs	Harm reduction and behavioural interventions are also effective in reducing risk of infection/transmission of HBV and HCV. • Facilitate peer to peer support to people who inject drugs to reduce the incidence of viral hepatitis • Screen for HBV and HCV at first contact • Offer HBV vaccine for Hepatitis B negative PWID as recommended in table 1.47 of this guideline. • Offer treatment to clients with HBV/HCV infection **Note:** PWIDs have disproportionately higher incidences of hepatitis B and C due to overlapping factors.
Needle and syringe programmes (NSPs) for PWIDs	• Offer/link all PWIDs to safe needle and syringes
Opioid substitution therapy (OST)	• Identify and link all PWID who have opioid dependence for opioid substitution therapy • Provide intensive support to PWID with opioid dependence and living with HIV, including daily observed therapy and access to OST. • All PWID should be initiated the appropriate OST medication • For more details refer to the MAT guideline
Antiretroviral therapy	• Offer/link all HIV positive KVP to ART services

Intervention	Recommendations
	• HBV/HIV co-infected PWID should be started on TDF- or TAF-containing ART (the current recommended initial regimen is TDF/3TC/DTG) in addition to harm-reduction interventions to optimize adherence and treatment outcomes • Closely monitor ART in PWIDs to manage drug interactions and prevent renal or liver toxicity. • Provide PrEP negative partners of KVP living with HIV
Community outreach	• Conduct outreach from facilities or in collaboration with community-based groups to deliver harm-reduction, HIV treatment, and prevention services. • Implement peer-led, community-based approaches to improve adherence and retention in care.

5.2 Adolescents and Young People (AYP)

Adolescents and young people (10–24 years) face heightened risk of HIV, Hepatitis B, and STIs such as Human papillomavirus (HPV) due to biological susceptibility, limited access to age-appropriate services, stigma, poverty, harmful gender norms, and exposure to sexual and gender-based violence.

In Kenya, AYP, particularly adolescent girls and young women, experience high rates of new HIV infections. The burden of STIs and viral hepatitis among this population is also of growing concern, yet routine screening and access to prevention services remain limited. Many adolescents lack the autonomy or support to seek care and often delay accessing services. This gap presents a missed opportunity for early intervention and prevention.

Programs must be adolescent and young people-responsive, confidential, inclusive, and delivered in safe, supportive, and non-judgmental settings, with meaningful engagement of AYP. Programmatic Priorities for AYP are as described in table 5.5

Table 5.5: Integrated HIV, Viral Hepatitis, and STI Programmatic Priorities, Strategies, and Rationale for Adolescents and Young People

Integrated Programmatic Priorities	Implementation Strategies	Rationale
Adolescent and young people-responsive Differentiated Service Delivery (DSD)	• Deliver services in AYP-friendly clinics, schools, community centres, mobile units, and digital platforms. • Offer flexible hours and integrate services with 2022education and social support.	Increase service accessibility, confidentiality, and acceptability among young people.
Integrated Service Delivery	• Co-locate HIV, hepatitis B, and STI prevention and treatment services. • Include contraception, mental health, and HPV vaccination. • Screen for HIV, STIs and Hepatitis B	Promotes early detection, continuity of care and reduces stigma by normalizing AYP health services.

Integrated Programmatic Priorities	Implementation Strategies	Rationale
Age-appropriate Comprehensive Sexuality Education (CSE)	• Provide accurate, age-appropriate information on sexuality in and out of school.	Empowers AYP with knowledge and skills to make informed decisions and reduce risk behaviours.
Combination Prevention	• Distribute condoms, PrEP, PEP, hepatitis B and HPV vaccines • Offer safer sex counselling, HIV self-testing, and STI screening.	Reduces new infections through diverse, layered approaches tailored to young people's needs.
Mental Health and Psychosocial Support	• Incorporate screening for depression, anxiety, and substance use. • Provide referrals or onsite counselling.	Addresses the psychological challenges that can hinder adherence and health-seeking behaviours.
Youth Participation and Peer Support	• Involve AYP in program planning, implementation, and peer education. • Train peer navigators to support care linkage.	Builds trust, increases uptake and retention, and ensures services are relevant and AYP informed.

Table 5.6: Integrated HIV, Viral Hepatitis, and STI Programmatic Priorities, Strategies, and Rationale for Adolescents Girls and Young Women

Priority Area	Implementation Strategies (AGYW-specific)	Rationale / Expected Outcomes
GBV Prevention & Response (integrated into HIV/STI services)	Screen routinely for GBV at entry points; provide on-site or fast-track referral to psychosocial, legal, and safe shelter services; train providers in confidential, trauma-informed care; set up anonymous reporting and linkage with community protection services.	Early identification and response reduces ongoing risk, improves retention in HIV care, and supports mental health and adherence.
Economic Empowerment & Social Protection	Link AGYW to cash-transfer programs, vocational training, microfinance, conditional education stipends and job-readiness programs; integrate livelihood counselling into clinics and community hubs.	Reduces transactional sex and dependence that increase HIV/STI risk; improves autonomy and retention in care.
Adolescent Pregnancy Care (integrated MCH & HIV services)	Provide one-stop ANC/postnatal care with HIV testing, PMTCT, family planning counselling, and postpartum support; ensure	Improves maternal and infant outcomes, reduces vertical transmission, and maintains continuity of HIV care for AGYW.

Priority Area	Implementation Strategies (AGYW-specific)	Rationale / Expected Outcomes
	adolescent-friendly delivery and breastfeeding counselling; link to parenting programs.	
Digital Health Tools & Confidential Platforms	Scale secure telehealth, SMS reminders, appointment booking apps, anonymity-preserving chatbots for counselling, e-mLearning for comprehensive sex education, and digital cash transfers for incentives.	Enhances reach, maintains confidentiality, improves adherence, supports remote follow-up, and engages digitally connected AGYW.
School Retention & Education Linkages	Partner with education sector to provide conditional cash transfers, keep girls in school campaigns, menstrual health support, flexible scheduling for clinic visits, and on-site SRH services.	Education reduces HIV risk, supports economic opportunities, and improves long-term health outcomes.
Clinical HIV Prevention & Treatment	Prioritize PrEP delivery through youth-friendly sites, facilitate same-day ART, integrate FP and STI care, and use peer navigators for retention.	Directly reduces incidence and ensures continuity of care tailored to AGYW needs.
Mental Health & Psychosocial Support (tailored)	Provide trauma-informed counselling, support groups for young mothers and survivors of GBV, and link to psychiatric care when needed.	Addresses co-morbidities that impair adherence and engagement with services.

5.3 People in Humanitarian and Emergency Settings

Kenya's frequent humanitarian crises such as droughts, floods, conflicts, and displacement disrupt HIV service delivery, increasing vulnerability among women, adolescents, and displaced populations. To ensure continuity of care, HIV services must be integrated into emergency response plans, with equitable access for refugees and IDPs, and linked to other sectors for holistic support. Healthcare workers should pre-position ART, provide multi-month refills, use mobile and digital platforms, and establish cross-border referral systems.

Community health workers and peer educators play a vital role in tracing clients and supporting youth-friendly, stigma-free services. Strong coordination with government, NGOs, and humanitarian actors, coupled with sustainable financing and innovative solutions such as telemedicine, drones, and community dispensing points, is essential. Above all, healthcare workers must prioritize continuity of ART, community engagement, and multi-sectoral collaboration to ensure that no client is left behind during emergencies.

5.4 People who inject drugs (PWID)

Table 5.7: People who inject drugs (PWID)

Domain	Key Components	Notes
Guiding Principles	Rights-based care; harm reduction; integration; low-threshold access; peer involvement; gender-responsive services	Deliver services without stigma, discrimination, or punitive barriers; prioritize confidentiality and inclusiveness
Needle & Syringe Programs (NSPs)	Provide sterile needles/syringes, swabs, sharps bins, disposal	Free, anonymous access via Drop-In Centres (DICs), outreach, peer-led sites; safer injecting education
Opioid Substitution Therapy (OST/MAT)	Methadone or other medication-assisted treatment	Provide integrated HIV, hepatitis, SRH, and mental health services at OST clinics; support retention
HIV Testing & Prevention	HTS, self-testing, ART, PrEP	Routine testing at all contact points; immediate ART when needed; PrEP for HIV-negative PWID
Viral Hepatitis (HBV/HCV)	Screening, HBV vaccination, treatment of infected persons	Screen all PWID at first contact; vaccinate HBV-negatives; provide or link HCV-positives to treatment
STI Services	Screening and treatment of STIs, partner services	Routine STI screening and treatment in all PWID service settings
TB Services	Screening, TB preventive therapy, treatment	Integrate TB screening and referral into PWID platforms
Overdose Prevention	Education, safer-use messaging, naloxone distribution	Provide overdose training; distribute naloxone where allowed; establish emergency referral pathways
Mental Health & Psychosocial Support	Screening, counselling, referral for care if needed	Address depression, anxiety, trauma, and substance-use disorders; deliver trauma-informed care
Wound & Vein Care	Basic wound management, hygiene supplies	Provide wound/abscess care and refer severe cases
Condom/Lubricant Distribution	Condoms and lubricants	Continuous availability for PWID and partners
Peer-led Outreach & Navigation	Peer educators, linkage to services	Support case finding, linkage, adherence, retention, and follow-up
IEC & Behavioural Interventions	Safer injecting, safer sex, education on hepatitis and overdose	Provide tailored harm-reduction information across all platforms
Service Delivery Models	DICs, OST clinics, mobile outreach, facility integration, peer-led delivery, WUID-focused services	Use multimodal, flexible delivery platforms to reach diverse PWID groups

Domain	Key Components	Notes
Structural & Enabling Interventions	Stigma reduction, rights protection, legal aid, safe spaces, sensitization of law enforcement agencies	Remove punitive/legal barriers; strengthen trust and safety; engage community networks
Monitoring & Evaluation	NSP coverage, OST retention, HIV/HBV/HCV indicators, STI/TB outcomes, overdose data, peer outreach metrics	Integrate indicators into national KP dashboards; track service quality and outcomes
Referral Pathways	ART, hepatitis care, TB services, mental health, emergency care, GBV services	Maintain updated county-level mapping of referral networks

MONITORING EVALUATION SURVEILLANCE AND DATA SYSTEMS

6.1 Purpose and Scope

This section provides national standards and operational guidance for implementing integrated monitoring, evaluation, surveillance, and data systems for HIV, sexually transmitted infections (STIs), and viral hepatitis programs in Kenya. It establishes the framework for collecting, analyzing, and using data to track progress toward national and global targets, inform evidence-based decision-making, and ensure accountability across all levels of the health system.

6.2 Guiding Principles

The implementation of integrated M&E and surveillance systems shall be guided by the following principles:

1. **Integration First:** Data systems shall be designed to support and measure integrated service delivery across HIV, STIs, and viral hepatitis.
2. **Person-Centered:** Systems shall capture the holistic health journey of individuals across multiple conditions and services.
3. **Digital by Design:** Digital tools and electronic systems shall be prioritized to enhance data quality, timeliness, and utility.
4. **Evidence-Driven:** Data shall be systematically used for disease surveillance, program monitoring, inform policy, program planning, and quality improvement.
5. **Accountability and Transparency:** Data shall be accessible to relevant stakeholders, including communities, to foster accountability.
6. **Sustainability:** Systems shall be designed with long-term maintenance, capacity building, and resource allocation in mind.

6.3 Digital Health Systems and Electronic Medical Records

All health facilities providing HIV, STI, or viral hepatitis services shall implement or transition to interoperable electronic medical record (EMR) systems that integrate data across these conditions. EMR systems shall employ data minimization principles, collecting only essential indicators required for clinical care, program monitoring, and national reporting. Priority shall be given to digitizing Maternal and Child Health Services (MCHS) to support tracking of triple elimination indicators and mother-baby pair monitoring.

Clinical decision support functionalities shall be embedded within EMRs to alert healthcare providers about required screenings, tests, vaccinations, and follow-ups for HIV, STIs, and viral hepatitis. Machine Learning models and AI agents will be used for individual and population level predictive features to improve health at an individual and population level. Laboratory information systems shall be integrated with EMRs to ensure electronic transmission of test results, including Early Infant Diagnosis, viral load, CD4, STI NAATs, and hepatitis serology.

Telemedicine platforms shall be integrated to support differentiated service delivery models, particularly for stable patients on multi-month dispensing, PrEP users, and persons living with chronic viral hepatitis, with all consultations documented within EMR systems.

6.4 Integrated Surveillance Systems

6.4.1 Case Surveillance and Mandatory Reporting

All healthcare facilities shall implement systematic case surveillance for HIV, reportable STIs, and viral hepatitis. Mandatory reporting of minimum dataset elements from EMRs to the national surveillance system shall be required for all confirmed cases, including diagnosis date, demographic information, treatment initiation, and key clinical outcomes. The minimum dataset for case reporting shall include but not limited to: unique patient identifier, age, sex, geographical location, diagnosis date, test type, treatment initiation status, laboratory information, and relevant clinical outcomes. Facilities shall ensure complete and accurate reporting of these elements through automated extraction from EMR systems where available, or through standardized manual reporting mechanisms where digital systems are not yet implemented. Case surveillance will form core strategy for monitoring HIV, STIs and VH epidemics, transmission and programmatic gaps. Using fully digitized health facilities and the full potential of individual level data in centralized data repositories, case surveillance strategy will enable addressing innumerable questions from effectiveness of biomedical prevention interventions, mother to child transmission of HIV, to mortality and causes of death.

6.4.2 HIV Incidence Surveillance through Use of Recency Assays

Recency assays shall be integrated into antenatal and postpartum HIV screening to understand incidence among pregnant and postpartum women and guide targeted interventions.

6.4.3 HIV Drug Resistance Surveillance

Routine HIV drug resistance surveillance shall be conducted through systematic sampling of patients with confirmed treatment failure, those exposed to integrase inhibitor-based regimens and in future, for those on long term PrEP molecules.

6.4.4 STI Surveillance

STI surveillance shall transition from syndromic to etiologic reporting where laboratory capacity exists, with priority given to monitoring *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and antimicrobial resistance patterns.

6.4.5 Viral Hepatitis Surveillance

Viral hepatitis surveillance shall be integrated into the national Integrated Disease Surveillance and Response (IDSR) system, with mandatory reporting of confirmed HBV and HCV cases.

6.4.6 Integrated Biological and Behavioural Surveillance

Integrated biological and behavioural surveillance shall be conducted periodically among key populations to inform combination prevention strategies.

6.4.7 Integrated population-based surveys

To understand health in populations outside of the walls of a health facility, periodic integrated surveys will be conducted either using national survey methods such as the Demographic and Health Surveys or focused surveys based on specific health issues or in a specific geography (e.g., national integrated HIV, TB, Malaria surveys within a DHS or surveys to obtain population-based measurement of mother to child transmission of HIV to measure progress towards elimination of MTCT).

6.4.8 Use of Emergency Operations Centers for Coordinating Public Health Response

Public health response based on case surveillance and HIV incidence signals will form the core strategy for monitoring the HIV, STI and VH epidemics, programmatic gaps and provide the framework for addressing these gaps. Using the Emergency Operations Centers (EOCs) for coordinating response activities enables a unified platform for data consumption, communication and coordination across multi-disciplinary response teams and addressing the gaps in a near real-time manner.

6.5 Unified Monitoring and Evaluation Framework

A standardized set of core indicators shall be used across HIV, STI, and viral hepatitis programs to monitor integration, coverage, and outcomes. Data collection tools and reporting formats shall be harmonized to minimize duplication and reduce the reporting burden on healthcare workers. Health facilities shall implement automated indicator reporting systems that extract data directly from EMRs to generate routine program reports, reducing manual compilation errors and improving reporting efficiency.

Integrated dashboards shall be developed at facility, county, and national levels to provide real-time visualization of program performance and co-infection trends. Routine data quality assessments shall be conducted quarterly at all service delivery points to ensure accuracy, completeness, and timeliness of data.

6.6 Data use and Accountability Mechanism

Program performance review meetings shall be conducted routinely at facility, sub-county, and county levels to analyze data, identify bottlenecks, and plan corrective actions. Community-led monitoring shall be institutionalized, with trained community representatives participating in data validation, facility assessments, and performance reviews.

