THE REPUBLIC OF UGANDA

MINISTRY OF HEALTH

CONSOLIDATED GUIDELINES FOR THE PREVENTION AND TREATMENT OF HIV AND AIDS IN UGANDA

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FOREWORD

The Government of Uganda promotes a combination of interventions to control a generalized HIV epidemic in the country. These interventions include structural, behavioral and biomedical. The Ministry of Health, which is responsible for the public health response, has prioritized those interventions that are evidence based for impact. Over the past ten years, the AIDS Control Program has integrated antiretroviral therapy (ART) into the comprehensive response to HIV prevention, care and support. These Guidelines have been implemented with a focus on those interventions that will lead to HIV epidemic control by 2020 and end AIDS by 2030.

The 2016 version of the "Consolidated Guidelines for Prevention and Treatment of HIV in Uganda" expanded the HIV "test and treat" policy to all people diagnosed with HIV. The "test and treat" policy involves providing lifelong ART to people living with HIV irrespective of CD4 or World Health Organisation HIV clinical staging. In compliance with WHO recommendation, all limitations on eligibility for ART among people living with HIV were removed: all populations and age groups became eligible for treatment. In addition, we recommended HIV pre-exposure prophylaxis for HIV uninfected persons at substantial risk of HIV acquisition and a host of other HIV prevention priorities.

In the 2018 version of the "Consolidated Guidelines for Prevention and Treatment of HIV in Uganda, we recommended treatment optimization by the introduction of an Integrase Inhibitor Dolutegavir, a newer drug, in combination with Tenofovir and Lamivudine as the preferred first line regimen for adults living with HIV. We also provided guidance on HIV self-testing to increase access to testing and a renewed focus on screening and treating for syphilis in pregnant women and their partners. In addition, we provided guidance on differentiated service delivery models for targeting different client categories to catalyze the pace towards achieving universal access to ARVs.

The 2020 revision of the "Consolidated Guidelines for Prevention and Treatment of HIV in Uganda", reaffirms the optimization of ART by using Dolutegravir-containing regimens as preferred first-line for all eligible people living with HIV (including pregnant and breastfeeding adolescent girls and women, as well as children). Further guidance has been provided on service delivery modalities for targeting different client categories to catalyze the pace towards achieving epidemic control. The guidelines also emphasize pharmacovigilance for screening, reporting and timely management of adverse effects of medicines including ART and anti-TB drugs.

These guidelines provide a simplified framework for healthcare workers, district health teams and Managers of HIV, TB and Reproductive Health programs and Essential Medicines. They also act as a reference tool for AIDS Development Partners, implementing partners, training institutions, researchers, civil society organizations and the community of people living with HIV.

I call upon all Stakeholders in the fight against HIV and AIDS in Uganda, to support the successful implementation of these guidelines.

Dr. Henry Mwebesa

Director General Health Services

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ABBREVIATIONS AND ACRONYMS

3TC Lamivudine
ABC Abacavir
ACTs Artemisinin-based combination therapies
AFHS Adolescent-friendly health services
AFP Alpha-fetoprotein
AIDS Acquired Immune Deficiency Syndrome
ALT Alanine Amino-Transferase
ANC Antenatal care
ARM Artificial rupture of membranes
ART Antiretroviral Therapy
ARV Antiretroviral medicines
AST Aspartate Aminotransferase
ATV/r Atazanavir/ritonavir
AZT Zidovudine
BCC Behavioral change communication
BCG Bacillus Calmette-Guerin
BP Blood pressure
CASA Community ART Support Agents
CBC Complete bloodcount
CBO Community-based organizations
CCLAD Community client-led ART Delivery
CD4 Cluster of differentiation 4
CDC Centers for Diseases Control and Prevention
CDDP Community drug distribution Points
CDO Community Development Officer
CHEW Community Health Extension Worker
CITC Client-initiated Counseling and Testing
CM Cryptococcal meningitis
CMV Cytomegalovirus
COPD Chronic obstructive pulmonary disease
CPT Cotrimoxazole preventive therapy
CQI Continuous quality improvement
CrAg Cryptococcal Antigen
CSF Cerebral spinal fluid
CTX Cotrimoxazole
DBS Dried blood spot
DM Diabetes mellitus
DNA Deoxyribonucleic Acid
DRV/r Darunavir/ritonavir
DSDM Differentiated service Delivery Models
DTG Dolutegravir
EBF Exclusive breastfeeding
EFV Efavirenz
EGPAF Elizabeth Glaser Pediatric AIDS Foundation
eMTCT Elimination of mother-to-child HIV transmission
ETV Etravirine
FBO Faith-Based Organizations
FP Family Planning
FPG Fasting Plasma Glucose
FTC Emtricitabine
GBV Gender-based violence
GFR Glomerular filtration rate
HBcAg Hepatitis B core antigen

HBHTC Home-based HIV testing and Counseling
HBsAg Hepatitis B surface Antigen
HBV Hepatitis B Virus
HCC Hepatocellular Carcinoma
HCIII Health Centre III
HCIV Health Centre IV
HCV Hepatitis C virus
HEI HIV-exposed infants
HIV Human immunodeficiency virus
HIVST HIV Self-Testing
HMIS Health Management Information Systems
HPV Human Papilloma Virus
HTS HIV Testing Services
IAC Intensive adherence counseling
ICF Intensified Case Finding
IFN Interferon
IGAs Income Generating Activities
IMNCI Integrated maternal, newborn and childhood illnesses
INH Isoniazid
IPD Inpatientdepartment
IPT Isoniazid Preventive Therapy
IRIS Immune reconstitution inflammatory syndrome
IRS Indoor residual spraying
ITC In-patient therapeutic center
LLINs Long-lasting insecticide-treated nets
IUD Intrauterine device
IYCF Infant and young child feeding
KP Key populations
LFTs Liver function tests
LMIS Laboratory management information system
LP Lumbar puncture
LPV/r Lopinavir/ritonavir
MAM Moderate acute malnutrition
MCH Maternal child health
MDR Multi-drug resistant
MNCAH Maternal, newborn, child and adolescent health
MOH Ministry of Health
MUAC Mid-upperarm circumference
NAC National ART Advisory Committee
NACS Nutrition assessment, counseling and support
NCD Non-Communicable Diseases
NDA National Drug Authority
NGO Non-government organization
NNRTI Non-nucleoside Reverse Transcriptase Inhibitor
NRTI Nucleoside Reverse Transcriptase Inhibitor
NVP Nevirapine
OI Opportunistic infection

OPD Outpatient department
OTC Outpatient therapeutic center
OVC Orphans and vulnerable children
PCR Polymerase chain reaction
PEP Post-exposure prophylaxis
PHDP Positive health dignity and prevention
PHQ Patient health questionnaire
PI Protease inhibitor
PITC Provider-initiated HIV testing and counseling
PJP *Pneumocystis jiroveci* pneumonia
PLHIV People living with HIV
PNC Postnatal care
PrEP Pre-exposure prophylaxis
PSS Psychosocial Support
PTT Prothrombin time
PWDs Persons with disabilities
PV Pharmacovigilance
QI Quality improvement
R Rifampicin
RAL Raltegravir
RFTs Renal function tests
RH Reproductive health
RUTF Ready-to-use therapeutic feeds
SAM Severe acute malnutrition
SBCC Socio-behavioral change communication
SFP Supplementary feeding programs
SMC Safe male circumcision
SP Sulfamethoxazole-pyrimethamine
STIs Sexually transmitted infections
TB Tuberculosis
TDF Tenofovir
TPHA Treponema pallidum hemagglutination assay
USAID United States Agency for International Development
UTI Urinary tract infection
VCT Voluntary counseling and testing
VHT Village health team
VIA Visual inspection with acetic acid
VL Viral load
VMMC Voluntary medical male circumcision
WAOS Web-based ordering system
WFL/H Weight for length/height
WHO World Health Organization
YAPS Young People and Adolescent Peer Support(ers)
YCC Young child clinic

1 INTRODUCTION

1.1 CONTEXT

These guidelines provide guidance on the diagnosis of human immunodeficiency virus (HIV) infection, the care of people living with HIV and the use of antiretroviral (ARV) drugs for treating and preventing HIV infection. The guidelines are structured along the continuum of HIV testing, prevention, treatment and care. The goal of these guidelines is to furtherexpand access to antiretroviral therapy (ART) and to optimize treatment.

Uganda has implemented the "test and treat" policy for all HIV-infected children, pregnant and breastfeeding women, HIV and TB or Hepatitis B co-infected people, the HIV-infected partner in a serodiscordant relationship and HIV-infected individuals among key populations since 2014. The 2016 guidelines expanded this policy to all adolescents and adults living with HIV. The test and treat policy involves providing lifelong ART to people living with HIV irrespective of CD4 count or clinical stage.

The 2018 version of the guidelines recommended optimizing ART using Dolutegravir-based regimen as preferred first-line for eligible PLHIV considering the rising levels of pre-treatment drug resistance to Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs). These guidelines also provided operational and service delivery guidance to districts and health facilities to implement other new approaches including:

- HIV Self-Testing and Assisted Partner Notification.
- Effective integration of elimination of mother-to-child HIV transmission (eMTCT) services into maternal, newborn,child and adolescent health services(MNCAH).
- Differentiated service delivery,whichreduces clinic visits and allowscommunity ART distribution to PLHIV who are stable on ART.
- Working with community structures to optimize delivery of HIV services; and
- Retention, adherence to treatment, adolescent-friendly and responsive health services.

The 2020 version of the guidelines recommend the optimization of ART using Dolutegravir-based regimens as preferred first line for all eligible PHLIV including pregnant and breastfeeding adolescent girls and women. The guidelines also recommend procedures for ARV substitution in adults, adolescents, and children already on first-line ART and recommend options for subsequent second- and third-line regimens. These guidelines also emphasize the importance of Pharmacovigilance (PV) and describe the procedures for identifying, investigating, reporting, and managing adverse effects of ART, anti-TB and other medications.

1.2 OBJECTIVES

The objectives of these guidelines are:

1. To provide a standardized and simplified guide for offering HIV testing services.
2. To provide guidance and updates on other HIV Prevention strategies: Behaviour Change Communication, eMTCT and Safe Male Circumcision.
3. To provide an updated, evidence-based and simplified guide to providing ARV drugs for HIV treatment and prevention to all age groups and populations.

4. To provide a standardized and simplified guide on infant and young child feeding for HIV-infected or exposed infants and children.
5. To provide guidance on key operational and service delivery issues with the aim of increasing access to HIV services and strengthening the continuum of HIV care.

1.3 TARGET AUDIENCE

The primary audiences for these guidelines are:

- Healthcare workers and district health teams
- Program managers of HIV, Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCAH)and TB programs as well as national medicines warehouses, and
- AIDS development partners, Implementing Partners, Training institutions, Researchers, Civil society organizations and PLHIV

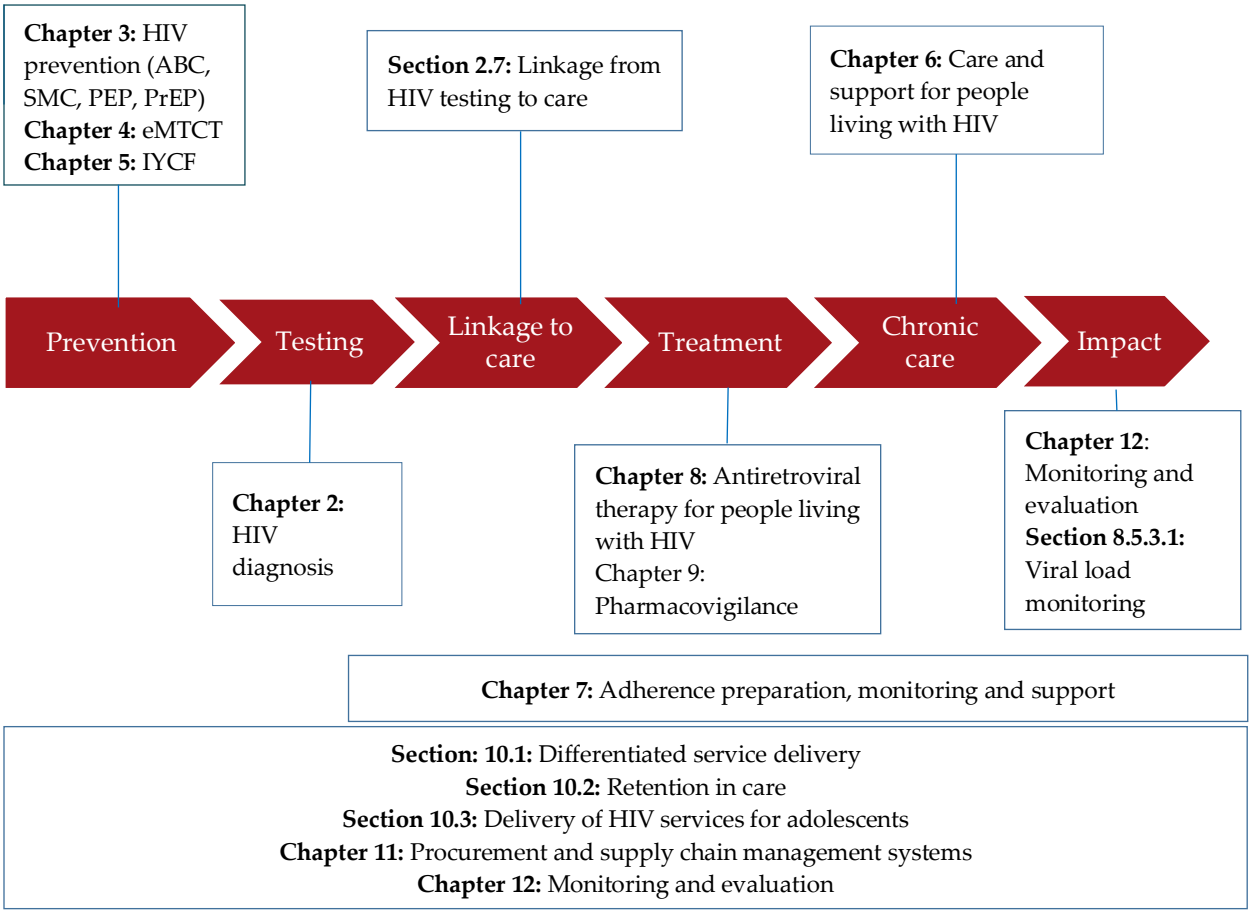
1.4 GUIDELINES DEVELOPMENT PROCESS

These guidelines were developed by a team of internal and external technical experts with the engagement of PLHIV. The guidelines development process was comprehensive and involved adaptation of the guidelines, approval of the Guidelines by the National ART Advisory Committee, and the senior and top management of Ministry of Health. There were a series of writing workshops and peer review with the guidance of a Consultant. The adaptation of the guidelines by the different subcommittees involved reviews of evidence cited in the WHO guidelines, presentation, and review of local evidence with discussion and agreement on the adaptation at all stages. We also received technical support and peer review from external experts including those from the World Health Organisation, Centers for Disease Control and Prevention, United States Agency for International Development,Clinton Health Access Initiative and Elizabeth Glaser Pediatric AIDS Foundation.

1.5 COMPONENTS OF THE GUIDELINES

The components of these guidelines are structured along the continuum of HIV prevention, testing, treatment, and care. **Figure 1** shows the different components of the guidelines at each stage of the continuum of prevention and care.

Figure 1: HIV continuum of prevention and care



Box 1: Key Highlights in the Introduction

- The 2020 version of the guidelines recommend using Dolutegravir-based regimens as preferred first- and second-line ART for all eligible PHLIV including pregnant and breastfeeding women.
- The guidelines recommend procedures for substituting ARVs in adults, adolescents, and children already on first-line ART and recommend options for subsequent second- and third-line regimens.
- These guidelines emphasize the importance of Pharmacovigilance (PV) and describe the procedures for identifying, investigating, reporting and management of adverse effects of ART, anti-TB and other medications.

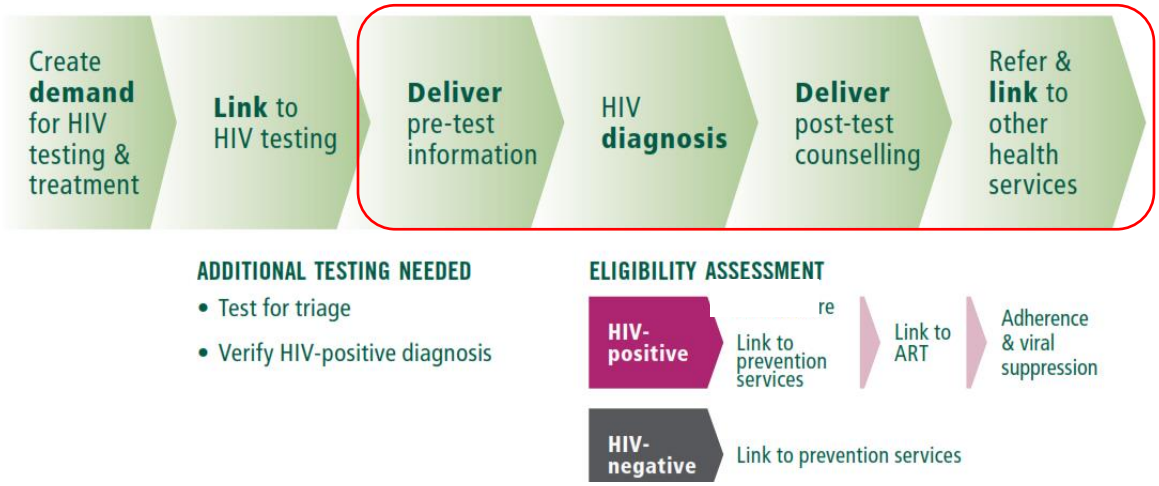
2 HIV TESTING SERVICES AND LINKAGE TO HIV CARE

2.1 INTRODUCTION

HIV testing is the entry point to HIV prevention, care, treatment, and support services. The aim of HIV testing services (HTS) is to diagnose HIV early to ensure early linkage to prevention, treatment, and support services. By 2019, only 88% of the estimated 1.4 million HIV-positive persons in Uganda knew their HIV serostatus, and 87% of these were receiving antiretroviral treatment (Program data). To improve access and efficiency, HIV testing services (HTS) should be made available to all persons at risk of HIV infection using cost-effective and high-impact approaches. Since only 12% of PLHIV do not know their status, HTS should be highly targeted and based on HIV risk of exposure.

HTS delivery includes a range of activities and services that are described on the pathway in Figure 2 below. This section guides the provision of quality HTS for reaching populations more likely to be living with HIV. Health workers should use this guidance alongside the national HTS policy and implementation guidelines (2016), the national HTS policy addendum (2018) and in observance of the HIV Prevention and Control Act 2014.

Figure 2: Continuum of Linkage to Care and Prevention



Adopted from WHO consolidated guidelines on HTS, 2015.

2.2 PRINCIPLES OF HIV TESTING SERVICES (HTS)

HTS delivery shall be non-discriminatory and offered using a Public Health approach that observes the 5Cs (Confidentiality, Consent, Counselling, Correct test result and Connection to appropriate services) irrespective of HTS approach. These principles are described below with emphasis on newer HTS approaches.

- **Confidentiality:** All providers should ensure privacy during HTS provision. All information discussed with clients should not be disclosed to another person without the client's consent. Confidentiality in the HIV Self- testing (HIVST) context should be maintained around the distribution of HIV self-test kits, testing and sharing HIV self-test result.

- **Consent:** All persons 12 years and above should consent to HTS on their own. In situations where consent cannot be obtained, the parent or guardian (of a child), next of kin, or legally authorized person should consent. Verbal consent is sufficient for HIVST. For Assisted Partner Notification Testing (APN), age of consent is 15 years. All index clients MUST consent to APN before being interviewed to identify their sexual contacts.
- **Counseling:** All persons accessing HTS should be provided with quality counseling before and after testing as per the approved HTS protocol. Adequate information before and after the HIVST should be made available to individuals through health worker demonstrations, instructional/demonstration videos and print material, among others.
- **Correct test result:** HTS providers should adhere to the national testing algorithms and must follow the Standard Operating Procedure (SOP) for HIV testing to ensure that clients receive correct HIV test results. Adequate and clear instructions with graphic illustrations on how to conduct HIVST should be provided with the test kits to ensure a person can ably follow the correct procedure to obtain accurate results.
- **Connection to care:** Providers should link HTS clients to appropriate HIV prevention, treatment, care and support services. All clients seeking HIVST should be linked to HIV post-test services based on outcome of the test. For those with HIV negative HIVST, link to HIV prevention services. Individuals whose HIV self-test results are reactive/positive should be advised on further HIV testing for diagnosis at the nearest health facility and if found to be HIV positive should be linked to HIV treatment services. Information on linkage including a helpline for any additional support should be provided.

2.3 THE CONCEPT OF TARGETED HIV TESTING

Definition

Targeted HIV testing is the process in which HTS is focused on an individual or group of individuals who are at high risk of HIV acquisition. Unlike routine HTS which entails systematically offering an HIV test to patients seeking health care regardless of known risk factors, targeted HIV testing requires HTS providers to follow a set criterion to determine eligibility of an individual or groups of individuals before HTS is provided.

Why Targeted HIV testing?

With 88% PLHIV identified in Uganda, it is difficult to identify the undiagnosed PLHIV with general population approaches. However, based on the dynamics of the HIV epidemic in Uganda, specific risk factors that drive the epidemic have been identified. These include:

- Being in a sexual relationship with multiple concurrent partners
- Belonging to a key or priority population
- Being a sexual contact to an index client
- Being a biological child to an HIV positive client
- Not knowing your Partner's status
- Being in discordant relationship

HTS therefore needs to focus on such people who are at high risk of being HIV positive.

Benefits of Targeted HIV testing

- Early identification for population groups with high incidence
- Maximizes use of testing resources
- Allows health facilities to focus their activities on higher risk populations
- Yields a higher positivity rate than routine or standard testing
- Reduced workload from the already constrained health workforce

Examples of Targeted HIV Testing approaches in Uganda

In Uganda, Targeted HIV testing is provided in various ways and is also referred to as ''**Risk Based Testing''**. The forms of Targeted HTS include the following:

- Index client contact testing (including Social Networks testing, APN)
- HIV Self Testing (HIVST) through ''focussed'' distribution of HIVST kits

It is important that all HTS providers learn how to provide targeted HTS since it maximises identification of PLHIV, saves resources, reduces workload.

2.4 HIV TESTING SERVICES MODELS & APPROACHES

To improve access and efficiency of HTS, a mix of health facility and community-based models should be utilized. Under each of these two models, the two main approaches for HTS will included: Provider-initiated HIV testing and counseling (PITC) and Client-initiated testing and counseling (CITC). Refer to chapter 10 for more details on service delivery models for HTS.

2.4.1 FACILITY-BASED HTS MODEL

HTS approaches under the Facility-based model are further described below:

2.4.1.1 Provider-initiated HIV testing and counseling (PITC)

This is HIV testing and counselling provided by health care providers to persons attending health care facilities, as a standard component of medical care. It offers an opportunity to the client to opt in or opt out of the HIV testing. Under this approach, HTS should be initiated by the health worker as part of standard health care. It can also be provided within community settings when the health worker initiates the HTS process e.g. index testing.

Routine HIV testing is no longer encouraged except in special circumstances. As much as possible, Risk Based Testing (RBT) is encouraged. However, the following categories of individuals should be prioritized for HIV testing:

TB presumptive clients, malnourished and in-patient children, clients with current STI, pregnant and breastfeeding women, sexual offenders and survivors, blood donors, body tissue and organ donors. The following clients need to be screened for eligibility before HIV Testing: Clients seeking SMC/VMMC, inpatients due to trauma and partners of pregnant and breastfeeding women.

Within OPD settings, HIV testing should be guided by the adult and Pediatric& Adolescent Screening Tools to determine eligibility. PITC will be offered as an ‘opt–out’ HTS service.

Screening for HTS for all clients attending OPD should be documented in the OPD register (column 14).

2.4.1.2 Diagnostic testing

This shall be carried out on individuals as deemed necessary by the attending health care team with the purpose of better patient management. Such situations may include symptomatic, unconscious, very sick and mentally impaired patients.

2.4.1.3 Index client contact testing

This involves tracing contacts of index HIV infected clients and offering them testing services. Examples of these approaches include: Assisted Partner notification (APN) services, Know Your Child Status campaigns and Social network Testing services (SNS).

2.4.1.4 Client-initiated testing and counseling (CITC)

CITC formerly known as voluntary counseling and testing is where individuals and couples seek HIV testing services on their own. These clients should receive HIV testing and counseling from any trained and certified HTS providers or designees who may be lay providers or medical workers at any entry point in the facility after screening for eligibility.

2.4.2 COMMUNITY BASED HTS MODEL

HIV testing services at communities will aim to serve especially most at-risk populations (key vulnerable and priority populations) that otherwise would not access facility-based HTS. All community HIV testing services should ensure that all clients diagnosed with HIV are effectively linked to HIV prevention, treatment and support services. HTS approaches under the Community-based model are further described below:

2.4.2.1 Provider-initiated HIV Testing and counseling (PITC)

In this approach, the index client is used to help identify subsequent clients for testing or through a snowball approach.

a. Home-based HIV counselling and testing (HBHCT)

Home-based HIV testing and counseling is where HTS is provided in a home setting through an index HIV client invitation or a door-to-door approach. Index-client HBHCT should be prioritized for household members of all HIV-positive individuals in care as well as confirmed and presumptive TB patients. Index testing may be provided through HBHCT.

b. Index Client Testing or index case HIV testing

A focused approach to HIV testing in which the household and family members (including children) of people diagnosed with HIV are offered HIV testing services. HIV testing services should be offered to family members/household members that are exposed to HIV through the index client. Other forms of index testing include APN and Know Your Child Status.

c. Social Network Strategy (SNS) for HIV Testing

Social Network Strategy (SNS) for HIV Testing is based on the underlying principle that persons within the same social network who know, trust, and can exert influence on each other, share the same risks and risk behaviors for HIV. The approach to SNS includes identifying clients or peers who are HIV positive or at high risk for HIV and enlisting them to become recruiters. Unlike peer advocates or peer educators, recruiters are short term and require coaching rather than training and supervision. The recruiters identify network associates in their social networks (e.g., friends, sex or drug partners, family members, etc.) who may be at risk for HIV and who they believe would benefit from HIV testing. The recruiters talk with the network associates they identified and refer or accompany them to HIV testing. The core elements for SNS include recruiter enlistment, engagement, recruitment of network associates and HIV Testing. More operational guidance is provided in the HTS/APN training curriculum.

d. Snowball Approach

In this approach, the HTS team works with the index client to invite other members of the group for HTS. This approach is recommended for use among sex workers and men who have sex with men. It is a form of index client contact tracing.

2.4.2.2 Client initiated Counselling and testing (CITC)

a. HTS Outreach/Mobile:

This approach should target priority populations that otherwise have limited access to HTS services (see section on target populations below). Outreach HTS can include:

i. *Door-to-door HIV testing* which should be implemented only in high HIV prevalence settings or communities with key populations such as the fisher folk or hotspots for sex workers.
ii. *HTS integrated into health outreaches* like immunization or VMMC.
iii. *HTS outreaches in locations frequented by target populations* like key population hotspots, sporting events or workplaces. These outreaches could include moonlight testing and mobile clinics.

b. Workplace HTS

This approach gives opportunities to employees, their families, and communities to access HTS services in the workplace. Workplace HIV testing should be confidential, delivered in a safe environment and should not be abused. Disclosure of HIV sero-status is at the discretion of the employee.

i. KP/PP Hotspot HTS
ii. Social Events HTS (E.g. Sports Events)
iii. Other HTS Outreaches

However, screening for risk of exposure must be done to determine eligibility for HIV testing even among Key populations.

For additional information refer to the HTS Policy and Implementation Guidelines 2016.

2.4.3 HIV SELF-TESTING (HIVST)

HIV Self-Testing (HIVST) is a process in which a person collects his or her own specimen (oral fluid or blood), performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts. HIV self-testing is offered as an additional approach to the traditional HIV Testing Services in Uganda. However, oral-based screening for children 2-14 years and HIVST for adolescents aged 15-17 shall be implemented upon further guidance by MOH. HIVST in the public domain focuses on individuals at risk and with limited access to the conventional health care dependent facility-based HIV rapid testing. The focus for HIVST under the public sector domain includes men, adolescents, key populations, and priority populations. Under the private sector domain, HIVST is recommended for all individuals with perceived exposure to HIV and would wish to know their status. All mothers in MCH settings, whose sexual partners are of unknown HIV status and have not come to the facility for testing should receive HIVST kits to deliver to their partners if they consent. The HIVST kits are already on the market in some pharmacies around the country. Professional HIV test kits (Determine, Stat-pak and SD Bioline) should only be sold on wholesale basis (to certified HIV testing facilities) and not as single self-test devices. Selling professional test kits to individuals for the purpose of self-testing is prohibited and is discouraged. Only approved HIV self-testing kits should be sold over the counter to the public. Currently, Oraquick, Sure-check and INSTI have been evaluated and approved for use in Uganda as HIVST kits. HIVST does not confirm a diagnosis for HIV. All reactive self-test results should be confirmed using the approved national HIV testing algorithm. In addition, care must be taken to screen for potential of occurrence of adverse events following HIVST provision including intimate partner violence (IPV). It should also be routine to follow up clients to document results and address incident cases of adverse events following HIVST (including IPV). A toll-free line is available for all guidance, inquiries and reports related to HIVST: **080 020 5555.** Further reference of this can be made to the HTS policy and implementation guidelines addendum 2018 for further guidance on implementation of HIVST.

2.4.4 ASSISTED PARTNER NOTIFICATION

Assisted Partner Notification (APN) is part of a comprehensive array of services offered to persons infected with HIV or STDs and their partners in the community or at the facility. The critical function of APN is partner notification where HIV-positive index clients are interviewed to elicit information about their sexual partners, who can then be confidentially notified of their possible exposure or potential risk and are offered HIV testing services. Assisted Partner Notification is offered as an additional approach to HIV Testing Services in Uganda. All the 5 principals of HTS (Counselling, Consent, Confidentiality, Correct results, Connection to care) MUST be observed throughout the process of offering APN. In Addition, care must be taken to screen for potential of occurrence of adverse events following APN provision including intimate partner violence (IPV). It should also be routine to follow up clients to document incident cases of adverse events following APN (including IPV).

Refer to HTS policy and implementation guidelines addendum 2018 for further guidance on implementation.

2.5 HIV TESTING SERVICES PROTOCOL

HTS service provision should follow the steps described in **Table 1** below.

Table 1: HIV testing provision steps/protocol

	Activity	Description
1.	Pre-test information and counseling	Help the client/patient to know the ways HIV is transmitted and basic HIV preventive measures, benefits of HIV testing, possible test results and services available, consent and confidentiality, individual risk assessment, and fill the HTS card. Allow clients/patients to ask questions.
2.	Risk assessment	Carry out risk screening to assess for risk factors for HIV including: being in a sexual relationship with multiple concurrent sexual partners, belonging to a key or priority population, being a sexual contact to an index client and being a biological child of an HIV positive client.
3.	HIV testing	Will be done using blood. For those below 18 months, a DNA PCR test will be done and those above 18 months an antibody test will be done. Refer to the HIV testing algorithms for the different age groups. See 2.5.1, 2.5.2, 2.5.3 and 2.5.4.
4.	Post-test counseling (individual/couple)	Assess readiness to receive results. Give results simply. Address concerns, disclosure, and partner testing and risk reduction. Provide information about basic HIV care and ART care; complete the HTS card and HTS register.
5.	Linkage to HIV Prevention, Treatment, Care, and support Services	Provide information about available prevention, treatment, care and support services. For HIV positive individuals fill the triplicate referral form and complete Linkage and Pre-ART Register. For Negative individuals refer for appropriate HIV prevention services.

2.5.1 HIV Testing Eligibility Screening Tool for Children and Adolescents with Unknown HIV Status (18 months-14 years)

Tool Guide for health workers

Purpose: The tool guide describes how to use the HIV testing eligibility screening tool and job aid.

Applicability: This tool guide is applicable to all personnel involved in screening children and adolescents aged 18 months14 years for eligibility to test for HIV.