Community feedback mechanisms, including scorecards and client satisfaction surveys, shall be integrated into routine M&E activities. Data shall be disaggregated by age, sex, key population, pregnancy status, and geographic location to monitor equity in service access and outcomes.

6.7 Institutional Arrangements and Capacity Building

Integrated M&E technical working groups shall be established at national and county levels to provide oversight and coordination of data systems. The Ministry of Health shall develop and implement e-learning modules on integrated data management, digital tool utilization, and evidence-based decision making for healthcare workers at all levels. These modules shall be

accessible through national digital health platforms and integrated into continuous professional development programs to enable efficient, scalable capacity building.

Sustainable financing shall be secured for digital infrastructure, system maintenance, and human resources to ensure long-term functionality of integrated data systems. Partnerships with academic institutions, research organizations, and technology providers shall be strengthened to support innovation and continuous improvement of M&E systems.

6.8 Research and Evaluation

Operational research shall be conducted on emerging priorities, including integrated service delivery models, STI management approaches, and hepatitis elimination strategies. Findings from research and evaluations shall be systematically translated into updated guidelines, training materials, and program adaptations.

Predictive analytics and geographic mapping tools shall be utilized to identify coverage gaps, forecast commodity needs, and optimize resource allocation. Research on digital health innovations, including telemedicine and mHealth interventions, shall be encouraged to build evidence for scalable technology-enabled service delivery models.

6.9 Monitoring and Reporting

All facilities shall submit integrated monthly, quarterly, and annual reports through the Kenya Health Information System (KHIS) or designated digital platforms. Data shall be reported according to national timelines, with facilities submitting reports by the 5th of each month for the preceding month. Regular data audits and validation exercises shall be conducted to ensure reporting compliance and data accuracy.

Automated data quality checks shall be built into reporting systems to flag inconsistencies, missing data, and outliers for immediate corrective action. Facilities shall maintain backup systems and data recovery protocols to prevent loss of essential health information.

6.10 Reference and Related Documents

- Kenya Health Information System Policy
- National Digital Health Strategy
- Kenya HIV Prevention and Treatment Guidelines (previous editions)
- WHO Global Health Sector Strategies on HIV, Viral Hepatitis, and STIs
- Kenya National Guidelines for Community Health Services
- Kenya Telemedicine Guidelines and Standards
- Kenya Health Information System Policy
- National Digital Health Strategy
- Kenya HIV Prevention and Treatment Guidelines (previous editions)
- WHO Global Health Sector Strategies on HIV, Viral Hepatitis, and STIs
- Kenya National Guidelines for Community Health Services
- Kenya Telemedicine Guidelines and Standards

ANNEXES

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

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

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

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

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

Annex 3: DSD Models for Children, Adolescents, Adults and Pregnant and Breastfeeding Women

Population / Group	DSD Model Adaptations (Established vs Unestablished)	Package of Services	Eligibility	Integration Points (STI, Viral Hepatitis, RH, GBV, TB)	Follow-Up / Review Frequency
Children 0–9 years	Established: Family-centred model with synchronized caregiver–child visits (PAMA); community refill/MMD (PAMA); school-calendar alignment; Unestablished: Facility-based frequent reviews; PAMA case management; home visits if needed.	Standard package of care including; Prevention: caregiver education, OI prevention drugs as indicated, vaccination (incl. HBV). Testing: EID and repeat testing per national algorithm, facility /community based HTS as indicated / recommended Treatment/continuity: paediatric ART with weight-band dosing, adverse-event checks, age-appropriate disclosure support at each visit/contact. Viral suppression: routine VL per schedule; trigger EAC if VL ≥200 c/mL. Co-infections: HBV vaccination catch-up; TB symptom screen each visit and TPT when eligible.	Established: On ART with evidence of treatment success (≥1 suppressed VL in past 6 months), no current illness needing intensive monitoring. Unestablished: New ART start, no suppressed VL yet/known, OIs, toxicity, growth faltering or adherence challenges.	HBV vaccination, GBV/safety check where indicated, TB symptom screens each visit; link to nutrition and social services.	Established: 3 monthly clinical review. Unestablished: 1–2monthly (or more frequent) until stable /suppressed. VL: 3 months post-initiation, then every 6 months. MMD: up to 3-month refills when stable; monthly–2-monthly if unestablished.
Adolescents 10–14 years	Established: Adolescent-friendly clinic hours/spaces; peer-supported (e.g., OTZ, teen/youth clubs); community refills; school-holiday clinics.	Standard package of care including; Prevention: condoms, SRH education, VMMC (boys), risk-reduction counselling. Testing: periodic HIV re-testing for at-risk negatives (siblings/ partners as appropriate), STI screening. Treatment/continuity: age-	Established: Established: Suppressed VL within past 6 months; clinically stable. Unestablished: New initiators; VL unsuppressed/unknown;	Routine STI screen & treatment; HPV vaccination; RH (menstrual health, contraception counselling);	Established: 3 monthly clinical review. Unestablished: 1–2monthly (or more frequent) until stable /suppressed. VL: 3 months post-initiation, then every 6 months.

Population / Group	DSD Model Adaptations (Established vs Unestablished)	Package of Services	Eligibility	Integration Points (STI, Viral Hepatitis, RH, GBV, TB)	Follow-Up / Review Frequency
	Unestablished: OTZ more frequent facility reviews with intensified EAC Facility based adherence support groups peer mentor support	appropriate counselling, regimen optimization, age-appropriate disclosure, transition planning. Viral suppression: routine VL and targeted adherence support if VL ≥200 c/mL. Co-infections: routine STI testing/treatment; HPV vaccination.	psychosocial/adherence challenges.	GBV screening/support; TB screen each visit.	MMD: up to 3-month refills when stable; 1–2-monthly for unestablished. Scale youth-friendly/peer DSD models for established.
AYPs 15–24 years	Established: Youth-friendly services; OTZ; blended facility–community refills; digital/SMS reminders; peer navigators. Unestablished: Facility-based frequent reviews with EACs; OTZ case management;	Standard package of care including; Prevention: condoms, PrEP for HIV-negative at-risk peers, substance-use risk reduction. Testing: routine STI (incl. syphilis) screening and HIV testing for at-risk negatives/partners. Treatment/continuity: ART optimization, side-effect management, life-skills training. Viral suppression: routine VL and EAC for elevated VL. Co-infections: HBV vaccination/testing as indicated; STI diagnosis/treatment.	Established: WHO "established on ART" definition met. Unestablished: new ART start, VL unsuppressed or unknown, significant psychosocial instability.	Quarterly STI screening where feasible; HBV vaccination/testing; RH services (contraception, pregnancy testing), GBV screening/support, TB screen each visit; linkage to education /employment services.	Established: 3–6-monthly reviews; 3–6-month refills depending on supply. Unestablished: 1–3-monthly until stable; Increase frequency if VL ≥200 c/mL. VL: 3 months post-initiation, then every 6 months (age 0–24). MMD: 3–6-month refills for stable AYPs where supply allows; 1–2-monthly if unestablished.
Pregnant & Breastfeeding AYPs (10–24 years)	Established: Integration of OTZ Plus (adapted for PBFW adolescents	Standard package of care including; Prevention: partner testing & PrEP for HIV-negative partners; condoms; SRH counselling.	Established: Suppressed VL; no conditions needing intensive monitoring; stable on ART. Unestablished:	ANC/PNC services including; HIV–syphilis–HBV testing & treatment;	VL: At confirmation of pregnancy or breastfeeding if already on ART, then every 6 months. If initiating ART baseline VL, at 3

Population / Group	DSD Model Adaptations (Established vs Unestablished)	Package of Services	Eligibility	Integration Points (STI, Viral Hepatitis, RH, GBV, TB)	Follow-Up / Review Frequency
	and young women) within ANC/PNC visits; peer mother /adolescent mentor support; AGYW friendly services/safe spaces/days synchronized mother–infant visits Unestablished: OTZ Plus; Frequent facility reviews with EAC peer mentor follow-up; close clinical monitoring during pregnancy/postpartum. Case management	Testing: Triple elimination (HIV, syphilis, HBV) in ANC/PNC; repeat maternal HIV VL and infant EID. Treatment/continuity: OTZ Plus support for disclosure, adherence, and self-care skills; same-day ART start if new diagnosis; adherence and side-effect monitoring. Viral suppression: maternal VL per recommended schedule; intensified support for unsuppressed VL (for PBFW VL suppression cutoff should be 50 copies/ml). Co-infections: syphilis testing/treatment; HBV management with infant birth dose if HBsAg+.	Newly initiating ART in pregnancy/breastfeeding ; unsuppressed VL; psychosocial/adherence challenges.	RH counselling; GBV/IPV screening; TB screening; peer mentor/OTZ Plus linkage.	months, then every 6 months. MMD: 1–2-month refills initially; 3-month refills once stable.
Pregnant women (ANC)	Established: If already on ART and suppressed, integrate ART follow-up within ANC; appointment spacing where appropriate. Unestablished: Newly initiating ART in pregnancy or unsuppressed—	Standard package of care including; Prevention: partner testing & PrEP for HIV-negative partners; condoms. Testing: Triple elimination (HIV, syphilis, HBV) at ANC with immediate linkage. Treatment/continuity: same-day ART start for new diagnosis; regimen optimization; adherence /side-effects review.	Established: Suppressed VL; no conditions needing intensive monitoring; stable in pregnancy. Unestablished: Newly initiating ART in pregnancy; unsuppressed VL; intercurrent illness/complications.	ANC services including; HIV–syphilis–HBV testing & treatment; RH counselling; GBV/IPV screening; TB screen each visit; prioritize POC/priority lab for VL and EID in PBFW.	Established: Reviews aligned to ANC schedule; consider 1–3-month refills by stability. Unestablished: Monthly or more frequent until suppression; immediate EAC for high VL. VL: If already on ART—at confirmation of pregnancy, then every 6 months until breastfeeding ends; if

Population / Group	DSD Model Adaptations (Established vs Unestablished)	Package of Services	Eligibility	Integration Points (STI, Viral Hepatitis, RH, GBV, TB)	Follow-Up / Review Frequency
	closer clinical follow-up – Facility based frequent visits Facility-based support groups Case management	Viral suppression: VL per Kenya pregnancy algorithm with rapid action for viremia. Co-infections: treat syphilis; if HBsAg+, infant HBV birth-dose and maternal management per protocol.			initiating in pregnancy—VL at 3 months, then every 6 months. MMD: 1–3 months depending on stability and gestation.
Breastfeeding women (PNC)	Established: If suppressed postpartum, align ART with immunization visits; mother–infant pair clubs; community refills in targeted CARGs Unestablished: Unsuppressed or postpartum ART initiation—close facility follow-up. case management. Facility based support groups	Standard package of care including:- Prevention: condoms; partner testing; PrEP for eligible HIV-negative partners. Testing: repeat maternal HIV VL per schedule; infant testing/EID and repeat testing per breastfeeding algorithm; syphilis re-testing where indicated. Treatment/continuity: continued ART with adherence/toxicity checks; HEI prophylaxis as per national algorithm. Viral suppression: targeted EAC and rapid clinical action for maternal viremia. Co-infections: manage STIs; HBV infant birth-dose and series; maternal HBV care as indicated.	Established: WHO definition met postpartum with stable clinical status and suppressed VL. Unestablished: postpartum start or unsuppressed VL; intercurrent illness; adherence challenges.	PNC integrated services including; HIV–syphilis–HBV re-testing as indicated; RH/FP, GBV screening/support; TB screen each visit; linkage to nutrition and infant growth monitoring.	Established: 1–3-monthly early postpartum then spacing 3–monthly once stable; refills aligned to infant immunizations. Unestablished: Monthly (or more frequent) until suppressed and clinically stable. VL: If already on ART—VL at confirmation of breastfeeding, then every 6 months until breastfeeding stops; if initiated during breastfeeding—VL baseline, at 3 months, then every 6 months. MMD: 1–2 months early postpartum; expand to 3 months once stable; align refills to immunization schedule.

Population / Group	DSD Model Adaptations (Established vs Unestablished)	Package of Services	Eligibility	Integration Points (STI, Viral Hepatitis, RH, GBV, TB)	Follow-Up / Review Frequency
Adults ≥25 years (non-pregnant, non-breastfeeding)	**Established:** Fast-track refills (facility or pharmacy-only visits). Community ART refill models (CARGs), community pick-up points, DDD. Appointment spacing with de-linked clinical and refill visits. ART refills every 3–6 months (up to 6 months). Clinical review every 6–12 months (annual comprehensive review allowed in Kenya). **Unestablished:** Facility-based care with full clinical review. Monthly–2 monthly visits with intensive adherence counselling (EAC). Case management, home visits and closer monitoring as needed.	Standard adult HIV care including: **Prevention:** condoms, partner testing, safer conception counselling, PrEP referral for negative partners. **Testing & monitoring:** VL per Kenya adult algorithm; BP, BMI, glucose, renal function, lipids. **Treatment & continuity:** ART optimization (DTG-based), toxicity checks, adherence support. **Viral suppression:** routine VL; immediate EAC for VL ≥200 c/mL; failure evaluation if VL ≥1000 c/mL. **Comorbidities:** TB screening, HBV vaccination/testing, mental health, alcohol/substance use, NCD screening.	**Established:** WHO "established on ART" definition met. **Unestablished:** New ART start, VL unsuppressed or unknown, significant psychosocial instability.	**TB** symptom screen at every contact; TPT provision. **STI** screening and treatment; **HBV/HCV** testing and vaccination. **RH/FP and cervical cancer** screening where applicable. **GBV/IPV** screening and referral. **Integrated NCD care** (HTN, diabetes, mental health).	**Established:** Clinical review: every 6–12 months; ART refills: 3–6-monthly (up to 6 months Max); VL: 3 months post-initiation, 12 months, then annually if suppressed. **Unestablished:** Clinical review: monthly–2 monthly until stable; Refills: 1–2 monthly; Increase frequency if VL ≥200 c/mL.
Men (≥25 years)	**Established:** Male-friendly service models: Men-only clinic days/rooms/queues.	Standard adult HIV care including: **Prevention:** condoms, VMMC, partner testing, risk-reduction counselling.	**Established:** WHO "established on ART" definition met. **Unestablished:** New	**TB** screening and TPT. **STI** services; viral hepatitis testing/vaccination.	**Established:** Clinical review: 6–12 monthly (annual comprehensive review

Population / Group	DSD Model Adaptations (Established vs Unestablished)	Package of Services	Eligibility	Integration Points (STI, Viral Hepatitis, RH, GBV, TB)	Follow-Up / Review Frequency
	Extended hours (evenings/weekends), workplace/mobile outreach. Men-only CARGs and peer-led adherence clubs. Fast-track refills and community pick-up points. 3–6 month (up to 6 month) dispensing for stable men. **Unestablished:** Facility-based frequent reviews with intensified EAC. Targeted adherence and psychosocial support addressing masculinity norms, mobility, and substance use. Active follow-up for missed appointments.	**Testing & monitoring:** routine VL, STI screening (including urethral/rectal where indicated), HBV testing. **Treatment & continuity:** ART optimization; sexual health and relationship counselling. **Comorbidities:** HTN, diabetes, mental health, harmful alcohol use, prostate symptom screening.	ART start, VL unsuppressed or unknown, significant psychosocial instability.	**RH and fertility** counselling; partner services. **GBV** (as survivor or perpetrator)/mental health services. **Integrated NCD** screening and care.	where appropriate); ART refills: 3–6-monthly (up to 6 months); VL: annually if suppressed. **Unestablished:** Clinical review: monthly–2 monthly; Refills: 1–2 monthly with closer follow-up.
Older Adults ≥50 years	**Established:** Integrated HIV–NCD chronic care model with aligned visits/refills. Community or facility refills with synchronized ART + NCD medicines. 3–6 month ART refills with ≥6-monthly clinical review and	Standard adult HIV care including: **Prevention:** lifestyle counselling, tobacco/alcohol reduction, falls prevention. **Testing & monitoring:** VL per adult schedule; BP each visit; glucose, lipids, renal/liver function at least annually; depression and cognitive screening.	**Established:** WHO "established on ART" definition met. **Unestablished:** New ART start, VL unsuppressed or unknown, significant psychosocial instability.	**TB** screening and TPT. **STI and viral hepatitis** services where relevant. **Full NCD integration** (HTN, diabetes, mental health).	**Established:** Clinical review: at least 6-monthly with annual comprehensive review; ART refills: 3–6 monthly (up to 6 months) aligned with NCD meds where possible; VL: annually if suppressed.