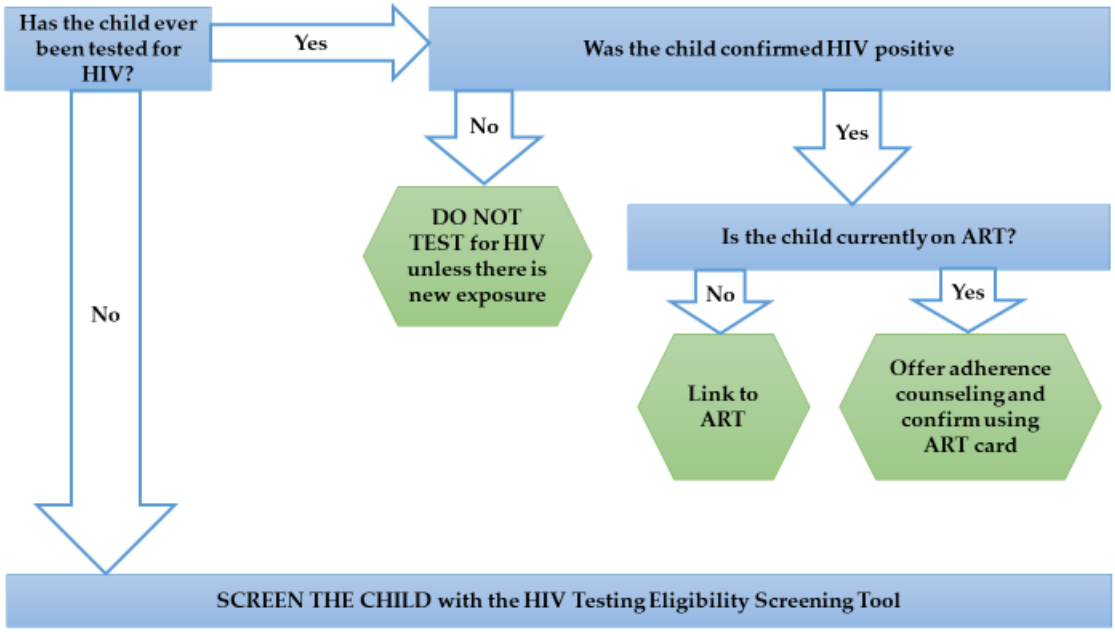
Procedure and instruction: The eligibility screening tool will be administered directly to children and adolescents aged 12 years and above and to caregivers if children are aged below 12 years. Please see the following instructions:

- Create a rapport with the child/adolescent and caregiver.

- Assure confidentiality of all information being shared during the process of eligibility screening.
- Be alert in observing both verbal and non-verbal communication from the child/adolescent and/or caregiver during the screening. Interject when necessary to confirm they are okay.
- Clarify questions when asked or if something is unclear to the child/adolescent and/or the parent/caregiver.
- Be empathetic.

Determine if the child's HIV status is known or unknown using the diagram below:

Figure 3: Determining child's HIV status



Ask the following screening questions for all children of unknown HIV status.

Table 2: Screening questions for all children of unknown HIV status

No	Screening Question	Guidance
1	Is the child's mother HIV positive?	Ask the mother whether she knows her current HIV status. If the mother is not present, ask if the child or caregiver knows the HIV status of the child's mother. The response may be 'Yes' or 'No.' If the mother's HIV status is known, ask if positive or negative. If the mother's HIV status is positive, test the child for HIV. If the mother's HIV status is negative or not known, continue to ask questions 2-6 as shown below.

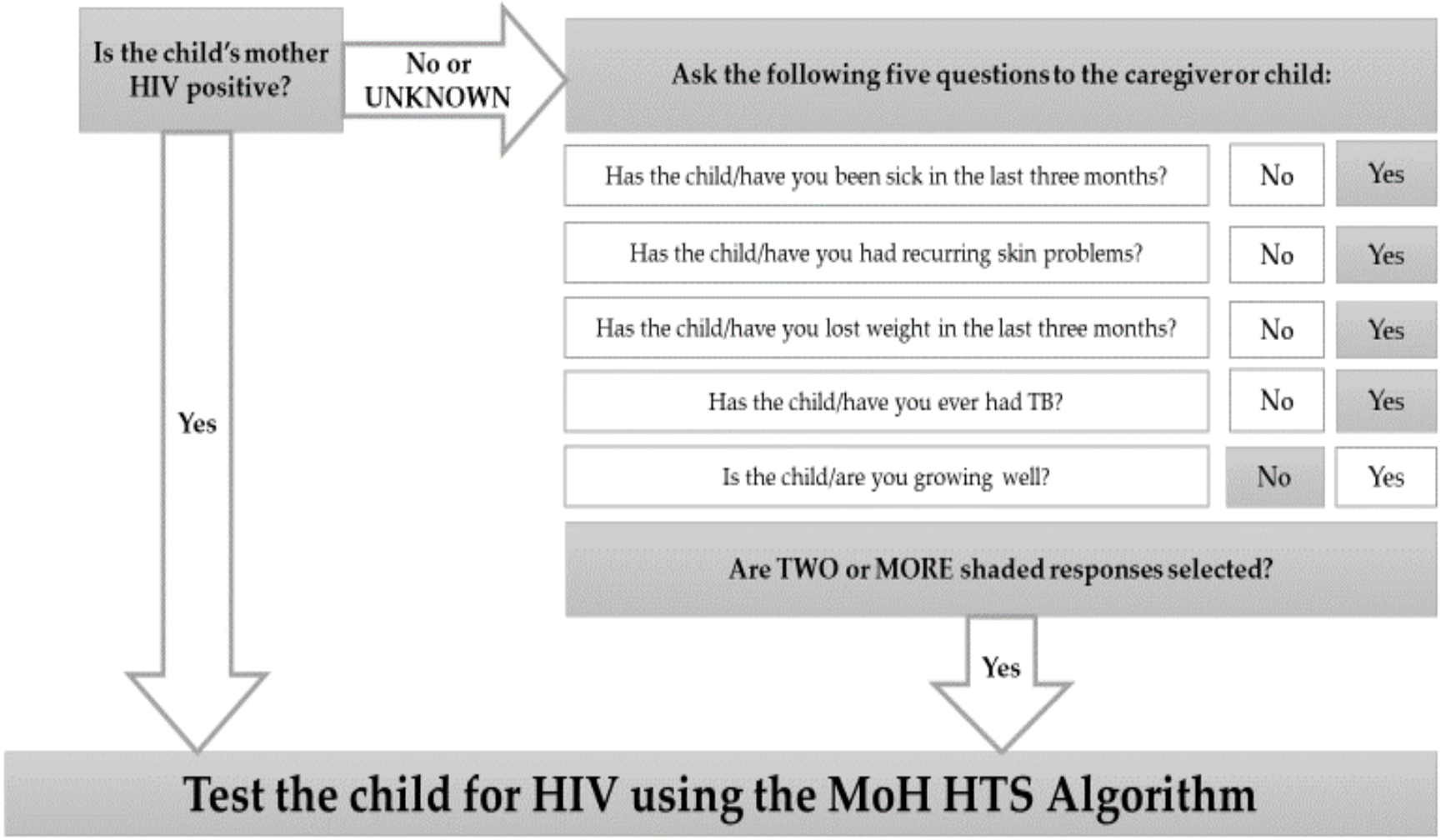
No	Screening Question	Guidance
2	Has the child/have you been sick in the last three months?	The answer to this question is 'Yes' if there has been any change in the health condition, even if it is relatively minor. Ask if the child received medication or made a clinic visit in the last 3 months, or if they were bedridden or not playing.
3	Has the child/have you had recurring skin problems?	You may need to ask this question in two parts: 1) If there was any skin problem (e.g., rash, itching and sores) and 2) If these were recurrent. Observe the child for any skin rash or scars suggestive of a previously treated skin rash. If child/caregiver reports 1 or 2 isolated incidents of a skin problem that disappeared on its own or with treatment, select 'No' to this question.
4	Has the child/have you lost weight in the last few months?	Weight loss may not be easy to determine. Use different examples to describe weight loss, such as a decrease in body size, muscles, and/or loose or sagging clothes. Choose either 'Yes' or 'No' depending on whether the child has lost weight in the last 3 months. If the respondent is 'Not sure', the answer is likely 'No'.
5	Has the child/have you ever had TB?	Establish if the child has ever had or been treated for TB. Select 'Yes' if child has ever been diagnosed or treated for TB. Select 'No' if TB was suspected but not confirmed, or a persistent cough is reported, or if child reports that 'I think I was treated for TB, but not sure', or if the caregiver reports this on behalf of the child.
6	Is the child/are you growing well?	A child or caregiver may not easily be able to tell what growing well means. To assess if a child is growing well, ask if the child's height, weight or milestones compare with those of other children in the same class or of the same age or not.

Select children that should be tested: For each screening question on the right, a "YES" response for the first four questions and "NO" for the last question are shaded in gray because of their significance in determining if a child should be tested.

- If the answer to the question, "Is the child's mother HIV-positive?" is 'Yes', test the child for HIV.
- If the answer to the question, "Is the child's mother HIV-positive?" is 'No' or 'I don't know', ask the set of 5 questions to the right.

If 2 or more responses to the 5 questions on the right shaded in gray are selected, test the child for HIV.

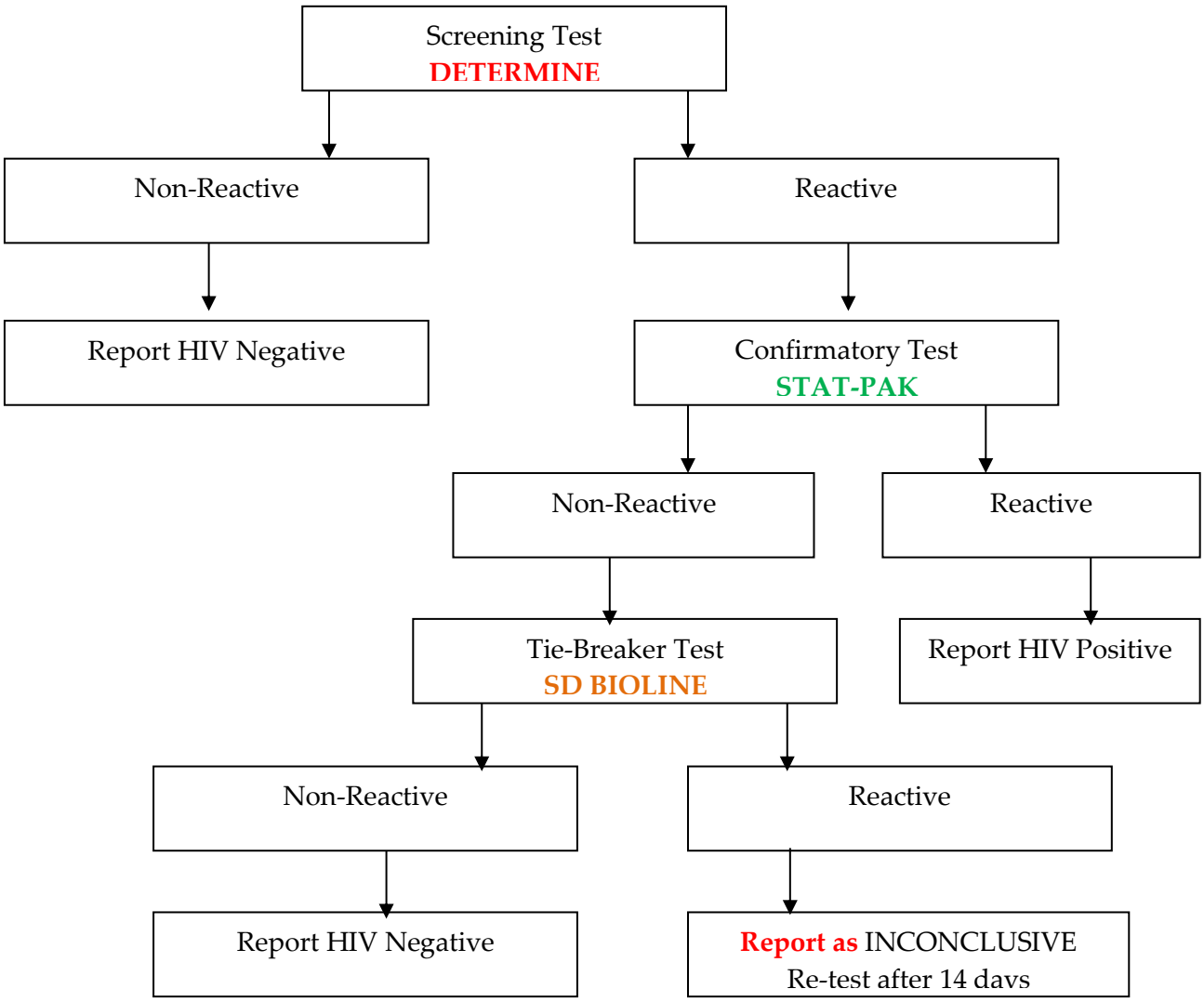
Figure 4: HIV Testing Eligibility Screening Tool for Children and Adolescents with unknown HIV status (18 months to 14 years)



2.5.2 THE HIV TESTING ALGORITHM FOR PERSONS AGED 18 MONTHS AND ABOVE

The HIV testing algorithm for persons aged 18 months and above is in Figure 5 below. Note: if the child is still breastfeeding at 18 months or above and the HIV test is negative, a final test should be done 3 months after the child stops breastfeeding.

Figure 5: Serial HIV testing algorithm for persons above 18 months of age



Inconclusive results

To ensure accuracy and reliability of HIV test results, WHO recommends this for all HIV antibody tie breaker tests. Therefore, the final HIV test result in the HTS client card, HTS register and the Daily Activity Register should be recorded as: NEGATIVE, POSITIVE, or INCONCLUSIVE.

Resolving inconclusive HIV Test Results following a first Inconclusive result

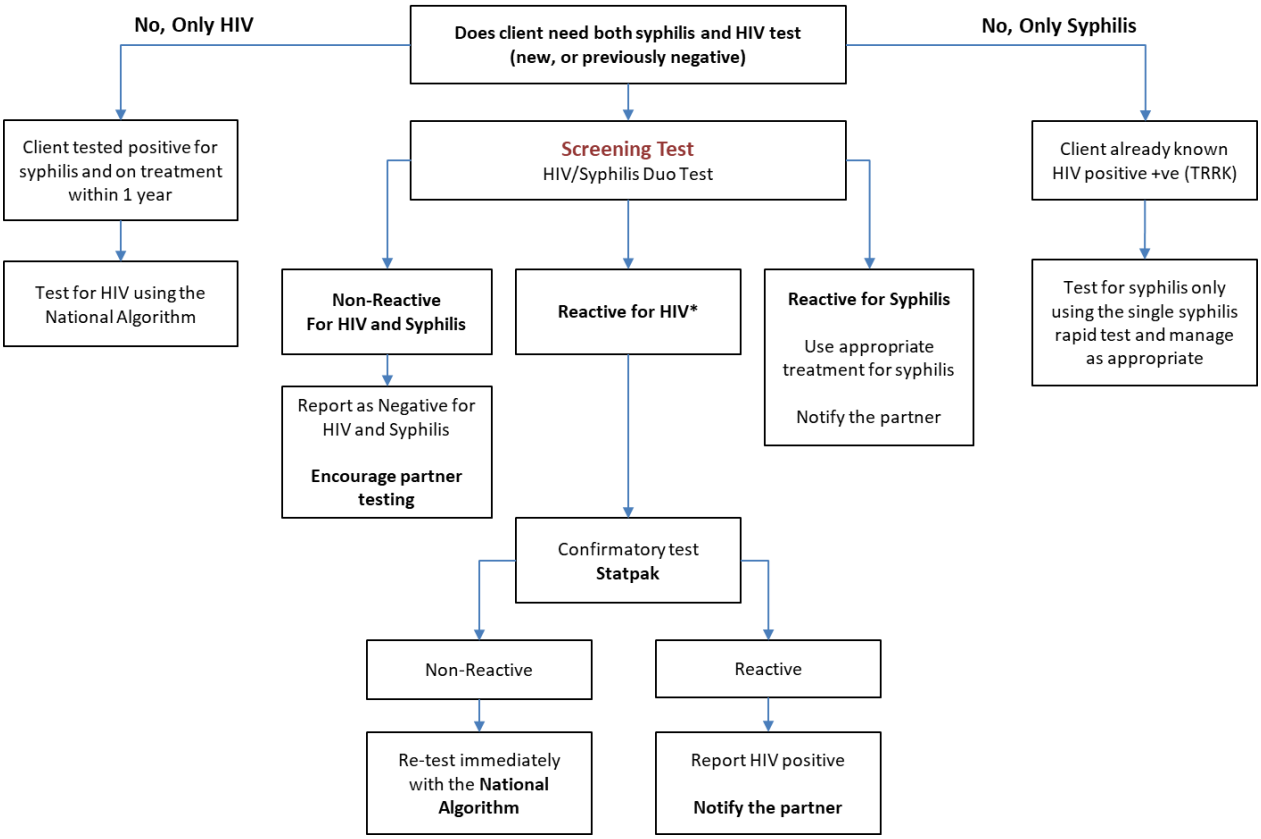
For clients whose results are inconclusive after the recommended 14 days following a first inconclusive test result, a sample should be collected, labelled "2nd INC" and sent to the national reference laboratory (UVRI) for testing. A result will be sent back as either POSITIVE or NEGATIVE. Sample and result transportation will utilize the existing hub system.

2.5.3 MATERNAL AND CHILD HEALTH- HIV AND SYPHILIS TESTING ALGORITHM

Within Maternal and Child Health settings, the HIV /syphilis duo test will be used as screening test with Stat-pak as confirmatory for women who previously tested negative for HIV and syphilis or those whose status is unknown. Women whose HIV positive status is already known should be tested for Syphilis using the single rapid syphilis tests. Women who have tested positive for syphilis and with evidence of having been treated for syphilis within a year should be tested using the Serial HIV testing algorithm for persons above 18 months of age in Figure 5 above.

There is need to take advantage of Duo kit for syphilis testing and treatment scale-up. For those where HIV status cannot be ascertained on the MCH algorithm, re-testing should be done by laboratory using the National adult HTS algorithm (i.e. Determine-Stat-pak, Bio-line) in Figure 5 above. Very few mothers will require the tie breaker. APN should be provided for those testing positive for HIV or Syphilis and encourage partner testing for negative. HIV syphilis DUO testing for Key and Priority populations using the approved National algorithm shall also be considered upon availability of HIV/syphilis DUO commodities.

Figure 6: HIV Testing Algorithm using the HIV-Syphilis Duo Kit in MCH Settings



2.5.4 HIV TESTING ALGORITHM FOR INFANTS AND CHILDREN BELOW 18 MONTHS OF AGE

A virological test (DNA/PCR) is recommended for determining HIV status in infants and children below 18 months of age. The sample for testing should be collected using dried blood spot (DBS) specimens.

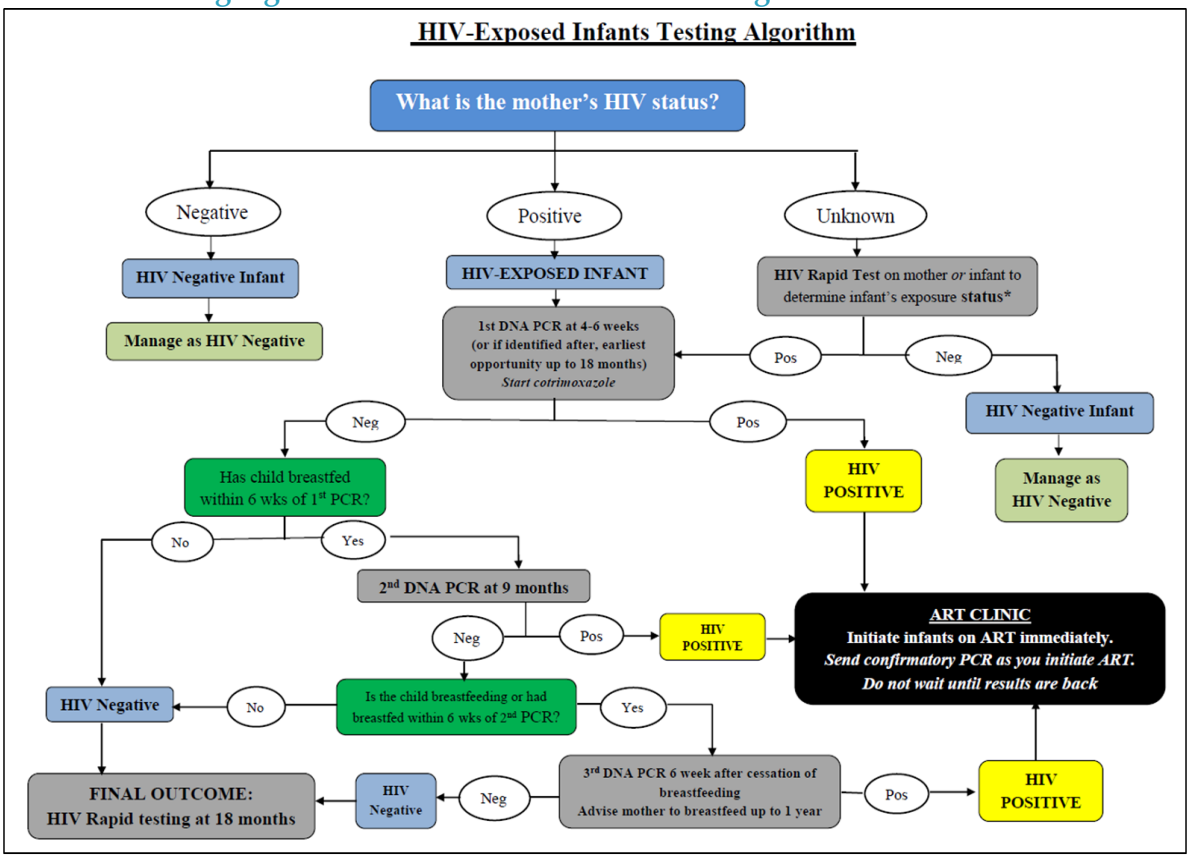
HIV testing schedule for infants

The 1st DNA/PCR test should be done at six weeks of age or the earliest opportunity thereafter. Another PCR test has been introduced to be done at 9 months of age as the second test for all infants irrespective of breastfeeding status. The 3rd PCR should be done 6 weeks after cessation of breastfeeding. Interpretation of the results and further testing are guided by the testing algorithm in Figure 7.

A POSITIVE DNA/PCR test result indicates that the child is HIV-infected. All infants with a positive DNA/PCR test result should be initiated on ART and another blood sample should be collected on the day of ART initiation to confirm the positive DNA/PCR HIV test result.
A NEGATIVE FIRST DNA/PCR test result means that child is not infected but could become infected if they are still breastfeeding. Infants testing HIV negative on first DNA/PCR should be re-tested using DNA/PCR at 9 months of age irrespective of breastfeeding status and six weeks after cessation of breastfeeding. Infants with negative third DNA/PCR test should have a final rapid antibody test performed at 18 months using the national HIV testing algorithm.

Note: *A rapid HIV antibody test can be used to establish if an infant is exposed to HIV before the age of 18 months. This can be done if the infant doesn't present at the health facility with a biological mother. A reactive HIV rapid antibody test will confirm* ***exposure*** *to HIV but not HIV* ***infection. In that case, if the HIV test is reactive, a DNA PCR sample*** *should be taken as explained above to establish if the infant is HIV infected or not.*

Figure 7: HIV testing algorithm for children <18 months of age



*If an infant with a negative previous PCR is symptomatic while still breastfeeding, take off a PCR sample at that point in time. If negative, another PCR sample must be taken according to the algorithm either 9 months or 6 weeks after breastfeeding.
*If mother's status cannot be ascertained, may use rapid test in babies to determine HIV exposure status. Should perform DNA PCR for baby who is symptomatic, malnourished or has TB as routine.
*If breastfeeding is stopped before 9 months then a final DNA PCR can be done at any point 6 weeks after cessation of breastfeeding.

2.6 RE-TESTING FOR HIV

2.6.1 Re-testing for verification

What is Re-testing for Verification?

All individuals newly diagnosed using the National HIV testing algorithm should be retested before ART initiation. This test is called a **retest for Verification**.

Note:

i. Re-testing for verification refers to the process of retesting all HIV Positive clients identified both within the facility and those referred from another facility or community.
ii. All individuals are retested before enrollment in care (Pre-ART and ART)
iii. Clients who are currently on ART, or those who were previously on ART for the purpose of HIV Treatment should not be Re-tested unless otherwise recommended by the attending clinician.

Who should perform the retest for Verification and where should the retesting take place?

i. The retest for verification shall be performed by a health worker (Tester), other than the one who performed the first test using a different blood sample drawn from the same individual (client).
ii. It is preferred that retesting for verification shall be performed at the point of ART initiation. This may be performed at the Mother Baby Care Point (MBCP) or the HIV/ART clinic.
iii. The national HIV testing algorithm should be followed during retesting for verification.

How to Resolve Discrepant Results on Retest for Verification

For clients whose results are negative on retest for verification, samples should be collected, labelled "Discrepant" and sent to the UVRI for testing. A result will be sent back as either positive or negative. Sample and result transportation will utilize the existing hub system.

Note: Before discrepant results are sent to UVRI, rule out errors at facility level such as improper handling of samples or testing kits and recording.

2.6.2 Re-testing for HIV-positive infants

All babies testing HIV-positive at the first or second DNA/PCR HIV testing should be re-tested for HIV. The DBS sample should be collected on the day the child is initiated on treatment.

2.6.3 Re-testing for HIV-Negative individuals

The following population categories should be re-tested for HIV as summarized below:

Table 3: Categories of HIV-negative persons to re-test at specified time points

Population category	When to re-test
Individuals exposed to HIV within four weeks before HIV testing	Four weeks after the 1st test
Key populations	Depending on risk of exposure in the past 3 months
HIV-negative partners in discordant couples	Depending on risk of exposure in the past 3 months

Population category	When to re-test
Pregnant women	1st trimester/1st ANC visit, then in the 3rd trimester/during labor or delivery
Breastfeeding women	Every three months until three months after cessation of breastfeeding
Confirmed and presumptive TB Patients	Four weeks after the 1st test
TB, Hepatitis and STI patients	Four weeks after testing
PEP clients	At one month, three months and six months after completing the PEP course
PrEP	Depends on risk of exposure in the past 3 months
HIV-exposed infants (HEIs)	Nine months of age, six weeks after cessation of breastfeeding and at 18 months of age
Children who are still breastfeeding beyond 18 months of age	3 months after cessation of breastfeeding
INCONCLUSIVE results	14 days after the last test
VMMC clients (10-14 years)	Risk based
Children and adolescents (2-14years)	Risk based with exceptions explained earlier in these guidelines
Family planning clients	Risk based
Sexual offenders and survivors of SGBV	Four weeks after the 1st test
Index testing-Sexual partners and biological children	Four weeks after the 1st test
Blood, Tissue donors	Four weeks after the 1st test
General Population	Once a year depending on risk of exposure for the duration in which they have not had an HIV test.>-3 months

2.6.4 HIV Recency Testing:

HIV Recency testing provides insight into the timeline of HIV infection in an individual. Currently HIV recency testing is implemented as a pilot in controlled settings. MOH shall develop implementation guidelines for recency testing after the field pilot. Recency test results shall be used for surveillance purposes only and not for patient care decision making, therefore, recency test results shall not be returned to clients.

2.7 LINKAGE FROM HIV TESTING TO HIV PREVENTION, CARE AND TREATMENT

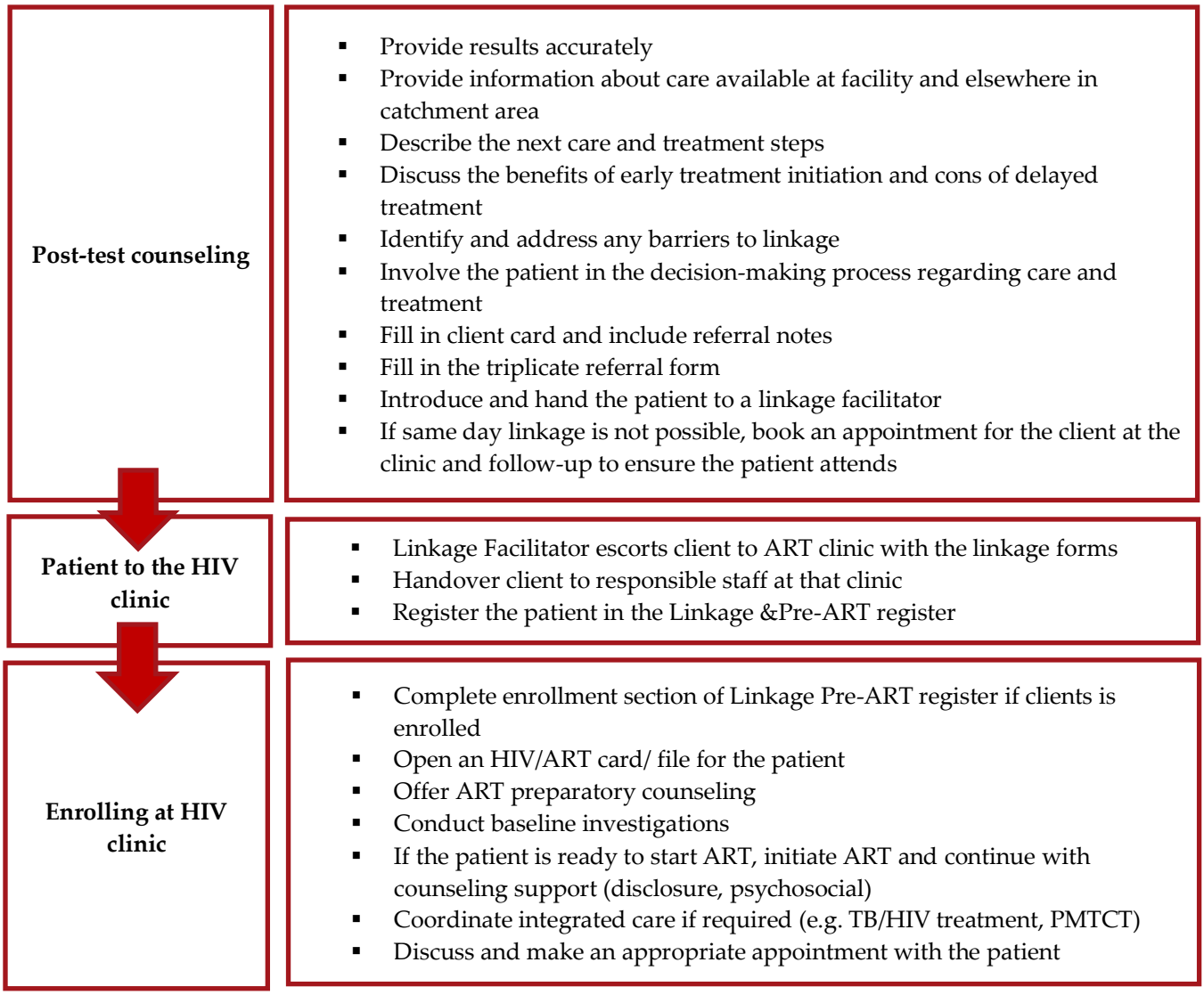
Linkage refers to the process of connecting individuals who have tested for HIV from one service point to another. Linkage to HIV prevention, care and treatment is successful if the client receives the services they have been referred to receive. For all clients who test HIV-positive, linkage is considered successful when a client is enrolled in HIV care and treatment. Linkage should occur within seven days (within the same facility) and 30 days for inter-facility or community-facility

referrals. For HIV negative individuals, linkage to HIV prevention services packages as may be found appropriate should be encouraged.

2.7.1 Intra Health Facility Linkage

The process of linkage within the same health facility is described in **Figure 8** below.

Figure 8: Intra Health Facility Linkages



2.7.2 Inter-Facility Linkages

Inter-facility linkage refers to connecting a newly diagnosed patient at one facility to another facility for HIV treatment, care, and support services. The referring facility should track (follow-up) all HIV-positive clients referred to other facilities and ensure they are enrolled in HIV care and treatment within 30 days, using the follow-up/tracking schedule described in **Table 4**.

Table 4: Schedule for follow-up/tracking inter-facility linkages

Timeline	Action
Day 1(referral day)	A client diagnosed HIV positive and referred to the facility of choice. Linkage facilitator documents clients' contacts. Linkage facilitator obtains client's consent for home visiting. Linkage facilitator introduces the client to community health worker.
Week 1	Linkage facilitator calls a client or the contact in the health facility where the client was referred to. If client reached the new facility, document complete linkage.
Week 2	If the client didn't reach the new facility by week 1, the community health worker (VHT) visits client's home to remind about the referral.
Week 3	Linkage facilitator calls client or new facility to confirm if the VHT visit to client's home made any impact. If client reached the new facility, document complete linkage. If the client didn't reach the new facility, the linkage facilitator visits client's home to discuss reasons for the client's failure to reach the referral point.
Week 4	Linkage facilitator calls client or facility to confirm if client reached. If yes, document linkage as complete. If no, document as lost.

2.7.3 Community-Facility Linkages

Community-facility linkage refers to connecting a client who tests HIV-positive in the community to a health facility for HIV treatment, care, and support services. Facility HTS teams should establish functional community health systems with linkage systems including Peer Leaders, Expert Clients, VHTs and CHEWs. These should be involved in the mobilization for the targeted outreaches and follow up to link all individuals testing positive. Linkage from community to facility should be done within 30 days after diagnosis. The process of community-facility linkage is described in **Table 5**.

Table 5: Schedule for follow-up/tracking community-facility-community linkages

Timeline	Action
Day 1 (referral day)	A client is diagnosed HIV positive and referred to the preferred facility using a triplicate referral form. A copy of the referral form is given to CHW who documents the address and contact information into the follow-up register, schedules an appointment for facility visit and obtains client's consent for home visiting. Triplicate referral form copy should be delivered to the facility where the client has been referred.
Week 1	The organization doing community testing should call the client or the contact in the health facility where the client was referred. If client reached the facility, document complete linkage. The health facility linkage facilitator identifies referred clients who have come to the facility and documents those referrals as linked/complete. The facilitator notifies the CHW of all clients who have not yet been linked.

Timeline	Action
Week 2	The CHW visits client's home to ascertain reasons for failure to reach the facility and makes a new appointment for facility visit. The CHW documents the outcome of the visit and notifies the health facility team.
Week 3	The health facility linkage facilitator ascertains if the client was linked and notifies CHW of the pending clients
Week 4	The CHW makes a final visit to client's home; discusses reasons for failure to reach the facility; makes a final appointment if the client is willing or documents outcome (refused, not ready, relocated, etc.). If the client has not yet decided to enroll in care, the CHW will continue to make contact and encourage them to seek care. *A client is lost to linkage if he/she is not in care within 30 days of HIV diagnosis*.

This process should be replicated for patients identified in the facility and linked to community for other support services**.**

2.7.4 HIV TESTER AND SITE CERTIFICATION

Certification is the process by which an independent and authorized agency assesses the quality system of a facility/site and/or competency of a provider based on certain pre-defined standards. Certification gives formal recognition that a facility/site or tester is authorized to carry out a specific task such as HIV rapid testing for diagnosing HIV infections.

The Certification Framework for Uganda details the governance and coordination structure, roles and responsibilities of stakeholders, standards for HIV rapid testing, the process of auditing and assessing for compliance as well as monitoring and evaluation.

HIV Testing Certification Goal: To ensure that sites and testers accurately and reliably perform HIV rapid testing as per the set national standards.

Specific Objectives of Certification include:

1. Ensuring adherence to national standards of delivering HIV rapid testing
2. Ensure availability of competent personnel for HIV rapid testing
3. Ensure conformity of sites to national standards to ensure quality results

Why the HIV Testing Certification?

The national HIV testing policy 2016 and national health laboratory strategic plan 2016-2020 provide for tester and site certification as a key strategy to enhance the quality of HIV testing services.

Despite many interventions to strengthen quality of HIV testing, gaps in quality assurance still exist including few and/or inadequately trained staffs, unavailability of testing supplies, lack of post market surveillance practices, deviation from testing procedures, low participation and performance rates in proficiency testing programs and under-utilization of testing data for timely

corrective actions. A national certification program for HIV rapid testing may prove to be not only a healthcare cost saving approach, but also an expansion of quality of care.

It also provides clinical governance to support health care providers involved in testing by creating an enabling environment for health-care providers to be accountable for providing the quality of HIV Rapid testing services and safeguarding high standards of care and excellence in clinical care.

Implementation and maintenance of HIV rapid testing site and tester certification program adds credibility to any testing site, provides the means to ensure and monitor adherence to quality standards and instill confidence in the results for patient care. The national certification program for HIV testing sites and testers provides an umbrella under which all aspects of quality HIV testing shall be gathered and continuously monitored.

2.7.4.1 The HIV Testing Certifying Body

The Uganda Virus Research Institute (UVRI) is mandated by the Ministry of Health to conduct quality assurance for HIV rapid testing in Uganda. By virtue of this role, UVRI shall be the Certifying Body for HIV rapid testing sites, auditors and testers. UVRI shall work closely with the AIDS Control Program and the Quality Assurance Department of MOH in fulfilling her role in the certification program.

2.7.4.2 Implementation of the HIV Testing Certification

Certification is done at regular intervals to ensure maintenance of standards and reliability of results generated to support clinical and public health activities by the HIV Testing point (referred to as site here) and provider.

Site Certification verifies that at a specific HIV Testing Point, testing procedures are in place and followed, results are technically valid, only competent staff performs testing, and confirms that the site conforms to a quality management system.

Tester Certification verifies that the provider performing HIV testing is adequately trained, is authorized to do so and there is evidence of demonstrated competency.

HIV Testing Certification Framework Implementation Plan: The implementation plan includes the process of assessments/audits of the testers and testing sites, certification, decertification, recertification, Monitoring and Evaluation.

Refer to HTS Policy and Implementation Guidelines addendum 2018 on HIV Testing Certification Framework.

Box 2: Key Highlights in HIV Testing Services and linkage to HIV care

- A mix of facility -based and community-based HIV testing models should be used to increase access.
- All individuals testing HIV positive in communities or at facilities should be linked into care and treatment. Linkage is considered successful when an HIV positive individual is enrolled into care and treatment.
- Guidance on specific policy changes:
  - Re-testing for verification: All newly diagnosed individuals should be retested before ART initiation.
  - All babies testing HIV-positive at DNA/PCR HIV testing should be re-tested, but ART initiation should not be delayed pending confirmatory results. A confirmatory sample DBS should be collected on the day the child is initiated on ART.
  - Testing in VMMC: Perform risk screening, applying appropriate HTS screening tool to various age groups.
  - Testing for lactating mothers: Re-test all HIV negative breastfeeding mothers every 3 months until cessation of breastfeeding (no risk screening). Align re-testing to immunization schedule where possible
  - Age for APN: All individuals ≥ 18 years are eligible for APN. Individuals <18 years should be considered for APN if sexually active. Social network testing (SNS) should be implemented as a form of index testing.
  - Testing every 3 months for KPs & PPs should not be routine but rather based on risk. Assess for risk every 3 months and test for HIV if there is exposure risk in the last 3 months.
  - HIV Self Testing (HIVST):
    - HIVST kits are available off the counter for the public in pharmacies across the country.
    - Risk-based HIVST in the public domain will target HIV negative KPs, PPs, men, adolescents, and index clients through APN.
    - HIVST in MCH should be non-discriminative: all mothers whose sexual partners are of unknown HIV status and have not come to the facility for testing should receive HIVST kits to deliver to their partners if they consent.
    - Men in the general population should be targeted in addition to the current targeted populations for HIVST.
    - Oral based screening for children 2-14years and HIVST for adolescents aged 15-17 shall be implemented upon guidance by MOH.
  - Regulation of HIV rapid tests on private market: HIV test kits made for Professional use should only be sold on wholesale basis and not as single self-test devices. Selling these test kits to individuals for the purpose of self-testing is prohibited and should be discouraged. Only approved HIV self-testing kits should be sold over the counter to the public. Currently, Oraquick, Sure-check and INSTI have been evaluated and approved for use in Uganda as HIVST kits.
  - HIV syphilis DUO testing for Key and Priority populations using the approved National algorithm shall be considered upon availability of HIV/syphilis DUO commodities.

3 HIV PREVENTION SERVICES

3.1 INTRODUCTION

In Uganda, the HIV epidemic is driven by multiple behavioral, biomedical and structural factors. As such there is no single HIV prevention intervention that is enough to prevent all HIV transmissions. The country, therefore, adopted a combination HIV prevention approach which uses a mix of biomedical, behavioral and structural interventions to meet the HIV prevention needs of the population to have the greatest possible impact on reducing new infections. This chapter will provide guidance on how to implement interventions that reduce new infections among HIV children, adolescents, young people, adults, and key and priority populations.

3.2 BEHAVIORAL CHANGE AND RISK REDUCTION INTERVENTIONS

The priority of behavioral interventions is to delay sexual debut; reduce unsafe sex especially concurrent sexual partnerships, discourage cross-generational and transactional sex, and promote consistent condom use.

Table 6 below describes services for behavioral change and risk reduction.

Table 6: Services for Behavioral Change and Risk Reduction

Area	Guidance
Service delivery	• Each health facility/program should have a focal person for HIV prevention • All staff offering HIV prevention services need to be trained, including training in Gender and Sexuality Diversity (GSD) • Peer-led model for priority key populations including young people • Outreaches & Drop-in Centres for key and priority populations • Job aides to support standardization for quality assurance • Linkage and follow-up between facility and community is important • Promote youth and key population friendly services
Risk assessment for client	• Assess sexual behavior of the client (ask if condoms are used, frequency, the number of partners, transactional sex/sex work) and if the client is involved in transactional sex/sex work encourage correct and consistent condom use. • Discuss knowledge of partner HIV status and sexual behavior. • Assess for STIs and link to treatment. • Asses for gender-based violence (GBV) • Discuss sexual and reproductive health services and link to services as appropriate. • Offer HTS to sexually active clients who have not tested in the last 12 months or have had unprotected sex in last three months. • Conduct psychosocial assessment
Provide socio-behavioral change communication (SBCC) and link to services as appropriate	• Build a lifestyle of prevention among young people • Discuss delay of sexual debut in children and adolescents (abstinence) • Discuss correct and consistent condom use and offer condoms as appropriate. • Discourage multiple, concurrent sexual partnerships and promote faithfulness to a partner of known HIV status. • Discourage cross-generational and transactional sex. • Discourage risky cultural practices such as widow inheritance, wife replacement and child marriages.

Area	Guidance
	• Identify, refer and link clients to other available services at facility and community level. • Assess for violence, (physical, emotional, or sexual); if client discloses sexual violence, assess if the client was sexually assaulted and act immediately. (See Section 3.5.1 for GBV case management and Section 3.3.3 for PEP)
Condom promotion and provision	• Discuss correct and consistent condom use as an option for risk reduction • Discuss benefits of condom use • Clarify any questions and dispel myths around condoms • Demonstrate how to use condoms • Demonstrate negotiation skills for safer sex • Allow the client to role play negotiation skills for safer sex and how to introduce condoms in relationship. • Provide condoms to client.

3.3 BIOMEDICAL PREVENTION INTERVENTIONS

The key biomedical interventions include STI screening and treatment, eMTCT, safe male circumcision (SMC), ART for prevention, PEP, PrEP, condom and blood transfusion safety. Key and priority populations in particular should receive STI screening and treatment. This section will discuss condom programing, SMC, PEP and PrEP, blood transfusion safety. Other biomedical interventions will be discussed in other chapters including: eMTCT (Chapter 4), ART (Chapter 8) and STI screening and treatment (Section 6.14.1).

3.3.1 COMPREHENSIVE CONDOM PROGRAMMING

Condom programming for HIV prevention is a means of ensuring that sexually active persons at risk of HIV and unintended pregnancies are motivated to use condoms, have access to quality condoms, and can use them correctly and consistently. Condoms do not offer 100% protection from HIV and should therefore be used in combination with other prevention interventions. The Ministry of Health have a comprehensive condom program that addresses demand, supply, and support for male and female condom utilization as a means of protection from STIs/HIV and unintended pregnancies.

Total Market Approach (TMA)

The MoH is highlighting a Total Market Approach to ensure availability of condoms to all sectors of the population. With the TMA, free condoms will target the poor and disadvantaged population segments while the higher wealth quintile population segment of the community will either buy subsidized condoms from social marketing or full profit condoms from the commercial sector.

Target Groups for Condom use

The following have been identified as target populations and include the populations at high risk of HIV transmission or acquisition, such as:

- Adults and youth engaged in multiple sexual partnerships.
- Men and women who engage in transactional sex and their clients.

- Adults working away from home such as transport and migrant workers, uniformed forces, fisher folk, boda-boda riders.
- People who inject drugs and men who have sex with men.
- Adults and youth who access Family planning/Contraception clinics/service delivery points.
- Discordant couples.
- Individuals taking PEP and PrEP.

3.3.2 SAFE MALE CIRCUMCISION (SMC)

The Government of Uganda is promoting Safe Male Circumcision (SMC) as an important intervention for HIV prevention. Male circumcision is the surgical removal of the foreskin of the penis. SMC reduces the risk of HIV acquisition among circumcised men by approximately 60%. **Table 7** describes the process involved in providing SMC.

Table 7: Process of providing safe male circumcision

Process	Description
Priority groups for SMC	• All males including infants although focus is on pivotal age of 15-29 years
Recommended methods for SMC	• Conventional surgery using the dorsal slit method and Shangring for adults; Mogen clamp for infants • WHO pre-qualified devices
Eligibility Screening for SMC	• Screen for STIs: If STIs are present defer the circumcision and treat the STIs (See Section 6.14.1.2) • Tetanus immunization status: ○ Administer three dose TT vaccination schedule for both conventional and device methods: First TT shot on day 0, 2nd TT shot on day 28 and 3rd TT shot after 6 months. • Penile abnormalities: If there are any penile abnormalities, refer for specialist care. • Bleeding disorders: If there is a history of bleeding disorders, defer SMC and refer. • Existence of chronic disease conditions such as diabetes or hypertension: Defer SMC and refer.
Consent/assent	• All clients should receive information regarding SMC and understand the benefits and risks of SMC. • The client should provide consent/assent prior to the procedure.

HIV Testing	• All SMC clients should be offered HTS, though clients may opt out.
	  ○ A positive HIV test is not a contraindication to circumcision.
	  ○ Initiate ART in men and adolescents who test positive.

Follow up after SMC	• Following conventional surgery: at 48 hours, seven days, 14 days and at six weeks • Following device circumcision: follow the manufacturer guidance for the device used

Refer to the SMC Guidelines for details

3.3.3 POST-EXPOSURE PROPHYLAXIS FOR HIV

Post Exposure Prophylaxis (PEP) for HIV is the short-term use of ARVs to reduce the likelihood of acquiring HIV after potential exposures. The main desired outcome is to provide quality PEP services to all the eligible clients. It is also important to prevent exposures to blood and body fluids, by complying with Infection Prevention and Control Standard Precautions. It is equally critical that all the key PEP stakeholders are effectively engaged and coordinated to improve PEP service demand and utilization.

Types of Exposure:

- Occupational exposures occur in the health care settings and include SHARPS e.g. needlestick injuries and splashes of body fluids to the skin and mucous membranes.
- Non-occupational exposures include sexual assault (rape and defilement), road traffic accidents, unprotected sex with an HIV infected person, unprotected sex with person of unknown HIV status.

Steps in Providing Post-Exposure Prophylaxis (PEP)

Health facilities providing PEP must have trained healthcare workers on infection prevention and control including management of PEP. The healthcare workers should use the steps in **Table 8** to assess clients for PEP eligibility and provide PEP.

Table 8: Steps for Providing Post-Exposure Prophylaxis (PEP)

Step	Description
Step 1: Clinical Assessment and Providing First Aid	Conduct a rapid assessment of the client to assess exposure and risk and provide immediate care. Occupational exposure: After a needle stick or sharp injury • Do not squeeze or rub the injury site • Wash the site immediately with soap and water. • Don't use strong, irritating antiseptics (like bleach or iodine) After a splash of blood or body fluids in contact with intact skin • Wash the area immediately • Don't use strong, irritating antiseptics (like bleach or iodine) For exposure-specific injuries, refer to the PEP Guidelines
Step 2: Eligibility assessment	Provide PEP when: • Exposure occurred within the past 72 hours; and • The exposed individual is not infected with HIV; and • The 'source' is HIV-infected, has unknown HIV status or is high risk Do not provide PEP when: • The exposed individual is already HIV-positive • The source is established to be HIV-negative • Individual was exposed to bodily fluids that do not pose a significant risk (e.g. tears, non-blood-stained saliva, urine, sweat) • Exposed individual declines an HIV test

Step	Description
Step 3: Counseling and support	Counsel on: • The risk of HIV from the exposure • Risks and benefits of PEP • Side effects of ARVs (see **Table 60**) • Enhanced adherence if PEP is prescribed • Importance of linkage for further support for sexual assault cases
Step 4: Prescription	• PEP should be started as early as possible, ideally within first 2 hours but not beyond 72 hours after exposure • Recommended regimens include: o Adults and adolescents weighing≥30Kg: Preferred: TDF+3TC+DTG First Alternative: TDF+3TC+ATV/r Second Alternative: TDF+3TC+EFV o Children weighing <30kg Preferred: ABC+3TC+LPV/r Alternative: ABC+3TC+DTG • A complete course of PEP should run for 28 days • Do not delay the first doses because of lack of baseline HIV test or any reason • Document the event and patient management in the PEP register (ensure confidentiality of patient data).
Step 5: Provide follow-up	• Review client after one week for adherence support. • Discontinue PEP after 28 days. • Perform follow-up HIV testing at one month, three and 6 months after exposure. • Counsel and link to HIV clinic for care and treatment ifHIV-positive. • Provide prevention education and risk reduction counseling if HIV-negative.

Refer to National Policy guidelines on Post Exposure Prophylaxis for HIV, Hepatitis B and Hepatitis C, November (2013).

3.3.4 ORAL PRE-EXPOSURE PROPHYLAXIS (PrEP)

Definition: PrEP is the use of ARV drugs by HIV uninfected persons to prevent the acquisition of HIV before exposure to HIV. **Table 9** describes processes involved in offering PrEP.

Table 9: The process of providing pre-exposure prophylaxis (PrEP)

Process	Description
Screening for risk of HIV	PrEP provides an effective additional biomedical prevention option for HIV-negative people at substantial risk of acquiring HIV infection. These include people who: • Live in discordant sexual relationships • Have had unprotected vaginal sexual intercourse with more than one partner of unknown HIV status in the past six months • Have had anal sexual intercourse in the past six months • Have had sex in exchange for money, goods or a service in the last six months

Process	Description
	• Use or abuse of drugs especially injectable drugs in the last six months • Have had more than one episode of a STI within the last twelve months • Are part of a discordant couple, especially if the HIV-positive partner is not on ART or has been on ART for less than six months or not virally suppressed. • Recurrent post-exposure prophylaxis (PEP) users. (Recurrent implies PEP use more than 3 times a years). • Are members of key or priority populations who are unable or unwilling to achieve consistent use of condoms. NB: Eligibility is likely to be more prevalent in populations such as discordant couple, sex workers, fisher folk, long-distance truck drivers, men who have sex with men (MSM), uniformed forces, and adolescents and young women including pregnant and lactating AGYW at substantial risk.
Screening for PrEP eligibility	After meeting the substantial risk for HIV criteria: • Confirm HIV-negative status using the national HTS algorithm • Rule out signs and symptoms of acute HIV infection • Assess for hepatitis B infection: if negative, patient is eligible for PrEP; if positive, refer patient for Hepatitis B management. **Note:** • HEP B positive test is not a contraindication for initiating PrEP, however precaution needs to be taken when making a decision to stop PrEP to avoid HEP B viral load flare. • Creatinine test and creatinine clearance calculation using GFR formula is done. Do not offer PrEP if Creatinine clearance is less than 1.2mg/dl. **Note:** Absence of this should not delay PrEP initiation in persons with no signs and symptoms of renal impairment. If available, creatinine test can be done at initiation and repeated every 6 months. • Assess for contraindications to TDF/FTC or TDF/3TC.
Steps to initiation of PrEP	Provide risk-reduction and PrEP medication adherence counseling: • Provide condoms and education on their use • Initiate a medication adherence plan • Prescribe a once-daily pill of TDF (300mg) and FTC (200mg) or TDF (300mg)/ 3TC (300mg) • Initially, provide a 1-month TDF/FTC or TDF/3TC prescription (1 tablet orally, daily) together with a 1-month follow-up date • Counsel client on side effects of TDF/FTC or TDF/3TC
Follow-up/ monitoring clients on PrEP	• After the initial visit, the patient should be given a two-month follow-up appointment and thereafter quarterly appointments • Perform an HIV antibody test using the national HTS algorithm and every three months. **Note:** HIVST is not recommended in patients on PrEP. • For women, perform a pregnancy test if there is history of amenorrhea. • Review the patient's understanding of PrEP, any barriers to adherence, tolerance to the medication as well as any side effects.

Process	Description
	• Review the patient's risk exposure profile and perform risk-reduction counseling. • Evaluate and support PrEP adherence at each clinic visit. • Evaluate the patient for any symptoms of STIs at every visit and treat according to current STI treatment Guidelines.
Guidance on discontinuing PrEP	• Acquisition of HIV infection • Suspected signs and symptoms of acute HIV infection following a recent exposure within 4 weeks • Changed life situations resulting in lowered risk of HIV acquisition (no longer at substantial risk of HIV acquisition) • Intolerable toxicities and side effects of ARVs • Chronic non-adherence to the prescribed regimen despite efforts to improve daily pill-taking. • Personal choice • HIV-negative in a sero-discordant relationship when the positive partner on ART for >6months has achieved sustained viral load suppression (condoms should still be used consistently). The HIV negative partner can be allowed to continue PrEP even if the positive partner is virally suppressed if they choose to.
For detailed guidance on the provision of PrEP, please refer to the Technical Guidance on Pre-Exposure Prophylaxis for Persons at High Risk of HIV in Uganda, 2020.	

3.3.5 Blood Transfusion Safety

Provision of safe blood is a key component in Uganda's minimum health care package. It is also one of the biomedical interventions for HIV prevention.

- *Donor selection*: Blood should only be accepted from voluntary, non-remunerated, low risk, safe and healthy donors aged between 17 and 65 years. Efforts are directed towards maintaining adequate numbers of repeat donors.
- *Pre-donation counselling* should be given to provide accurate information including modes of transmission of disease (HIV, Hepatitis B and C, Syphilis), risk behavior, prevention interventions and to allow for self-exclusion for patient safety.
- *Clinical assessment* should be carried out to further screen for risk and determine overall health status and suitability of the donor.
- *Blood testing:* All donated blood should be routinely screened for transfusion transmissible infections including HIV, Syphilis, Hepatitis B and Hepatitis C.
- *Post-donation counselling* should be provided to donors whose test results are positive for HIV, Syphilis, Hepatitis B or C. Donors with positive results should be referred for care and treatment services.
- *Safe and appropriate use of blood and blood products:* Hospitals should have the capacity to carry out assessments and tests to ensure that those in most need of a blood transfusion are identified and prioritized. They should have the capacity to carry out blood group and compatibility tests on recipients to ensure that donor and recipient blood are matched and that a safe transfusion can be executed.

Hospitals should also have the capacity and SOPs in place to manage complications arising from a blood transfusion.

3.4 KEY AND PRIORITY POPULATION PROGRAMMING

Worldwide, Key/priority populations are disproportionately burdened by HIV and contribute significantly to new HIV infections. Globally, while the key populations are defined as sex workers, men who have sex men, trans-genders, injecting drug users and prisoners. This definition is informed by the fact that they are more burdened by HIV, and are surrounded by stigma, discrimination, legal and socio-cultural dimensions that make it harder to access interventions. Priority populations are country context specific and in Uganda these include fisher folk, truckers, uniformed forces, immigrant workers among others. It should be noted that in Uganda, the priority populations though may be at high risk of HIV, do not have legal, socio-cultural issues that affect them because of who they are, and are not stigmatized or discriminated although they may have access issues that could arise from other environmental factors that surround them. Targeted services for KP/PP increase access/uptake to services and reduce stigma. Innovative approaches/models have improved reach of these populations within their communities and increased access and uptake of health services.

The success of these models is based on having service providers trained to provide friendly services to key, vulnerable and priority populations, in addition to involving key population communities as peers-educators and engaging duty bearers/stakeholders. Several strategies including APN, SNS, and Differentiated Services Delivery approaches (see DSD tool kit for KP), Drop-in Centers-DICs (detail in DIC guidelines) have also been adopted/developed to increase access to services among Key populations.

3.5 STRUCTURAL INTERVENTIONS

Structural interventions are approaches that reduce HIV risk at the individual or group level. These are elements outside individual knowledge or awareness that have the potential to influence peoples' vulnerability to HIV infection. The intervention focusses on addressing social (stigma, gender inequality), cultural (religious beliefs), economic (lack of livelihood opportunities) and legal- political (laws and regulation) factors. Structural interventions call for a multi-sectoral approach. The health sector will focus on interventions to address gender-based violence within health care settings.

3.5.1 PREVENTION AND MANAGEMENT OF GENDER-BASED VIOLENCE

Gender-based violence (GBV) has the potential to increase the risk of acquiring HIV. GBV can also negatively affect retention and ART adherence of clients leading to poor treatment outcomes. Screening for preventing and responding to GBV promptly will reduce the risk of HIV infection and may improve treatment outcomes of those at risk for GBV. Some of the service delivery points recommended for GBV screening include: OPD, ART clinic, ANC/MCH and IPD. Every site providing GBV services and post-violence care should have the following:

- A written algorithm with steps for active case identification and follow-up
- At least one staff member trained to provide post-violence care

- A focal point for GBV services at each facility
- Provision of PEP

3.5.1.1 Screening for GBV

All PLHIV should be routinely screened for GBV. Clients should therefore be assessed for GBV at least once every six months as part of the HIV program. For individuals outside HIV care settings, GBV screening should be provided at contact with the health care system. All individuals identified with signs of GBV should be linked to the GBV focal person at the facility for further assessment and help. A simplified screening tool adapted from the GBV assessment tool should be used to screen for GBV as shown in **Table 10**.

Table 10: A Four Question Screening Tool for GBV

No.	Question	Y	N
1.	Has client felt psychologically or emotionally harmed by anyone?		
2.	Does client have any bruises, cuts, or physical injuries?		
3.	Has client been touched or fondled inappropriately?		
4.	Has client been forced to have sexual contact or intercourse?		

Action: If the response is 'Y' to any of the questions above, provide counseling and link to GBV services and document appropriately.

When managing rape victims, the minimum package of services is indicated in Table 11 below.

Table 11: Minimum package for post-rape care services

Health facilities should provide the following clinical services as part of post-rape care:
Initial assessment of the client • Rapid HIV testing and referral to care and treatment if HIV-positive • Post-exposure prophylaxis (PEP) for HIV if tested negative (see Section 3.3.3) • STI screening/testing and treatment (see Section 6.14.1.2) • Forensic interviews and examinations • Emergency contraception, where legal and according to national guidelines, if person reached within the first 72 hours • Counseling
The health facility should also identify, refer and link clients to non-clinical services:
Some of the services include the following: • Long-term psychosocial support • Legal counseling • Police (investigations, restraining orders) • Child protection services (e.g. emergency out-of-family care, reintegration into family care when possible, permanent options when reintegration into family impossible) • Economic empowerment • Emergency shelters • Long-term case management
Reporting:
• Health facilities should use HMIS 105 to report GBV

Box 3: Key Highlights in HIV Prevention Services

- In order to address the multiple factors affecting the different sub-populations, a combination HIV prevention approach using a mix of biomedical, behavioral and structural interventions are recommended to reduce new HIV infections.
- HIV prevention biomedical interventions include STI screening and treatment, eMTCT, safe male circumcision (SMC), ART for prevention, PEP, PrEP, condom use and blood transfusion safety.
- Condoms should be used by sexually active persons at risk of HIV to prevent both HIV and unintended pregnancies.
- PEP is given to uninfected persons that have exposed to HIV. It is a short-term use of ARVs, and HIV status of the individual should be ascertained before initiation.
- SMC is done to reduce the risk of HIV acquisition by approximately 60%. It should be coupled with other prevention interventions including condom use.
- PrEP is offered to HIV negative persons at substantial risk of acquiring HIV before exposure to HIV. Populations such as discordant couples, sex workers, fisher folk, long-distance truck drivers, men who have sex with men (MSM), uniformed forces, and adolescents and young women including pregnant and lactating women at substantial risk should always be assessed for eligibility for PrEP.
- Targeted services to key and priority populations increases access and decreases stigma. Reaching KPs and PPs with HIV care and treatment interventions is critical for epidemic control. However, there are still several factors that hinder access to services including capacity of health service providers, stigma, socio-cultural and legal environment which need to be addressed. Using innovative approaches including DSDM, DIC, APN, Social Network strategies is critical to ensuring they access and utilize services.

4 ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION OF HIV (eMTCT) AND IMPROVING MATERNAL, NEWBORN, CHILD AND ADOLESCENT HEALTH (MNCAH)

4.1 INTRODUCTION

Mother-to-child transmission of HIV accounts for up to 18 percent of all new infections in Uganda and is the primary source of infections among children. Current evidence shows that with effective interventions including use of antiretroviral therapy, the rate of transmission could be reduced to less than 5% in a breastfeeding community like in Uganda. Over the past decade, tremendous gains have been made in the prevention of mother-to-child transmission of HIV, primarily as a result of bold policies, including universal antiretroviral therapy (option B+) for pregnant and breastfeeding women, which catalysed important programmatic leaps. In 2018, the estimated new annual paediatric HIV infection (case rate) was 466 per 100,000 live births, far above the elimination target of <50 new infections per 100,000 live births, and most of the infections occurred during the breast-feeding period. The transmission rate was 3.8% at 6 weeks and 7.9% at the end of breast-feeding, which implied that the country is progressing towards elimination of mother-to-child transmission of HIV.

The World Health Assembly in 2016 endorsed three inter-linked global health sector strategies on HIV, viral hepatitis and sexually transmitted infections for the 2016 – 2021 period, which set ambitious targets for elimination of mother-to-child transmission (EMTCT) of HIV, hepatitis B and syphilis. This was based upon the pretext that mother-to-child transmission of the three infections can be effectively prevented by simple interventions including antenatal screening and treatment for women and their partners, and vaccination for infants within the reproductive, maternal, newborn and child health platform. The similarity in interventions to prevent mother-to-child transmission of HIV, syphilis and hepatitis B, means that an integrated approach to triple elimination is highly feasible. The move towards triple elimination shall result in greater collaboration between the related programmes and thus improve accessibility, effectiveness, efficiency and sustainability of maternal, newborn and child health services to the individual family and community at large.

4.1.1. Pregnant and breastfeeding adolescent girls and young women

Although pregnant and breastfeeding adolescent girls and young women (AGYW) share some characteristics with their adult counterparts, their individual, physical, psychological, socio-economic and biological MCH/PMTCT health care needs vary significantly. Therefore, there is growing recognition that the approaches used to respond to the unique MCH/PMTCT health care needs for pregnant and breastfeeding AGYWs significantly differ from those of older mothers and this necessitates the need for adolescent friendly interventions tailored to meet their special needs.

4.2 eMTCT STRATEGY

The eMTCT strategy comprises a package of interventions summarized in four approaches (see **Table 12**). These interventions must be offered simultaneously within the platform of MNCAH services throughout the continuum of eMTCT services as will be described in **Figure 9**.

4.3 INTEGRATING eMTCT AND MATERNAL, NEWBORN, CHILD AND ADOLESCENT HEALTH (MNCAH) SERVICES

eMTCT interventions should be integrated into the MNCAH services which include but not limited to the ANC, labour and delivery, postnatal care, adolescent clinics, sick child clinic and YCC at health facilities and community sites. The section defines which services in each eMTCT prong are offered in each of the parts of the MNCAH services continuum: before pregnancy, antenatal, labour and delivery, postnatal and community (see **Figure 9**).