Population / Group	DSD Model Adaptations (Established vs Unestablished)	Package of Services	Eligibility	Integration Points (STI, Viral Hepatitis, RH, GBV, TB)	Follow-Up / Review Frequency
	annual comprehensive assessment (HIV, NCDs, functional status). **Unestablished / Complex:** Clients with frailty, cognitive impairment, uncontrolled NCDs or frequent hospitalizations require shorter intervals (1–3 monthly). Enhanced medication review for polypharmacy and drug–drug interactions.	**Treatment & continuity:** ART optimization considering renal, bone and CV risk; adherence support for sensory or cognitive limitations. **Comorbidities:** HTN, diabetes, CKD, CVD, osteoporosis, chronic pain, malignancy screening.		**Cancer screening** (cervical, breast, prostate as per policy). **Elder abuse/GBV** screening and social protection referrals.	**Unestablished / Complex:** Clinical review: 1–3 monthly; Refills: 1–3 monthly; Increase visit frequency after clinical or NCD decompensation.

Annex 4. Routine Immunization Schedule in Kenya

Contact	Age of Child	Vaccine/Dose	Dosage	Route/Remarks
1	At birth or at first contact (within 2 weeks of life)	BCG	0.05 ml (<1 yr), 0.1 ml (>1 yr)	Intradermal
		OPV birth dose (bivalent)	2 drops	Oral
2	At 6 weeks (or after 6 weeks)	OPV 1	2 drops	Oral
		DPT-HepB+Hib 1	0.5 ml	Intramuscular, left thigh
		PCV10 – 1	0.5 ml	Intramuscular, right thigh
		Rotavirus – 1	0.5 ml (5 drops)	Oral
3	At 10 weeks (or 4 weeks after OPV 1)	OPV 2	2 drops	Oral
		DPT-HepB+Hib 2	0.5 ml	Intramuscular, left thigh
		PCV10 – 2	0.5 ml	Intramuscular, right thigh
		Rotavirus – 2	0.5 ml (5 drops)	Oral
4	At 14 weeks (or 4 weeks after OPV 2)	OPV 3	2 drops	Oral
		DPT-HepB+Hib 3	0.5 ml	Intramuscular, left thigh
		PCV10 – 3	0.5 ml	Intramuscular, right thigh
		IPV	0.5 ml	Intramuscular, right thigh (2.5 cm from PCV site)
		Rotavirus – 3	0.5 ml (5 drops)	Oral
5	At 6 months	Vitamin A	100,000 IU	Oral
		Measles-Rubella (special cases)[1]	0.5 ml	Subcutaneous, right deltoid
		RTS,S/AS01 (Malaria Vaccine – 1, high-risk counties)[2]	0.5 ml	Intramuscular, left deltoid
6	At 7 months	RTS,S/AS01 (Malaria Vaccine – 2, high-risk counties)	0.5 ml	Intramuscular, left deltoid

Contact	Age of Child	Vaccine/Dose	Dosage	Route/Remarks
7	At 9 months (or after 9 months)	Measles-Rubella 1st dose	0.5 ml	Subcutaneous, right deltoid
		IPV	0.5 ml	Intramuscular, right thigh
		Yellow Fever (high-risk counties)	0.5 ml	Subcutaneous, left deltoid
		RTS, S/AS01 (Malaria Vaccine – 3, high-risk counties)	0.5 ml	Intramuscular, left deltoid
8	At 12 months	Vitamin A	200,000 IU	Oral
9	At 18 months (or after 18 months)	Measles-Rubella 2nd dose	0.5 ml	Subcutaneous, right deltoid
		Vitamin A	200,000 IU (1 capsule)	Oral
10	At 24 months	RTS, S/AS01 (Malaria – 4, high-risk counties)	0.5 ml	Intramuscular, left deltoid
11	At 10 years (girls extend to 14 Years for catch up)	HPV Vaccine 1	0.5 ml	Intramuscular, left deltoid
12	1-2 months after initial dose	HPV Vaccine 2	0.5 ml	Intramuscular, left deltoid
13	At 10 yrs + 6 months (or 6 months after HPV 1)	HPV Vaccine 3	0.5 ml	Intramuscular, left deltoid

Notes:

Infection with HIV is not a contraindication to vaccination. In circumstances where the child's HIV status cannot be established, live vaccines should not be administered to children who are symptomatic for HIV infection

[1]All **asymptomatic** HIV infected children should receive BCG at birth

[2]Asymptomatic Children living with HIV and HIV-exposed Infants should receive Measles/rubella vaccine at 6 months, plus boosters at 9 and 18 months

[3] Children in malaria endemic counties should receive the full course of the Malaria vaccine. 8 endemic malaria counties are Kisumu, Homabay, Siaya, Migori, Vihiga, Kakamega, Busia, Bungoma

[4]Children in yellow fever endemic counties (Baringo, Elgeyo Marakwet, West Pokot and Turkana)

Annex 5: Paediatric Disclosure Procedure

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

Annex 6. HEADSSS Assessment Tool for Adolescents and Young Persons

H: Home and Environment	Who lives at home with you? How is your relationship with your family members? Are there any recent changes at home (e.g., moving, divorce, etc.)? Do you have your own space at home? Do you feel safe at home?
E: Education and Employment	Are you currently in school or employed? How are your grades or work performance? Do you enjoy school or work? Have you missed any days recently? If yes, why? What are your future goals in education or career?
A: Activities	What do you do for fun or relaxation? Are you involved in any sports, clubs, or hobbies? How do you spend time with friends? What do you do on weekends or after school/work?
D: Drugs and Substance Use	Have you ever tried smoking, alcohol, or drugs? Do any of your friends use substances? How often do you use any substances (if applicable)? Have you ever felt pressured to use drugs or alcohol?
S: Sexuality	Are you in a relationship currently? Have you ever been sexually active? Do you use protection during sexual activity? Do you have any concerns about your sexual health?
S: Suicide/Depression	How have you been feeling emotionally lately? Have you ever felt very sad or hopeless for an extended period? Do you ever think about hurting yourself or ending your life? How do you cope with stress or difficult emotions?
S: Safety	Do you feel safe at home, school, and in your community? Have you ever been bullied or physically harmed? Are there any situations where you feel unsafe? Do you know who to contact in case of emergencies?

Annex 7. ART Readiness Assessment Form

Criteria	Y	N*
A. Psychosocial/Knowledge Criteria (applies to patients and caregivers)		
Understands the nature of HIV infection and benefits of ART?		
Has screened negative for alcohol or other drug use disorder, or is stable on treatment (see Section 4.6)		
Has screened negative for depression or other psychiatric illness, or is stable on treatment (see Section 4.6)		
Is willing to disclose/has disclosed HIV status, ideally to a family member or close friend?		
Has received demonstration of how to take/administer ART and other prescribed medication?		
Has received information on predictable side effects of ART and understands what steps to take in case of these side effects?		
For patients dependent on a caregiver: is the caregiver committed to long-term support of the patient, daily administration of ART, and meets the criteria above?		
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.)?		
Has the Patient/caregiver provided accurate locator information and contact details?		
Patient/caregiver feels ready to start ART today?		
B. Support Systems Criteria (applies to patients and caregivers)		
Has identified convenient time/s of day for taking ART, and/or associated dose/s with daily event/s?		
Treatment supporter has been identified and engaged in HIV education, or will attend next counselling session?		
Is aware of support group meeting time/s?		
If facility has SMS reminder system: Has enrolled into SMS reminder system?		
Other support systems are in place or planned (e.g., setting phone alarm, pill box)?		
C. Medical Criteria (applies to patients)		
Newly diagnosed with TB: defer ART until patient tolerates anti-TB medication; initiate ART as soon as possible preferably within 2 weeks; for TB meningitis delay ART for 4 to 8 weeks); monitor closely for IRIS		
Newly diagnosed cryptococcal meningitis (CM), or symptoms consistent with CM (progressive headache, fever, malaise, neck pain, confusion): defer ART until completed 5 weeks of CM treatment, or until ruling out CM as the cause of symptoms; monitor closely for IRIS		
*If the response to any of the psychosocial criteria or support systems criteria is "No": develop a strategy to address the issue as quickly as possible and consider assigning a case manager. ART may be initiated with adequate adherence support while the criteria is being addressed, on a case-by-case basis		

Annex 8. Initial, Subsequent and Constructive ART Regimens

Category	Scenarios	Regimen Composition
Initial ART Regimen		
Initial INSTI-based ART regimen	(a) ART naïve (b) Optimized from NNRTI or initial PI without treatment failure	TDF/3TC/DTG (TLD) once daily TAF/XTC/DTG ABC/3TC/DTG if renal
Initial PI-based ART regimen	(a) ART naïve (b) Optimized from NNRTI without failure (c) INSTI intolerant or contraindicated	TDF/3TC/DRV/r TDF/3TC/ATV/r
Subsequent ART Regimen		
Subsequent INSTI-based ART	(a) Initial NNRTI or PI-based treatment failure (b) Optimized from subsequent PI without treatment failure	TDF/3TC/DTG (recycle TDF acceptable)
Subsequent PI-based ART	(a) INSTI failure (with resistance) (b) NNRTI treatment failure with INSTI intolerance	DRV/r + NRTIs (± ETR/RAL optimized as per DRT)
Constructive ART Regimen		
Multiple-drug ART-experienced	a) NNRTI failure + PI resistance b) NNRTI failure + INSTI resistance c) Triple failure: NNRTI, INSTI & PI failure	Optimized as per DRT & history Maintain HBV-active TDF/TAF in backbone if indicated. Options include: DTG + 3TC + DRV/r DTG + AZT + 3TC + DRV/r DTG + ABC (or TDF) + 3TC + DRV/r ETR + 3TC + DRV/r DTG + TDF + 3TC + DRV/r DTG + TDF (or AZT) + 3TC

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

Management Protocol for patients switching to 3rd line ART

Pre – Initiation MDT Meeting

Confirm what 3rd line ARV regimen is prescribed, its availability and the management plan

Assign a case manager to patient

Initiation of 3rd Line ART

Triage

- Record vital signs and take actions as needed

Adherence support

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

Clinical assessment

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

Dispensing

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

Community follow-up

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

Patient Follow Up after Treatment Initiation

Frequency

First follow-up should be within 2 weeks of initiation of 3rd line ART

Subsequent visits should be monthly (or more frequent) until confirmed viral sup- pression at 6 months

Management Protocol for patients switching to 3rd line ART
Thereafter, follow-up can be 1-3 monthly Triage Record vital signs and take action as needed
Adherence Support (adherence should be reinforced during every clinic visit, in addition to enhanced adherence counselling sessions) Review and address knowledge deficits on new regimen Confirm understanding of adherence, conduct adherence assessment, and reinforce key adherence messages Document reasons for missed doses and manage obstacles to perfect adherence. Review and reinforce adherence support systems Clinical Assessment Take history and conduct physical examination Complete Clinical Encounter Form and MOH 257 (blue card) Manage any co-infections and co-morbidities Evaluate for potential drug interactions Evaluate for and manage any drug side effects and adverse events Conduct adherence assessment and review adherence support systems Reinforce patient education messages on new regimen Review and address knowledge gaps on ART regimen Need for perfect adherence (>95%) Dosing schedule and timing Potential side effects and what the patient should do Prescribe 3rd line ARVs Viral load should be conducted 3 months after change of regimen Dispensing Confirm ARV dosing as per the weight Conduct medication use counselling Dispense 3rd line ARVs Community Follow up Review linkage to community adherence support systems Conduct home visits as required Continue DOTS
NOTE: 3rd line annual report with viral load, adherence, and outcomes to be sent to NASCOP

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

Drug	Strength of tablet	Number of tablets or capsules by weight band once daily					Strength of adult tablet	Number of tablets or capsules by weight band once daily
		3–5.9 kg	**6–9.9 kg**	**10–13.9 kg**	**14–19.9 kg**	**20–24.9 kg**		**25–34.9 kg**
pALD	Tablet (dispersible) 60mg/30mg/5 mg	1	3	4	5	6	NA	NA
ABC/3TC	Tablet (dispersible) 120mg/60 mg	½	1½	2	2½	3	600 mg/300 mg	1
DTG	Scored tablet (dispersible) 10 mg	½	1½	2	2½	3[2]	NA	
DTG	Tablet 50 mg	-	-	-	-	1	50 mg	1
TDF/3TC/DTG (TLD)	Tablet 300mg/300mg /50mg	-	-	-	-	-	300mg/300mg /50mg	1 **(>30kg)**
TAF/3TC/DTG	Tablet 25/300/50mg	-	-	-	-	-	25mg/300mg/ 50mg	1

Notes

[1]For infants younger than 4 weeks of age refer to Annex 13 below for more accurate dosing information

[2] If unable to swallow the tablets whole, the dispersible pDTG 10mg tablets may be given at a dose of 30 mg daily.

Annex 10b: Simplified Dosing of Darunavir Solid Formulations for Once-Daily Dosing in Infants & Children ≥ 4 Weeks of Age

Drug	Strength of tablet	Number of tablets or capsules by weight band once daily					
		10–11.9 kg	**12-13.9kg**	**14–19.9 kg**	**20–24.9 kg**	**25–34.9 kg**	**≥40kg**
DRV [1]	Tablet 75mg	5	6				
DRV	Tablet 150mg		3	4	4	4	-
DRV	Tablet 600mg	-		1	1	1	-
DRV/r FDC[2]	Tablet 400/50mg	-	-	-	-	-	2
RTV	Tablet 50mg	2	2	2	2		
RTV	Tablet 100mg	1	1	1	1	1	

[1] Children with previous PI exposure, dose DRV boosted with RTV twice daily (see Annex 11 below). DRV is used only for children ≥3 years and ≥10kg

[2] DRV/r 400/50 FDC is recommended for use among children ≥12 years and ≥40kg

Annex 11: Dosing of Solid and Liquid Formulations for Twice-Daily Dosing in Infants and Children 4 Weeks of Age and Older[1]

Drug	Strength of tablets	Number of tablets by weight band morning and evening													
		3–5.9 kg		6–9.9 kg		10–11.9 kg		12–13.9 kg		14 – 19.9 kg		20–24.9 kg		25–34.9 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
LPV/r[2]	Tablet 100/25 mg	–	–	–	–	2	1	2	1	2	2	2	2	NA	NA
DRV[3]	Tablet 75 mg	–	–	–	–	3	3	4	4	5	5	5	5	6	6
DRV	Tablet 150mg	-	-	-	-			2	2					3	3
DRV	Tablet 600mg													1	1
RTV	Tablet 50mg					1	1	1	1	2	2	2	2	1	1
	Tablet 100mg									1	1	1	1	1	1
	Syrup 80mg/ml					0.5ml	0.5ml								

Notes

[1]For infants younger than 4 weeks of age, refer to annex 13 for more accurate dosing information

[2] The LPV/r heat-stable tablet formulation must be swallowed whole and should not be split, chewed, dissolved or crushed.

[3] DRV should be administered with 0.5 ml of RTV 80 mg/mL oral suspension if less than 15 kg and with RTV 50 mg or 100mg solid formulation in children 15 to 30 kg. Children with previous PI exposure should receive twice-daily dosing of DRV boosted with Ritonavir. DRV cannot be used in children less than 3 years and weighing below 10 kg

Annex 12: Dosing charts for ART (ABC+3TC+DTG) for Term infants (>37weeks), 0-4 weeks >2kg

Drug	Strength of paediatric formulation	Dose (at age in weeks) for <4 weeks[1]	
		0-<2 wks	2-<4 wks
ABC/3TC	Double-scored tablet (dispersible) 120 mg/60 mg [2]	¼ (on alternate days)	¼ (Daily)
DTG[3]	Tablet (dispersible) 10mg	½ (on alternate days)	½ (daily)
pALD	Tablet (dispersible) 60mg/30mg/5mg	-	-

[1]For infants <4 weeks of age and >2kg, use ABC/3TC(120mg/60mg) and pDTG (10mg) as per the dosages and schedule of administration as shown above

[2]Critical to use the double-scored ABC/3TC 120/60mg tablet for ART dosing for infants < 4 weeks

[3]DTG should not be administered to infants <37 weeks of gestation. For pre-term infants <37 weeks gestation use AZT/3TC and NVP

[4]For infants age 4 weeks and above, and ≥ 3kg, use pALD (60mg/30mg/5mg) as per the dosing chart above

Infants at high risk of HIV acquisition should receive triple infant prophylaxis with ABC+3TC+DTG for 14 weeks, after which they should continue with NVP prophylaxis until 6 weeks after complete cessation of breastfeeding

Annex 12b: Paediatric Abacavir-Lamivudine-Dolutegravir (pALD) administration Instructions

GIVING YOUR CHILD PEDIATRIC ABACAVIR/ LAMIVUDINE (3TC)/DOLUTEGRAVIR (pALD) (pALD) TABLETS

THESE ARE THE INSTRUCTIONS ON HOW TO GIVE YOUR CHILD pALD (ABC/3TC/DTG) 60/30/5mg TABLETS. ALWAYS FOLLOW THE GUIDANCE OF YOUR HEALTHCARE PROVIDER.

Step 1

Add the correct number of paLD tablets to a clean, empty glass based on your child's weight, as determined by the healthcare provider (See dosing table).
This picture shows the dose for a child 6 to <10 kg.

Weight	Number of pALD ABC/3TC/ (60/30/5mg) tablets per day
3 to < 6 kg*	2
*Only for infants ≤ 4 weeks, for infants younger than 4 weeks, see dosing provided.	
6 to < 10 kg	3
10 to < 14 kg	4
14 to < 20 kg	5
20 to < 25 kg	6

Step 2

Add 2–4 teaspoons (10–20ml) of clean water into a glass. See tcurter provider (See dosing).

Stir until the tablets fully dissolve. If the tablets do not dissolve completely, stir and slowly add another 2 teaspoons (10ml) of extra water until the tablets fully dissolve.

Give the medicine to your child to drink. The child can drink the mixture directly from the glass OR give the mixture to the child using a spoon. Make sure they drink all the medicine with or within 30 minutes.

Step 3

Repeat until no medicine remains in the glass.

REMINDERS:

- ☑ Remember to give your child their pALD at the same time everyday.
- ☑ Only give your child another full dose of pALD when vomit within 30 minutes of their initial dose.

ASK YOUR CHILD'S HEALTH PROVIDER IF YOU HAVE ANY QUESTIONS ABOUT ADMINISTERING pALD!

Annex 13: Dosing Chart for ART for Infants <37 weeks (premature infants)

Formular for Calculation of Corrected Gestational Age

Corrected Age= Actual age in weeks since birth - number of weeks premature (40 weeks [term age] - infants gestational age in weeks)

Drug	Age of Infant	Gestational Age		
		< 30 weeks	**30 – 35 weeks**	**>35 weeks**
AZT	0 – 4 weeks	2 mg/kg BD	2 mg/kg BD	4 mg/kg BD
	> 4 – 8 weeks	3 mg/kg BD	3 mg/kg BD	12 mg/kg BD
	8 – 10 weeks	12 mg/kg BD	12 mg/kg BD	12 mg/kg BD
		32– 34 weeks	**34– 37 weeks**	**> 37 weeks**
3TC	< 4 weeks	2 mg/kg BD	2 mg/kg BD	2 mg/kg BD
	> 4 weeks	4 mg/kg BD	4 mg/kg BD	4 mg/kg BD
		32– 34 weeks	**34– 37 weeks**	**> 37 weeks**
NVP	0 – 2 weeks	2 mg/kg BD	4 mg/kg BD for 1 week then 6 mg/kg BD	6 mg/kg BD
	2 – 4 weeks	4 mg/kg BD		

Annex 14a. Twice Daily Administration of ART Liquid Formulations for Infants Less than 4 Weeks of Age

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

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

Annex 14b: Use of Protease Inhibitors in Adults

Drug name	Dose (in adults)	Dietary restrictions	Major side effects	Comments
Lopinavir/ritonavir (LPV/r) Available as 200mg + 50mg RTV	[LPV 400 mg + RTV 100 mg] 2 tablets BD	Take with food. Moderate fat increases bioavailability.	GI intolerance; nausea; vomiting; diarrhoea	Tablets should be swallowed whole
Atazanavir (ATV) **Available in 100mg, 150mg, 200 mg capsules** **Available as FDC with RTV**	ATV 300mg / RTV 100mg OD	Take with food. Take 2 hours before or 1 hour after antacids and buffered medications such as buffered ddI (reduced ATV concentrations if administered together)	Jaundice; headache; fever; depression; nausea; diarrhoea and vomiting; paraesthesia; spontaneous bleeding episodes in haemophiliacs.	Indirect hyperbilirubinaemia. When used with TDF should always be given with RTV. Experienced patients should also be given ATV/RTV.
Ritonavir (RTV) **Available as 100mg capsules** **Capsules should be refrigerated until dispensed; stable at room (up to 25ºC) for 30 days**	Recommended for use as a booster of other PIs	Administration with food increases absorption and helps reduce gastrointestinal side effects.	Exacerbation of liver disease; fat redistribution and lipid abnormalities; diarrhoea; abdominal discomfort; headache; nausea; paraesthesia; skin rash; spontaneous bleeding episodes in haemophiliacs.	Potent CYP450 inhibitor, thus its use as a booster of other PIs
Darunavir (DRV)	DRV 600 mg/ RTV 100 mg BID DRV 400 mg/ RTV 50 mg BD (only if PI naïve, or have no PI Drug Resistant Mutations)	Take with a meal to limit ADR	GIT upsets, rash, dyslipidaemia, hepatitis. Caution in patients with sulphur allergy.	Metabolized by CYP3A and is an inhibitor of CYP3A. Contains sulphur moiety. Monitor liver functions, especially in patients at risk or with pre-existing liver disease. May cause hormonal contraceptive failure.

Annex 15a: Simplified Dosing of INH and CTX Prophylaxis for Infants and Children Who Are at Least 4 Weeks of Age

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

Annex 15b: Dosing Charts for TB Preventative Therapy using 3HP (drug sensitive TB) and levofloxacin (Drug Resistant TB)

3HP[1] for <25kg			
Weight (kg)	**Number of 100mg Isoniazid dispersible tabs**	**Number of Rifapentine 150 mg dispersible tabs**	**How to reconstitute the medicine**
3-5.9 (<3 months)	6mL	5mL	Disperse one (1) tablet of Isoniazid and one (1) tablet of Rifapentine in 10 mL of safe drinking water. Once completely dispersed, give the prescribed volume measured using an oral syringe or a measuring cap
3-5.9 (≥3 months)	7mL	7mL	
6-9.9 (<6 months)	1 tabs	1½ tabs	Disperse the prescribed tablets of Isoniazid and Rifapentine in 20 mL of safe drinking water water. Once fully dispersed, give the entire suspension measured with an oral syringe or a measuring cap
6-9.9 (≥6 months)	1½ tabs	1½ tabs	
10-14.9	2 ½ tabs	2 tabs	
15-19.9	3 tabs	3 tabs	
20-24.9	4 ½ tabs	4 tabs	

3HP for ≥ 25kg			
Weight (kg)	**Number of Rifapentine 300 mg and Isoniazid 300mg FDC tabs**		
25-29.9	2 tabs		
30-34.9	2½ tabs		
35-39.9	3 tabs		
40-44.9	3 tabs		
45-49.9	3 tabs		
> 50 kg	3 tabs		
Six months of daily levofloxacin (6Lfx)			
6Lfx for < 25kg			
Weight (kg)	**Number of levofloxacin 100mg dispersible tabs**	**Number of levofloxacin 250 mg tabs**	**Number of levofloxacin 500 mg tabs**
3-5.9(<3months)	½ tab[a]	2.5mL[b]	-
3-5.9(≥3months)	1tab[a]	5mL[b]	-
6-9.9(<6months)	1tab[a]	5mL[b]	-
6-9.9(≥6months)	1 ½ tabs[a]	10mL[b]	-
10-14.9	2 tabs[a]	1 tab[c]	-
15-19.9	2 ½ tabs[a]	1 ½ tabs[c]	-
20-24.9	3 tabs[a]	1 ½ tabs[c]	-
6 Lfx for ≥ 25kg			
25-29.9		2 tabs[c]	1 tab
30-34.9		2 tabs[c]	1 tab
35-39.9		2 tabs[c]	1 tab
40-44.9		2 tabs[c]	1 tab
45-49.9		2 tabs[c]	1 tab
> 50 kg		3 tabs[c]	1 ½ tabs

[a] Disperse the prescribed number of Levofloxacin 100mg Dispersible tablets into 20 mL of safe drinking water. Once fully dispersed, give the entire suspension measured with an oral syringe or a measuring cap

[b]Crush one Levofloxacin 250mg tablet and disperse the crushed content into 10mL of safe drinking water. Once fully dispersed, give the prescribed volume measured with an oral syringe or a measuring cap.

[c]Crush the prescribed number of Levofloxacin 250mg tablets and disperse the crushed content into 20mL of safe drinking water. Once fully dispersed, give the entire suspension measured with an oral syringe or a measuring cap.

[11]3HP cannot be used among children on PI-based ART, Nevirapine, Etravirine, and Tenofovir Alafenamide

Annex 16. Dosing for RTV super-boosting of LPV/r for children receiving rifampicin-containing TB treatment*

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

[1] Suggested RT V dose for super-boosting to achieve the same dose as LPV in mg, in a ratio equal to or approaching 1:1.

[2] The LPV/r heat-stable tablet formulation must be swallowed whole and should not be split, chewed, dissolved, or crushed.

Annex 17: Infant Prophylaxis Dosing Charts

Annex 17a. Infant prophylaxis with AZT+NVP (6 weeks) and Extended Infant Prophylaxis Using Nevirapine for Term Infants >37 weeks: Low Risk of Vertical Transmission

Infant Age/Weight (kg)	Nevirapine Once Daily Dose (10 mg/ml)	Zidovudine Twice Daily Dosing (10mg/ml)
Birth to 6 weeks		
≤ 2.0 kg	2mg/kg/dose	4mg/kg/dose
2.0 – 2.49	10mg (1 ml)	10mg (1ml)
>2.5	15mg (1.5 ml)	15mg (1.5ml)
6 – 12 weeks	20mg (2 ml)	-
12 weeks – 6 months	20mg (2ml)	-
6 – 9 months	30mg (3ml)	-
9 – 24 months	40mg (4ml)	-

Annex 17b: Triple Prophylaxis Dosing using ABC+3TC+DTG for Term Infants (≥37 weeks Gestation) with birth weight > 2kg, at High Risk of Vertical Transmission

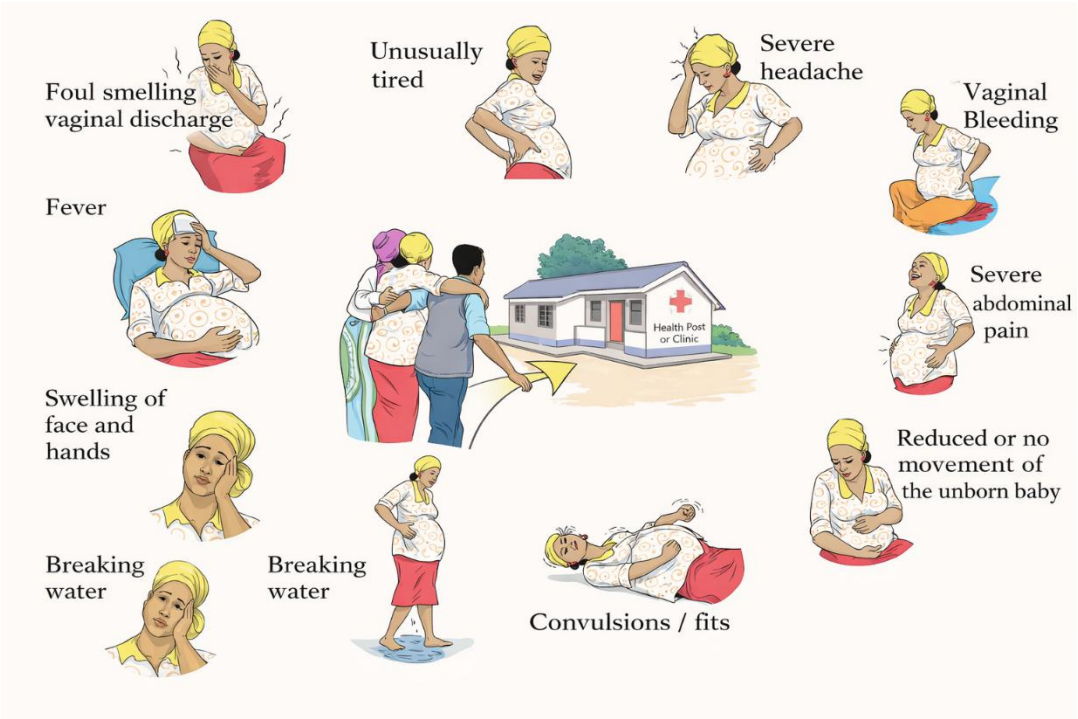
Drug	Strength of paediatric formulation	Dose (at age in weeks) for <4 weeks		Dose at Age > 4 weeks[3]		
		0-<2 wks	2-<4 wks	3 to 5.9 kg	6 - 9.9 kg	10-13.9 kg
ABC/3TC	Double-scored tablet (dispersible) 120 mg/60 mg [1]	¼ (on alternate days)	¼ (daily)	-	-	-
DTG[2]	Tablet (dispersible) 10mg	½ (on alternate days)	½ (daily)	-	-	-
pALD	Tablet (dispersible) 60mg/30mg/5mg	-	-	1 (once daily)	3 (once daily)	4 (once daily)

Annex 17c: AZT/3TC/NVP Infant Prophylaxis Dosing for Premature Infants <37 weeks Gestation at High Risk of HIV Acquisition

Triple Prophylaxis for preterm infants <37 weeks and <4 weeks at High Risk of Vertical Transmission							
Drug	Strength of oral solution	2–<3 kg		3–<4 kg		4–<5 kg	
		AM	PM	AM	PM	AM	PM
AZT	10 mg/mL	1 mL	1 mL	1.5 mL	1.5 mL	2 mL	2 mL
NVP	10 mg/mL	1.5 mL	-	2 mL	-	3 mL	-
3TC	10 mg/mL	0.5 mL	0.5 mL	0.8 mL	0.8 mL	1 mL	1 mL

Annex 18. Danger signs for the mother and baby

DANGER SIGNS DURING PREGNANCY



NB: Be prepared always to seek skilled care at the health facility in case of any of the above signs.

Source: Mother and Child Handbook 2025

CARE OF THE MOTHER AND BABY AFTER BIRTH

Eat two extra small meals and plenty of fluids during breastfeeding period

Give breast milk only to the baby for the first 6 months of life

Keep baby warmly wrapped, including cap and socks at all times

Sleep with the baby under a Long Lasting Insecticidal Net (LLIN)

If childbirth occurs at home, immediately take the mother and the health facility

Exposure of baby to sunlight, early morning (before 10am) / (after 4pm)

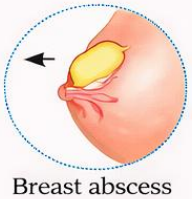
DANGER SIGNS FOR THE MOTHER AND BABY AFTER CHILDBIRTH

Mother has:

Heavy bleeding

Fever

Severe Headache

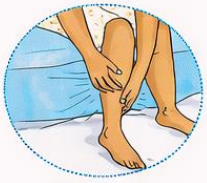


Breast abscess

Chest pain/ difficulty in breathing

Foul smelling vaginal discharge

Fits/Convulsions



Calf pain

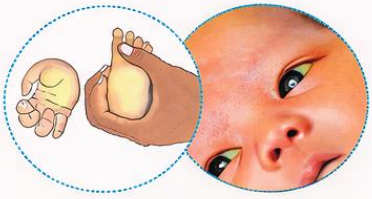
Newborn:

Stops breastfeeding well

Has difficult or fast breathing

Feels hot or unusually cold

Becomes less active
Body becomes yellow
especially on the eyes, palms soles



Body becomes yellow especially on the eyes, paims and soles

Note: In case of any of these danger signs, immediately visit a health facility.