Figure 9: The eMTCT continuum of services

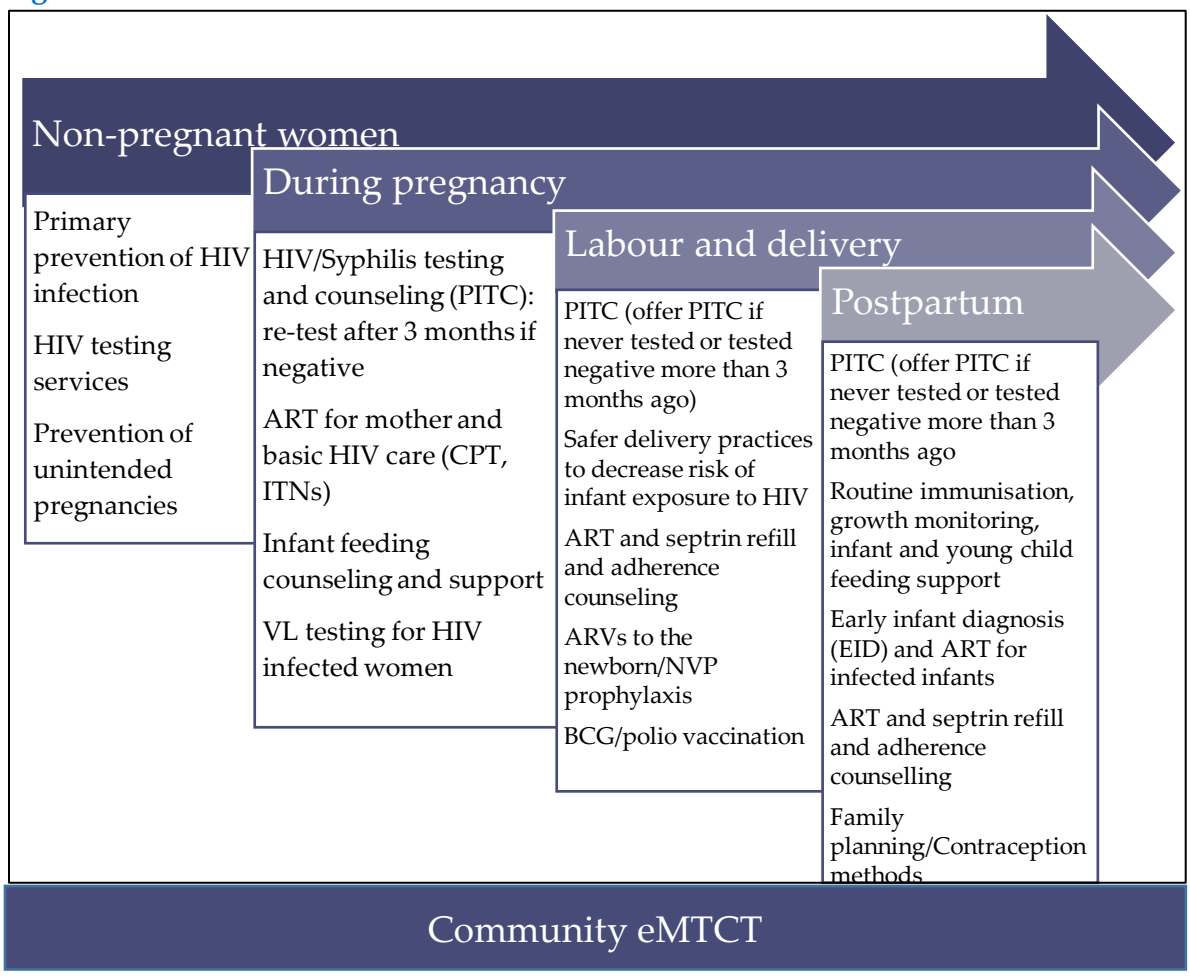


Table 12: The eMTCT Strategy

Intervention area	Target group	Additional information

Intervention area 1: Primary prevention of HIV infection	Adolescents, women, and men of reproductive age	This prong aims to prevent HIV in women and girls of reproductive age, and male partners. Interventions include:
		• HIV testing services for pregnant and non-pregnant women of reproductive age
		  ○ Couples counseling and partner testing and re-testing for the HIV-negative individuals
		• Routine HIV testing services for pregnant and non-pregnant adolescents
		• Behavioral change communications and risk-reduction counseling to avoid high-risk sexual behavior including:
		  ○ Safer sex practices, including dual protection (condom promotion) and delay of onset of sexual activity
		  ○ Health information and education about risky behavior, life skills and benefits of HTS
		• SMC; PrEP for discordant couples as well as pregnant and lactating mothers at substantial risk of HIV acquisition; and GBV screening and management
		• STI, and HBV screening and management

Intervention area 2: Prevention of unintended pregnancies among women living with HIV	Adolescent girls and women living with HIV and their partners	• Family planning/Contraception (FP) counseling and voluntary services (informed decision/consent) • HIV testing and counseling in sexual and reproductive health (SRH) and FP settings • Safer sex practices, including dual protection (condom use promotion) • Pre-conception counseling and referral for infertility investigation and treatment
Intervention area 3: Prevention of HIV transmission from women living with HIV to their infants	Pregnant and breastfeeding women living with HIV	This prong focuses on: • Quality antenatal, labour and delivery, and postnatal care • Access to HTS during ANC, labour and delivery, and postpartum period • Initiation of ARVs for prevention of HIV transmission and mother's health • Adherence counseling and support • Retention monitoring • Viral load testing and monitoring • ARV prophylaxis for HIV-exposed infants

Intervention area	Target group	Additional information		
		• Safe delivery practices to decrease risk of infant exposure to HIV • Infant and young child feeding counseling • Community outreach and efforts to support partner involvement and testing • TB screening, diagnosis and treatment • INH prophylaxis • STI and HBV screening and treatment		
Intervention area 4: Provision of treatment, care, and support to women infected with HIV, their children and their families	Women living with HIV and their families	This prong addresses the treatment, care and support needs of HIV-infected women, their children and families (family-centered approach)		
		Package of services for mothers includes: • Lifelong ART • Cotrimoxazole prophylaxis • TB screening, diagnosis, and treatment • INH prophylaxis • Prevention, diagnosis and treatment of malaria • Continued infant feeding, assessment, counseling and support • Nutrition assessment, counseling, and support • Sexual and reproductive health	Package of services for HIV-exposed and infected children: • ARV prophylaxis for HEI • ART for HIV-infected children • OI prophylaxis and treatment (e.g. CTX) • INH prophylaxis for TB exposed • Routine immunization and growth monitoring • HIV testing • Infant and young child feeding (IYCF) assessment, counseling and support	Package of services for partner and the family: • HIV testing of partners, children and other family members and linkage to prevention and care services • ART for HIV-infected family members • Cotrimoxazole prophylaxis for HIV-positive family members • TB screening, diagnosis, and treatment and advice on TB infection control in the family • INH prophylaxis • Prevention, diagnosis, and treatment of malaria • Nutrition assessment counseling and support • Sexual and reproductive health services including FP and condom provision

Intervention area	Target group	Additional information		
		services including FP and condom provision • STI and HBV screening and treatment • Breast and cervical cancer screening and referral • Adherence, disclosure and psychosocial support • Risk-reduction counseling • Routine laboratory monitoring (CD4 and viral load) • Routine follow-up, ARV refills and other routine MCH supplements and drugs (Fe/Folic, Mebendazole) • Effective referrals and linkages to other services (community and facility) • Symptom management and palliative care	• Nutrition assessment, counseling and support • Prevention, screening and management of infections • Psychosocial care and support • Routine follow up and refills and provision of age-appropriate supplements • Effective referrals and linkages to other services (community and facility)	• STIand HBV screening and treatment • Adherence, disclosure and psychosocial support • Risk reduction counseling • Routine laboratory monitoring (CD4 and viral load) for the HIV-positive • Routine follow-up, ARV refills and other routine supplements and drugs (Mebendazole) • Effective referrals and linkages to other services (community and facility) • Symptom management and palliative care

4.4 SERVICES FOR NON-PREGNANT WOMEN

4.4.1 PRIMARY PREVENTION OF HIV INFECTION

Preventing HIV in women and girls of reproductive age reduces the risk of HIV infection to infants because over 90% of pediatric HIV infections are through MTCT. Some of the services to prevent HIV infection in women and girls of reproductive age are presented in **Table 13**.

Table 13: Services for preventing HIV infection in women and girls of reproductive age

Service	Description
Routine HTS and syphilis testing in the MNCAH setting	Provide HTS to all women and girls of reproductive age and their partners. Link all who test positive to HIV care and treatment services and offer risk reduction counseling to all who test HIV negative. Also test for syphilis and link to care as necessary.
BCC	Safer sex practices, including dual protection (condom promotion) and delay of onset of sexual activity (see **Table 6**.)
Other prevention services	SMC: Offer and refer SMC services to male partners of the girls and women GBV: Screen all adolescent girls and women of reproductive age, for GBV and offer services within MCH including PEP PrEP: Offer PrEP to eligible adolescent girls and women of reproductive age in line with the guidelines for PrEP (see PrEP section); special consideration should be given to women and adolescents in discordant relations who desire to get pregnant (see Table 9).
STI and HBV screening and treatment	Counsel and screen adolescent girls and women for STIs including syphilis and HBV and manage the STIs (see Section 6.14.1.2).

4.4.2 PREVENTION OF UNINTENDED PREGNANCIES AMONG WOMEN LIVING WITH HIV

Family planning (FP)/contraception for adolescent girls and women living with HIV reduces the number of unintended pregnancies, thereby reducing the number of infants exposed to HIV and the overall risk of MTCT. FP/contraception also provides intrinsic benefits by saving lives and enhancing the health status of women and their families. However, FP services should be provided based on respect and fulfillment of reproductive rights and choices. Women and girls should not be coerced into contraception; their sexual and reproductive choices should be respected and safeguarded. **Table 14** describes the process of offering FP/contraception.

Table 14: Family planning/contraception services for HIV-infected women of reproductive age.

Service	Explanation
Counsel adolescent girls and women routinely for FP/contraception	Provide routine FP/contraception information and counseling to women and adoelscent girls attending ANC, PNC, YCC and ART services: Encourage HIV-infected adolescent girls and women to discuss their reproductive health choices and support them as appropriate. Information provided during counseling should cover: • Family planning/contraceptive methods, advantages and side effects • Common misconceptions about family planning/contraception • Advantages of dual protection and also how to negotiate condom use

Service	Explanation
	• What to do when pregnancy occurs Address misconceptions. Some are below: *"Using hormonal contraception increases the risk of HIV acquisition"* Correct response: There is no increased risk of HIV acquisition in women using oral hormonal contraception. Since oral contraceptives are not a mode of barrier protection it is still important to use condoms to prevent all STIs including HIV. *"Hormonal contraception causes a decrease in CD4 count, increased viral load and progression to AIDS event or death."* Correct response: There is no evidence that hormonal contraception causes a decrease in CD4 count, an increase in viral load, or progression to AIDS event or death.
Counsel on safe conception	*For HIV-positive women/couples who desire to become pregnant discuss strategies to:* • Reduce the likelihood of HIV transmission to infants • Among discordant couples, reduce the risk of transmission to the partner through conception strategies including initiating and adhering to ART and providing PrEP for the negative partner
After counseling, offer FP on a one-on-one basis	*For HIV-positive women/couples who do not desire to become pregnant:* • Offer effective contraception • Encourage dual contraception (use of both hormonal contraception and condoms) to prevent pregnancy, STIs, HIV transmission, and re-infection • The choice of contraceptive methods in HIV-infected women is much the same as in HIV-negative women Consider some drug interactions between HIV medicines and contraceptives when offering FP methods to women and adoelscent girls on ART (see **Table 15**)
Ongoing support for adolescent girls and women when using FP	• Counselling and adherence supportfor the chosen method • Assess for possible side effects and manage accordingly • Clients on injectable FP (Depo-Provera) and ART should be counseled to return for injection on appointment date or before if they cannot make it on scheduled appointment date

4.4.2.1 Recommendations for hormonal contraceptive use among women at high risk of HIV infection (Medical Eligibility Criteria –MEC for family planning/contraceptive methods)

Women/adolescent girls and couples at high risk of HIV infection continue to be eligible to use all forms of hormonal contraception. Informed decision-making is a key organizing principle and standard in a human rights-based approach to contraceptive information and services. A shared decision-making approach to contraceptive use should be taken with all individuals, but special attention should be paid to using this approach with vulnerable populations, such as adolescent girls and women at high risk of acquiring HIV. Adolescent girls and women at high risk can use the following hormonal contraceptive methods without restriction (MEC category 1): combined oral contraceptive pills (COCs), combined injectable contraceptives (CICs), combined contraceptive patches and rings, progestogen-only pills (POPs), and levonorgestrel (LNG) and etonogestrel (ETG) implants.

There continues to be evidence of a possible increased risk of acquiring HIV among progestogen-only injectable users. Uncertainty exists about whether this is due to methodological issues with the evidence or a real biological effect. In many settings, unintended pregnancies and/or pregnancy-related morbidity and mortality are common, and progestogen-only injectables are among the few types of methods widely available. Adolescent girls and women should not be denied the use of progestogen-only injectables because of concerns about the possible increased risk. Adolescent girls and women considering progestogen-only injectables should be advised about these concerns, about the uncertainty over whether there is a causal relationship, and about how to minimize their risk of acquiring HIV.

Contraceptive counselling is a core component for supporting informed choice and decision-making by clients. Health care providers need support to provide adolescent girls and women with comprehensive, evidence-based information on the full range of available methods and the advantages and disadvantages associated with their use.

4.4.2.2 Interactions between ART and Contraceptives

Interactions between ART and some contraceptives may sometimes interfere with the effectiveness of contraceptives and women need to be counseled about this and encouraged to use dual protection.

Table 15: Interactions between ART and Contraceptives

Type of contraception	ARV Drug					
	NRTI(TDF/ABC/AZT/3TC/FTC)	DTG	EFV	LPV/r	ATV/r	NVP
Combined oral contraception (Microgynon, Lofeminal)	Nil		Risk of contraceptive failure: must be used with a barrier method			
Emergency contraception (Postinor 2)	Nil		Levels of contraceptive reduced: Double dose of emergency contraceptive to 4 tablets			
Injectable (Depo-Provera)	Nil					
Implants (Implanon, Jadelle)	Nil		Levels of contraceptive reduced: additional barrier method advised			
IUD (TCu 380A)	Nil					
Condoms	Nil					

4.5 DURING PREGNANCY

This section outlines ANC services for all pregnant women with specific services for the HIV-infectedand HIV-negative pregnant women. Table 16 describes services offered during pregnancy.

Table 16: ANC and eMTCT Services for Pregnant Women

Service	Description
Provide HTS and syphilis testing in ANC	• Offer routine HTS and testing for syphilis to pregnant women and their partner(s) with same-day results using the SD-Bioline duo HIV/syphilis test according to algorithm in **Figure 6** (in chapter 2). If found positive treat for syphilis in order to reduce HIV transmission from mother to child using the following: o Pregnant women/girls with early syphilis: give Benzathine Penicillin G 2.4 million units intramuscularly once. Early syphilis for this guideline is: (primary, secondary and early latent syphilis of not more than two years' duration). o In late syphilis or unknown stage of syphilis: give Benzathine Penicillin G 2.4 million units intramuscularly once weekly for three consecutive weeks. Late syphilis for this guideline is defined as infection of more than two years' duration without evidence of treponemal infection. o Note: Adequate maternal treatment for prevention of congenital syphilis is defined as at least one injection of 2.4 million units of intramuscular Benzathine Penicillin at least 30 days prior to delivery. o Alternative treatment with Procaine Penicillin or Erythromycin, Azithromycin and Ceftriaxone if allergic to penicillin. o Refer to **Figure 10: Management of HIV and Syphilis in MCH.** • Offer syphilis screening using syphilis rapid tests for mothers who are already on ART. o Offer HTS (including PITC, VCT and couple testing) and support mutual disclosure. • Link all HIV-positive seroconcordant couples as well as HIV-positive individuals in serodiscordant relationships to ART. • Offer PrEP to negative partners in the discordant couples. • For HIV-negative pregnant women, re-test in the third trimester, during labor, or shortly after delivery, because of the high risk of acquiring HIV infection during pregnancy. • Re-test HIV-negative pregnant women in a discordant relationship every three months. • Re-test the following HIV negative pregnant women within four weeks of the first test: o STI, HBV or TB-infected pregnant women. o Those with a specific incident of HIV-exposure within the past three months • Provide risk reduction counseling to HIV-negative women. • Test pregnant women/girls and their partners for Hepatitis B during antenatal (See Figure 11) o For patients who are HBsAg positive assess the HBeAg and HBV viral load. Patients who are HBeAG negative with a HBV VL of <200,000 IU/ml should be monitored with CBC, LFTs and VL at 6 and 12 months (see Figure 10).

Service	Description
	○ For patients who are HBsAg positive assess the HBeAg and HBV viral load. Patients who are HBeAg positive with HBV VL of >200,000 IU/ml should initiate prophylactic treatment at 24 weeks gestation or at the earliest contact. Discontinue medication at the end of 3 months. After starting treatment, LFTs should be monitored at 4, 8, 12 and 24 weeks and thereafter annually. Monitor HBV viral load at 6 and 12 months (see Figure 10).
Antenatal care package for all pregnant women (regardless of HIV status)	General care: • All pregnant women/girls should have at least eight ANC visits: encourage and support mothers to start ANC in the first trimester • Routinely provide iron, folic acid, and multivitamin supplements • Deworm in the 2nd trimester using Mebendazole • Provide nutrition assessment, counseling and support (see Chapter 5) • Counsel and encourage women to deliver at the health facility • Screen for TB and take appropriate action • Take weight and BP at every visit Laboratory services: • Screen and treat for syphilis, HIV, hepatitis B, other STIs and anemia. Use syndromic approach to treating STIs • Perform urinalysis to detect a urinary tract infection (UTI), protein in the urine (proteinuria), or blood in the urine (hematuria) indicating kidney damage, or sugar in urine suggesting diabetes • Do a blood slide for malaria for all pregnant women. • Perform a blood group test in anticipation of blood transfusion and check for hereditary conditions if suspected (sickling test)
Laboratory investigations specific to HIV-positive pregnant women	• For HIV-positive women, perform a baseline CD4 count. The test result is not required for ART initiation. • Do Hb test for women/girls beginning AZT-based ART at baseline and four weeks after initiating ART. • For HIV-positive pregnant women/girls already on ART, do VL test at first ANC visit, then follow the VL testing algorithm for pregnant and breast feeding women (see Viral load algorithm for pregnant and breastfeeding mothers in Figure 27) . • For newly diagnosed HIV-positive pregnant women/girls, do VL test 6 months after initiating ART and then follow the VL testing algorithm for pregnant and breast feeding women (See Figure 27)
Comprehensive care for pregnant women with HIV	At each visit provide: • Comprehensive clinical evaluation • Provide cotrimoxazole preventive therapy (CPT) ○ Pregnant women on CPT should not be given Sulphadoxine-Pyrimethamine (Fansidar) for intermittent preventive treatment for malaria (IPTp) • Screen for TB and take appropriate action • INH for eligible women/girls (see Section 6.7.4.1.1) • Screening and management of opportunistic infections (OIs)
Assess risk of unborn baby among pregnant	• Conduct a risk assessment of the unborn baby at 1st ANC among all HIV positive pregnant women and flag those at high-risk including: ○ Newly initiated on ART in the 3rd trimester or breastfeeding period ○ Most recent VL is non-suppressed • Closely monitor all high-risk pregnancies

Service	Description	
women with HIV at ANC 1		
ART	○ All women/girls living with HIV identified during pregnancy, labour and delivery or while breastfeeding should be started on lifelong ART (option B+) irrespective of CD4 counts or WHO clinical stage. ○ ART should be initiated on the same day, and adherence counseling should be initiated and sustained intensively for the first three months then maintained for life. ○ Initiate mother on once-daily FDC of TDF+3TC+DTG with pharmacovigilance (See Sec 8.5.3.2). ○ The mothers initiated on TDF + 3TC +EFV400 shall be transitioned to TDF + 3TC + DTG at 6-9 months post-partum if VL within past 6 months is suppressed. ○ If mother is already on ART >6 months with TDF/3TC/EFV, do VL test. If she is virally suppressed, maintain her on TDF/3TC/EFV400 until 6-9 months after delivery and then substitute EFV with DTG if VL within the past 6 months is suppressed. ○ If she is already on a DTG-based 1st-line regimen and virally suppressed, maintain on the same regimen. ○ If she is already on ART and VL is not suppressed, manage as treatment failure and switch to DTG-based 2nd line regimen (if no previous exposure to DTG). ○ If she is on 2ndline ART with ATV/r or LPV/r and virally suppressed, maintain on the same regimen until 6-9 months after delivery and then substitute PI with DTG if VL within the past 6 months is suppressed and no previous exposure to DTG. ○ All women should receive Pre-ART adherence counseling before initiating ART and ongoing adherence support after that (see Chapter 7). ○ ART should be initiated and maintained in mother-baby care point in MCH.	
	What to do if mum refuses ART or if you know adherence is poor: Maternal VL suppression is key for preventing breastfeeding transmission, so if VL suppression is not certain infant prophylaxis may serve as a "back up" to prevent MTCT - similar to "Option A". Clinical providers should continue infant prophylaxis with NVP for these specific scenarios. Continuation of prophylaxis should be seen as an interim measure while maternal adherence is improved	
Risk reduction counseling and support	• Encourage consistent and correct condom use • Encourage women to deliver at the health facilities • For negative pregnant women, offer other prevention services like SMC to partner and mitigate or manage GBV	
Visit schedules for HIV-infected pregnant women	HIV-positive pregnant woman/ girl already on ART and stable: Stable pregnant and breastfeeding mother • Viral suppression • Adherence above 95% • On ART for more than one-year Stage T1 and no active OIs	HIV-positive pregnant woman/girl initiating ART in ANC (new clients): Unstable pregnant and breastfeeding women/ adolescent girl • Recently initiated on ART (less than one year on ART) • Poor viral suppression: most recent VL of above 1000copies/ml • Adherence less than 95%

Service	Description	
	• Not due for vital lab tests in the next twomonths,e.g., viral load • Has disclosed to significant other/ household member/ family member	• Stage T3,4 and active OIs • Comorbidities/ co-infection • CD4 less than 500 • Due for vital lab tests in the next two months,e.g., viral load • Has not disclosed to significant other/ household member/ family member
	• 8 ANC visits • Synchronize ART refills and adherence support with the ANC visits	• Two weeks after initiating ART • After that, monthly until delivery • Follow routine MCH schedule after delivery together with the exposed infant visit schedule (see Annex 2)

Figure 10: Management of HIV and Syphilis in Maternal and Child Health care settings

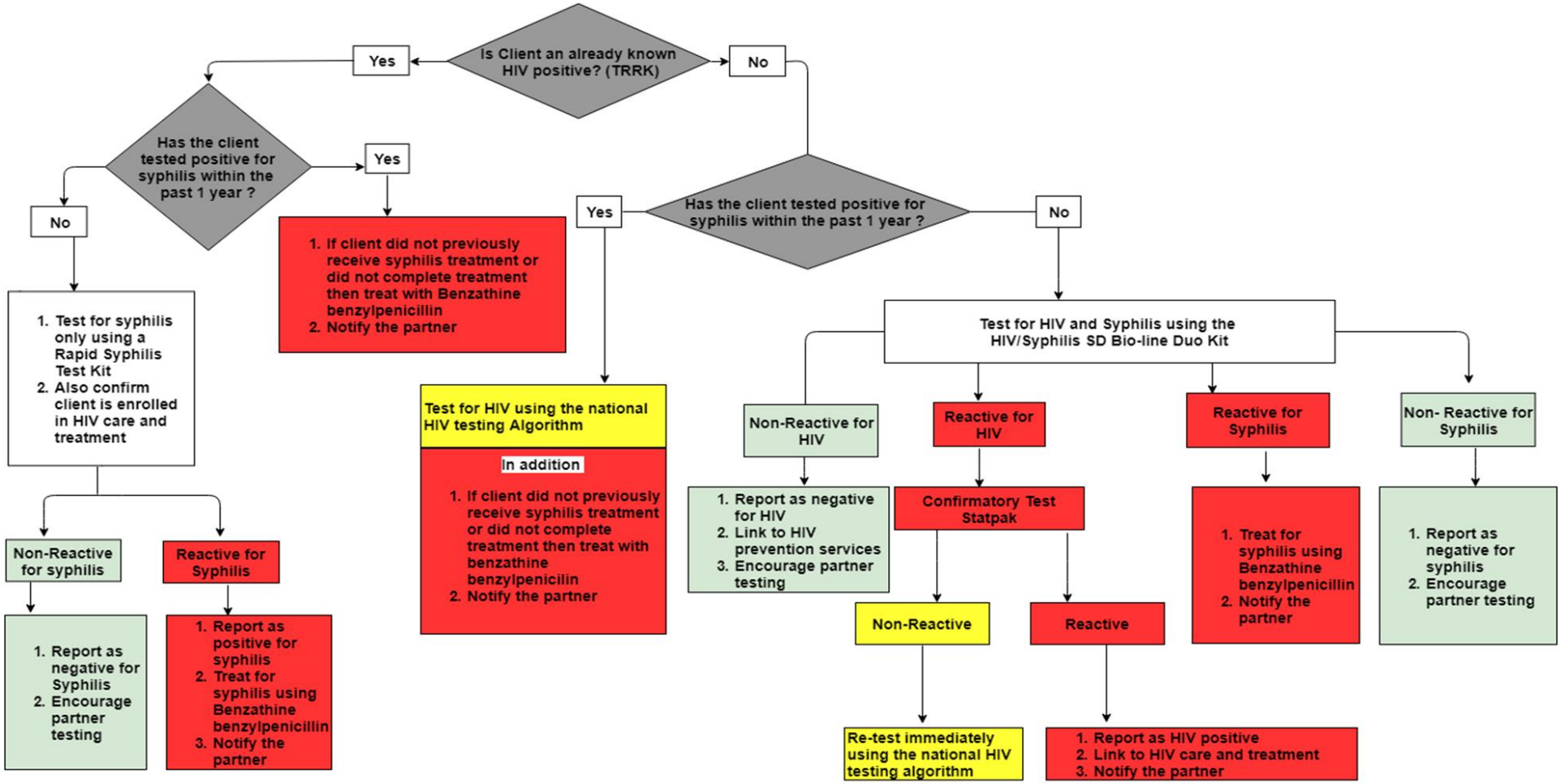


Figure 11: Algorithm for Hepatitis B testing in MCH

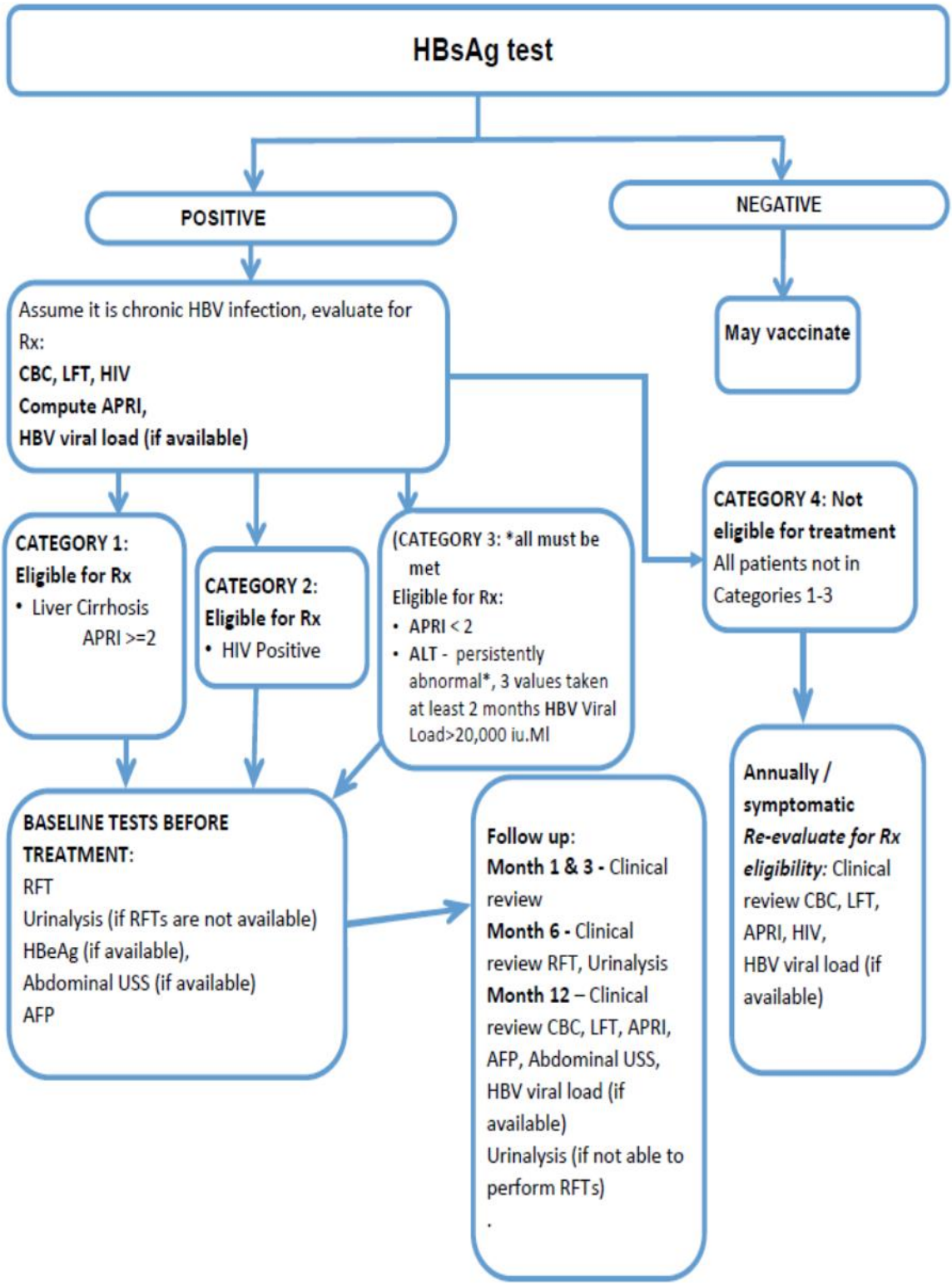
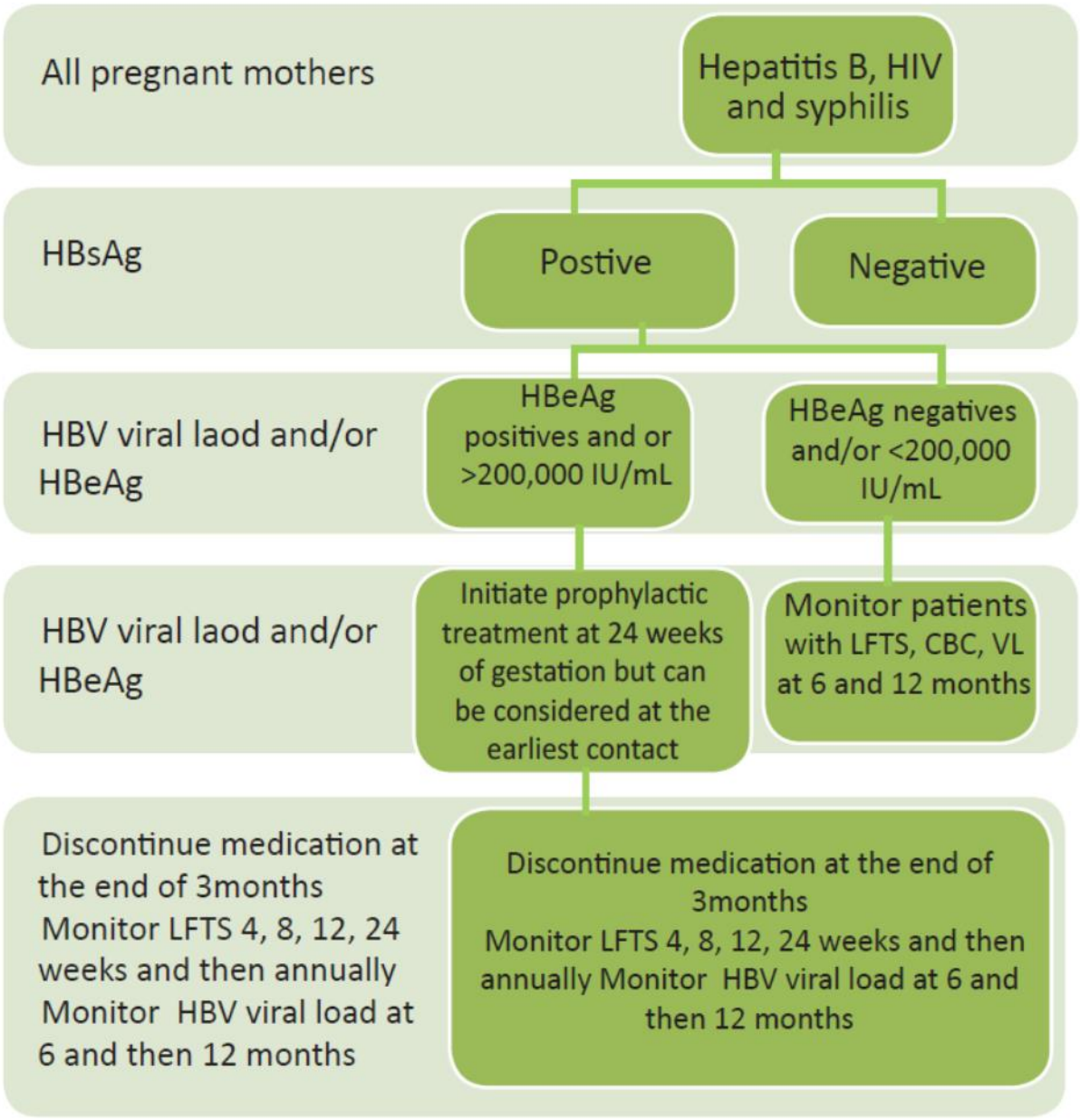


Figure 12: Algorithm for the management of Hepatitis B in pregnancy for PMTCT



4.6 SERVICES TO BE PROVIDED DURING LABOUR AND DELIVERY

Labour and delivery are the periods of highest risk of transmission and should be handled with extra care to avoid transmission from mother to the child. This section outlines specific services to be offered during that period (see Table 17).