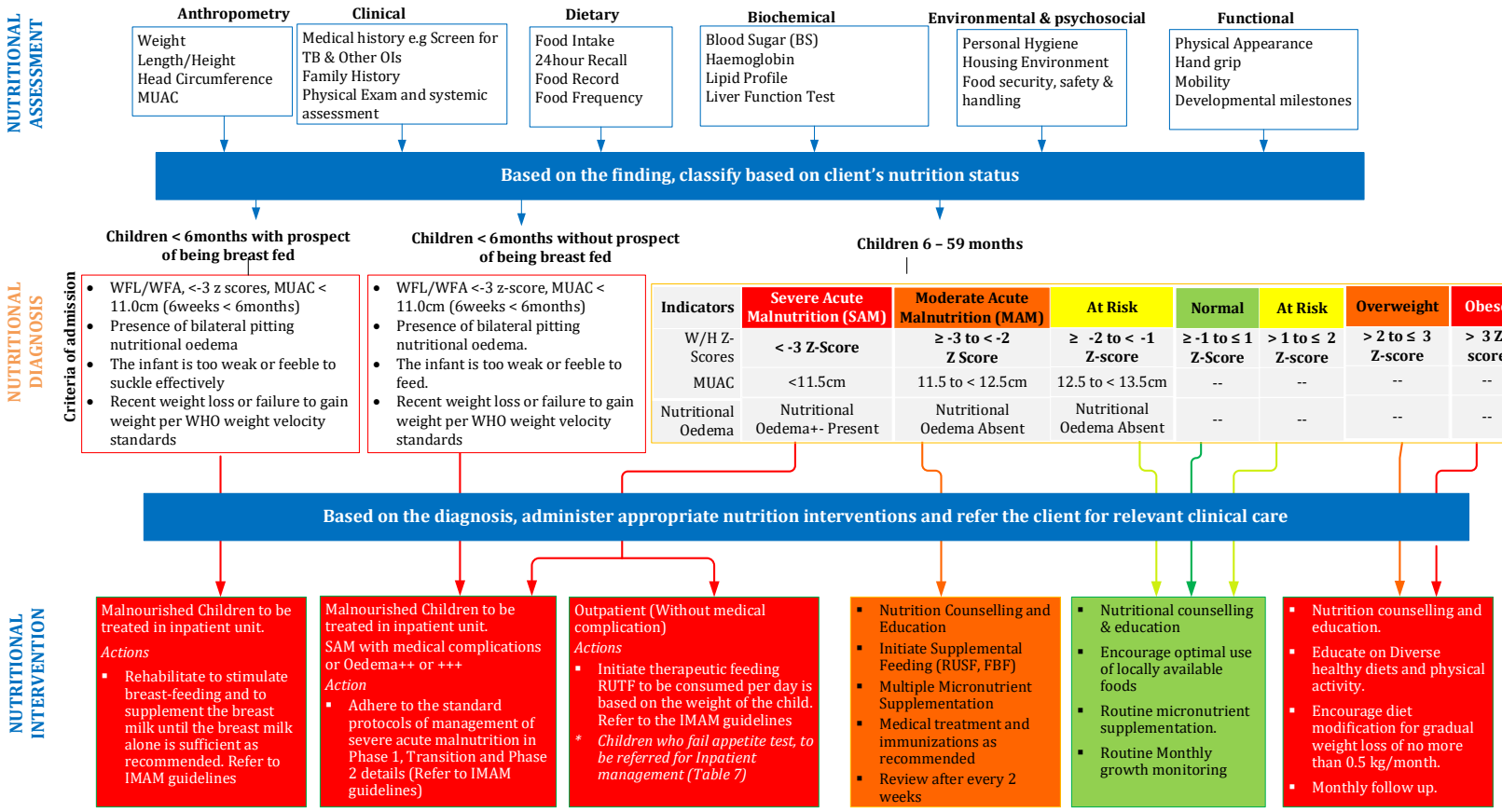
Note: In case of any of these danger signs, immediately visit a health facility.

Photo: NHS weedale for England

Annex 19. Ten Steps to Successful Breastfeeding

Ten Steps to Successful Breastfeeding
Critical management procedures:
a. Comply fully with the Breast Milk Substitutes (Regulation and Control) Act, 2012 and its regulations of 2022.
b. Have a written infant feeding policy that is routinely communicated to staff & parents.
c. Establish ongoing monitoring and data-management systems.
Ensure that staff have sufficient knowledge, competence & skills to support breastfeeding.
Key clinical practices:
● Discuss the importance and management of breastfeeding with pregnant women and their families.
● Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth.
● Support mothers to initiate and maintain breastfeeding and manage common difficulties.
● Do not provide breastfed newborns with any food or fluids other than breast milk, unless medically indicated.
● Enable mothers and their infants to remain together and to practice rooming-in 24 hours a day.
● Support mothers to recognize and respond to their infants' cues for feeding.
● Counsel mothers on the use and risks of feeding bottles, teats and pacifiers.
● Coordinate discharge so that parents and their infants have timely access to ongoing support and care.

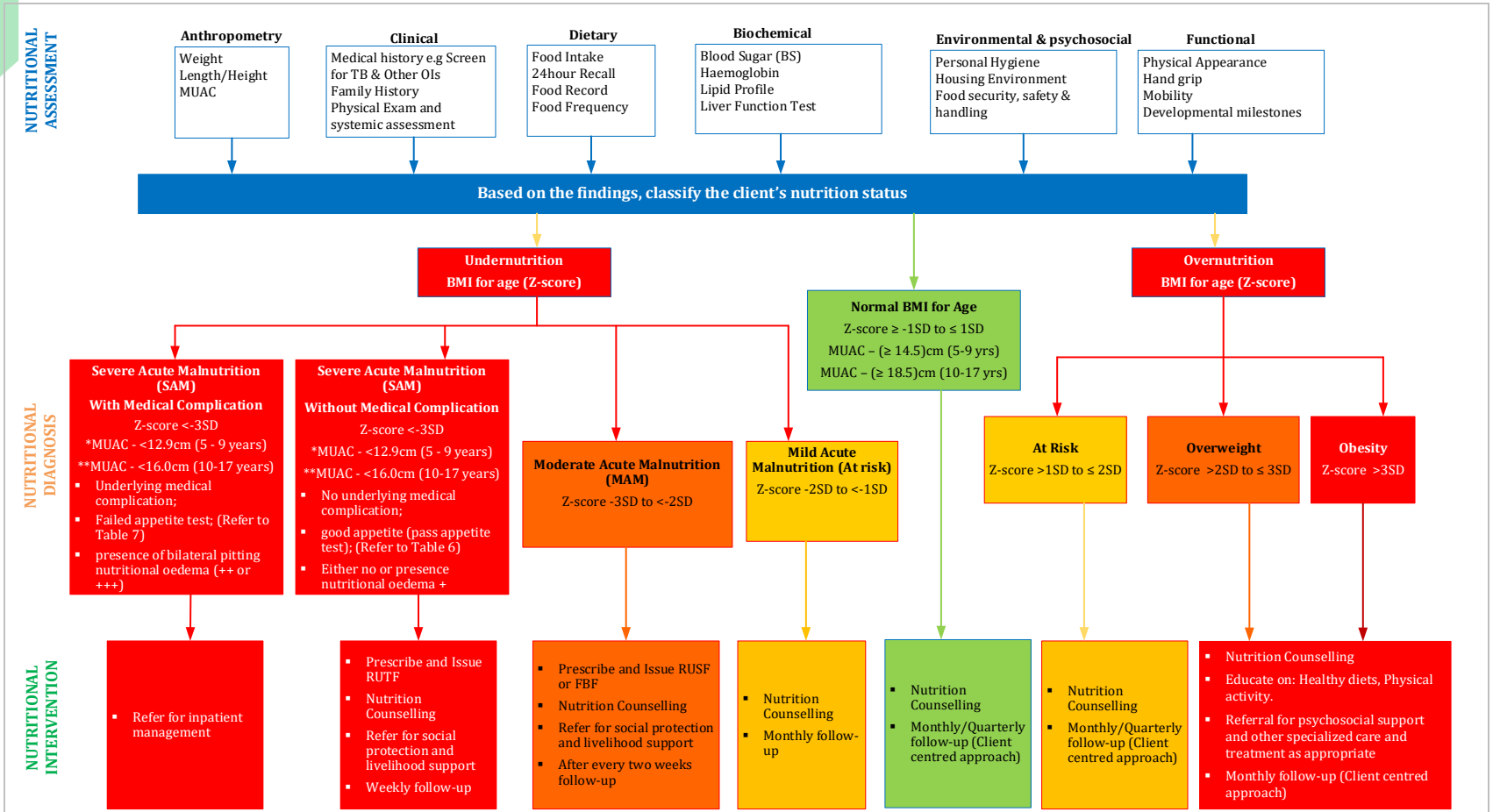
Annex 20. Diagnosis and Management of Malnutrition in Children Under 5 years



Indicators	Severe Acute Malnutrition (SAM)	Moderate Acute Malnutrition (MAM)	At Risk	Normal	At Risk	Overweight	Obese
W/H Z-Scores	< -3 Z-Score	≥ -3 to < -2 Z Score	≥ -2 to < -1 Z-score	≥ -1 to ≤ 1 Z-Score	> 1 to ≤ 2 Z-score	> 2 to ≤ 3 Z-score	> 3 Z-score
MUAC	<11.5cm	11.5 to < 12.5cm	12.5 to < 13.5cm	--	--	--	--
Nutritional Oedema	Nutritional Oedema+- Present	Nutritional Oedema Absent	Nutritional Oedema Absent	--	--	--	--

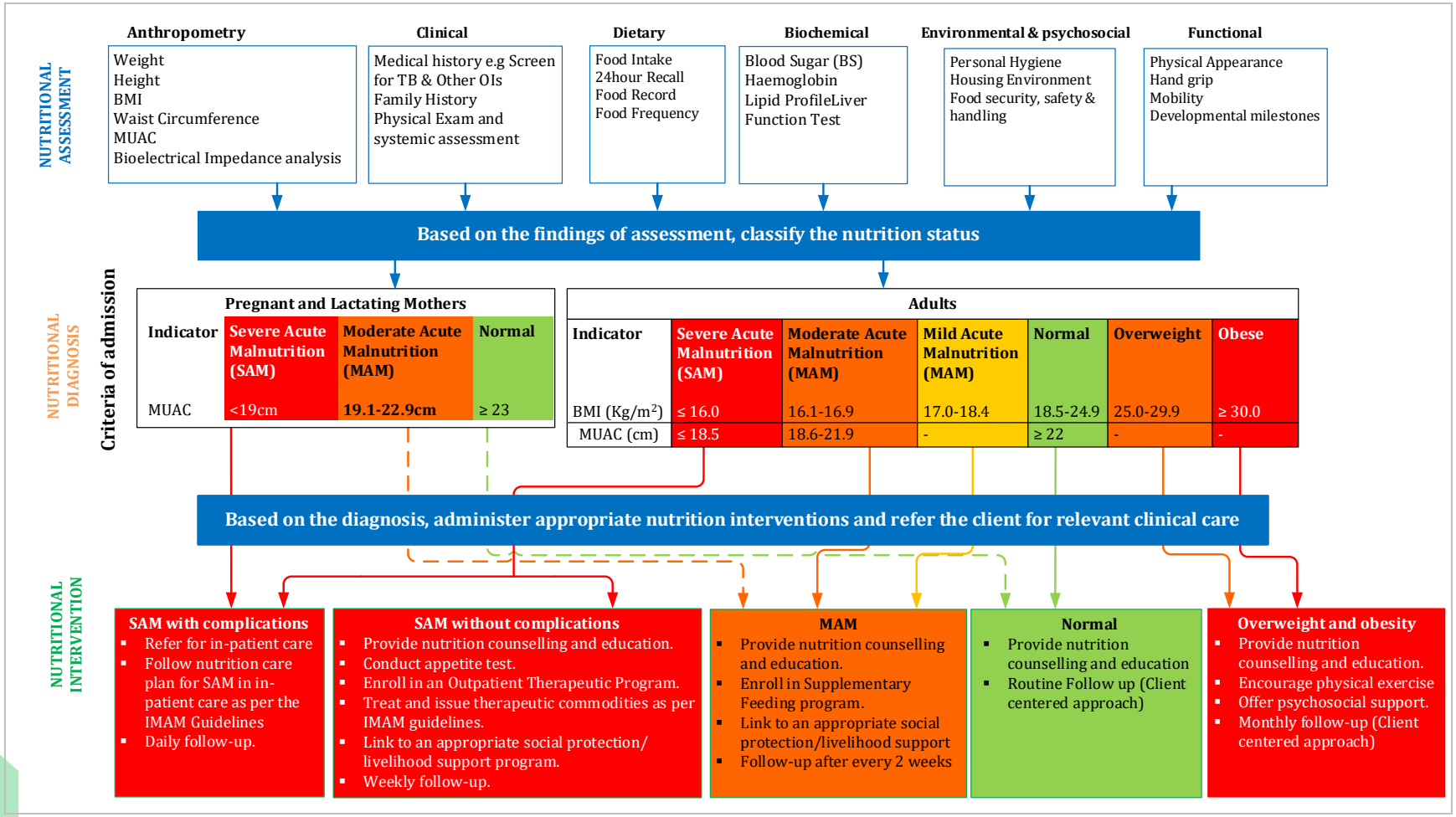
NOTE: Infants to be exclusively breastfed for the first six months of life and start complementary feeding at six months with continued breastfeeding up to two years or beyond.
Mothers and infants living with HIV should adhere to Antiretroviral Therapy and Prophylaxis respectively as per the current National ART Guidelines.
Health care workers should provide nutrition counselling focusing on healthy meal patterns and age appropriate physical activity for children with overweight obesity aged less than 5 years (refer to NATIONAL GUIDELINES FOR HEALTHY DIETS AND PHYSICAL ACTIVITY, 2017)

Annex 21. Diagnosis and Management of Malnutrition in Older Children and Adolescents (>5-17 years)



Source: * This cutoff was determined because it is equivalent to -3 z-score of the WHO Growth Standards for boys aged 5 years.
** This cutoff is based on the WHO Integrated Management of Adolescent and Adult Illness guidelines

Annex 22. Diagnosis and management of Malnutrition for Adults



Annex 23. Household Hunger Score

A: NO	B: QUESTION	C: RESPONSE OPTIONS	D: CODE
1.	In the past four weeks, was there ever no food of any kind to eat in your household because of lack of resources to get food?	0 = No (skip to Question 2) 1 = Yes	….|_____|
1.a	How often did this happen?	1 = Rarely (once or twice in the past four weeks) 2 = Sometimes (three to ten times in the past four weeks) 3 = Often (more than ten times in the past four weeks)	….|_____|
2.	In the past four weeks, did you or any household member go to sleep at night hungry because there was not enough food?	0 = No (skip to Question 3) 1 = Yes	….|_____|
2.a	How often did this happen?	1 = Rarely (once or twice in the past four weeks) 2 = Sometimes (three to ten times in the past four weeks) 3 = Often (more than ten times in the past four weeks)	….|_____|
3.	In the past four weeks, did you or any household member go a whole day and night without eating anything because there was not enough food?	0 = No (questionnaire is finished) 1 = Yes	….|_____|
3.a	How often did this happen?	1 = Rarely (once or twice in the past four weeks) 2 = Sometimes (three to ten times in the past four weeks) 3 = Often (more than ten times in the past four weeks)	….|_____|

Creating a Household Hunger Score for a household

Step1. The response for each question (column C) is recorded under column D (Code). 'Never' should always be coded as 0. 'Rarely' or 'Sometimes' should be coded as 1. 'Often' should be coded as 2.

Step 2. The responses given by a household in column D for the three questions are added to obtain the household's aggregated HHS score.

Interpretation[1]

Based on the HHS score, each household is categorized as follows:

HHS SCORE	CATEGORY
0 - 1	Little to no household hunger
2 - 3	Moderate household hunger
4 - 6	Severe household hunger

[1] The minimum score possible is 0. This would be the HHS score for a household that responded "NO/never" to all three questions. The maximum possible score is 6. This would be the HHS score for a household that responded "YES/often" to all three questions. Households in this category merit food aid and livelihood support.

[2] Deitchler, Megan, Terri Ballard, Anne Swindale and Jennifer Coates. Validation of a Measure of Household Hunger for Cross-Cultural Use. Washington, DC: Food and Nutrition Technical Assistance II Project (FANTA-2), AED, 2010

Annex 24. Drug Nutrient Interactions & Management of Side Effects Associated with ARVs and Drugs for Opportunistic Infections

Drug Nutrient interactions and management of side effects associated with ARVs and OI medications		
Side effects that affect nutrition status	**Possible Causative ARVs**	**Management of ARVs side effects** **Advise the client to:**
Diarrhoea	Dolutegravir (DTG) Lamivudine (3TC) Abacavir (ABC) Emtricitabine (FTC) Lopinavir (LPV) Atazanavir (ATV) Ritonavir (RTV) Darunavir (DRV) Etravirine (ETR) Cotrimoxazole	Take ORS Take Zinc Sulphate 10 mg or 20 mg, depending on the age of the client. Drink plenty of fluids. Practice food and water safety Practice personal hygiene to ensure it is not the cause of Diarrhoea. Continue eating during and after the diarrhoea episodes. Eat small frequent meals with plenty of fibre from fruit and vegetables. Eat food rich in potassium such as bananas. Closely monitor weight
Nausea	Lopinavir (LPV) Atazanavir (ATV) Ritonavir (RTV) Darunavir (DRV) Etravirine Dolutegravir (DTG) Lamivudine (3TC) Abacavir (ABC) Emtricitabine (FTC) Cotrimoxazole Amphotericin B	Take small quantities of dry, bland or lightly salted foods, and boiled foods at intervals. Take plenty of fluids after meals. Suck on a lemon – the sour taste reduces nausea. Take ginger water. Avoid greasy, fried food and foods with strong smells, coffee and alcohol.
Constipation	Etravirine (ETR)	Maintain a regular eating schedule and not to skip meals. Drink plenty of fluids. Avoid highly refined foods. Eat foods high in fibre. Exercise as much as possible. Avoid laxatives as they cause loss of fluids from the body.
Elevated blood cholesterol	Lopinavir (LPV) Atazanavir (ATV) Ritonavir (RTV) Darunavir (DRV)	Reduce consumption of saturated fats. Consider supplementation with Vitamin B3. Eat a high fibre diet. Do some physical exercise regularly.

Drug Nutrient interactions and management of side effects associated with ARVs and OI medications		
Side effects that affect nutrition status	**Possible Causative ARVs**	**Management of ARVs side effects** **Advise the client to:**
Insomnia and occasional dizziness	Tenofovir Disoproxil, Lamivudine, Dolutegravir (TAF-LD)	Take small quantities of dry, bland, or lightly salted foods, and boiled foods at intervals. Limit fluid intake 2 hours before bedtime. Get plenty of rest and practice quality sleep hygiene. Suck on a lemon – the sour taste reduces nausea. Take ginger water. Avoid greasy, fried food and foods with strong smells. Avoid coffee. Avoid alcohol.
Abdominal discomfort and cramping	Flucytosine	Avoid carbonated or fizzy drinks, Take fermented drinks such as porridge, probiotics (e.g. yoghurt, fermented milk) Seek medical attention if the pain is unbearable and is not relieved by dietary measures
Bone marrow suppression	Flucytosine	Maintain a healthy diet. Eat food rich in iron like green leafy vegetables and fruits. Eat foods rich in Vitamin C and iron to increase iron absorption.
Notes: Lopinavir (LPV) *Syrup is very bitter and needs to be taste-masked using locally available foods like porridge Alcohol increases ABC levels by 41% therefore avoid alcohol while on ABC. Dolutegravir (DTG), PIs: Low-fat-diet recommended PIs, Etravirine, cotrimoxazole: Take with food		

Annex 25. Side Effects Associated with TB Drugs and Food Intake Recommendations

Side effects related to TB drugs and food intake recommendations			
Drug name	**Dietary Restrictions**	**What to Avoid**	**Possible side effects**
Rifampicin	Take 1 hour before food or 2 hours after food Take 1 hour before antacids	Alcohol	Nausea, vomiting, appetite loss
Isoniazid	Take 1 hour before food or 2 hours after food. Take 50 mg of Vitamin B6 daily	Alcohol	Interference with liver function, Cutaneous hypersensitivity, Peripheral neuropathy
Rifapentine	Take 1 hour before food or 2 hours after food. Take 1 hour before antacids	Alcohol	Red–orange staining of body fluids, rash and pruritus
Ethambutol	May be taken with food	Alcohol	Retrobulbar neuritis, Arthralgia
Pyrazinamide	May be taken with food	None	Nausea, Vomiting, Arthralgia
Ofloxacin	Take 2 hours before food or after food	Antacids Milk products	Gastrointestinal reactions, Insomnia
Bedaquiline	Take with or after meals (Supplement with Vit B6).	Alcohol	Prolonged QT, Hepatotoxicity, nausea, vomiting, arthralgia, headache, itchiness,
Linezolid	Avoid foods rich in tyramine (fermented meat products, pickles)	Alcohol	Myelosuppression, Lactic acidosis, optic and peripheral neuropathy, skin reaction

Annex 26. Use of Nucleoside & Nucleotide Reverse Transcriptase Inhibitors in Adults

Drug name	Dose (in adults)	Dietary restrictions	Major side effects	Comments
Zidovudine (AZT or ZDV) Available in 300mg tablets and as FDC with 3TC and 3TC/ NVP	300mg/ dose BD	No food restrictions	Bone marrow suppression), including anaemia; granulocytopenia; headache; gastrointestinal intolerance; myopathy; myositis; liver toxicity; discoloured nails; lactic acidosis and severe hepatomegaly with steatosis (fatal cases have been reported)	Monitor for anaemia in the first 3 months of treatment
Lamivudine (3TC) Available in 150mg tablet and as FDC with AZT and AZT/NVP, NVP and with TDF and TDF/ EFV	150mg/ dose BD OR 300 mg/dose OD	No food restrictions	Headache; fatigue; nausea; diarrhoea; skin rash; pancreatitis; peripheral neuropathy; hepatotoxicity/ hepatitis; lactic acidosis and severe hepatomegaly with steatosis (rare fatal cases have been reported).	A well-tolerated drug. Adjust dose in renal impairment. Also active against hepatitis B. Ideally, patients should be screened for hepatitis B virus (HBV) before starting therapy; exacerbation of hepatitis B has been reported in patients on discontinuation of 3TC.
Abacavir (ABC) Available in 300mg tablets and in combination with 3TC and DTG	300mg/ dose BD or 600mg OD	No food restrictions. Alcohol increases ABC levels by 41%	Hypersensitivity reaction (potentially fatal) whose symptoms include fever, fatigue, malaise, nausea, vomiting, diarrhoea and abdominal pain or respiratory symptoms such as shortness of breath, lymphadenopathy, ulceration of mucous membranes and skin rash. Patients suspected of having hypersensitivity reaction should have ABC stopped and never be restarted. Pancreatitis; lactic acidosis with hepatic steatosis is rare	Educate patient on hypersensitivity reaction. Once hypersensitivity has occurred, the patient should never be re-challenged with ABC. Avoid alcohol while on ABC.
Emtricitabine (FTC)	200mg/ dose OD	No food restrictions	Well tolerated. Lactic acidosis and severe hepatomegaly with	Effective against hepatitis B. Ideally, patients should be screened for chronic

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

Annex 27. Use of Non-Nucleoside Reverse Transcriptase Inhibitors for Adults

Drug name	Dose (in adults)	Dietary restrictions	Major side effects	Comments
Efavirenz (EFV) Available in 200mg & 600mg tablets and as FDC with TDF/3TC	600mg OD Best taken at bedtime	Preferably taken on an empty stomach. Can be given with food, but avoid high fat meals which increase absorption.	CNS symptoms (somnolence, insomnia, abnormal dreams, confusion, hallucination, amnesia, etc. Avoid in patients with history of psychiatric disease); Skin rash; avoid use in during the first trimester	Can be used with rifampicin in TB patients
Etravirine (ETR) Available in tablets of 200 mg	200 mg BD	Take with food	Severe but rare: SJS and erythema multiforme Common & minor: Rash, nausea, vomiting, diarrhoea, abdominal pain, hepatotoxicity, dyslipidaemia and CNS disturbances (less than EFV)	Avoid concurrent use with rifampicin, and boosted tipranavir.

Annex 28. Use of Protease Inhibitors in Adults

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

Annex 29. Integrase Strand Transfer Inhibitors - INSTIs

Drug name	Dose (in adults)	Dietary restrictions	Major side effects	Comments
Dolutegravir (DTG) Available as DTG 50mg, 10mg dispersible tablet Or FDCs: ABC/3TC/DTG (600/300/50mg) and TDF/3TC/DTG (300/300/50mg)	50 mg once daily If co-administering with EFV, carbamazepine, or rifampicin, use DTG 50 mg BD If suspected or confirmed INSTI resistance use DTG 50 mg BD	No food restrictions	Rare - Hypersensitivity; Hepatotoxicity especially in those with HBV and HCV infection, fatigue Insomnia, headache, diarrhoea, nausea is common but usually minor and resolve with continued use	Interacts with carbamazepine, phenobarbital and phenytoin, use alternative anticonvulsants. Administer DTG at least 2 hours before or 6 hours after taking supplements or antacids containing Mg, Al, Fe, Ca and Zn. For Ca or Fe, if DTG is taken with a meal then dose separation is not required
Raltegravir (RAL)	ADULT and CHILD over 16 years, 400 mg BD	No food restrictions	Nausea, vomiting, diarrhoea, flatulence, constipation Severe skin (SJS and TEN) and hypersensitivity reactions have been reported	Contraindicated in breast- feeding mothers Safety in paediatric patients has not been established

Annex 30. Drug-drug Interactions - NNRTIs

Drugs Affected	Nevirapine (NVP)	Efavirenz (EFV)
ANTIRETROVIRALS		
Dolutegravir	Co-administration not Recommended because NVP decreases levels of DTG	Co-administration not recommended because EFV decreases levels of DTG. If must be used together then increase DTG to 50 mg BD when co-administered with EFV
Raltegravir	No interaction or not studied	Efavirenz decreases RAL plasma levels but it is unlikely to be clinically significant
Atazanavir/ritonavir	Co-administration not recommended because ATV/r may increase the serum concentration of NVP leading to increased risk of toxicity, and NVP decreases the serum concentration of ATV/r which may lead to resistance and treatment failure	Co-administration not recommended because EFV decreases the serum concentration of ATV/r which may lead to resistance and treatment failure
Lopinavir/ritonavir	Co-administration not recommended because NVP decreases levels of LPV/r	AVOID: this combination increased risk of prolonged-QT syndrome and sudden cardiac death
Darunavir/ ritonavir	No significant interaction when NVP is combined with ritonavir-boosted darunavir	Co-administration not recommended because DRV/r may increase the serum concentration of EFV leading to increased risk of toxicity, and EFV decreases the serum concentration of DRV/r which may lead to resistance and treatment failure
ANTIFUNGALS		
Ketoconazole	Levels: ketoconazole ↓ 63% NVP ↑ 15 – 30% Dose: Not recommended	No data
Voriconazole	Metabolism of Voriconazole may be induced by NVP. Voriconazole may inhibit NNRTI metabolism. Frequently monitor for NNRTI toxicity and antifungal outcome	Levels: EFV ↑ 44% Voriconazole ↓ 77% This combination is not recommended

Fluconazole	NVP Levels: Cmax, AUC, and Cmin ↑ 100% Fluconazole Levels: No change Risk of hepatotoxicity may increase with this combination. If concomitant use is necessary, recommend monitoring NVP toxicity	No clinically significant changes in EFV or Fluconazole concentrations
ANTI-MYCOBACTERIALS		
Rifampicin	Levels: NVP ↓ 20%-58%. Virologic consequences are uncertain; the potential for additive hepatotoxicity exists. Use of this combination is not recommended; however, if used, co administration should be done with careful monitoring	Levels: EFV ↓ 25%. Dose: Consider ↑ EFV to 800 mg QD
Clarithromycin	Levels: NVP ↑ 26%. Clarithromycin ↓ 30%. Monitor for efficacy or use alternative agent	Levels: Clarithromycin ↓ 39%. Monitor for efficacy or use alternative agent
Bedaquiline (BDQ)	No dose adjustment required	Do not co-administer
Delamanid (DLM)	No interaction expected	No interaction
ORAL CONTRACEPTIVES		
	Levels: ethinyl estradiol approx. 20%. Use alternative or additional methods.	Levels: Ethinyl estradiol 37%. No data on other components. Use alternative or additional methods

LIPID-LOWERING AGENTS		
Simvastatin **Lovastatin**	No data	Levels: Simvastatin AUC by 58%; EFV unchanged Dose: Adjust simvastatin dose according to lipid responses, not to exceed the maximum recommended dose
Atorvastatin	No data	Levels: Atorvastatin AUC 43%; EFV unchanged. Dose: Adjust atorvastatin dose according to lipid responses, not to exceed the maximum recommended dose
Pravastatin	No data	No data

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

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

Annex 31. Drug-Drug Interactions – PIs

Drugs Affected	Atazanavir (ATV)	Ritonavir (RTV)	Darunavir (DRV)	Lopinavir (LPV)
ANTIRETROVIRALS				
EFV	Co-administration not recommended because EFV decreases the serum concentration of ATV/r which may lead to resistance and treatment failure	See interaction with specific ritonavir-boosted PI	Co-administration not recommended because DRV/r may increase the serum concentration of EFV leading to increased risk of toxicity, and EFV decreases the serum concentration of DRV/r which may lead to resistance and treatment failure	AVOID: this combination increased risk of prolonged-QT syndrome and sudden cardiac death
ETR	No significant interaction	See interaction with specific ritonavir-boosted PI	No significant interaction	No significant interaction
DTG	No significant interaction	See interaction with specific ritonavir-boosted PI	No significant interaction	No significant interaction
RAL	ATV/r may increase RAL levels but interaction in not clinically significant	See interaction with specific ritonavir-boosted PI	No significant interaction	No significant interaction
ANTIFUNGALS				
Itraconazole	Limited data, minimal effect	No data, but potential for bi- directional inhibition between Itraconazole and RTV, monitor for toxicities Dose: dose adjustment for patients receiving >400 mg Itraconazole may be needed, or consider monitoring Itraconazole level	↑ Levels of azoles and DRV	↑ Levels: itraconazole when administered with LPV/r Dose: itraconazole – consider not to exceed 200 mg/day or monitor level and toxicity
Ketoconazole	Limited data, minimal effect	Levels: Ketoconazole ↑ 3X Dose: Use with caution; do not exceed 200 mg ketoconazole daily	↑ levels of azoles and DRV	Levels: LPV AUC ↓ 13% Azole ↑ 3-fold. Dose: Use with caution; do not exceed 200 mg ketoconazole daily