Table 17: eMTCT services during labour and delivery

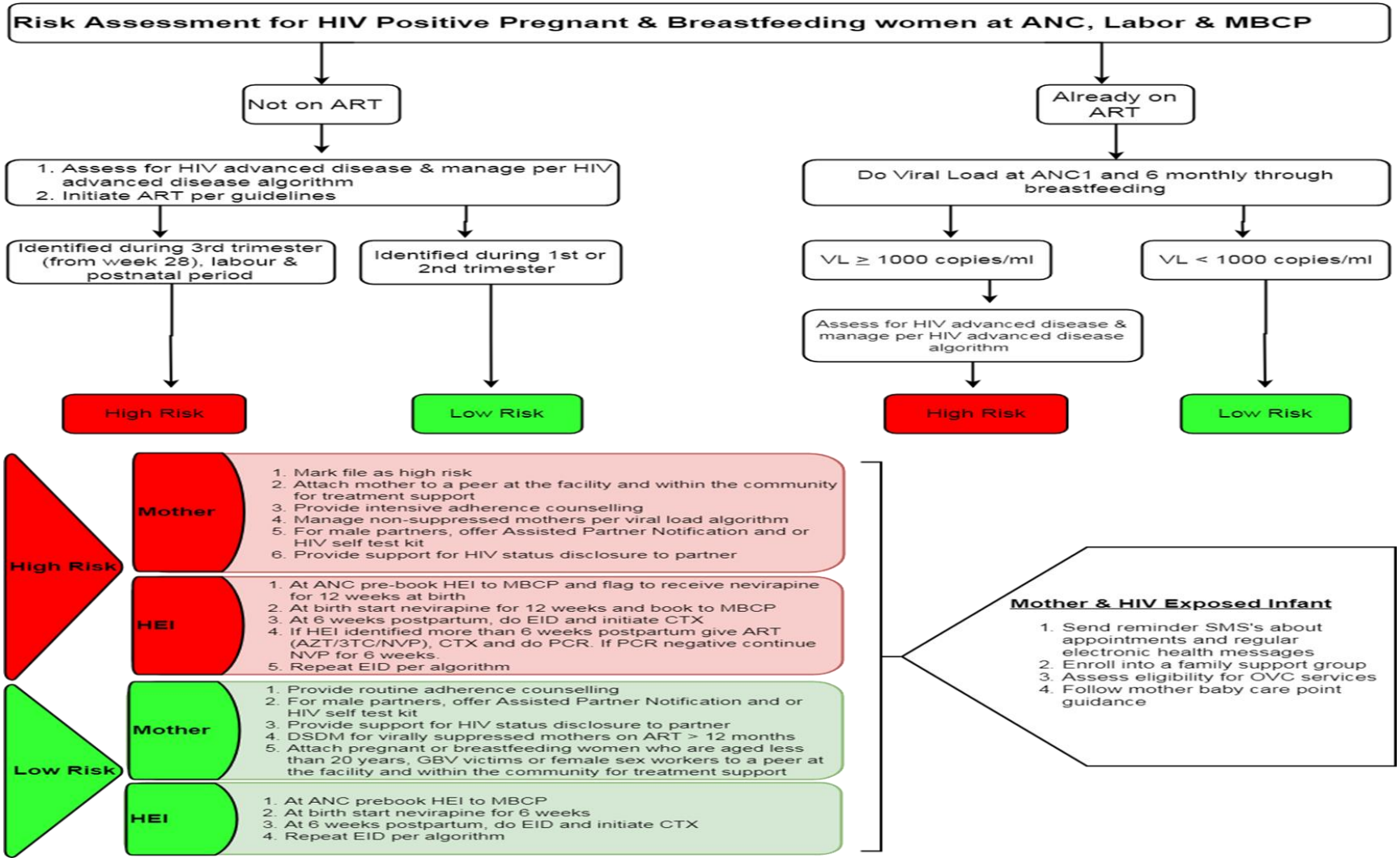
Service	Description
Ascertain HIV status, offer PITC for the partner	• Offer HTS and syphilis testing to all women who have never tested • Link all HIV-negative mothers to prevention services • Re-test HIV-negative women who did not re-test in 3rd trimester
Safe obstetric practices	Safe obstetric practices help to reduce the risk of HIV transmission during labour and delivery and reduce maternal and infant death. They include: • Use of a partogram to allow for early detection and management of prolonged labour • Avoid routine (artificial) rupture of membranes (ARM); if prolonged labour is due to poor uterine contraction, perform ARM at ≥6cm cervical dilation and augment with oxytocin (Pitocin)or misoprostol • Do not perform routine episiotomy except for specific obstetric indications • Avoid instrument delivery including vacuum extraction • Avoid frequent vaginal examinations • Do not 'milk' the umbilical cord before cutting • Actively manage the third stage of labour: Active management reduces the risk of postpartum hemorrhage which increases exposure of the newborn to maternal blood. Active management of the third stage of labour involves three important components: (i) giving oxytocin within 1 minute following the birth of the baby (ii) delivery of the placenta using controlled cord traction (iii) massaging the uterus after delivery of the placenta
ART for the mother	• Give ART (for mothers on treatment, continue the same ART regimen) • Initiate ART for mothers not yet on treatment (see Section 8.5.3.2)

ARV prophylaxis for the HIV-exposed infant	• Initiate NVP prophylaxis for the infant at birth
	  ○ Low risk: Counsel mother and provide NVP syrup for six weeks
	  ○ High risk: Counsel mother and provide NVP syrup for up to 12 weeks (high-risk infants are described in Figure 13)
	  ○ High-risk infants are breastfeeding infants whose mothers:
	  ▪ Have received ART for four weeks or less before delivery.
	  ▪ Have VL >1000 copies in four weeks before delivery; or diagnosed with HIV during 3rd trimester or breastfeeding period (postnatal).

	What to do if baby presents after 6 weeks: a. Do first PCR b. Give ART (AZT+3TC+NVP bd; give weight appropriate dose) for 6weeks c. If PCR results are negative, give NVP for 6 weeks (after completing the 6 weeks of AZT/3TC/NVP) d. If PCR results are positive, stop AZT+3TC+NVP immediately and initiate recommended first line (ABC/3TC/LPV/r). Irrespective of timing, the mother should be started on ART as soon as possible for her own health and to decrease risk of transmission to breastfeeding baby.

Service	Description
Establishing breastfeeding	• Support the mother to initiate breastfeeding within 30 minutes of delivery • Offer infant feeding counseling to the mother according to the guidance and chosen method during pregnancy (see Chapter 5)
At discharge	• Counsel the mother and provide an appointment to return for postnatal services and exposed infant testing and care at six weeks • If the mother is not going to receive services at this facility, link the mother to HIV care services at the facility of their choice using linkage guidelines in Section 2.7

Figure 13: Assessment for High-Risk Mother-Infant pairs



4.7 SERVICES TO BE PROVDED DURING THE POSTPARTUM PERIOD

Following delivery, address the treatment, care and support needs of HIV-infected mothers, their children and families (Intervention area 4), provide family planning/contraception services (Intervention area 2) and continue to prevent HIV in mothers who were negative during pregnancy, labour, and delivery. The HIV-infected mother should continue to receive her care in the mother-baby care point until the baby is 18 months of age. This section will describe postnatal services for the mother (see Table 18). Services for infants (including care for the HIV-exposed infant (HEI) and infant and young child feeding counseling) are described in Section 4.8.2 and Chapter 5.

Table 18: eMTCT services during the postpartum period

Service	Description
Postnatal services for all mothers regardless of HIV status	Follow-up for the mother is usually scheduled at six weeks following delivery and this coincides with the baby's immunization schedule. At the postnatal visit: • Check for sepsis, anemia, high blood pressure,etc. and provide vitamin A • Offer family planning/contraception counseling and services (see Table 14) • Screen for TB and treat if infected • Breast cancer screening • Cervical cancer screening
HIV and syphilis testing services	• Provide HTS and syphilis testing for breastfeeding mothers who have never tested and their partner • Provide repeat HIV testing to mothers who were negative at ANC, labour and delivery • Provide ART for all mothers newly diagnosed at PNC according to the guidance in Section 8.5.3.2 • Continue to provide risk-reduction counseling and support to HIV-negative mothers • Do repeat testing every three months during breastfeeding for all HIV negative mothers
HIV care and management for the HIV-infected mother and family	• ART • Cotrimoxazole prophylaxis • Regular TB screening and provide INH prophylaxis if eligible • Continued infant feeding counseling and support • Nutritional assessment, counseling and support • Sexual and reproductive health services including FP/contraception • Psychosocial support • Adherence counseling and support • Monitor retention in care • Assess all mothers who delivered outside the facility for OIs,provide appropriate care and initiate ART
Psychosocial support services	• Link the mother to support services like FSG if they exist in addition to other services

4.8 CARE OF THE HIV-EXPOSED INFANT/CHILD

HIV-exposed infants should receive care at the mother-baby care point, together with their mothers, until they are 18 months of age. The goals of HIV-exposed infant care services are:

- To prevent the infant from being infected with HIV through MTCT
- To diagnose HIV infection early and treat
- To offer child survival interventions to prevent early death from preventable childhood illnesses

4.8.1 VISIT SCHEDULE FOR HIV-EXPOSED INFANTS

Regular follow-up is the backbone of caring for HIV-exposed and infected children. It ensures optimal healthcare and psychosocial support to the family. The HEI and the mother should consistently visit the health facility at least nine times during that period. The mother-baby pair should be supported to adhere to the visit schedule. The visits are synchronized with the child's immunization schedule Annex 2.

4.8.2 HEALTH CARE SERVICES FOR THE HIV-EXPOSED INFANTS

Table 19 below summarizes the services for HEI during the 18 months of follow-up.

Table 19: HIV-exposed infant care services

Service	Description	
Identification of HIV-exposed infants	• Identify all HIV-exposed infants; document the HIV status of the mother in the child card and mothers' passport. Infants whose HIV status is not documented or is unknown should be offered rapid HIV testing; including those whose mothers did not receive eMTCT services or have become newly infected after pregnancy. The entry points for identification of HIV-exposed infants include YCC, OPD pediatric wards and outreaches. Special attention should be paid during immunization both at static and outreach areas to ensure that all children have their exposure status ascertained.	
HIV testing for infants	Follow the infant testing algorithm in Figure 7 to test and interpret the test results: • Provide 1st PCR within 4-6 weeks or the earliest opportunity thereafter. • Provide 2nd PCR at 9months thereafter • Provide 3rdPCR 6 weeks after cessation of breastfeeding • Do DBS for confirmatory DNA PCR for all infants who test positive on the day they start ART • Do a DNA PCR test for all HEI who develop signs/symptoms suggestive of HIV during follow-up, irrespective of breastfeeding status. • Conduct rapid HIV test at 18 months for all infants who test negative at 1st, 2nd and 3rdPCR Refer to Figure 7	For POC Testing Provide 1st PCR within 4-6 weeks or the earliest opportunity
Routine immunization	• HIV-infected children are more susceptible to diseases preventable by immunization than their HIV-uninfected counterparts. • HIV-infected infants and children can safely receive most childhood vaccines if given at the right time. All HIV-infected and exposed children should be immunized as per EPI immunization schedule. • Health workers should review child immunization status at every visit • Some special considerations/modifications for HIV-exposed children: o BCG: When considering BCG vaccination at a later age (re-vaccination for no scar or missed earlier vaccination), exclude *symptomatic* HIV infection. Children with symptomatic HIV infection should not receive BCG.	

Service	Description
	○ Measles: Although the measles vaccine is a live vaccine, it should be given at six and nine months even when the child has symptoms of HIV. The measles illness from the vaccine is milder than that from the wild measles virus, which is more severe and likely to cause death. ○ Yellow Fever: Do not give yellow fever vaccine to symptomatic HIV-infected children; asymptomatic children in endemic areas should receive the vaccine at nine months of age.
Growth monitoring and nutritional assessment	Growth and child nutrition should be monitored using weight, length/height, and MUAC at all encounters with a child, and recorded on the growth monitoring card (see Annex 11). • MUAC should only be measured starting at six months of age. ○ Failure to gain weight or height, slow weight or height gain, and loss of weight may be an indication of HIV infection in an infant/young child. Failure to thrive affects as many as 50% of HIV-infected infants and children. HIV-infected infants and children who are failing to thrive have a significantly increased risk of mortality. • Counsel the mother/caregiver on the child's growth trend and take appropriate action where necessary.
Development monitoring	At each visit assess the infant's age-specific developmental milestones. The age-specific milestones are summarized in Annex 2. • Infants are at high risk for HIV encephalopathy and severe neurologic disease • Early identification of developmental delay can facilitate intervention and these children can improve with treatment. • Some forms of development delay are: ○ The child may reach some developmental milestones but not others. ○ The child may reach some milestones but lose them after some time. ○ The child may fail to reach any developmental milestones at all. • Test children with developmental delay for HIV and, if infected, initiate on ART. • Measure the infant's head circumference.
Early Childhood Development	• The first two years of life are the most critical for brain development and influences during this period significantly contribute to longer-term developmental outcomes. • ECD therefore comprises all the essential care and support a young child needs to survive and thrive in life and spans the period from prenatal to eight years of age across multiple domains consisting of physical, cognitive, language and communication, social and emotional and spiritual development. Years 0-8 most critical stage of life because the brain undergoes most dramatic growth • It is well established that infants and young children exposed or affected by HIV have poorer health and developmental outcomes compared to their non-HIV affected peers. Prevention of mother-to-child transmission (PMTCT) services, which focus on mothers and infants throughout the exposure period provide an ideal platform during a period of life that affects both longer-term health and developmental potential, moreover, the services along the PMTCT cascade are well aligned with intervention points for ECD. • ECD services and messages will therefore be well integrated into PMTCT/HEI services to improve outcomes of HEI.
ARV prophylaxis	• Provide NVP syrup to HEI from birth until six weeks of age. • For high-risk infants, give NVP syrup from birth until 12 weeks of age.

Service	Description

	• High-riskinfants are breastfeeding infants whose mothers:
	  ○ Have received ART for four weeks or less before delivery; or
	  ○ Have VL >1000 copies in four weeks before delivery; or
	  ○ Diagnosed with HIV during 3rd trimester or breastfeeding period (postnatal).

	What to do if baby presents after 6 weeks: a. Do first PCR b. Give ART (ABC/3TC/LPV/r bd; give weight appropriate dose) for 6weeks c. If PCR results are negative, give NVP for 6 weeks (after completing the 6 weeks of ABC/3TC/LPV/r) d. If PCR results are positive, continue with ABC/3TC/LPV/r as first line ART. Irrespective of timing, the mother should be started on ART as soon as possible for her own health and to decrease risk of transmission to breastfeeding baby.
Opportunistic infection prophylaxis	Cotrimoxazole prophylaxis Cotrimoxazole (CTX) prophylaxis significantly reduces the incidence and severity of *Pneumocystis Jiroveci* pneumonia. It also offers protection against common bacterial infections, Toxoplasmosis and Malaria. • Provide CTX prophylaxis to all HIV-exposed infants from six weeks of age until they are proven to be uninfected. • Infants who become HIV-infected should continue to receive CTX prophylaxis for life. • If CTX is contraindicated, offer Dapsone at dose of 2mg/kg once daily (up to 100mg). TB Preventive Treatment (TPT) • Give INH for six months to HEI who are exposed to TB after excluding TB disease. • For newborn infants, if the mother has TB disease and has been on anti-TB drugs for at least two weeks before delivery, INH prophylaxis should not be given. Malaria prevention: • All HEI and HIV-infected children should receive insecticide treated nets and CTX. Using both reduces risk of malaria by 97%.
Actively look for and treat infections early	HEI are susceptible to common infections and OIs. • Counsel caregivers to seek care to receive timely treatment. • At every visit, assess HEI for signs and symptoms of common childhood illnesses using the *Integrated Maternal, New-born and Childhood Illnesses Guidelines* and provide treatment.
Counseling and feeding advice	Provide infant feeding counseling and advice according to guidance in Chapter 5.
Educate the caregiver and family	• HEI depend on their caregivers to receive care. • Provide information to the caregivers and family about the care plan including what to expect and how to provide care for the infant. • Caregivers should participate in making decisions and planning care for the child, including decisions about therapy and where the child should receive care. • Empower caregivers to be partners with the health facility.

Service	Description

	• Provide key aspects of home-based care for the child, including:
	  ○ Dispensing prophylaxis and treatment
	  ○ Maintaining adherence
	  ○ Complying with the follow-up schedule
	  ○ Ensuring good personal and food hygiene to prevent common infections
	  ○ Seeking prompt treatment for any infections or other health-related problem
	• The most important thing for the child is to have a healthy mother. Ensure the mother/infected caregiver is receiving their care. If the mother is sick, the infant will not receive care.
	• When members of the same family such as mother-baby pair are in care, their appointments should be on the same day.

Referrals and Linkage	• Link the caregiver and HEI to appropriate services like OVC care, psychosocial support including FSG and other community support groups.
ART for infected infants	Initiate ART in infants who become infected according to guidance in Section 8.5.5

4.9 EPI/PMTCT/EID INTEGRATION

DNA-PCR coverage still remains a challenge with only 64% of HIV exposed infants (HEI) receiving a 1st DNA PCR test; less than 55% of HEI receiving a virological test within 2 months of birth; and only 28% of these HEI receiving their final rapid test at 18 months of age (MoH PMTCT annual report 2014/15).

In contrast, the coverage of the Expanded Program on Immunizations (EPI) is over 97% for DPT 1 of the target population from the Annual Health sector report 2014/15 and whereas many women deliver outside health facilities, most infants will routinely attend immunization or YCC clinics. According to the 2016 Uganda Demographic health survey, Childhood immunization coverage was 94.9% at 6weeks (DPT1-HepB-Hib); 89.9% at 10 weeks (DPT2-HepB-Hib) and 78.6% at 14 weeks (DPT3-HepB-Hib).

Integrating EID with EPI services should be implemented to increase infant HIV testing; increase the number of infants identified early, improve enrollment in EID care and ultimately improve maternal retesting.

Table 20: Integration of EID into EPI services

At each immunization visit	• Proactively check need for re-testing at every immunization encounter.
	• Immunization card should have PMTCT section completed at discharge from delivery.
	• Screening for eligibility (for infant testing)
	  ▪ Screening for testing eligibility can take place at registration
	  ▪ Standardize screening process of infants for HIV-exposed status at 6-week immunizations
	  ▪ If mother's status is unknown (or >3 months have elapsed since last test), re-test the mother (per algorithm for testing breast feeding mothers)
	  ▪ If mother is unavailable for testing, do a rapid test on the infant < 4 months of age. If >4 months of age, DBS should be sent for PCR testing.

	▪ If DBS cannot be collected at the same time as outreach, strong referral/linkage must be ensured with follow-up by the peer/mentor mother or community-based volunteer. ▪ If an infant is deemed to require EID or the mother (or infant) needs re-testing, then mentor mother should escort mother-baby pair to designated testing area Schedule: • Week 6 immunization (Polio, Penta, Pneumovax): First PCR • Month 9 immunization (Measles): Second PCR • Final outcome: 18 months if no longer breastfeeding, or 6 weeks after cession of breastfeeding ▪ If < 18 months, PCR ▪ If ≥ 18 months, RDT. Date of last HIV test should be clearly noted on the immunization card. If mother is newly positive during breastfeeding, immediately flag as high risk and link to treatment and facility or community psychosocial supportive services. Data collection should include number of infants and mothers screened and number of newly identified mothers and HEIs

4.10 COMMUNITY eMTCT SERVICES

4.10.1 INTRODUCTION

Community eMTCT services should be provided through existing community structures and support networks for PLHIV. These structures and networks should be supported to provide unique services that meet the needs of pregnant and breastfeeding mothers and their infants. All eMTCT implementing sites should establish a network of community-based structures and systems within their catchment area to support the health facility to deliver a minimum package of community-based MTCT services.

4.10.2 MINIMUM PACKAGE OF COMMUNITY eMTCT SERVICES

The minimum package of community eMTCT services include:

- Community sensitization and mobilization for HIV prevention, reproductive health and eMTCT services
- Identification, counseling, and referral of pregnant/lactating mothers for comprehensive ANC services including screening for TB symptoms, skilled delivery, eMTCT services for mother and baby including EID, post-natal care, IYCF and FP.
- Identification of partners and children of pregnant and breastfeeding women in communities and ensuring that they know their HIV status, either through outreaches/home-based HTS or through referral
- Address social and behavioral factors that affect uptake of eMTCT services including stigma, disclosure, discrimination,GBV, etc.
- Adherence support.
- Follow-up, linkage, and tracking of mother-infant pairs through at least 18months postpartum and ensure infant's final survival and HIV status is known.
- Community ART and cotrimoxazole refills.

- Provision of psychosocial support through Family Support Groups or other community based PLHIV support groups, OVC programs, and household economic strengthening/income generating activities.
- Assess all eMTCT families for eligibility for OVC programs.
- Promote family care, treatment, and support, including treatment support for those who are not part of the family.
- Health education and advocacy for eMTCT services.

This package should be delivered using continuous quality improvement approaches and monitored using a well-defined monitoring and evaluation (M&E) structure.

4.10.3 ESTABLISHMENT OF COMMUNITY eMTCT SERVICES.

eMTCT sites should do the following in order to establish community eMTCT services:

1. Establish partnerships and networks with community-based organizations (CBOs), NGOs and networks of PLHIV for community service delivery. The networks and partnerships should be established by:
   - Conducting or updating community mapping of resources, identifying referral trigger factors, developing referral directories and supporting documentation of referral processes.
   - Connecting with the community development officers, CBOs, FBOs, NGOs and networks of PLHIV and other networks involved in community-based eMTCT and meeting to agree on acommon objective and agenda.
   - Establishing and strengthening comprehensive referral network systems and coordination of two-way referrals between community and health facilities. In addition, establish mechanisms for assessing performance of these systems.
   - Promoting integration of eMTCT and HIV into reproductive health, MCH, and other programs.
   - Identifying and collaborating with relevant sectors for community empowerment and economic strengthening activities to reduce gender inequalities as well as increase women's access to assets.
   - Promoting partner support by using different strategies to engage male partners.

2. Identify, train, and facilitate community health workers.
   - Identify, train, and facilitate community health workers, including peer educators, in the catchment area to implement the community eMTCT minimum package.

3. Establish coordination mechanism.
   - Each health facility should establish a mechanism for coordinating with the community structures. Communication channels between the partners should be open, and health facilities should organize regular meetings to assess performance.

Box 4: Key highlights in Elimination of Mother-to-child transmission of HIV (eMTCT) and improving Maternal, Newborn, Child and Adolescent Health (MNCAH)

- The eMTCT strategy comprises a package of four approaches: Primary prevention of HIV among females of reproductive age and their partners, prevention of unintended pregnancies among HIV infected women, prevention of HIV transmission from HIV infected women to their infants and provision of treatment, care, and support to women/ adolescent girls infected with HIV, their children and their families.
- eMTCT interventions should be integrated and offered simultaneously within the platform of MNCAH services.
- Provide Syphilis and Hepatitis B screening and treatment during ANC.
- Provide HIV prevention services to HIV-negative pregnant women in ANC and re-test in the third trimester, during labor, or shortly after delivery due to the high risk of acquiring HIV infection during pregnancy and every 3 months during breastfeeding.
- Initiate HIV positive pregnant or breastfeeding women in ANC/PNC onto ART on the same day as diagnosis and give adherence counseling for at least the first three months. The preferred 1st line ART regimen is TDF + 3TC + DTG.
- Pregnant and breastfeeding women who are on TLE or other regimens and have suppressed VL at ANC 1, should remain on the same regimens until 6-9 months postpartum when they should be transitioned to TLD if VL within past 6 months is suppressed.
- Integrate EID and EPI services to increase HIV testing of infants.
- Infant testing: Do 1st DNA PCR at 4-6 weeks after birth, 2nd DNA PCR at 9 months and 3rd DNA PCR 6 weeks after cessation of breastfeeding. Conduct HIV rapid test for all infants testing negative at 1st, 2nd and 3rd DNA PCR at 18 months.
- Conduct HIV rapid test 3 months after cessation of breastfeeding for HIV exposed infants still breastfeeding ≥ 18 months.
- All HIV infected infants should be immediately started on ART.
- At birth, give low-risk HIV exposed infants NVP prophylaxis for 6 weeks and high-risk HIV exposed infants NVP prophylaxis for 12 weeks. If HIV exposed infants presents after 6 weeks, give ABC+3TC+LPV/r for 6 weeks followed by NVP for 6 weeks if the fist PCR result is negative.
- Establish adolescent friendly RH/PMTCT services including peer led groups for psychosocial support and adolescent ANC/PNC days at MCH clinics and MBCP.

5 MATERNAL, INFANT AND YOUNG CHILD FEEDING GUIDELINES

5.1 INTRODUCTION

Infant feeding in the context of HIV has implications for child survival. Balancing the risk of infants acquiring HIV through breast milk with the higher risk of death from malnutrition, diarrhea, and pneumonia among non-breastfed infants is a challenge. Protecting the infant from the risk of death from these causes is as important as avoiding HIV transmission through breastfeeding. Current evidence indicates that exclusive breastfeeding and the use of antiretroviral drugs greatly reduce MTCT. The effectiveness of ARV interventions with continued breastfeeding by HIV-infected mothers until the infant is 12 months of age capitalizes on the maximum benefit of breastfeeding to improve the infant's chances of survival while reducing the risk of HIV transmission.

The objectives of maternal, infant and young child feeding guidelines are to:

1. Promote optimal feeding for the HIV-exposed children to ensure HIV-free survival:
2. Minimize HIV transmission through breastfeeding; and
3. Ensure a healthy mother.

This section gives guidance for optimal maternal and infant feeding counseling throughout the eMTCT service cascade.

5.2 SERVICES OFFERED DURING PREGNANCY

Nutrition counseling messages and services for HIV-infected pregnant women are in Table 21.

Table 21: Nutrition Counseling Messages for Pregnant Women

Nutrition Information	
Diet	• During pregnancy and breastfeeding: add extra meals; drink adequate fluids; eat plenty of fruits and vegetables; eat foods rich in vitamin C to enhance iron absorption; avoid tea or coffee within one hour or with meals as this may interfere with absorption of iron; and use iodized salt to prevent pregnancy complications (abortions, miscarriages, stillbirths, fetal growth retardation, and maternal goiter). • Maintain high levels of personal and food hygiene and food safety to prevent infections. • Advise adolescent mothers to take extra care to get adequate food and rest since they are still growing. • Avoid alcohol, narcotics or tobacco products, and medicines not prescribed by a trained health care provider.
Medications during pregnancy	Vitamins are important in pregnancy: include supplemental iron to prevent anemia and reduce the risk of low birth weight; folic acid to prevent fetal brain and spinal cord congenital disabilities; de-worming tablets to eliminate worms and prevent anemia. Provide 60mg of elemental iron (200mg of ferrous sulphate) and 400ug folic acid OR combined iron (150mg with 0.5mg folic acid) after three months of gestation and continue to take them daily for six months. Take supplements with food to overcome side effects.

Nutrition Information	
	Give iron 120mg + 4000ug folic acid daily for three months to pregnant women with mild to moderate anemia. After completing this treatment, continue with routine supplementation for three months.

Initiatives to promote active Breastfeeding

The following activities should be done to promote breastfeeding:

- Counsel pregnant women on the benefits of breastfeeding, the importance of adhering to ART regimen, and the risk of MTCT.
- Counsel on the benefits of exclusive breastfeeding for the first six months regardless of the HIV serological status.
- Link mothers to support systems such as mother support groups on discharge from the hospital or clinic.
- Demonstrate to mothers how to position infants when breastfeeding, and how to maintain lactation should they be separated from their infants. Pay attention to prevention of conditions such as cracked nipples or mastitis that increase the risk of HIV transmission.

5.3 SERVICES OFFERED DURING LABOUR AND DELIVERY

- Help mothers initiate breastfeeding within half an hour after delivery including in cases of caesarean section.
- Newborn infants should be fed only colostrum (the first milk) and SHOULD NOT be given pre-lacteal feeds such as glucose, dill/gripe water, mushroom soup, herbal extracts, etc.
- Continue to counsel on demand feeding, exclusive breastfeeding, and ways of holding and putting the baby to the breast (positioning and attachment) to enhance breastfeeding.
- Mothers should continue supplementation with iron one tablet/day and folic acid one tablet/day for three months after delivery in addition to intake of iron rich foods.

5.4 SERVICES OFFERED DURING THE POSTNATAL PERIOD

5.4.1 FEEDING A CHILD 0–6 MONTHS

HIV-Exposed Infants OR Unknown HIV status OR HIV-infected infants	• HIV-infected mothers should exclusively breastfeed (EBF) their Exposed infants or HIV-infected infants for the first six months of life. • Mothers should introduce nutritionally adequate and safe foods (appropriate complementary foods) at 6 months of life. • The mother should be encouraged to breastfeed as often as the infant wants (on demand). • Mothers should be supported to fully adhere to ART • Establish the HIV exposure status of those infants with unknown status.

5.4.2 Heat-treated expressed breast milk

HIV positive mothers known to be living with HIV may consider expressing and heat-treating breast milk as an interim feeding strategy in order to maintain exclusive breastfeeding under special circumstances considered to be high risk for HIV transmission:

- When maternal VL is not suppressed.

- The infant has low birth weight or is otherwise ill in the neonatal period and unable to breastfeed.
- The mother is unwell and temporarily unable to breastfeed or has a temporary breast health problem such as mastitis
- If ARV drugs are temporarily not available.

For the procedures of heat treatment, refer to the IYCF Guidelines

5.5 COMPLEMENTARY FEEDING

5.5.1 FEEDING A CHILD 6–12 MONTHS

- After six months of age, appropriate complementary foods should be introduced while continuing to breastfeed until **12 months.**
- Counseling messages on complementary feeding are summarized below:

F = Frequency	Feed the baby 3–5 times a day. Increase the frequency as the baby grows.
A = Amount	Start with 2–3 heaped tablespoons per feed. Gradually increase the amount of food to at least one-third (1/3) of a NICE cup. (A full NICE cup is 500 ml).
T = Thickness (consistency)	Mothers should mash and soften the food for easy swallowing and digestion. Use animal milk or margarine/ghee/oil (not water) to soften and enrich the food.
V = Variety	Encourage mothers to include at least one type of food from the three main food groups: Carbohydrates/fats/oils (Energy-giving foods), plant/animal protein (bodybuilding), and vegetables &fruits (protecting foods).
A = Active/ responsive feeding	Mothers should be encouraged to feed their infants and young children patiently and actively and to use a separate plate for the infant to ensure adequate intake.
H = Hygiene	Counsel mothers on hygienic food preparation and handling to avoid food contamination leading to diarrhea and illness. Encourage the use of clean, open cups. Discourage use of feeding bottles, teats, or spouted cups as they are very difficult to clean.

5.5.2 FEEDING A CHILD 12–24 MONTHS

HIV-exposed	Encourage mothers to discontinue breastfeeding at **12 months for infants who are HIV-negative at 12 months.** At least 500 ml (1 NICE cup) a day of alternative forms of milk (cow's milk, goat's milk, soya) should be given. Encourage mothers to feed their children five times a day: three main meals and two extra foods between meals (snacks).
HIV-infected	Encourage mothers to continue breastfeeding on demand, day and night up to **24 months** to maintain the baby's health and nutrition. Give one extra snack to children who are well; one extra meal (or 2 snacks) at onset of sickness; and three extra meals (or 2 extra meals and one snack) when sick and losing weight.

5.5.3 FEEDING A CHILD 2–6YEARS

- Encourage mothers to give a variety of foods prepared from the family meal (each meal should consist of a carbohydrate, protein, vegetables & fruits) at least three times a day.
- Encourage caregivers to give nutritious snacks between meals e.g. fruit (banana, pawpaw, orange, and mango), egg, bread, enriched thick porridge or a glass of milk.

Sick and recuperating infants and children should be fed on small, frequent meals which include porridge enriched with milk/groundnut paste/margarine/honey/or oil; cooked, skinned, or mashed beans; thickened soups; etc.

5.6 ADDITIONAL SUPPORT MESSAGES

- HIV-positive mothers who decide to stop breastfeeding at any time should stop gradually. This transition period should be between one to two weeks which is not too long to increase exposure and not too short to cause physical and psychological trauma to the mother and baby.
- The mechanisms of transition include:
  - Expressing breast milk and feeding infant/child by cup; and
  - Substituting the expressed breast milk with suitable replacement feed gradually.
- Replacement feeding (using alternative milk other than breast milk in the first six months of life) should be recommended only in extreme circumstances (e.g. mother is absent, dead or mentally challenged) in accordance with the regulations on the marketing of infant and young child foods.
- Follow-up all HIV-exposed infants and continue to offer infant feeding counseling and support to mothers/caregivers.
- If an HIV-exposed child falls sick, counsel the mother/caregiver to feed the child even more frequently than usual to meet that child's nutritional requirements.