ANTI-MYCOBACTERIALS				
Rifampicin	Atazanavir AUC: decreased 72%; Cmax: decreased 53%; Cmin: decreased 98%	Levels: RTV ↓ 35%. Dose: No change. Increased liver toxicity possible. Co-administration may lead to loss of virologic response is RTV sole PI. Alternate anti-mycobacterial agents, such as rifabutin, should be considered	↓ levels of DRV	Levels: LPV AUC ↓ 75%. Should not be co-administered as a safe and effective dose of LPV/r that can be given with rifampicin has not been established
Rifapentine	Do NOT co-administer	Do NOT co-administer	Do NOT co-administer	Do NOT co-administer
Clarithromycin	Clarithromycin AUC: increased 94%;	Levels; Clarithromycin ↑ 77% Dose: Adjust clarithromycin dose for moderate and severe renal impairment	↑ levels of clarithromycin by 59%	Levels: ↑ Clarithromycin AUC 77% Dose: Adjust clarithromycin dose for moderate and severe renal impairment
Bedaquiline (BDQ)	Increases BDQ exposure and increases risk of prolonged QT syndrome, monitor for increased toxic effects by frequent ECG and transaminases assessment	Increases BDQ exposure, monitor for increased toxic effects by frequent ECG and transaminases assessment	Increases BDQ exposure, monitor for increased toxic effects by frequent ECG and transaminases assessment	Do NOT co-administer because of increased risk of prolonged QT syndrome Increases BDQ exposure, monitor for increased toxic effects
Delamanid (DLM)	Increases DLM exposure, monitor for increased toxic effects by frequent ECG and transaminases assessment	Increases DLM exposure, monitor for increased toxic effects by frequent ECG and transaminases assessment	Increases DLM exposure, monitor for increased toxic effects by frequent ECG and transaminases assessment	Do NOT co-administer because of increased risk of prolonged QT syndrome Increases DLM exposure, monitor for increased toxic effects

ORAL CONTRACEPTIVES				
	Ethinyl estradiol	Levels: Ethinyl estradiol	Ethinyl estradiol	Levels: Ethinyl estradiol
	AUC: ↓	↓ 40%.	AUC: ↓ 44%	↓ 42%
		Use alternative or additional method		Use alternative or additional method

LIPID-LOWERING AGENTS				
Simvastatin	Avoid co- administration	Levels: potential	Avoid	Levels: Potential
Lovastatin		for large increase in statin levels. Avoid concomitant use		for large increase in statin levels
				Avoid concomitant use
Atorvastatin	Minimal interaction	Levels: 450% ↑ when administered with SQV/RTV combination. Use lowest possible starting dose of atorvastatin with careful monitoring	↑ AUC four-fold	Atorvastatin AUC ↑ 5.88-fold. Use lowest possible starting dose of atorvastatin with careful monitoring
Pravastatin	Minimal interaction	Levels: 50% ↓ when administered with SQV/RTV	↑ AUC 81%	Pravastatin AUC ↑ 33%; no dosage adjustment necessary
		Combination		
		Dose: Pravastatin dosage adjustment based on lipid response		

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

ANTICONVULSANTS				
Carbamazepine Phenobarbital Phenytoin	Reduce ATV levels	Carbamazepine; ↑ serum levels when co-administered with	Avoid	Many possible interactions: Carbamazepine: ↑ levels when
		RTV Use with caution Monitor anticonvulsant levels		co-administered with RTV. Use with caution. Monitor anticonvulsant levels. Phenytoin: levels of LPV, RTV, and ↓ levels of Phenytoin when administered together
				Avoid concomitant use or monitor LPV level
OTHER DRUG				
Methadone	No interaction with unboosted ATV Increased metabolism of methadone with boosted ATV	Methadone ↓ 37%. Monitor and titrate dose if needed	↓ levels of methadone by 16%	Methadone AUC ↑ 53%. Opiate withdrawal may occur
		May require ↑ methadone dose		Monitor and titrate dose if needed.
				May require ↑
				methadone dose

ERECTILE DYSFUNCTION AGENTS				
Sildenafil	Use reduced dose of sildenafil	Sildenafil AUC ↑ 11-fold. Use cautiously Start with reduced dose of 25 mg every 48 hours and monitor for adverse effects		Sildenafil AUC ↑ 11- fold in combination with RTV. Do not exceed 25 mg every 48 hours
Miscellaneous	Decreased GI absorption of atazanavir due to reduced acidity	Theophylline ↓ 47% monitor theophylline levels	Warfarin levels	
		RTV 100 mg bid significantly increases systemic exposure		
		of inhaled (oral or nasal fluticasone, may predispose patients to systemic		
		Corticosteroid effects. Co- administration not recommended unless benefit of fluticasone outweighs the risk		

Annex 32. Drug-Drug Interactions – Integrase Inhibitors

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

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

Annex 33. Health Facility Assessment to Provide Community ART Distribution

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

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

Annex 34. Formula for estimation of Creatinine clearance

Formular for estimating creatinine clearance in children:

If creatinine is in mg/dl use this formula:

$$\text{eGFR (mL/min/1.73 m}^2\text{)} = \frac{0.413 \times \text{Height (cm)}}{\text{Scr (mg/dL)}}$$

If creatinine is in µmol/L use:

$$\text{eGFR} = \frac{36.5 \times \text{Height (cm)}}{\text{Scr (µmol/L)}}$$

Estimated Glomerular Filtration Rate (eGFR) = Creatinine clearance Cl (mL/min/1.73 m^2)

Formular for estimating Creatinine clearance in adults:

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

Annex 35. PHQ-9 Depression Screening Tool

PHQ-9 Depression Screening **Name:** **Date:**				
Ask the patient the questions below for each of the 9 symptoms and circle the response for each question. After asking all questions, add the points for each column at the bottom. The total score is the sum of the column totals. Interpretation and management recommendations are provided at the bottom of the table.				
Question: "Over the last 2 weeks, how often have you been bothered by any of the following problems?"	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself, or that you are a failure, or that you have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things (linked with patient's usual activities, such as reading the newspaper or listening to a radio program)	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Total = (add the points from each column)	**0**	**+___**	**+___**	**+___**

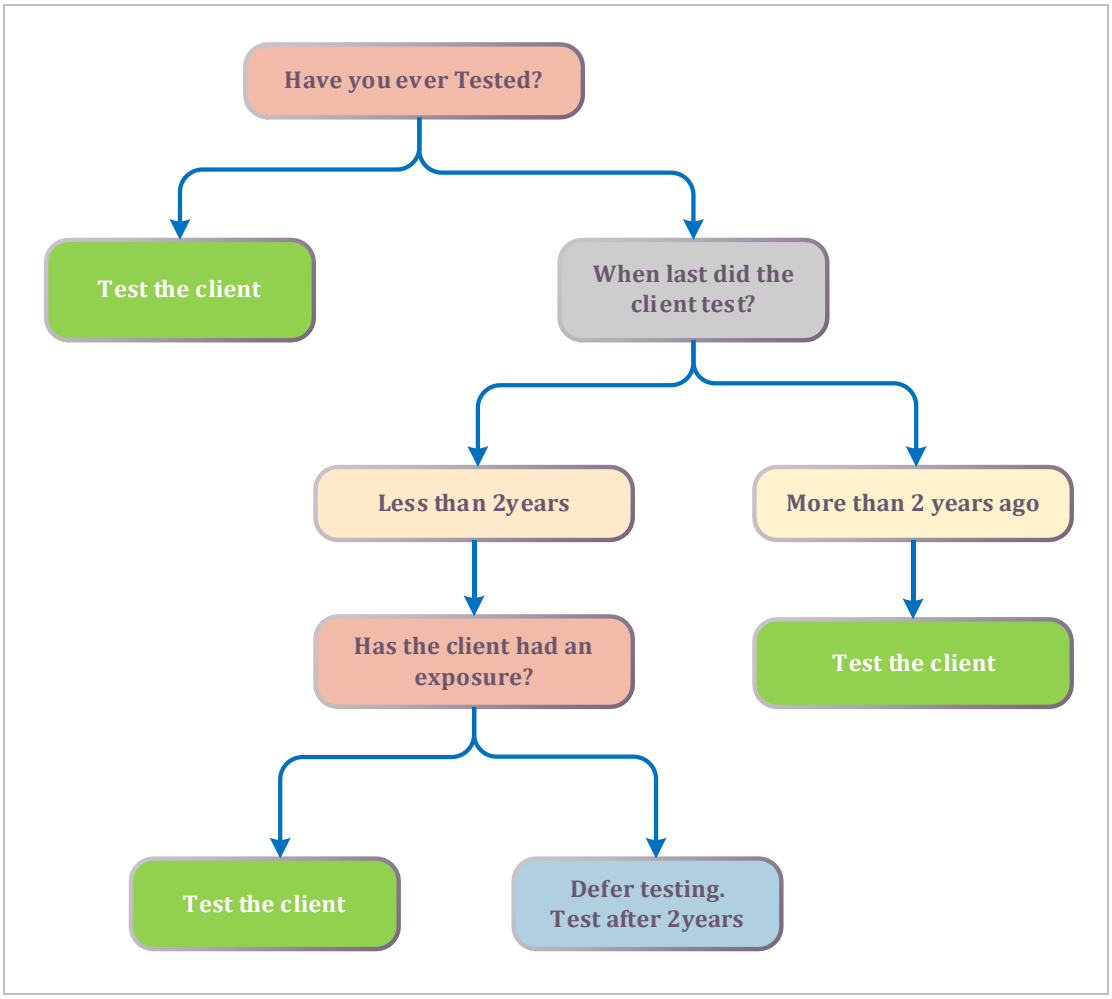
Total Score	**Provisional Diagnosis**
0-4	Depression unlikely
5-9	Mild depression
10-14	Moderate depression*
15-19	Moderate-severe depression*
20-27	Severe depression*

Annex 36. GAD -7 (Generalized Anxiety Disorder)

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

GAD-7 Score	Severity Level	Clinical Action
0–4	Minimal anxiety	No specific intervention required; provide reassurance and monitor.
5–9	Mild anxiety	Consider Psychoeducation or brief intervention and monitor the patient
10–14	Moderate anxiety	Initiate active treatment such as Counselling, psychological therapy (e.g., CBT) and/ medications
15–21	Severe anxiety	Strongly consider combined treatment (psychotherapy and medication); refer to mental health specialist if needed.

Annex 37. HIV Screening Eligibility Tool



Annex 38. Risk of renal failure by uACR and eGFR (Urine albumin to Creatinine Ratio)

				Albumin Categories		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/ mmol	30-299 mg/g 3-29 mg/mmol	≥ 300 mg/g ≥ 30 mg/mmol
GFR Stages	G1	Normal or high	≥90			
	G2	Mildly decreased	60 – 90			
	G3a	Mildly to moderately decreased	45 – 59			
	G3b	Moderately to severely decreased	30 – 44			
	G4	Severely decreased	15 – 29			
	G5	Kidney failure	<15			

Key to Figure:

Colours represent the risk for progression, morbidity and mortality, from best to worst

- **Green:** Low Risk (if no other markers of kidney disease, no chronic kidney disease)
- **Yellow:** Moderately increased risk
- **Orange:** High Risk
- **Red:** Very high Risk
- **Deep Red:** Highest risk

Annex 39: Contraceptive Methods for PLHIV Based on WHO 2018 Medical Eligibility Criteria

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

Category 1: No restriction for the use of the contraceptive method
Category 2: Advantages of using the method generally outweigh the theoretical or proven risks
Category 3: The theoretical or proven risks usually outweigh the advantages of using the method
*DTG was not included in the WHO 2018 MEC Guidelines, however, drug interactions between DTG and hormonal contraception have not been identified

Annex 40. Pre-Conception Counselling Messages and Services for PLHIV

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

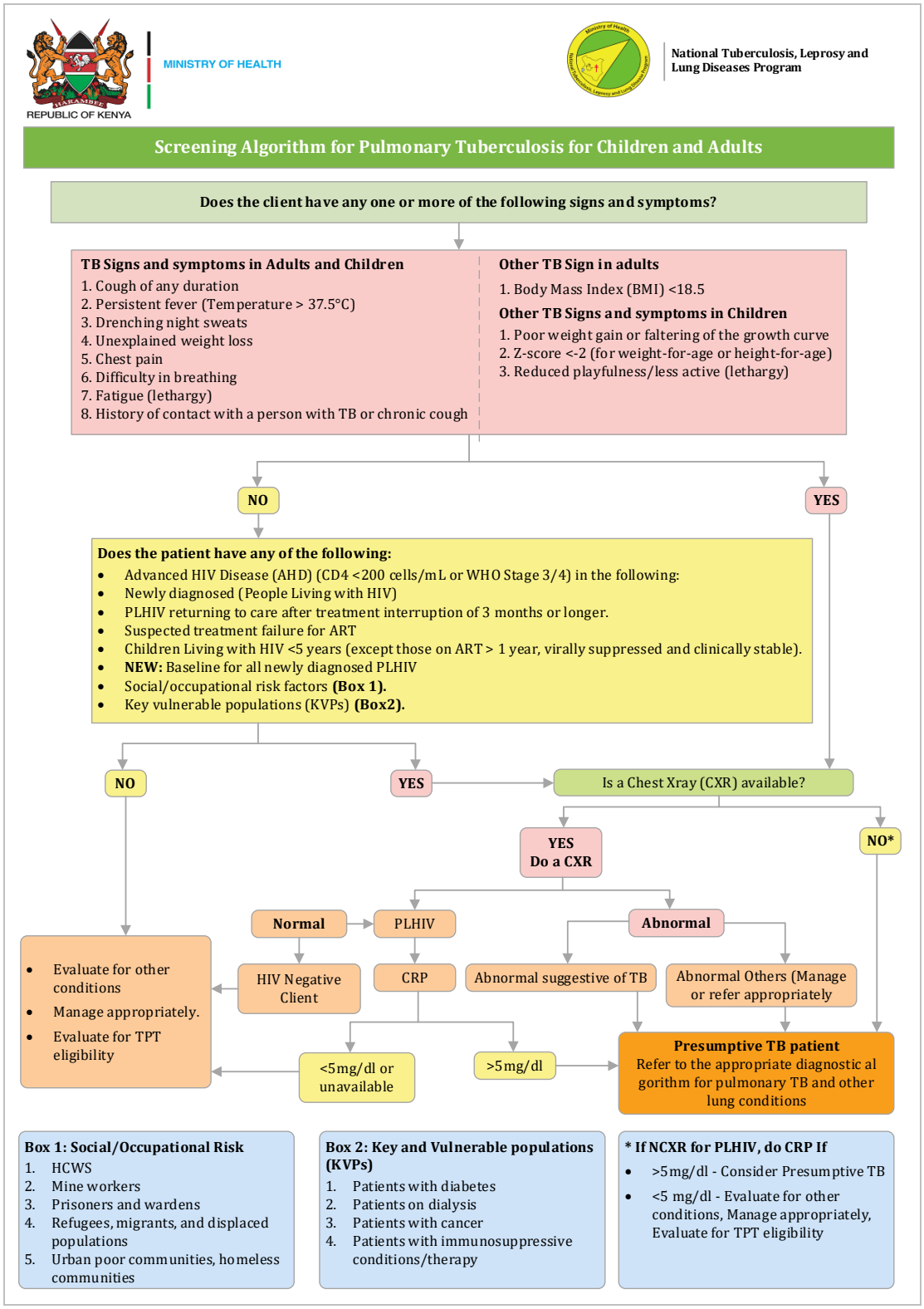
Annex 41. Cotrimoxazole preventive therapy

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

Annex 42. Management of Drug-Associated Skin Rash

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

Annex 43. Screening Algorithms for Pulmonary Tuberculosis for children and Adults.



Annex 44. Screening and Diagnosis Algorithms for Extrapulmonary Tuberculosis for Adults

MINISTRY OF HEALTH
REPUBLIC OF KENYA

National Tuberculosis, Leprosy and Lung Diseases Program

Screening and Diagnosis Algorithm for Extrapulmonary Tuberculosis for Adults

Does the client have any one or more of the following signs and symptoms?

TB Signs and symptoms in Adults and Children

1. Cough of any duration
2. Persistent fever (Temperature > 37.5°C)
3. Drenching night sweats
4. Unexplained weight loss
5. Chest pain
6. Difficulty in breathing
7. Fatigue (lethargy)
8. History of contact with a person with TB or chronic cough

Other TB Sign in adults

1. Body Mass Index (BMI) <18.5

Other TB Signs and symptoms in Children

1. Poor weight gain or faltering of the growth curve
2. Z-score <-2 (for weight-for-age or height-for-age)
3. Reduced playfulness/less active (lethargy)

NO → Evaluate for other conditions and manage appropriately.