Box 5: Key highlights in Maternal, Infant and Young Child Feeding guidelines

- ❖ Provide nutrition counseling and micronutrient supplementation for optimal maternal nutrient intake during pregnancy.
- ❖ Breastfeeding should be initiated within half an hour after delivery including in cases of caesarean section.
- ❖ Newborn infants should be fed only colostrum (the first milk) and SHOULD NOT be given pre-lacteal feeds such as glucose, dill/gripe water, mushroom soup, herbal extracts, etc.
- ❖ HEI should be exclusively breastfed for 6 months.
- ❖ After six months, appropriate complementary foods should be introduced while continuing to breastfeed until:
  - 12 months in HIV exposed infants.
  - 24 months in HIV infected infants.
- ❖ Cessation of breastfeeding should be a gradual process over 1-2 weeks.
- ❖ Increase number and quality of feeds incase the HEI falls ill.

6 CARE AND SUPPORT FOR PEOPLE LIVING WITH HIV

6.1 INTRODUCTION

The AIDS Control Program has developed a minimum healthcare services package for PLHIV to standardize the programming, implementation and delivery of integrated HIV services in Uganda. The details of this minimum healthcare services package can be found in *Integrated Health Care Services Package for HIV Prevention, Treatment and Care Services for Uganda*.

6.2 MINIMUM SERVICE PACKAGE FOR PEOPLE LIVING WITH HIV

The minimum care package should be offered to all people living with HIV upon enrollment and during their entire time in HIV care. The package should be tailored to their individual needs. The package is summarized in Table 22.

Table 22: Summary of Minimum Care Package for PLHIV

Service Area	Service Description
Clinical evaluation and monitoring of HIV disease	Provide clinical evaluation and monitoring to all PLHIV to ascertain the WHO clinical stage of disease and exclude comorbidities.
Antiretroviral therapy	Initiate at the earliest opportunity in all people with confirmed HIV infection; regardless of clinical stage or CD4 cell count (see Chapter 8).
Nutrition services	Conduct nutrition assessment, counseling and support (NACS) (see Section 6.13.2).
Opportunistic infection screening, prevention, and management	• Provide Cotrimoxazole prophylaxis if eligible. • Provide INH prophylaxis if eligible (see Section 6.7.4.1) • Screen and manage other OIs like TB and Cryptoccoccal infection (see Section 6.5)
Screening and treatment of co-morbidities	Screen and manage NCDs including: • Hypertension • Diabetes • Dyslipidemias • Mental health (especially depression) See Section 6.15 for detailed guidance on screening and managing NCDs.
Sexual and reproductive health services	• Screen and manage sexually transmitted infections • Provide family planning/contraceptive and pre-conception services (see Section 4.4.2) • Ensure resources for early identification of pregnant mothers and linking them to ANC • Promote facility delivery and postnatal care (see Chapter 4) • Provide cervical and breast cancer screening (see Section 6.14.2)
Adherence counseling	Do adherence preparation, monitoring and support (see Section 7.5)
Psychosocial support and palliative care	• Assess family and community support to the client • Assess for stigma and discrimination • Link client to a psychosocial support group • Assess for any social challenges the client might have • Refer for palliative care when required.

Service Area	Service Description
Orphans and vulnerable children (OVC)	• Conduct basic assessment for vulnerability • Provide HIV testing for family members either at facility or community level as appropriate • Refer and link to a CBO/CDO • Conduct nutrition assessment, counseling and support • Initiate ART for HIV-positive children and their caretakers • For details of OVC care, refer to the *SPPI, Ministry of Labor, Gender, and Social Development*
Positive health, dignity and prevention	• Support client to disclose HIV status to family and significant others • Provide active partner and family tracing for HIV testing • Educate, provide and promote correct and consistent use of condoms • Provide family planning counseling and services with consent of the patient • Provide STI screening, prevention and treatment services • Provide routine adherence counseling to patients on ART • Provide gender-based violence screening and support
Other prevention services	• Provide immunizations according to the national immunizations schedule • Educate and promote use of long-lasting insecticide-treated mosquito nets (LLINs) • Educate and promote use of safe water, sanitation and hygiene practices

6.3 WHO CLINICAL STAGING

Clinical staging should be performed at HIV diagnosis, on entry into HIV care, at ART initiation and at every visit thereafter to help guide patient care and monitor disease progress. HIV-related diseases are grouped into four WHO clinical stages that correlate with disease progression and prognosis of survival:

- Stage 1: asymptomatic
- Stage 2: mild
- Stage 3: advanced
- Stage 4: severe

See Annex 3 and Annex 4 for staging in adults and adolescents, and in children respectively.

6.4 PREVENTION, SCREENING AND MANAGEMENT OF CO-INFECTIONS AND NON-COMMUNICABLE DISEASES

This section will provide guidance on how to prevent, screen and manage co-infections and non-communicable diseases (NCDs). In particular, this section will provide guidance on Tuberculosis (TB), Cryptoccoccal Meningitis, Pneumocystis Jiroveci Pneumonia (PJP), Hepatitis B and C virus infections, and STIs as well as cervical cancer, diabetes, hypertension, depression. Management of other co-infections including oral Candidiasis, oesophageal Candidiasis, Toxoplasmosis and chronic diarrhea can be found in "*The Uganda Clinical Guidelines 2016*."

6.5. MANAGEMENT OF ADVANCED HIV DISEASE

6.5.1 Introduction

Definition of Advanced HIV Disease:

For adults, adolescents, and children five years or older, Advanced HIV Disease (AHD) is defined as CD4 cell count <200cells/mm3 or with a current WHO stage 3 or 4 event. All

children younger than five years of age with HIV regardless of CD4 cell count are considered as having advanced HIV disease due to high viremia and rapid disease progression with high mortality.

Background:
Approximately, 30% and 15% of newly identified PLHIV present to care with CD4 cell counts less than 200cells/mm3 and 100cells/mm3 respectively. Furthermore, a proportion of PLHIV in care experience treatment failure to ART regimens and approximately 25% of PLHIV are returning to care with advanced HIV disease after treatment interruption. PLHIV with advanced disease are particularly at high risk of death, even after initiating ART, with this risk increasing with decreasing CD4 cell count. The most common causes of death among adults with advanced disease include TB, Cryptoccoccal Meningitis (CM) and severe bacterial infections. All efforts should be made to identify these conditions early to avert mortalities. Despite the shift to 'test and treat' for ART, a baseline CD4 cell count remains an important parameter and should be done in all ART-naïve individuals in the HIV care program to guide identification of Advanced HIV Disease.

6.5.1.1 Identifying individuals with Advanced HIV Disease

- Identifying people with advanced HIV disease who are eligible for elements of the package of care requires performing a CD4 cell count for newly initiating patients, patients re-engaging in care after more than 90 days, patients who are not virologically suppressed and patients presenting with symptoms suggesting WHO Stage 3 or 4 disease.
- If a CD4 cell count is not readily available onsite, use a symptom screen that assesses for symptoms associated with opportunistic disease (refer to Figure 14 below), and send the CD4 sample to the hub for testing.
- Note that relying on WHO clinical staging alone risks missing substantial numbers of people living with HIV with severe immune suppression.

6.5.1.2 Components of the package of care for PLHIV with advanced disease

Table 23 below summarizes the recommended package of interventions for managing PLHIV with advanced disease. It includes interventions for screening, prophylaxis and treatment for opportunistic conditions, rapid ART initiation and enhanced adherence support. The package below should be offered to people with advanced disease who are new, re-engaging with care after 90 days of ART interruption, or to those with ART failure.

Table 23: Components of the Package of Care for PLHIV with Advanced HIV Disease

	Intervention	Eligibility criteria	Adults and adolescents (10-19)	Children (0-<10)
Diagnosis	Urine TB LAM	• CD4 ≤200 cells/mm3 or • Danger signs or • WHO Stage 3 or 4	Yes	Yes
	Sputum Xpert MTB/ RIF	• All presumptive TB cases regardless of CD4 count	Yes	Yes
	Cryptococcal antigen screening (CrAg)	• CD4 ≤200 cells/mm3 or • Danger signs or • WHO Stage 3 or 4	Yes	Screening not advised

	Nutritional assessment and support	• All regardless of CD4 count	Yes	Yes
Prophylaxis and Pre-emptive treatment	Cotrimoxazole prophylaxis	• Newly initiating PLHIV • WHO stage 3 or 4 event or other symptoms of AHD • Pregnant and breast-feeding women • Children (aged ≤15) • Patients suspected to have treatment failure	Yes	Yes
	TB preventive Therapy	• Negative TB Symptom Screen • Any CD4 count	Yes	Yes
	Fluconazole Pre-emptive treatment	• PLHIV with a Positive serum CrAg who have a negative CSF CrAg (on Lumbar Puncture)	Yes	Screening not advised
Rapid ART initiation	Rapid ART initiation	• Any CD4 and • Negative TB and CM Symptom Screen	Yes	Yes
	Defer ART initiation in presence of:	• Positive TB and CM Symptom Screen or • TB diagnosis or • Positive CrAg	Yes	Yes
Adherence support	Tailored counselling to ensure optimal adherence to the advanced disease package, including phone calls and home visits	• Any person with advanced HIV disease	Yes	Yes

6.5.1.2.1 Using TBLAM for TB diagnosis in advanced HIV disease.

The lateral flow urine lipoarabinomannan assay (Urine TB LAM) should be used as the preferred initial test for TB diagnosis, followed by Gene Xpert or microscopy in the following categories of patients:

- All newly diagnosed HIV positive adults and adolescents > 14 years: this is irrespective of signs and symptoms of TB, with advanced HIV disease or who are seriously ill regardless of CD4 cell count or if the CD4 cell count is unknown.
- All HIV positive adults and adolescents > 14 years returning into ART care with unsuppressed viral load (i.e. VL > 1000 copies/ml of blood) or seriously ill irrespective of signs and symptoms of TB and CD4 cell count or if the CD4 cell count is unknown.
- All HIV positive children (0 -14 years), including those with unsuppressed viral load and new HIV positive children with signs and symptoms of TB and with advanced HIV disease, or who are seriously ill irrespective of CD4 cell count or if the CD4 cell count is unknown.

Regardless of TB LAM results, a sputum sample should be collected and sent for Gene Xpert for simultaneous detection of M. tuberculosis and Rif-Resistance. All PLHIVs with a positive TB LAM should be classified as "Bacteriologically confirmed pulmonary TB patients-(P-BC)" and promptly started on TB treatment. Treatment monitoring for all TB LAM positive PLHIVs should be done by microscopy using a sputum sample. Follow up sputum smears should be done at the end of month 2 and beginning of 5 and 6 months of TB treatment.

6.5.1.3 Rapid ART Initiation

All patients should undergo the symptom screen for the Advanced Disease Pathway (see Figure 12 below). Patients presenting for the first time or those returning to care and not on ART should undergo the symptom screen for the Advanced Disease Pathway before rapid ART initiation is offered. Rapid ART initiation should be deferred when symptom screen is positive or there is a TB diagnosis, or the patient is CrAg positive. Note that CD4 testing is not a pre-condition for ART initiation.

6.5.1.4 Adherence support

People with advanced HIV disease require closer follow-up during the first 3 months to ensure adherence to treatment and review visits since they are likely to be ill, have a higher pill burden due to (treatment of comorbidities) and drop out of care. Follow up can be through clinic or home visits, telephone consultation, and text messaging.

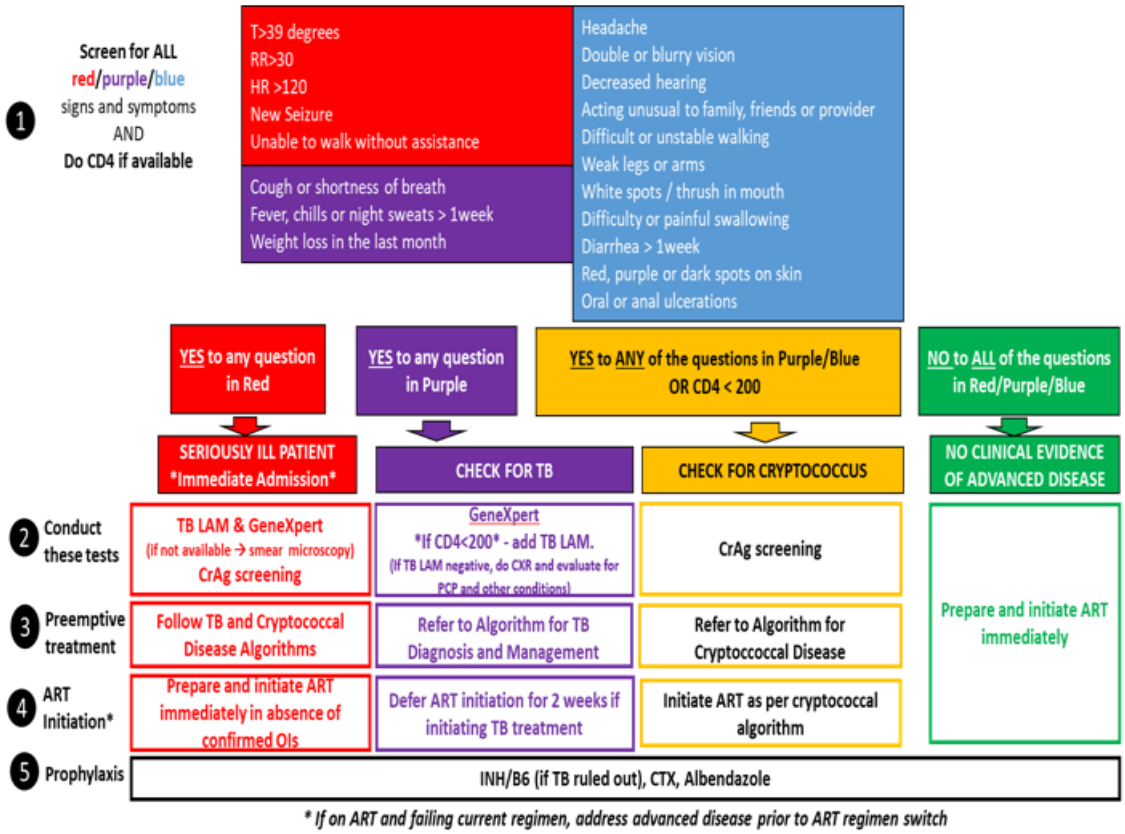
6.5.1.5 People interrupting treatment (more than 90 days)

Those who interrupted treatment for more than 90 days and have a negative symptom screen and CD4 >200 should be restarted on their old regimen, receive three intensive adherence counselling sessions with documented good adherence (one month apart) and a viral load test after 3 months of restarting therapy. Those with a CD4 <200 should be investigated for advanced HIV disease and a viral load test done immediately upon re-engaging in care.

6.5.1.6 People interrupting treatment (less than 90 days)

Those who interrupted treatment for less than 90 days and have a negative symptom screen should be restarted on their old regimen, receive adherence counselling and a viral load test as per original schedule of their follow-up. Refer to figure 12 for the management of patients with a positive symptom screen.

Figure 14: Symptom Screen and Advanced Disease Pathway



6.6 COTRIMOXAZOLE PREVENTIVE THERAPY (CPT)

Cotrimoxazole preventive therapy (CPT) can reduce the risk of malaria, diarrhea and pneumonia caused by bacterial infections; hospitalization; and mortality. However, the benefits of CPT reduce markedly in clients who are stable on ART. For this reason, only certain categories of PLHIV listed below should be maintained on CPT.

6.6.1 The following groups have been prioritized for CPT:

1. All PLHIV newly initiating on ART.
2. Having a current WHO stage 3 or 4 event or other symptoms of advanced disease.
3. Pregnant and breast-feeding women.
   Note: Additional intermittent preventive treatment for malaria using Sulfadoxine-Pyrimethamine (SP) is **not required** for pregnant women on CPT.
4. Children and adolescents aged 0-15 years.
5. Patients suspected to have treatment failure (refer to Table 61 for definition on treatment failure).

Table 24: Cotrimoxazole dosing

Weight	<5kg	5-14.9kg	15-29.9kg	≥30kg
Dose(once daily)	120mg	240mg	480mg	960mg

6.6.2 Co-trimoxazole toxicity

Adverse effects of Co-trimoxazole are rare but include skin rash, Stevens-Johnson syndrome, anaemia, neutropenia, jaundice and renal failure. In the event of skin reaction to Cotrimoxazole, see guidance on management in Table 25.

Table 25: Management of Cotrimoxazole hypersensitivity

Severity	Description	Management
Mild	Dry skin, erythema +/- fine papules or itching affecting <50% of body surface area	Continue CTX, monitor closely, consider symptomatic treatment with antihistamines +/- topical steroids (NOT oral steroids)
Moderate	Dry skin, erythema +/- fine papules, or itching affecting >50% of body surface area	Stop CTX, consider symptomatic treatment with antihistamines +/-topical steroids (NOT oral steroids), consider trial of desensitization after symptoms completely resolved
Severe	Mucosal involvement or blistering with associated fever affecting any % of body surface area (Steven-Johnsons syndrome)	Stop CTX, admit to hospital for supportive management (IV fluids, wound care, pain control, infection control, monitoring for superinfection), **patient should NEVER be re-challenged with CTX or other sulfa-containing drugs**

6.6.3 Guidance for when to stop CPT in stable PLHIV

To ensure that CPT is stopped without adversely affecting the health of PLHIV, health workers should carefully select PLHIV for CPT discontinuation. The five (5) conditions below should be fulfilled prior to CPT discontinuation:

1. Patient should be older than 15 years of age.
2. Patient should not be pregnant.
3. Patient should have been on ART for at least one year.
4. Patient's last VL should be suppressed.
5. Patient should not have a current WHO stage 3 or 4 event or other symptoms of advanced HIV disease at the time of stopping CPT.

6.6.4 Restarting CPT in PLHIV

CPT can be restarted in the following scenarios:

a. New pregnancy

In case CPT was stopped earlier (in stable women), re-start CPT and maintain it throughout pregnancy and in the immediate postpartum period (up to 6 weeks after delivery).

b. Suspected treatment failure

If VL becomes unsuppressed in a patient whose CPT was previously discontinued, re-start CPT and continue until the VL is suppressed once again.

c. New Treatment WHO stage 3 or 4 condition

In case CPT was discontinued earlier, it should be restarted when a patient develops an active WHO stage 3 or 4 infection and continued until the condition has been treated and resolved.

6.6.5 Contraindications to CPT

CPT should not be given to people with known allergy to sulphur-containing drugs or trimethoprim, severe anaemia,and/or severe neutropenia (<5000 cells/mm3).

6.6.5.1 Alternate drugs to use in case of hypersensitivity or contraindication to Cotrimoxazole

In patients with Cotrimoxazole hypersensitivity, Dapsone should be used. Dapsone provides protection against PJP. It does not have the other preventive benefits CPT provides. Therefore, pregnant women receiving Dapsone should also receive intermittent preventive therapy for Malaria with Sulphadoxine-pyrimethamine (Fansidar). In the rare event that patient who has hypersensitivity to Cotrimoxazole also reacts to Dapsone, Atovaquone can be given as an alternative.

Dapsone dosing

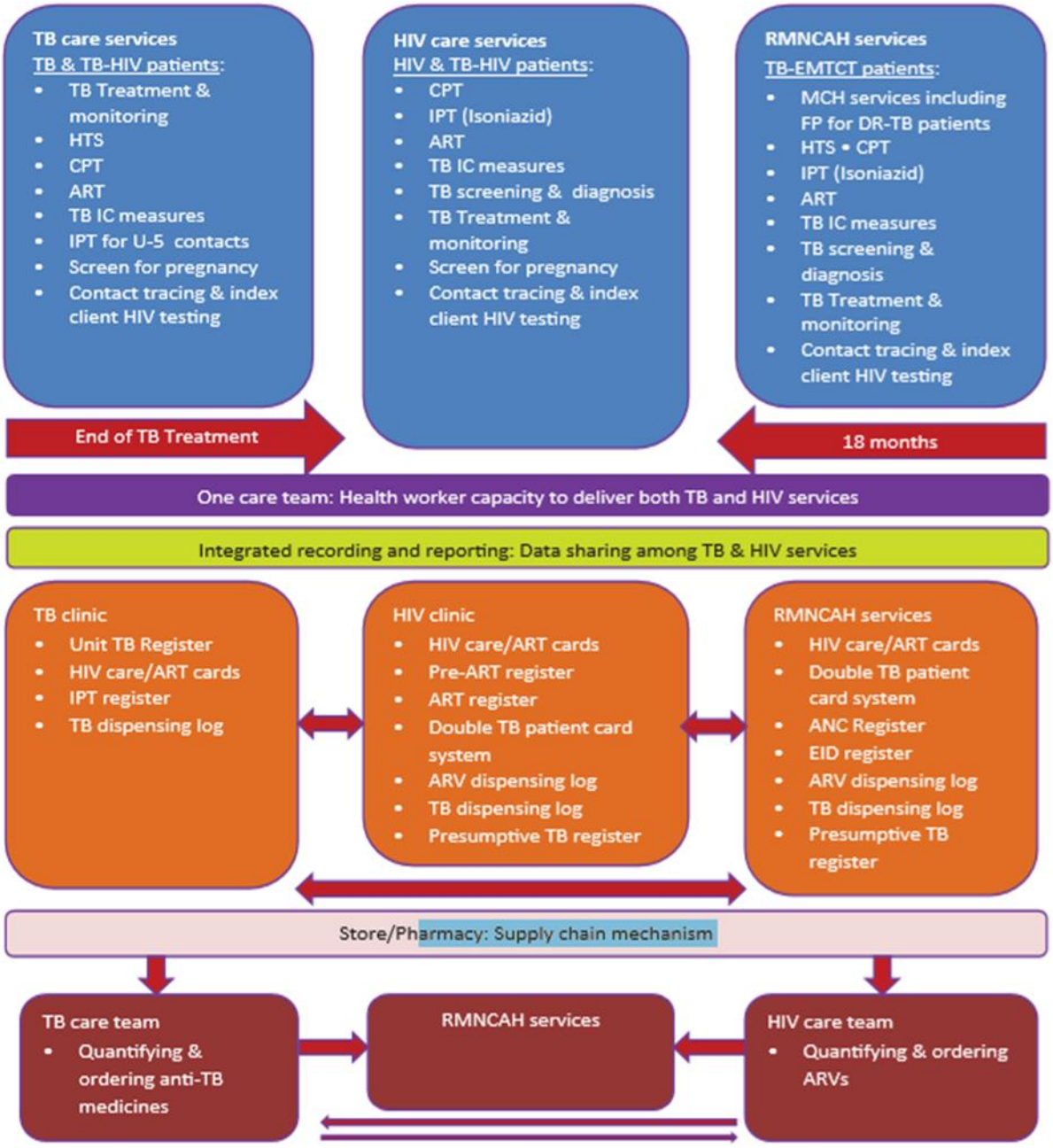
- Weight of ≥25Kg: 100mg once a day

6.7 TUBERCULOSIS (TB) SCREENING, TREATMENT AND PREVENTION

6.7.1 Introduction

HIV is the strongest risk factor for developing TB disease. PLHIV are 20–37 times more likely to develop TB than HIV-uninfected individuals. TB is also the leading cause of HIV-related hospitalization and mortality. TB accounts for 27% and 30% of deaths among hospitalized HIV-infected adults and children, respectively. Also, patients with TB and HIV have poorer treatment outcomes (such as death) compared to patients with TB alone. In Uganda, about 40% of all TB cases in clinical settings are co-infected with HIV. Therefore, all patients with presumptive or diagnosed TB should be routinely screened for HIV and all PLHIV should be routinely screened for TB. The Ministry of Health further recommends that TB/HIV services should be provided at the same location and preferably by the same health worker (see Figure 15).

Figure 15: One stop shop model for TBHIV service delivery



6.7.2 TB SCREENING IN INFANTS, CHILDREN, ADOLESCENTS AND ADULTS

TB screening should be conducted at each clinic visit using the intensified case finding (ICF) guide (see Annex 5). All HIV-positive infants and children who have any of the symptoms of TB, including cough of any duration, persistent fevers, poor weight gain and history of TB contact should be assessed for TB. All HIV-positive adolescents and adults who have any of the symptoms of TB including cough of any duration, persistent fevers, weight loss, or excessive night sweats should be assessed for TB. Where possible, chest X-ray can be used for screening.

6.7.2.1 TB diagnosis in HIV-infected infants, children, adolescents and adults

The Xpert MTB/RIF (GeneXpert) test is the recommended initial TB diagnostic test for all PLHIV (Annex 6 and Annex 7) with presumptive TB. For PLHIV with CD4<200 cells/ μL and seriously ill PLHIV (have danger signs), do a lateral flow urine lipoarabinomannan assay (Urine TB LAM) test because it has a shorter turnaround time followed by Gene Xpert which is more sensitive and can detect rifampicin resistance. If either test is positive, classify patient as PBC (Pulmonary Bacteriologically Confirmed) and start anti-TB treatment. In health facilities without on-site access to Xpert MTB/RIF, smear microscopy (Ziehl-Nielsen/Fluorescent microscopy) TB test should be performed and a second sample referred for GeneXpert testing using the hub transport system. If the Xpert MTB/RIF is positive and indicates rifampicin resistance, refer the patient to an MDR-TB treatment site.

In addition to the Xpert MTB/RIF test, chest radiography is another useful investigation for aiding diagnosis of TB especially among infants and children.

6.7.3 TB TREATMENT

The recommended TB treatment regimens for TB-HIV co-infected patients are similar to those used for HIV-negative individuals with TB (Table 26).

Table 26:Anti-TB treatment regimens for infants, children, adolescents, and adults

Population group	Site of TB disease	Regimen	
		Intensive phase	Continuation phase
Adults and Adolescents	All forms of TB (excluding TB Meningitis and bone TB)	2RHZE	4RH
	TB Meningitis Bone (osteoarticular) TB	2RHZE	10RH
Children	All forms of TB (excluding TB Meningitis and bone TB)	2RHZ+E*	4RH
	TB Meningitis Bone (osteoarticular) TB	2RHZ+E*	10RH
For all PLHIV patients: 1. Xpert MTB +ve/Rif sensitive: Treat as a new patient. 2. Xpert MTB +ve/Rif resistant: Refer to MDR-TB treatment site for further management. 3. Xpert MTB +ve/Rif indeterminate: Start First line TB treatment and send sample for culture and drug susceptibility testing. 4. Xpert MTB Trace/Rif indeterminate: Start First line TB treatment and send sample for culture and drug susceptibility testing. *In children, Ethambutol should be given as separate tablet using the recommended dosages			

Table 27:Dosage of Anti TB medicines by weight band for children

Weight Bands	Intensive Phase		Continuation Phase
	RHZ(75/50/150)	E (100)	RH(75/50)
4-7kg*	1	1	1
8-11kg	2	2	2
12-15kg	3	3	3
16-24 kg	4	4	4
25 - 32 kg	4	4	4

** If a child is < 4kgs, determine the appropriate dose based on patient's weight using table 28 below*

Table 28: Dosage of Anti TB medicines by weight band for adults

Weight bands	Intensive Phase	Continuation Phase
	RHZE (150+75+400+275) mg	**RH (150+75) mg**
33 – 39 kg	2 tablets	2 tablets
40 – 54 kg	3 tablets	3 tablets
55 – 70 kg	4 tablets	4 tablets
>70 kg	5 tablets	5 tablets

If an adult is < 33kgs, determine the appropriate dose based on patient's weight using table 29 below

Table 29: Dosage of Anti TB medicines by weight for children and adults

TB drug	Children	Adults
Rifampicin	15 (10 – 20) mg/kg body wt. (max. 600mg)	10mg/kg body wt. (max.600mg)
Isoniazid	10 (7 – 15) mg/kg body wt. (max. 300mg)	10 mg/kg body wt. (max.300mg)
Pyrazinamide	35 (30 – 40) mg/kg body wt.	30 – 40 mg/kg body wt. (max dose 2500 mg)
Ethambutol	20 (15 – 25) mg/kg body wt.	15mg/kg body wt.

6.7.3.1 ART for TB/HIV co-infected patients

ART should be initiated in all TB/HIV co-infected people irrespective of their clinical stage or CD4 count. However, the timing of initiating treatment may differ based on whether the patient is diagnosed with TB before or after initiating ART.

6.7.3.2 Management of ART in TB/HIV co-infection

1. If the patient is already on ART, start TB treatment immediately and adjust the ART regimen as recommended below (Table 31).
2. If the patient is not on ART, initiate anti-TB treatment immediately and start ART two weeks after initiation of TB treatment.
    - For adults with CD4 count less than 50 cells/mm^3, ART should be initiated **BEFORE** completing two weeks of anti-TB treatment.

6.7.3.3 First-line ART regimen for TB/HIV co-infected patients diagnosed with TB but not on ART

There are situations when a new patient is diagnosed with both HIV and TB. The recommended first line regimen for a TB patient initiating ART are as indicated in Table 30.

Table 30: ART regimens for TB/HIV co-infected patients initiating First- and Second -line ART

Patient category	Recommended ART regimens	Alternative ART regimens
FIRST LINE		
Adults and adolescents ≥30Kg, including pregnant and breastfeeding women	TDF+3TC+DTG ***Increase dose of DTG to twice a day***	If TDF is contraindicated, use ABC:
		ABC+3TC+DTG ***Increase dose of DTG to twice a day***
		If DTG is contraindicated, use EFV:
		TDF or ABC→ +3TC+ EFV400 ***No dose adjustments***
		If DTG and EFV are contraindicated, use ATV/r:
		TDF or ABC → +3TC+ATV/r ***Substitute Rifampicin with Rifabutin***
Children ≥ 20Kg - <30Kg	ABC+3TC+DTG ***Increase dose of DTG to twice a day***	If ABC is contraindicated, use AZT or TAF:
		AZT or TAF→ +3TC+DTG ***Increase dose of DTG to twice a day***
		If DTG is contraindicated, use LPV/r or EFV:
		ABC or AZT or TAF→+3TC+LPV/r • ***Substitute Rifampicin with Rifabutin*** ***OR*** • ***Double both the morning and evening doses of LPV/r***
		ABC or AZT or TAF→+3TC+EFV ***In children >3 years - Substitute EFV with DTG or LPV/r after TB treatment***
Children< 20Kg	ABC+3TC+DTG ***Increase dose of DTG to twice a day***	If ABC is contraindicated, use AZT:
		AZT+3TC+DTG ***Increase dose of DTG to twice a day***
		If DTG is contraindicated use LPV/r or EFV or RAL or Triple NRTI:
		ABC or AZT→ +3TC+LPV/r • ***Substitute Rifampicin with Rifabutin*** ***OR*** • ***Double both the morning and evening doses of LPV/r***
		ABC or AZT→+3TC+EFV ***In children >3 years or weighing >10Kg- Substitute EFV with DTG or LPV/r after TB treatment***
		ABC or AZT → +3TC + RAL ***Double the dose of RAL -substitute RAL with DTG or LPV/r after TB Treatment***
		ABC+3TC+AZT ***In children <3 years or weighing <10Kg- Substitute AZT with DTG or LPV/r after TB treatment***

Patient category	Recommended ART regimens	Alternative ART regimens
SECOND LINE		
Adults and adolescents ≥30Kg, including pregnant and breastfeeding women	AZT or TDF→ +3TC+DTG ***Increase dose of DTG to twice a day***	AZT or TDF→ +3TC+LPV/r • ***Substitute Rifampicin with Rifabutin*** ***OR*** • ***Double both the morning and evening doses of LPV/r***
	AZT or TDF→ +3TC+ATV/r ***Substitute Rifampicin with Rifabutin***	
Children ≥ 20Kg – <30Kg	TAF or AZT or ABC→ +3TC+DTG ***Increase dose of DTG to twice a day***	TAF or AZT or ABC→ +3TC+LPV/r • ***Substitute Rifampicin with Rifabutin*** ***OR*** • ***Double both the morning and evening doses of LPV/r***
		TAF or AZT or ABC → +3TC + RAL ***Double the dose of RAL (substitute RAL with DTG or LPV/r after TB Treatment)***
	TAF or AZT or ABC→ +3TC+LPV/r • ***Substitute Rifampicin with Rifabutin*** ***OR*** • ***Double the am and pm dose of LPV/r***	TAF or AZT or ABC→ +3TC+DRV/r ***Substitute Rifampicin with Rifabutin***
		TAF or AZT or ABC → +3TC + RAL ***Double the dose of RAL (substitute RAL with DTG or LPV/r after TB Treatment)***
Children <20Kg	AZT or ABC→ +3TC+DTG ***Increase dose of DTG to twice a day***	AZT or ABC → +3TC+LPV/r • ***Substitute Rifampicin with Rifabutin*** ***OR*** • ***Double both the morning and evening doses of LPV/r***
		TAF or AZT or ABC → +3TC + RAL ***Double the dose of RAL (substitute RAL with DTG or LPV/r after TB Treatment)***
	AZT or ABC → +3TC+LPV/r • ***Substitute Rifampicin with Rifabutin*** ***OR*** • ***Double the am and pm dose of LPV/r***	AZT or ABC → +3TC+DRV/r ***Substitute Rifampicin with Rifabutin***
		TAF or AZT or ABC → +3TC + RAL ***Double the dose of RAL (substitute RAL with DTG or LPV/r after TB Treatment)***

6.7.3.4 Initiating ART in patients on TB treatment

Patients should be initiated on ART following the ART guidelines for initiating 1st and 2nd line ART (See Table 56), however considerations must be taken to avoid drug-drug interactions that interfere with effectiveness of ART (see Table 30 above and Table 64).

Note:

- The use of Rifampicin with PIs is contraindicated. These guidelines recommend substitution of Rifampicin with Rifabutin when using PIs. However, in the absence of Rifabutin:
    - LPV/r can be given at double the usual dose (give double the dose in the morning and double the dose in the evening).
    - Doubling the dose of ATV/r or DRV/r is NOT recommended. ATV/r and DRV/r should only be used with a TB regimen containing Rifabutin. In the scenario where Rifabutin is unavailable, an alternative ARV should be selected.
    - For patients initiating 2nd line ART, it is important to take into consideration the previous failing regimen to ensure selection of an effective regimen for use in 2nd line ART-TB co-treatment.
    - Raltegravir (given as a double dose) is recommended in TB-HIV co-treatment for children who cannot tolerate double dosing of LPV/r or for whom Rifabutin is unavailable for treatment with DRV/r.

- Children <20Kg on TB treatment should only be initiated on a triple NRTI regimen (ABC+3TC+AZT) if all the other options provided in the table above are not feasible, as this is an inferior regimen.
- **After completion of TB treatment, all ART regimens that are not optimal, should be optimized (in line with the ART guidelines (Table 56 and Table 63).**

6.7.3.5 ART regimen substitutions for patients diagnosed with TB while on ART

Anti-TB treatment should be initiated immediately upon diagnosis while continuing ART. However, the ARV regimen should be reviewed and may need substitutions to ensure optimal treatment of both TB and HIV and to decrease the potential for toxicities and drug–drug interactions (Table 31).

Table 31: ARV regimen substitutions for patients initiating TB treatment while already on ART

Age Group	Regimen when diagnosed with TB	Recommended action/substitution
Adults and adolescents ≥30Kg including pregnant and breastfeeding women	If on EFV-based regimen*	Continue with the same regimen and dose. After TB treatment optimize the regimen if virally suppressed (substitute EFV with DTG). If not virally suppressed switch to 2nd line ART.
	If on DTG-based regimen	Continue the same regimen but increase the dose of DTG (give DTG 50mg twice daily instead of once daily). After TB treatment return to DTG once a day.
	If on NVP-based regimen*	Substitute NVP with EFV. After TB treatment optimize ART regimen if virally suppressed (substitute EFV with DTG). If not virally suppressed switch to 2nd line ART.
	If on ATV/r-based regimen*	• Continue the same regimen but substitute Rifampicin with Rifabutin *OR* • If on 2nd line, substitute ATV/r with LPV/r and double both the morning and evening doses of LPV/r. If virally suppressed after TB treatment, return to ATV/r (if there is previous exposure to DTG) or optimize to DTG-based regimen if no previous DTG exposure. *OR* • If on 1st line and EFV is not contraindicated, substitute ATV/r with EFV for the duration of TB treatment. After TB treatment optimize the regimen if virally suppressed. • If not virally suppressed after TB treatment, switch to 2nd line or 3rd line (with HIVDR).
	If on LPV/r -based regimen*	Continue the same regimen but either: • Substitute Rifampicin with Rifabutin *OR* • Double both the morning and evening doses of LPV/r. If virally suppressed after TB treatment, return to normal dose of LPV/r (if on 2nd line with previous DTG-based regimen) or optimize to DTG-based regimen if no previous DTG exposure. • If not virally suppressed after TB treatment, switch to 2nd line or 3rd line (with HIVDR).
Children ≥ 20Kg- <30Kg	If on DTG-based regimen	Continue the same regimen but increase the dose of DTG to twice daily. After TB treatment, return to DTG once a day.
	If on EFV-based regimen*	Continue the same regimen. After TB treatment optimize the regimen if virally suppressed (substitute EFV with DTG). If not virally suppressed switch to 2nd line ART
	If on NVP -based regimen*	• Substitute NVP with EFV (if >3 years and >10Kg) *OR*

Age Group	Regimen when diagnosed with TB	Recommended action/substitution
		• If EFV is contraindicated, give a triple NRTI regimen (ABC+3TC+AZT). After TB treatment optimize treatment with a DTG-based regimen if virally suppressed. If not virally suppressed switch to 2nd line ART
	If on LPV/r-based regimen	• Continue the same regimen but either o Substitute Rifampicin with Rifabutin. *OR* o Double both the morning and evening doses of LPV/r. After TB treatment return to normal dose of LPV/r. *OR* *If the child cannot tolerate double dose of LPV/r* • Substitute LPV/r with Raltegravir. Double the dose of Raltegravir. Return to LPV/r after completion of TB treatment.
	If on DRV//r-based regimen	Substitute Rifampicin with Rifabutin
Children <20Kg	If on DTG-based regimen	Continue the same regimen but **increase the dose of DTG to twice daily**. After TB treatment, return to DTG once a day.
	If on LPV/r- based regimen	• Continue the same regimen but either o Substitute Rifampicin with Rifabutin. *OR* o Double both the morning and evening doses of LPV/r. After TB treatment return to normal dose. *OR* *If the child cannot tolerate double dose of LPV/r* • Substitute LPV/r with Raltegravir. Double the dose of Raltegravir. Return to LPV/r after completion of TB treatment.
	If on NVP-based regimen*	• If >3 years and >10Kg substitute NVP with EFV. • If EFV is contraindicated, give a triple NRTI regimen (ABC+3TC+AZT). • If <3 years and <10Kg give triple NRTI regimen (ABC+3TC+AZT). After TB treatment optimize treatment with a DTG or LPV/r -based regimen if virally suppressed. If not virally suppressed switch to 2nd line ART.
	If on DRV/r-based regimen	Substitute Rifampicin with Rifabutin

6.7.3.6 Initiating TB treatment in patients already on ART (Table 31)

Note:

- It is NOT recommended to initiate DTG and TB treatment concomitantly due to the risk of adverse events and complexity of ensuing management.
- In case ARVs are to be substituted in patients initiating TB treatment while on ART, careful consideration of previous ART regimens should be taken in order not to give an ARV to which the client may already have resistance.
- Raltegravir (given as a double dose) is recommended in TB-HIV co-treatment for children who cannot tolerate double dosing of LPV/r or for whom Rifabutin is unavailable for treatment with DRV/r.
- Children on NVP-based regimens should be switched to a triple NRTI regimen (ABC+3TC+AZT) only if EFV is contraindicated, as this is an inferior regimen.
- ***After completion of TB treatment, ensure that the ART regimen is optimized:**
    - **If virally suppressed, optimize the regimen.**
    - **For adults, when optimizing 2nd line PI-based regimens, ensure that the client was not previously exposed to DTG in the 1st line ART regimen. If the client was on a DTG-based 1st line ART Regimen and is currently on a PI-based 2nd line regimen and virally suppressed, maintain the PI-based regimen after TB treatment.**
    - **If viral load is not suppressed switch the client to 2nd or 3rd line following the recommendations in Chapter 8 (see recommended first and second line in Table 56 and Table 63, Chapter 8).**

6.7.4 TB PREVENTION

TB prevention should be based on the following principles:

- Vaccination with BCG to prevent severe forms of TB in children.
- Early identification and prompt treatment of TB patients.
- Providing TB Preventive Treatment (TPT).
- Implementation of infection control practices within the health facility and household settings.

6.7.4.1 TB Preventive Treatment (TPT)

TPT prevents the progression of TB infection to active TB disease. All PLHIV with a negative TB symptom screen should be evaluated for TPT eligibility and offered TPT if eligible (see section 6.7.4.1.1). TPT is currently **NOT** recommended for contacts of patients with MDR-TB.

The following regimens could be used for TPT as guided in Table 32 and Table 33 below:

- 6H: Daily Isoniazid for 6 months.
  Note: Isoniazid may be available in combination with co-trimoxazole and pyridoxine as a fixed dose combination referred to as Q-TIB: In this case, Q-TIB is also administered daily for 6 months.
- 3HP: Weekly Isoniazid and Rifapentine for 3 months (Recommended for patients aged more than 2 years).

- 3RH: Daily Rifampicin and Isoniazid for 3 months (Recommended for children less than 15 years).

6.7.4.1.1 Eligibility for TPT

- HIV-positive children (≥one year of age), adolescents and adults with no signs and symptoms of TB.
- HIV-positive infants and children <5 years with a history of TB contact who have no signs and symptoms of active TB disease, irrespective of previous TPT.
- HIV-positive pregnant mothers with a history of contact with a TB patient a after ruling out active TB.
- HIV-positive pregnant mothers with a WHO Stage 3 or 4 event and/or CD4<200 without active TB.

Note:

- For HIV-positive pregnant mothers **without a history of TB exposure , TPT will be deferred until 3 months after delivery.**
- For HIV positive women and adolescent girls **on TPT who get pregnant**, continue and complete the TPT while closely monitoring for side effects.

See *TB Preventive Treatment in Uganda 2020* for more information on determining eligibility for TPT.

Table 32: TPT regimen for adolescents ≥ 15 years and adults on ART

ARV Drug Regimen	TPT regimen Options	Rationale for TPT regimen
TDF or AZT or ABC + 3TC + DTG	Isoniazid (6H) or Isoniazid-Rifapentine-based regimens	No dose adjustment of DTG with Isoniazid-Rifapentin-based regimen
TDF or AZT or ABC + 3TC+ ATV/r TDF or AZT or ABC + 3TC + LPV/r	Isoniazid (6H)	Co-administration of rifamycins (such as rifampicin) with protease inhibitors has been associated with reduction in plasma levels of protease inhibitors.
TDF or AZT or ABC + 3TC+EFV	Isoniazid (6H) or Isoniazid/Rifapentine-based regimens	A higher dose of EFV, i.e. 600mg is recommended if Isoniazid/Rifapentin-based regimen is used

Table 33: TPT regimen for children < 15 years on ART

ARV Regimen	TPT regimen options	Rationale for TPT regimen
ABC or AZT +3TC+LPV/r ABC or AZT+3TC +ATV/r	Isoniazid (6H)	Co-administration of rifamycins (such as rifampicin) with protease inhibitors has been associated with reduction in plasma levels of protease inhibitors.
ABC or AZT+ 3TC+DTG	Isoniazid (6H) or Rifampicin/ Isoniazid (3RH) or	Double the dose of DTG if 3RH is used

ARV Regimen	TPT regimen options	Rationale for TPT regimen
	Isoniazid/Rifapentine-based regimens ***(for children aged > 2 years)***	Lack of data to support the use of Rifapentine among children aged < 2 years.
ABC or AZT +3TC+ EFV	Isoniazid (6H) or Rifampicin/ Isoniazid (3RH) or Isoniazid/Rifapentine-based regimens ***(for children aged > 2 years)***	 Lack of data to support the use of Rifapentine among children aged < 2 years.
ABC or AZT + 3TC+RAL	Isoniazid (6H) or Rifampicin/ Isoniazid (3RH) or Isoniazid/Rifapentine-based regimens ***(for children aged > 2 years)***	 Double the dose of RAL if 3RH is used Lack of data to support the use of Rifapentine among children aged < 2 years.

6.7.4.1.2 Timing of TPT in children

- **Contacts of known TB patients:** Initiate TPT immediately (or within 2 weeks of ART initiation if newly identified HIV positive)
- **Virally suppressed children currently on NNRTI:** Initiate TPT as soon as possible and complete course before ART optimization.
- **Virally suppressed children currently on PI or DTG:** Initiate TPT if the child has been on ART for at least 3 months.
- **Newly initiating ART:** Initiate TPT prophylaxis after 3 months on ART.

6.7.4.1.3 Co-administration of DTG and TPT

Although studies have found that the co-administration of DTG and INH is well tolerated, liver injury is a recognized adverse effect of each of these drugs. Since there is potential for hepatotoxicity, the following are recommendations for co-administration.

- **New Patient:** For newly identified patients, start on TLD with active symptomatic monitoring for adverse events (Chapter 9). Initiate TPT after 3 months to allow time for potential unmasking of TB and to monitor any toxicities that may arise from DTG, prior to initiation of TPT.
- For stable patients already transitioned to DTG: If patient has been on TLD for 3 months or more, initiate TPT immediately.
- If client is already on TPT and a non-DTG based regimen: Optimization to DTG will be deferred until completion of TPT.
- **Stable patients for DTG transition and have not received TPT before**:
    - In case TLE stock is available: First complete TPT and then transition to DTG.
    - In case TLE stock is not available: Transition to DTG and initiate TPT after 3 months.

Note: All patients receiving INH prophylaxis and DTG+INH should be closely monitored for signs and symptoms of liver toxicity as specified in the pharmacovigilance guidelines.

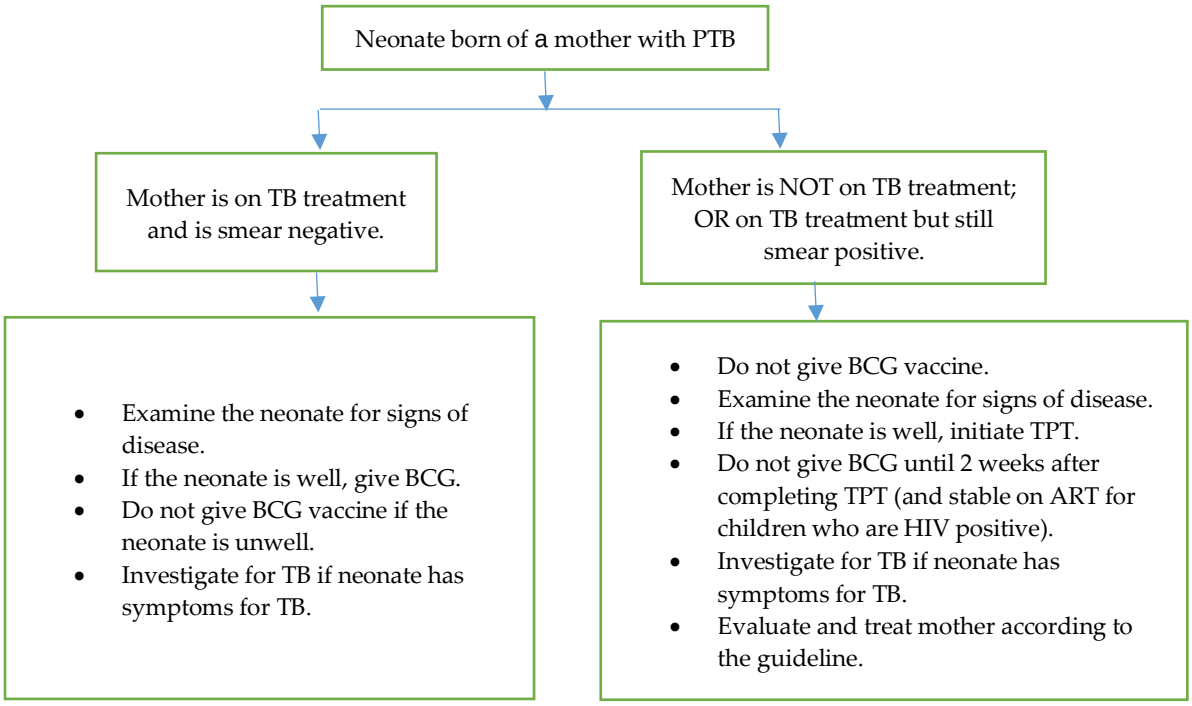
Table 34: Isoniazid dosing table

				Recommended number of tablets per body weight in kilograms							
Medicine frequency & duration	**Doze of TPT medicine (mgs)**	**Mg/kg**	**Formulation**	**3–5.9 kgs**	**6–9.9 kgs**	**10–13.9 kgs**	**14–19.9 kgs**	**20–24.9 kgs**	**25-32 kgs**	**32 – 50 kgs**	**> 50 kgs**
Daily isoniazid for 6 months	Isoniazid 100 mg	10mg/kg	Tablets	0.5	1	1.5	2	2.5			
	Isoniazid 300 mg	5mg/kg	Tablets						1	1	1
	Pyridoxine 25 mg		Tablets	0.5	0.5	1	1	1	1	1	1
Once weekly rifapentine/ isoniazid for 3 months	Rifapentine 150mg (For 2 years and above)					2	3	3	4	5	6
	INH 100 mg	2 -11years 25mg/kg				3	4				
	INH 300mg	≥12 years 15mg/kg						2	2.5	2.5	3
	Pyridoxine 25mg		Tablets	0.5	0.5	1	1	1	1	1	1
Daily Rifampicin/ Isoniazid for 3 months	150mg/75mg	10mg/kg						1	2	3	4
	75/50 mg	15mg/kg	Tablets	0.5	1	1.5					
	Pyridoxine 25mg		Tablets	0.5	0.5	1	1	1	1	1	1

6.7.4.2 BCG vaccination

BCG is protective against severe forms of TB such as miliary TB and TB Meningitis and is administered at birth in Uganda. However, if an infant did not receive BCG at birth and is **confirmed to be HIV-positive**, s/he should not be given BCG unless they are stable on ART. The follow up of a neonate born to an HIV-positive mother with active TB is summarized in Figure16.

Figure 16: Follow up of a Neonate born to an HIV-positive Mother with Active TB.



6.8 CRYPTOCCOCCAL INFECTION

Introduction

In Uganda, Cryptococcal Meningitis (CM) is associated with mortality of up to 39%. Patients with a CD4 cell count of <200 cells/mm^3 are at the highest risk of CM. This section describes screening and management of early Cryptococcal disease.

6.8.2 Screening and management of early Cryptococcal disease

The following categories of patients should be screened for Cryptococcal disease:

- All HIV-infected ART-naïve with CD4 <200 cells/mm^3
- ART experienced PLHIV returning to care after 90 days of treatment interruption with CD4 <200 cells/mm^3.
- All HIV-infected virologically unsuppressed patients with CD4 <200 cells/mm^3.
- All patients with WHO Stage 3 or 4 event.
- All PLHIV who have a positive symptom screen on the Advanced Disease Pathway.

6.8.2.1 How to screen for Cryptococcal disease

- To screen for Cryptococcal disease, health workers should do Cryptococcal antigen (CrAg) test using the lateral flow assay (LFA) on plasma, serum, or finger-prick blood. The LFA for Cryptococcal antigen has the advantage that does not require laboratory infrastructure. It can be done at the bedside using finger prick whole blood.
- The process of screening patients for Cryptoccoccal Meningitis is guided by the algorithm in Figure 17.

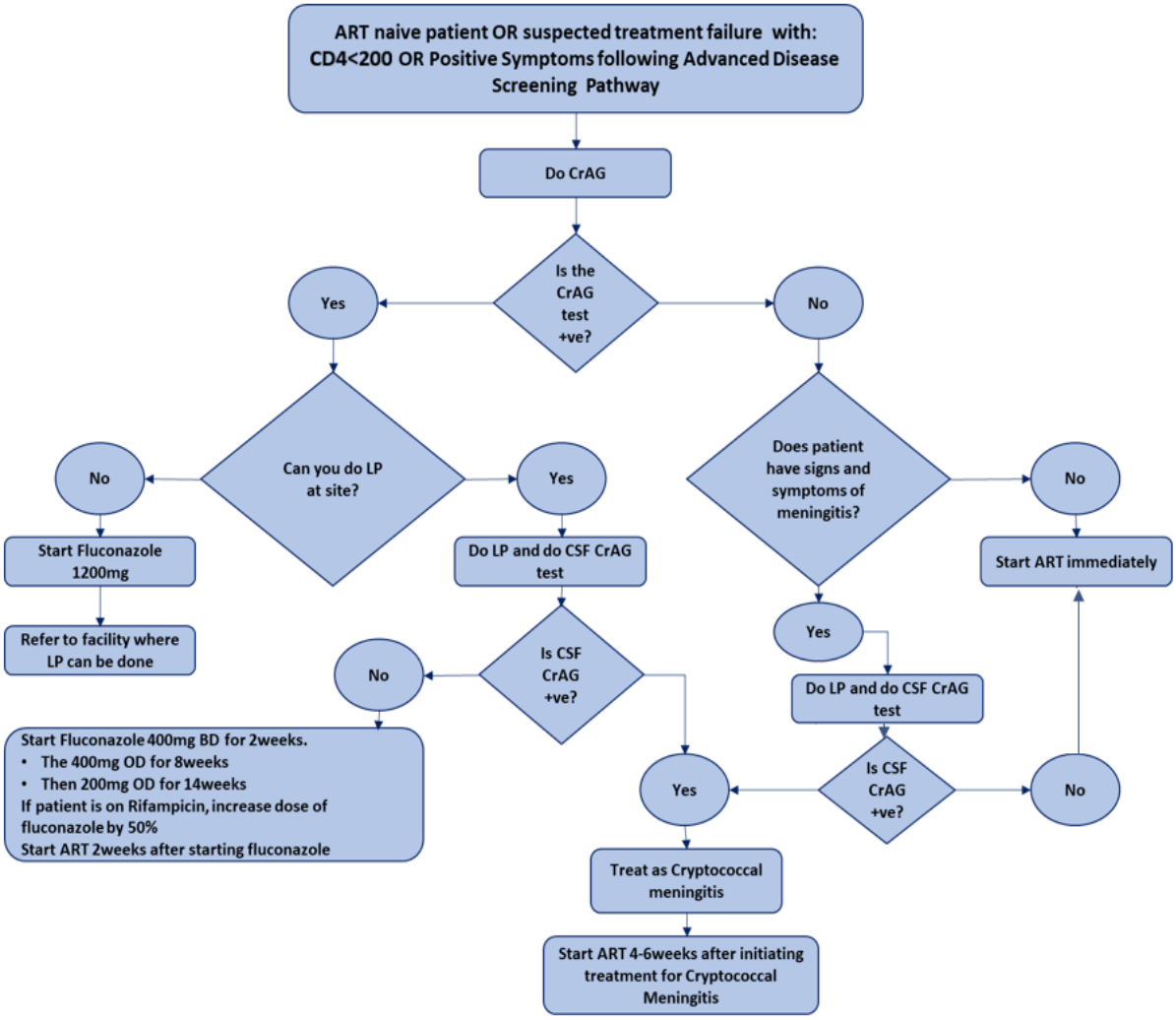
6.8.2.1.1 For serum CrAg positive patients at facilities where lumbar puncture can be performed

- Patients with a positive serum CrAg should be assessed for early and late signs and symptoms of CM including decreased hearing, dizziness or lightheadedness, cognitive delay (acting unusual to friends, family or provider), difficulty walking, double or blurry vision, weak arms or legs, headache, presence of seizures, altered consciousness, photophobia, neck stiffness, or a positive Kernig's or Brudzinski sign.
- Patients with a positive serum CrAg are at high risk of having CM even in the absence of symptoms. Therefore, a lumbar puncture is recommended for all patients with a positive serum CrAg test to exclude CM. The CrAg test should be conducted on CSF.
    - If the CSF CrAg test is negative with or without signs of CNS disease: the patient has Cryptoccoccal disease but without CNS involvement and the patient should be started on pre-emptive therapy.
    - If the CSF CrAg test is positive, the patient has CM and should be treated for Cryptococcal Meningitis (see
    -
    - Table 36: Management of Cryptococcal Meningitis).

Table 35: Treatment regimen for non-meningeal Cryptococcal disease

Induction Phase	Consolidation phase	Maintenance phase
Fluconazole 800 mg for 2 weeks or 12 mg/kg/day for children and adolescents	Fluconazole 400 mg (or 6 mg/kg/day up to 400mg) for 8 weeks	Fluconazole 200 mg for 14 weeks to complete 6 months of treatment
Note: For patients on rifampicin, increase Fluconazole dose by 50% across all phases		

Figure 17: Algorithm for screening and managing Cryptococcal disease



6.8.2.1.2 For serum CrAg-positive patients at facilities where lumbar puncture cannot be performed

Health workers at some health facilities may not be trained to do LPs. Patients at such sites should also be assessed for signs of CM. Patients with early or late Cryptococcal disease findings should be started on daily Fluconazole 1200mg, counseled and referred to a site where LP can be done.

6.8.2.1.3 For serum CrAg-negative patients

Assess the patient for signs and symptoms of Cryptococcal Meningitis including decreased hearing, dizziness or lightheadedness, cognitive delay (acting unusual to friends, family or provider), difficulty walking, double or blurry vision, weak arms or legs, headache, presence of seizures, altered consciousness, photophobia, neck stiffness, and a positive Kernig's or Brudzinski's sign.

- If there are no signs of Meningitis, start ART in the patient immediately
- If there are signs of Meningitis, do a lumbar puncture and CSF gram stain, including CSF CrAg and GeneXpert and manage accordingly.

6.8.2.2 Diagnosis of Cryptococcal Meningitis

The diagnosis of Cryptococcal Meningitis can only be made by demonstrating the presence of Cryptococcal antigen in cerebrospinal fluid or a positive culture showing Cryptococcal yeasts. A lumbar puncture and CrAg test on CSF (CSF CrAg) is the recommended diagnostic approach for Cryptococcal Meningitis. However, if a patient has signs and symptoms of Cryptoccoccal Meningitis and a lumbar puncture cannot be performed for any reason, it is recommended to perform a rapid serum CrAg using the LFA and treat as possible Cryptoccoccal Meningitis.

6.8.2.3 Treatment of Cryptococcal Meningitis

There are three phases in the treatment of Cryptococcal Meningitis: the induction phase, consolidation phase, and maintenance phase. The drugs for the different phases, duration of treatment, when to initiate ART, when to stop antifungals, how to prevent drug toxicity, how to manage increased intracranial pressure, and relapse disease are summarized in Table 36.

Considerations for drug interactions during treatment of Cryptococcal disease

- Antifungals and aminoglycosides (e.g. Gentamicin): Increased risk of nephrotoxicity. Avoid combining the drug classes.
- Antifungals and cardiac glycosides (e.g. Digoxin): Increased risk of cardiac toxicity, especially in clients with hypokalemia. Monitor potassium very closely.
- Antifungals and antiepileptic medicines: Antifungals may increase serum concentration of carbamazepine, alprazolam, and other benzodiazepines. May need to reduce antiepileptic by 50% if concurrently using or monitor very closely.
- Amphotericin B and non-potassium sparing diuretics: Increased risk of hypokalemia. Ensure adequate potassium supplementation.
- Amphotericin B and Flucytosine: Amphotericin B can decrease renal clearance of 5-FC, and increase cellular uptake, which may increase the risk of 5-FC toxicity. May require close monitoring of liver function.
- Nevirapine use and Fluconazole: Fluconazole increases plasma concentration of Nevirapine and some protease inhibitors. Monitor closely for toxicity.
- TB medicines and Fluconazole: Rifampicin increases the metabolism of Fluconazole, thus increase the dose of Fluconazole by 50%.
- Pregnant and breastfeeding women: Whereas there is no data against the use of Amphotericin B in pregnancy, it is not encouraged. There have been numerous reports of multiple congenital abnormalities associated with long-term use of high dose Fluconazole in the first trimester of pregnant women. The recommendation is to treat Cryptoccoccal Meningitis in pregnancy with Amphotericin B. Avoid Fluconazole during the first trimester and preferably start Fluconazole after delivery. Flucytosine is teratogenic in animals and should only be used when no alternative is available. In liver disease, use with caution.

Table 36: Management of Cryptococcal Meningitis

<table>
<tr><th>Phase</th><th>Drug</th><th>Comments</th></tr>
<tr><td colspan="3">Newly Diagnosed Patient</td></tr>
<tr><td rowspan="2">Induction Phase (2 weeks)</td><td>Recommended:
Amphotericin B liposomal (3mg/kg/day)/ deoxycholate (1mg/kg/day) + Flucytosine (100mg/kg/day in four divided doses) for 1 week, followed by 1 week of fluconazole (1200 mg/day for adults, 12 mg/kg/day for children and adolescents).
Or
Fluconazole (1200 mg daily for adults, 12 mg/kg/day for children and adolescents) + Flucytosine (100 mg/kg/day, divided into four doses per day.
Or
Amphotericin B deoxycholate (1mg/kg/day) + high-dose Fluconazole 1200mg/day.</td><td rowspan="2">Preventing Amphotericin toxicity:
To prevent nephrotoxicity and hypokalaemia, do the following:
• Pre-hydration with 1L normal saline before starting the daily Amphotericin dose.
• Monitor serum potassium and creatinine levels at initiation and at least twice weekly to detect changes in renal function.
• Routine administration of 40 mEq/day of potassium chloride can decrease the incidence of Amphotericin-related hypokalemia.
• Consider alternate day Amphotericin if creatinine is >3mg/dl.</td></tr>
<tr><td>Alternative:
Fluconazole 1200mg/day (or 6-12mg/kg/day in children)</td></tr>
<tr><td>Consolidation phase (8 weeks)</td><td>Fluconazole 800mg/day
(or 6-12mg/kg/day in children and adolescents)</td><td>Initiate ART 4–6 weeks after starting CM treatment and there is clinical response to antifungal therapy.</td></tr>
<tr><td>Maintenance Phase (18 months)</td><td>Fluconazole 200mg/day
(or 6 mg/kg/day up to 200mg in children and adolescents)</td><td>Criteria to stop after a minimum of 18 months of maintenance phase:
Adults: VL<1,000 copies/mm^3 & CD4 ≥ 200 or CD4 ≥200 (if viral load not available) after 12 and 18 months
Children: If CD4>25% or viral suppressed</td></tr>
<tr><td colspan="3">Note: For patients on rifampicin increase Fluconazole dose by 50%</td></tr>
<tr><td colspan="3">Relapse disease</td></tr>
<tr><td colspan="3">Presents with a recurrence of symptoms of Meningitis and have a positive cerebrospinal fluid culture following a prior confirmed diagnosis of Cryptococcal Meningitis.
• Evaluate for drug resistance: Send CSF to Central Public Health Laboratory (CPHL) for culture and sensitivity testing, if there are no drug resistance results, re-initiate the induction therapy for two weeks and complete other phases of treatment.</td></tr>
<tr><td colspan="3">Adequate control of elevated CSF pressure</td></tr>
<tr><td colspan="3">• Control of increased intracranial pressure improves survival by 25% in persons with Cryptococcal Meningitis.
• All patients with a CSF Pressure >250mm H_2O will need a therapeutic LP the following day to reduce the CSF pressure to <200 mm.
• In the absence of a manometer, one may use an IV giving set to create an improvised manometer measuring the height with a meter stick.</td></tr>
</table>

• Removing 20-30mL of CSF (even in the absence of a manometer) may be adequate to decrease CSF pressure. Most patients will need 2-3LPs during the induction phase.

6.9 PNEUMOCYSTIS JIROVECI PNEUMONIA

Pneumocystis Jiroveci Pneumonia (PJP), formerly known as *Pneumocystis carinii* pneumonia (PCP), is the most common opportunistic infection in persons with advanced HIV disease. However, the frequency is decreasing with the use of Cotrimoxazole prophylaxis and ART. Table 37 below describes the signs, symptoms and management of PJP.

Table 37: Signs/symptoms, management and prevention of *Pneumocystis Jiroveci Pneumonia*

Signs and symptoms	**Symptoms:** Progressive exertional dyspnea (95%), fever and chills (>80%), non-productive cough (95%), chest discomfort, difficult breathing, fast breathing and weight loss. **Signs:** Pulmonary symptoms: tachypnea, pulmonary examination may reveal mild crackles and rhonchi but may yield normal findings in up to half of the patients. Children may have cyanosis, nasal flaring, and intercostal retractions.
Diagnosis	Chest X-Ray is the main diagnostic tool • Diffuse interstitial infiltrates extending from the peri-hilar region • Pneumatoceles and pneumothorax are possible but not common. • Pleural effusions and intrathoracic adenopathy are rare. ***However, the chest X-Ray may also be normal***
Management and treatment	**Admit** **Give oxygen** **Preferred therapy:** Cotrimoxazole (10-20mg/kg/day IV) for 21 days **Adjunctive therapy:** Use corticosteroids only in patients with severe PJP
Prevention	Initiate all HIV-infected people on Cotrimoxazole preventive therapy

6.10 HEPATITIS B VIRUS INFECTION

Hepatitis B virus (HBV) is the leading cause of chronic liver disease among HIV patients in Uganda. The prevalence of Hepatitis B among HIV patients is estimated to be 17%. See Table 38 for signs, symptoms, and management of HBV infection.