YES → Evaluate for TPT eligibility Investigate appropriately for EPTB. Treat for DSTB or DRTB as per the guidelines

SYMPTOMS, SIGNS & INVESTIGATIONS FOR EPTB

Site of EPTB	Symptoms and signs for EPTB specific to the affected site	Investigation
• **TB lymphadenitis (cervical, axillary, or inguinal LN)**	• Lymph node enlargement for more than one month. • Painless, non-tender, often asymmetrical • With or without caseous (cheese like) discharge • It's most commonly in the neck area	• Fine needle aspiration (FNA) for: • Xpert, culture • Microscopy-predominance of lymphocytes, AFB • Lymph node biopsy Histology
• **Pleural TB**	• +/-Chest pain is often one-sided • +/- Cough • Large efflusion-fast breathing, breathlessness • Dullness on percussion, reduced breath sounds on the affected side	• CXR • Chest ultrasound • Pleural tap1
• **TB meningitis**	• **Persistent CNS symptoms:** • Early signs-Persistent headache, irritability/abnormal behaviour, one-sided weakness, changing gait, blurred vision, squint (signs progressively worsening over weeks) • Late (severe) signs reduced level of consciousness, convulsions, neck stiffness, bulging Fontanelle, cranial nerve palsies.	• Lumbar puncture-CSF1 • CT scan brain with contrast • Cranial ultrasound in infants & months with an open anterior fontanelle
• **Miliary TB**	• Non-specific signs: persisting fever, weight loss/poor weight gain, lethargy • Often have respiratory symptoms s signs (fast breathing, cough, wheeze, respiratory distress)	• CXR diffuse miliary opacities (micronodules) • Fundoscopy-see micro-nodules on retina • High risk for other extrapulmonary sites look for other lesions.
• **Abdominal TB**	• Abdominal pain >2 weeks • Progressive swelling of the abdomen over several weeks. • Exam: Abdominal swelling, ascites (shifting dullness, fluid thrill	• Ascitic tap1 • Abdominal ultra-sound2
• **Spinal TB**	• Persistent pain in a focal point in the back. • Early sign: Tender/pain when applying pressure to the part of the spine, loss of lordosis/reduced curvature in the lower back if located in the lumbar vertebrae. • Advanced disease • Deformity of the spine • Progressive lower limb weakness	• X-ray of the affected spine-lateral and antero-posterior views
• **Pericardial TB**	• Breathless with minimal exertion, palpitations (feeling of rapid heartbeat), and cough may be present • Cardiac failure (tachycardia, pedal cedema, infants-periorbital puffiness • Distant heart sounds • Apex beat is difficult to palpate	• CXUR-global enlargement of the heart • Echocardiogram (Cardiac ultrasound) Pericardial tap

1. Cerebrospinal fluid (CSF) pleural fluid, ascitic fluid specimens joint fluid the following findings are suggestive of TB Colo ur clear or light yellow colour Bis chemistry-high protein and low glucose Microscopy-increased white cell counts, predominantly lymphocytes. (note that bacteriologic tests rarely detect MTB from these body fluids)
2. Abdominal ultra sound shows ascites septation, enlarged abdominal lymph nodes

All specimens (FNA, CSP, aspirates etc.) may be sent for bacteriologic tests such as GeneXpert, AFB microscopy or TB culture as appropriate, however detection rate is lower than sputum

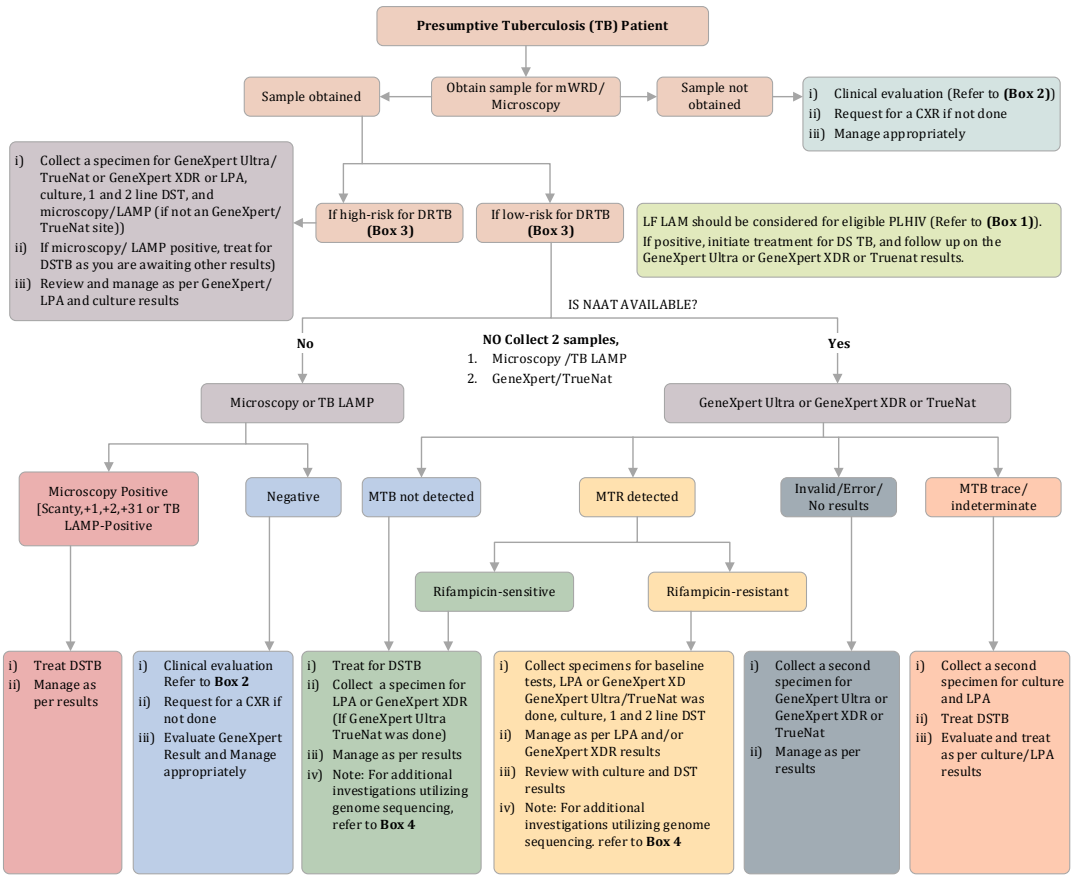
Annex 45: Pulmonary Tuberculosis Diagnostic Algorithms for Adults

REPUBLIC OF KENYA

MINISTRY OF HEALTH

National Tuberculosis, Leprosy and Lung Diseases Program

Diagnostic Algorithm for Adults



Box 1: Indications for use of LF-LAM as an adjunct test to GeneXpert Ultra/ Truenat

1. AHD characterized by:
   a. All PLHIV ≥ 5 years with CD4 cell count <200cells/mm^3
   b. WHO stage 3 and 4 disease
   c. All CLHV aged Less than 5 Years, regardless of other factors
2. PLHIV with danger signs of severe illness
3. PLHIV currently admitted in the hospital
4. PLHIV with presumptive TB in outpatient settings

Box 2: Clinical Evaluation

1. Review CXR If not done, request one
2. Additional imaging, e.g. CT scan, ultrasound, MRI
3. Re-evaluate and consider a clinical diagnosis of TB or EFTB
4. Evaluate for other respiratory conditions, e.g. Asthma, COPD, Lung cancer, PTLD, bronchiectasis, or others
5. Consider a diagnosis of Non-Tuberculous Mycobacterium (NTMs), especially if the patient not improving and is smear positive. Collect and send a sample for Culture for diagnosis
6. If sputum can not be obtained, consider bronchoscopy or interventional radiology, if indicated

Box 3: High-risk groups for DRTB

1. All previously treated 16 patients: treatment failures, relapses, treatment her loss to fol low-up
2. Contacts of Drug-Resistant TB patients
3. TB Patient with a positive smear result after 2 months of TB treatment
4. A patent who develops TB symptoms while on TPT or has had previous TPT exposure
5. Healthcare workers with TB symptoms
6. Prisoners with TB symptoms
7. Refugees with TB symptoms

Low-risk groups for DRTE

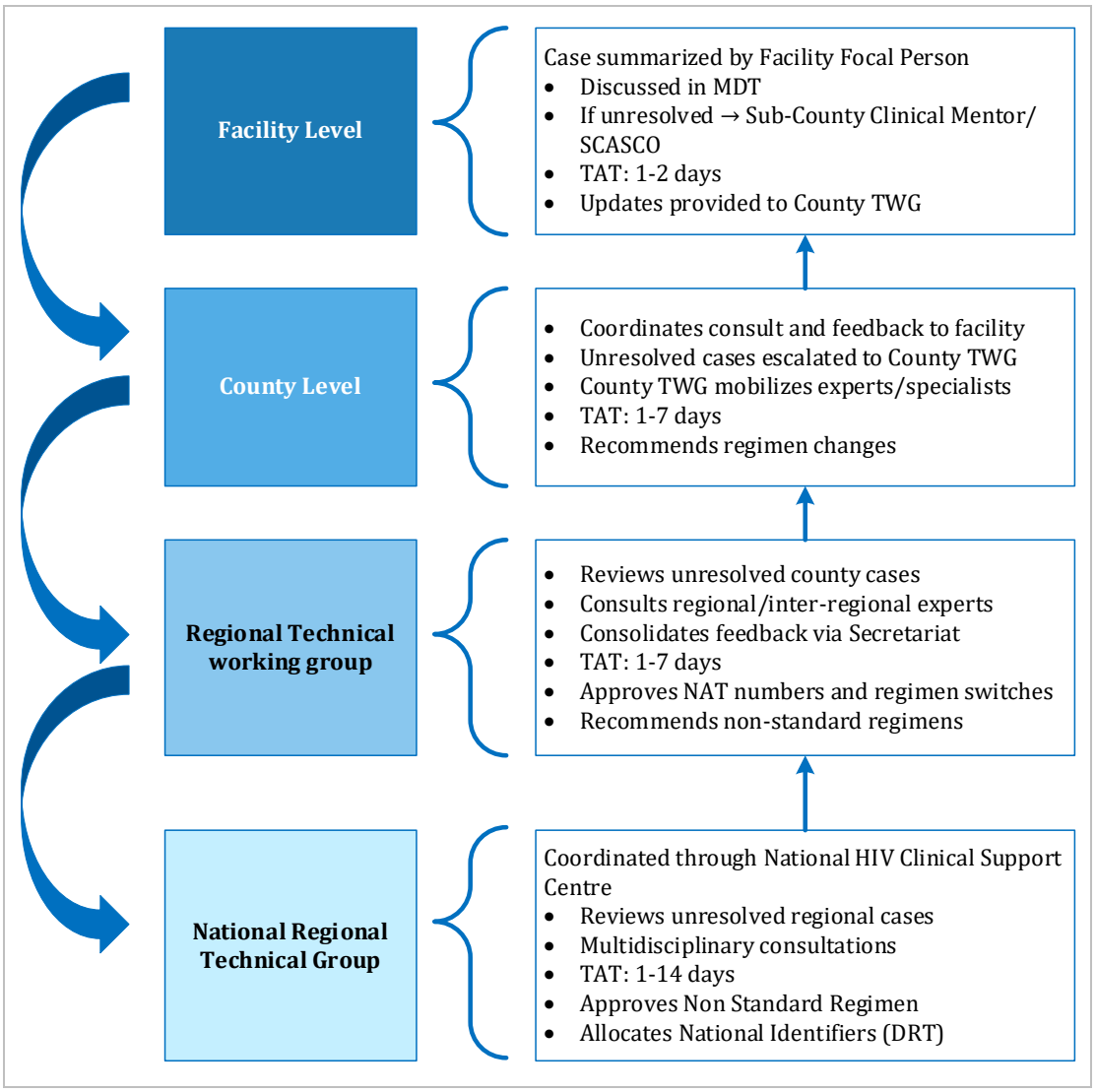
1. Any TB Patient who Is not in the high Risk groups

Box 4: Indications for TB sequencing

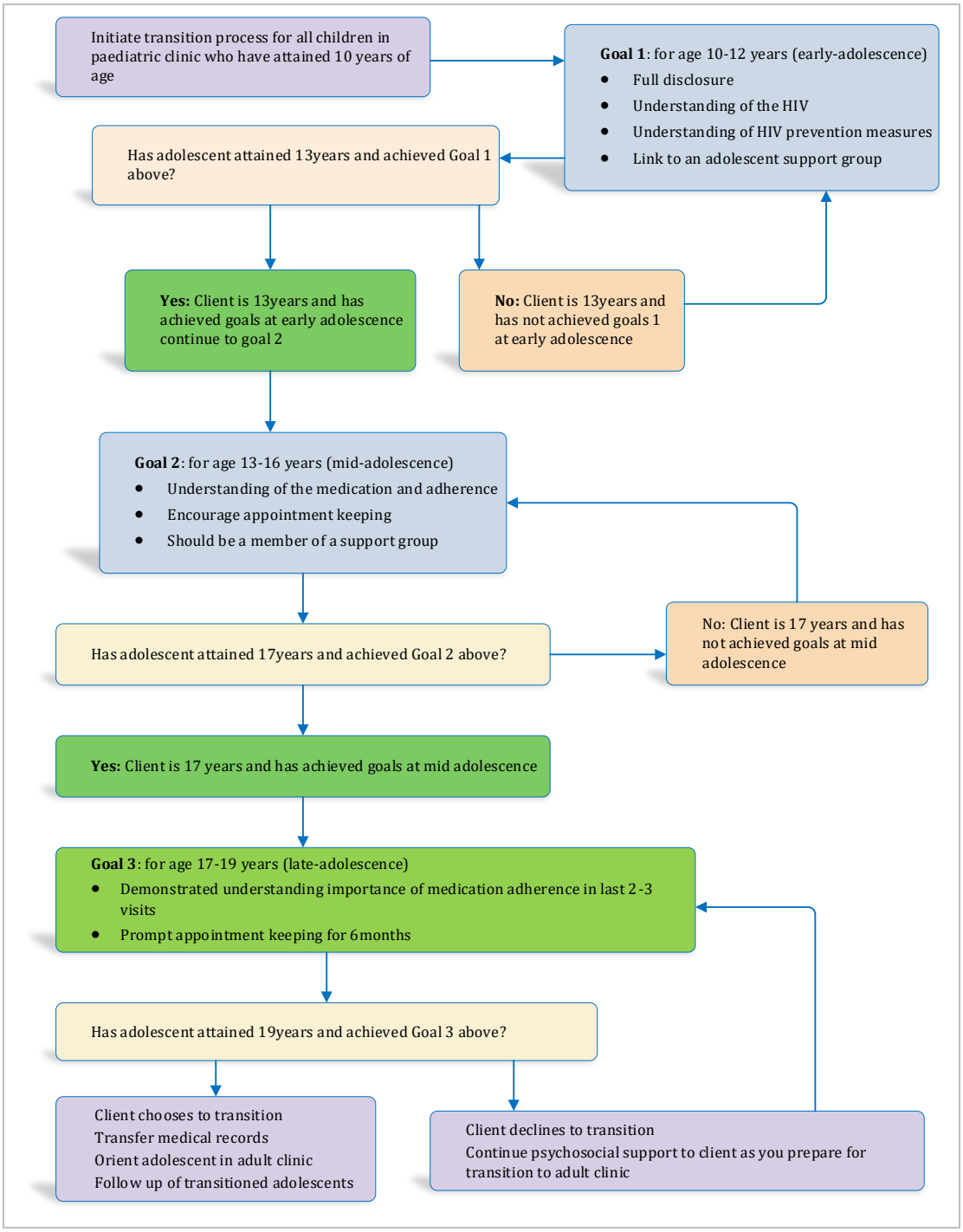
1. All patients diagnosed with DR for TB 2
2. Patients with discordant laboratory results
3. All previously treated patients with growth obtained from culture

TB – Tuberculosis; **DSTB** – Drug-susceptible TB; **DRTB** – Drug-Resistant TB**; mWRD** – molecular WHO Recommended Diagnostics;
DST – Drug susceptibility Testing; **LPA** – Line Probe Assay; **TB LAMP** – Loop Mediated Isothermal Mediated Isothermal Amplification Test;
LF LAM – Lateral Flow Lipoarabinomannan Assay; **CXR** – Chest X-ray; **PLHIV** – People Living with HIV

Annex 46. Consultation Pathway for Integrated HIV/STI/Hepatitis Virus Prevention and Treatment



Annex 47. Transitioning from Adolescent to Adult HIV Services



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