Table 38: Signs/symptoms, management, and prevention of Hepatitis B virus infection

Signs and symptoms	**Acute Phase** The patient may present with nonspecific signs and symptoms like abdominal pain, fever, nausea and vomiting, with or without jaundice. **Chronic Phase** • Chronic fatigue. • Signs of liver cirrhosis and portal hypertension like ascites, bleeding under the skin, jaundice, and mental derangement (hepatic encephalopathy). • In the later phases, patients may present with signs of hepatocellular carcinoma (HCC).
Screening for HBV	All HIV-infected patients who are initiating or failing on ART should be routinely screened for HBV infection using Hep B surface Antigen (HBsAg).
Tests in persons diagnosed with HBV infection	**These tests should be done at baseline and at six months** • A complete blood count. • Liver function tests (ALT,AST, albumin and bilirubin levels, and PTT).

	• Abdominal ultrasound scan to assess for liver fibrosis. • AFP and HBeAg if available.
Treatment of HBV/HIV co-infected person	Initiate ART with TDF-containing regimen. If ART cannot be given or if the patient refuses ART use: Peg-IFN-alfa 2a 180 mcg subcutaneously once weekly for 48 weeks *or* Peg-IFN-alfa 2b 1.5 mcg/kg subcutaneously once weekly for 48 weeks.
Follow-up after six months	Evaluate the patient for HBV treatment failure: • If jaundice, malaise and abdominal right upper quadrant pain are present **or** if liver function tests are abnormal→ **do a viral load test.** o Patients with HB VL >2000IU/ml at 24 weeks of therapy should be referred for further evaluation and management while continuing ART. o If viral load testing is unavailable, refer patients for further evaluation and management while continuing ART.
HBV prevention	• Counsel on sexual transmission and the risks associated with sharing needles and syringes, tattooing, body-piercing, or close household contact. • Screen all household members and sexual partners/contacts of HBV/HIV co-infected clients for HBV. • In non-endemic areas, provide HBV vaccination for all household members and sexual partners/contacts (unless they are known to be HBsAg+) regardless of whether they are HIV-infected or not. • Offer HBV vaccine to all people regardless of HIV status in endemic areas. Available vaccines and their schedules are below: o HBV vaccine IM (Engerix-B® 20 mcg/mL or Recombivax HB® 10 mcg/mL) at 0, 1, and 6 months. o HBV vaccine IM (Engerix-B® 40 mcg/mL or Recombivax HB® 20 mcg/mL) at 0,1,2 and a booster dose at 12 months for more accelerated protection.

6.11 HEPATITIS C AND HIV

Hepatitis C (HCV) affects 5–15% of PLHIV worldwide. HCV-related liver disease progresses more rapidly in people co-infected with HIV. HCV serology testing should be offered to individuals from populations with high HCV prevalence or who have a personal history of HCV risk exposure/behavior (e.g. injection drug users) as well as patients with jaundice or right upper quadrant pain. Refer for further evaluation and care if the HCV antibody test is positive.

6.12 MALARIA AND HIV

PLHIV in malaria endemic regions are at high risk of complications of malaria. Infants, children under five years of age, and pregnant women are at risk of severe and complicated malaria. Key malaria control interventions include early diagnosis, prompt and effective treatment with artemisinin-based combination therapies (ACT), use of long-lasting insecticide-treated mosquito nets (LLINs), indoor residual spraying (IRS) to control the vector mosquitoes, and intermittent preventive treatment during pregnancy (IPT). PLHIV (as for the general population) should routinely use LLINs or have access to IRS to reduce their risk of exposure to malaria.

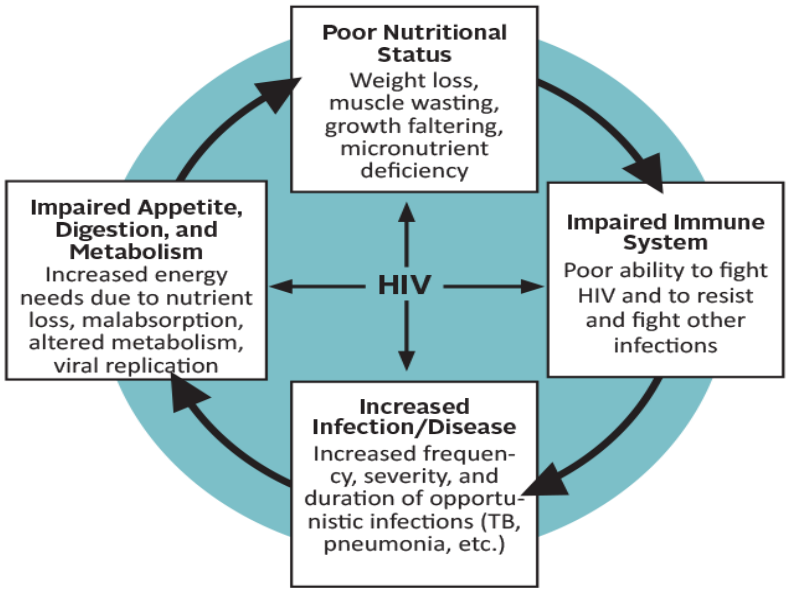
PLHIV who develop malaria should receive prompt and effective anti-malaria treatment using ACTs. PLHIV receiving AZT or EFV should, if possible, avoid Amodiaquine-containing artemisinin-based combination regimens because of the increased risk of neutropenia when used with AZT and hepatotoxicity when used with EFV. IPT with Sulfadoxine-Pyrimethamine should not be given to pregnant women with HIV receiving Cotrimoxazole prophylaxis.

6.13 NUTRITION CARE AND SUPPORT FOR PLHIV

6.13.1 INTRODUCTION

There is a synergistic and cyclical relationship between HIV and under nutrition. HIV affects nutrition by increasing nutrient requirements, decreasing food consumption, impairing nutrient absorption, and causing metabolic changes that lead to weight loss and vitamin and mineral deficiencies. Poor nutritional status is associated with faster HIV disease progression and death.

Figure 18: The Cycle of Under nutrition and HIV/AIDS



Adapted from Tomkins, Andrew and Fiona Watson. 1989. 'Malnutrition and Infection–A review', Nutrition Policy Discussion Paper No. 5. Geneva: United Nations Administrative Committee on Coordination Subcommittee on Nutrition.

Nutrition Assessment Counseling and Support (NACS) is an important component of comprehensive care for PLHIV. NACS therefore, should be conducted in PLHIV from enrolment and extended throughout the care continuum.

6.13.2 STEPS IN IMPLEMENTING NACS

NACS should be implemented in HIV care settings using the "The Seven Steps" approach in Table 39.

Table 39: Seven steps approach for implementing NACS

Step	Activities
Step 1 Nutrition and health education	• Create awareness on benefits of proper nutrition • Sensitize clients on how to ensure proper nutrition and monitoring of nutritional status
Step 2: Nutrition assessment	***Anthropometry:*** Take and record the anthropometric measurements (weight, length/height, or MUAC) of PLHIV at each visit. Routinely monitor and promote growth for children <5 years
	Biochemical analysis: Monitor micronutrient deficiencies such as haemoglobin level. Conduct Lipid profiling for ART clients annually.
	Clinical assessment: Check for signs of under nutrition including bilateral pitting oedema, wasting, hair changes, anemia (pale conjunctiva, gums, nails, skin), breathlessness, and rapid pulse. Assess for symptoms that affect food intake (diarrhea, nausea, vomiting, anorexia, mouth/throat sores and oral thrush).
	Dietary assessment: Collect information about the types and amounts of food consumed, appetite, and eating behaviours
	Living environment: Assess for the cleanliness and sanitation of the client's environment, access to and use of safe water, food hygiene especially for immune-compromised HIV patients.
	Lifestyle practices*:* Smoking, alcohol and drug abuse can affect food intake and decrease effectiveness of some medications.
Step 3: Nutrition classification	Classify nutritional status and decide on care plan, see Figure 19.
Step 4: Nutrition counselling	Encourage clients to consume a variety of locally available, high-energy and nutrient dense foods; increased feeding frequency and intake per meal; high-protein intake (especially animal); frequent hydration; intake of fats and sugar in moderation; exercise, hygiene, and sanitation.
Step 5: Nutrition therapy	*Severe acute malnutrition (SAM) with complications* Manage in inpatient therapeutic care (ITC) using F_{75}, F_{100}
	Severe acute malnutrition (SAM) without complications Counsel and manage in outpatient therapeutic care (OTC) using ready to use therapeutic food (RUTF) for children 6-59 months or nutrient rich/enhanced food for older children, adolescents and adults.
	Moderate acute malnutrition (MAM) Counsel and refer to supplementary feeding program or livelihood programs
	Micronutrient deficiencies Provide appropriate micronutrient (iron, folate, vitamin A, zinc) supplements, see *The Micronutrient Guidelines for Uganda, Ministry of Health 2013*
	Food and drug interactions Manage complications that affect food intake/utilization, drug adherence, and efficacy, *Integrated Nutrition Assessment, Counselling and Support into Health Service Delivery, Reference Manual, 2016*
Step 6: Follow-up for nutrition care and support	Follow-up all clients with acute malnutrition Routine and scheduled follow-up for clients on nutrition treatment: where appropriate, synchronize with other services

Step	Activities
Step 7: Community linkage	Link malnourished patients to livelihood and/or supplementary feeding programs where possible

6.13.3 Dietary Recommendations for PLHIV

HIV increases patient's energy needs. Encourage patients and devise strategies for patients to increase energy intake by eating smaller meals (and snacks) more frequently throughout the day, particularly if appetite is poor.

HIV-Infected adults in early/asymptomatic stage need 10% more energy or about 210 additional kilocalories, equivalent to one additional snack per day e.g. one mug of porridge.

HIV- Infected adults in advanced/symptomatic stages need 20% - 30% additional energy, which is 420 to 630 kilocalories depending on severity of symptoms. This is equivalent to 2-3 additional snacks e.g. 2 to 3 mugs of porridge taken during the day.

HIV- Infected children need 10% more energy to maintain growth if the child is asymptomatic. For children who are symptomatic, the energy needs increase by about 20-30% more per day. Children who are symptomatic and experiencing weight loss need between 50% - 100% more energy per day.

Encourage adequate protein intake from both animal and plant sources. Adequate protein intake ensures that the body uses protein to build and maintain muscle mass and support the immune system. Recommended protein intake for PLHIV is 12%-15% of total energy intake. Protein from animal sources is of higher quality than from plant sources and tends to have vitamins and minerals that are more easily absorbed.

PLHIV without fat malabsorption of diarrhea can be encouraged to consume fat in moderation to help meet their increased energy needs. Recommended fat intake for PLHIV is 20%-35% of total calories.

6.13.4 Nutrition Support for PLHIV

Under nourished PLHIV should be supported with therapeutic/supplementary foods for the purpose of improving their nutritional status and treatment outcomes.

6.13.4.1Management of Severely malnourished PLHIV

Severely malnourished PLHIV can be managed in Outpatient Therapeutic Care (OTC) or Inpatient Therapeutic Care (ITC). Patients who require inpatient care generally have a poor appetite and usually have medical complications. Thus, the patients will often require treatment for both the complication and the malnutrition. For children 6-59 months admitted in ITC, manage them with therapeutic commercial formulas; F75 and F100. Ready to-Use-Therapeutic food (RUTF) is used in OTC. For older children, adolescents, and adults, locally made F75 and F100 should be used and patients are transitioned to nutrient-rich/enhanced family foods after stabilization phase.

Justification: Adolescents and adults rarely associate wasting or oedema with their diet except in famine conditions resulting in disbelief that altering their diet will help them. Even in famine conditions, they are often very reluctant to eat anything except traditional foods,

which they view as perfectly satisfactory. They are often reluctant to take formula feeds and/or RUTF unless they can be persuaded that such feeds are a form of medicine. This problem is one of the most difficult aspects of treating adolescents and adults.

Clients with no appetite should be encouraged to consume smaller amounts of family food more frequently or sip feeding.

- Explain to the client how to prepare and use nutrient-rich family foods and locally available fortified blended flour enriched with oil, vitamins and minerals.
- Counsel on how to modify family foods to improve appetite.
- Counsel on 1) weight monitoring at least once a month, 2) increasing energy density of home foods, 3) managing HIV/Tuberculosis related symptoms through diet, 4) managing medicine-food interactions, 5) sanitation and hygiene, especially safe drinking water.
- Make an appointment for review after 2 weeks of discharge.

Newly identified PLHIV who are severely malnourished should receive nutrition rehabilitation first before initiation of ART- start treatment **as soon as possible after acute phase – stabilization of metabolic complications and sepsis or start 14 days after admission in patients failing to respond**.

For severely undernourished PLHIV who are not able to take food orally, health workers should administer nasal gastric tube and/or parenteral therapeutic nutrition.

HIV infected children with severe acute malnutrition generally respond slower to nutritional rehabilitation and therefore need close monitoring when they are started on antiretroviral treatment, they should be monitored closely in the first 6–8 weeks following initiation of ART to identify early metabolic complications and opportunistic infections.

Note: Avoid Amphotericin B in SAM patients with HIV because of its high toxicity.

PLHIV with severe acute malnutrition in whom persistent diarrhoea does not resolve with standard management should be investigated to exclude carbohydrate intolerance and infective causes, which may require different management, such as modification of fluid and feed intake, or antibiotics.

Successful management of the severely malnourished PLHIV requires that both medical and social problems be recognized and corrected. If the illness is viewed as being only a medical disorder, the patient is likely to relapse when they return home.

Refer to Integrated Management of Acute Malnutrition (IMAM) Guidelines, 2020 for more detailed information on management of malnutrition

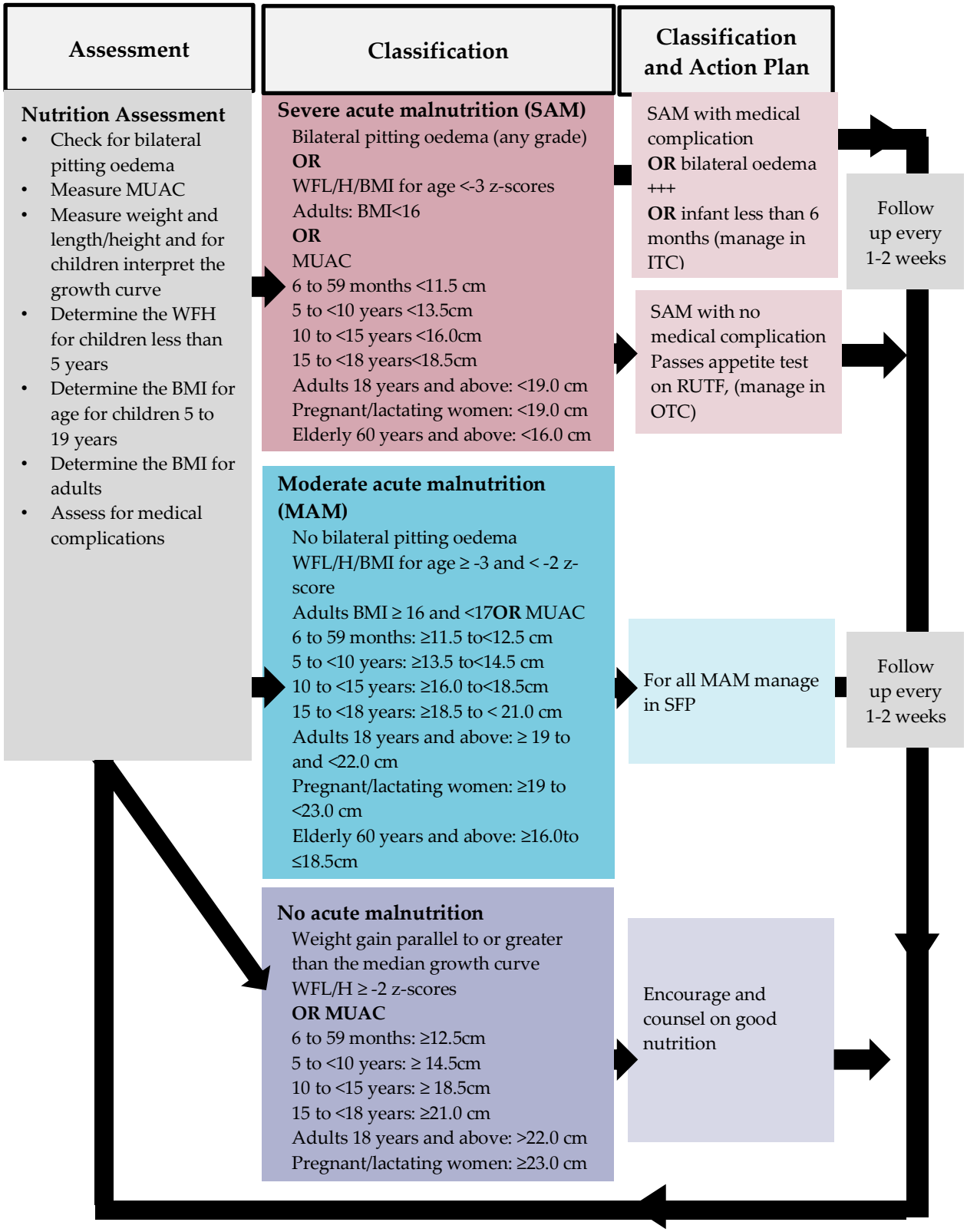
6.13.4.2Management of PLHIV with over nutrition (overweight/obese)

PLHIV with BMI greater than 30 should be counselled on how to reduce weight without compromising their nutritional status by:

- Controlling energy intake by increasing intake of low- energy foods such as vegetables and high fiber diets; whole grains are excellent sources of fiber and nutrients essential for weight control.

- Restricting intake of sugar, fats and oils, and salt.
    - Excess intake of fats/oils and sugar increases the risk of overweight/obesity.
    - Excess intake of salt increases the risk of high blood pressure
    - Reduce intake of processed drinks like sodas and sugar added drinks
    - Read food labels to be able to make healthy food choices
- Increasing daily water intake.
- Ensuring regular exercise/physical activity.
    - Adults should engage in 30mins of moderate intense physical activity per day.
    - Children and adolescent should engage in 60mins of moderate intense physical activity per day
    - Examples of moderate intense physical activities include walking, climbing stairs, domestic work, gardening, jogging, aerobics, cycling and sports.
- Ensure regular medical check- up.
  Regular medical check-up is crucial for the benefit of general wellbeing and overall health as it helps to detect any upcoming health issues that can be diagnosed and treated properly. It is therefore important to go for regular medical check-up every 6 months for:
    - Body Mass Index
    - Blood pressure
    - Blood sugar levels
    - Cholesterol levels
    - Cancers like, breast, prostate, cervical

Figure 19: Algorithm for nutrition assessment, classification, and care plan of acute malnutrition



6.14 SEXUAL AND REPRODUCTIVE HEALTH SERVICES

6.14.1 SCREENING AND MANAGEMENT OF SEXUALLY TRANSMITTED INFECTIONS (STIS)

6.14.1.1Introduction

STIs often coexist with HIV and are known to increase the risk of HIV transmission. On the other hand, HIV may alter the natural history of STIs by increasing recurrences and severity of STIs. The prevalence of STIs among HIV positive patients on ART and those not on ART is similar. It is, therefore, important to screen and appropriately manage STIs irrespective of whether the patient is on ART or not. All pregnant women living with HIV should have a syphilis test (RPR and/or TPHA) at the first antenatal visit.

6.14.1.2STI screening tool

All HIV-infected sexually active adults and adolescents should be screened for STIs at every clinic visit. The client should be asked about the following syndromes and if the answer is yes, explore related symptoms and treat according to Uganda syndromic management chart (Table 40: STI screening tool).

Table 40: STI screening tool

Syndrome	Key Symptoms
URETHRAL DISCHARGE	☐ Discharge from the urethral opening or vagina ☐ In men, blood in the semen or urine ☐ Difficulty starting urination
GENITAL ULCER DISEASE	For men: a genital sore is any sore or lesion that appears on the ☐ Penis ☐ Scrotum ☐ Urethra ☐ Perineum ☐ Anal and perianal region For women: a genital sore is any sore or lesion that appears on the ☐ Skin surrounding the vulva, ☐ Labia ☐ Vagina ☐ Perineum ☐ Anal and perianal region
ABNORMAL VAGINAL DISCHARGE	Fungal cause: ☐ Vaginal discharge that is thick, white, cheesy Bacterial cause: ☐ Vaginal discharge that is white, gray, or yellow and may have a fishy or foul odor
LOWER ABDOMINAL PAIN (PID)	☐ Dull pain in the stomach or lower abdomen ☐ Pain during sex

6.14.1.3 STI management

Uganda adopted the syndromic approach to the management of STIs, *National STI Treatment Guidelines, 2009/2010* (see Annex 8).

6.14.2 CERVICAL CANCER SCREENING

Women living with HIV have a higher risk for cervical cancer. Cervical cancer screening using HPV testing as the primary cervical cancer screening method in Uganda followed by thermocoagulation of the lesions for all HIV-positive sexually active girls and women at enrolment into HIV care.. Additionally visual inspection with acetic acid (VIA) is also recommended The cervical screening should be repeated annually. Patients with pre-cancerous cervical lesions should be managed using thermocoagulation or cryotherapy as guided by the eligibility criteria (Table 41: Eligibility criteria for cryotherapy).

Table 41: Eligibility criteria for cryotherapy

Eligibility criteria	• Positive screening test for cervical pre-cancer • Lesion small enough to be covered by the cryoprobe, with no more than 2mm beyond its edges • The lesion and all edges are fully visible, with no extension into the endocervix or to the vaginal walls • If the woman has recently delivered, she is at least six months postpartum
Exclusion criteria	• Evidence or suspicion of invasive disease or glandular dysplasia* • The lesion extends more than 2mm beyond the cryoprobe edges* • The lesion extends into the endocervix* • Pregnancy* • Pelvic inflammatory disease (until treated) • Active menstruation

* Refer for further management

6.14.2.1Prevention of cervical cancer

Cervical cancer is caused by the Human Papiloma Virus (HPV). The HPV vaccine is more effective for young girls and young women before the onset of sexual activity. In Uganda, girls aged 9-15 years are eligible for vaccination. Currently, HPV vaccination is not recommended for adolescent boys because it is not cost effective. Table 42: HPV vaccine and dosing schedule describes the available HPV vaccine.

Table 42: HPV vaccine and dosing schedule

	Quadrivalent vaccine
Manufacturer: Trade name	Merck: Gardasil®
Virus-like particles of genotypes:	6, 11, 16, 18
Dosing schedule:	0, 2, and 6 months
Recommended age at first dose:	Females: 9–15 years

6.15 SCREENING AND MANAGEMENT OF NON-COMMUNICABLE DISEASES

6.15.1 INTRODUCTION

PLHIV have a higher risk of liver, kidney and cardiovascular disease due to the chronic inflammatory state of the HIV infected individuals and the side effects of some of the ARVs used for treatment. Therefore, at each clinic visit, the patient should be screened for the common NCDs particularly diabetes mellitus and hypertension.

6.15.2 DIABETES MELLITUS (DM)

HIV-infected adults experience more chronic metabolic complications because of both the HIV infection itself and ART and are therefore more likely to develop Diabetes Mellitus (DM) as compared to HIV-negative individuals. Studies report that up to 10% of HIV-positive patients on ART develop DM within four years.

6.15.2.1 Risk factors for development of diabetes mellitus in HIV-positive patients

In addition to the usual risk factors for development of DM, there are several HIV-related risk factors:

- Fluctuating viral load and CD4 cell count which cause a chronic inflammatory state which may induce insulin resistance.
- Rapid weight gain, co-infection with Hepatitis C, dyslipidemia, and lipodystrophy.
- Anti-retroviral drugs are a major cause of the development of DM in PLHIV. Protease inhibitors such as Lopinavir, and Ritonavir cause insulin resistance by causing lipodystrophy, impaired glucose transporter type 4 translocation, reduced adipocyte differentiation, reduced insulin secretion, and dyslipidemia with lipotoxicity. Hyperglycemia has been reported among patients at risk for NCDs on DTG. Although causality has not yet been determined, systems for pharmacovigilance are recommended to assess the relationship and guide mitigation measures.

6.15.2.2 Screening and diagnosis

Patients should be assessed for risk factors for DM before initiation of ART and when clinically indicated. Those with risk factors should thereafter be re-evaluated every six months as shown in Figure 20.

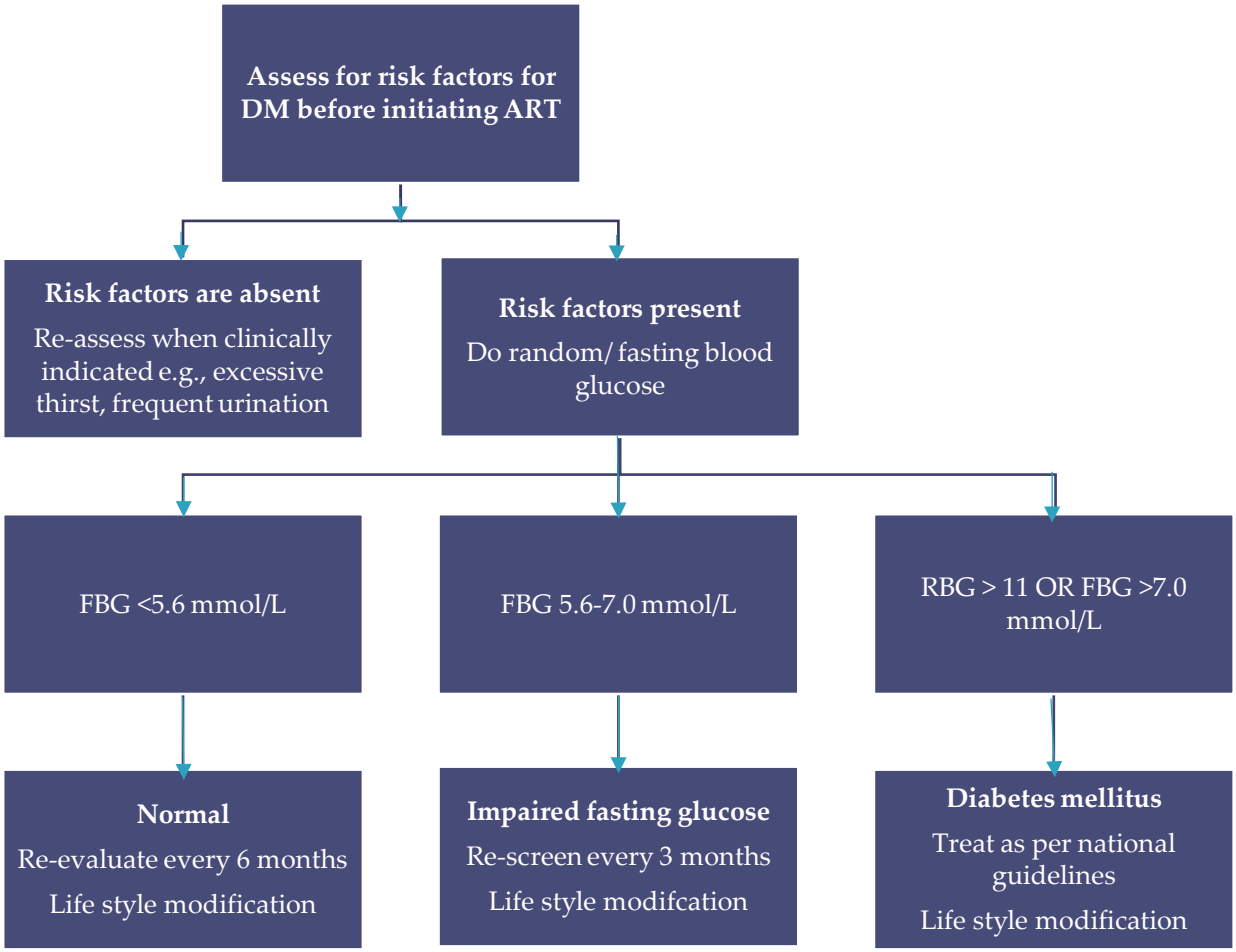
6.15.2.3 Treatment

HIV-positive patients with DM should be treated as per the *Uganda Clinical Guidelines, 2016*. However, the following should be observed:

- Reinforce lifestyle interventions at every clinic visit (refer to section 1.1.4)
    - Healthy heart diet
    - Adequate exercise (at least 30 minutes per day or 150 minutes per week)
    - Weight loss/management
    - Cessation of smoking
    - Elimination/reduction of alcohol consumption
- Metabolically neutral ARVs should be prescribed for patients at risk of developing DM. These include ABC, TDF and 3TC.
- Exclude HIV-associated nephropathy and liver toxicity before initiating metformin because it may lead to Metformin Associated Lactic Acidosis (MALA).

- HIV patients on metformin should be educated about the symptoms of lactic acidosis, including fatigue, weight loss, nausea, abdominal pain, dyspnea, and arrhythmia. Liver-related symptoms such as tender hepatomegaly, edema, ascites, and encephalopathy may occur, but jaundice is uncommon.
- The gastrointestinal side effects of metformin are increased in patients with HIV enteropathy. Metformin should, therefore, be started at a low dose and increased gradually.
- Lopinavir/r, ATV/r, and DRV/r can be used with close monitoring.
- DTG should not be used.

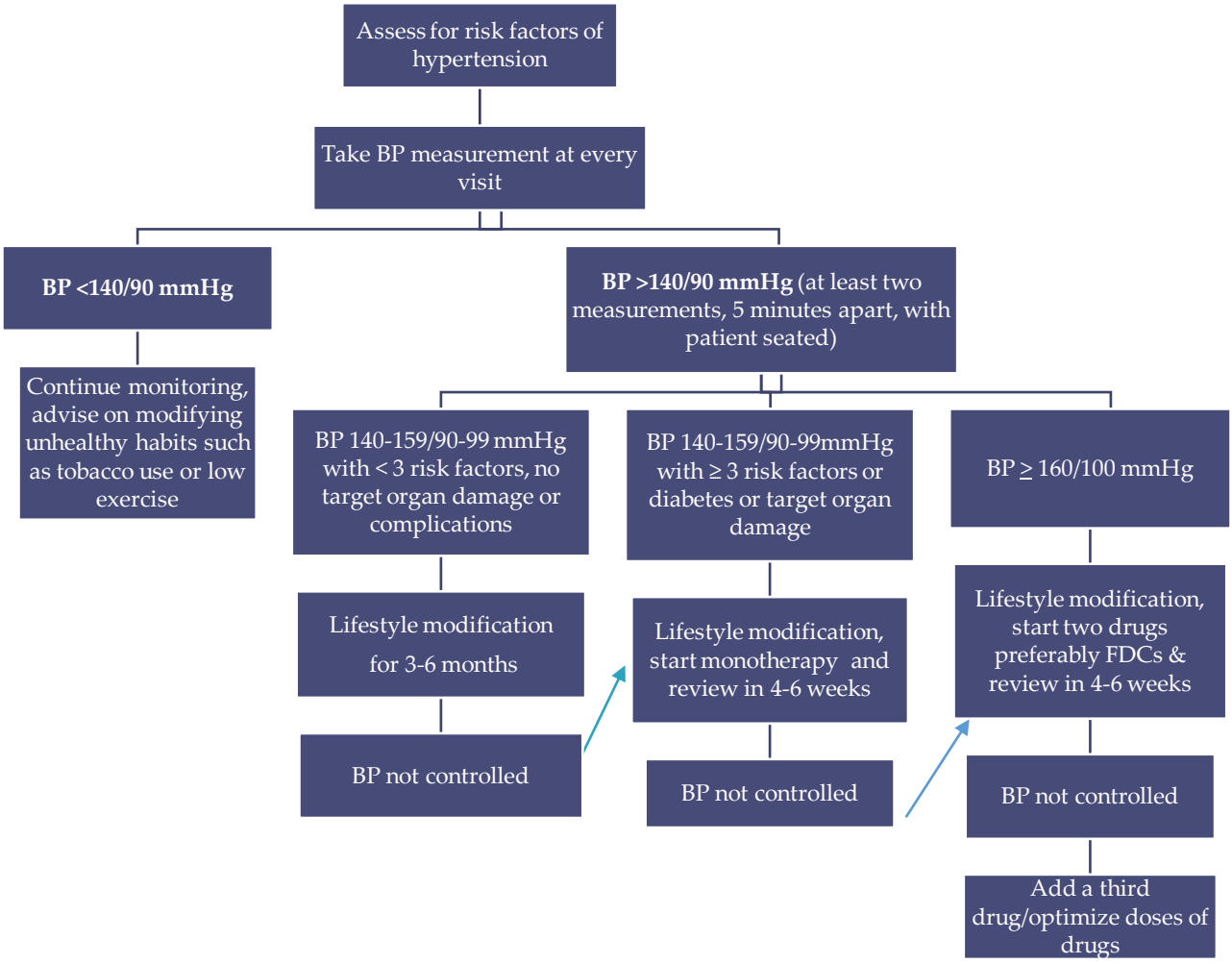
Figure 20: Algorithm for diagnosis and management of Diabetes Mellitus



6.15.3 SCREENING, DIAGNOSIS AND MANAGEMENT OF HYPERTENSION

All PLHIV should be screened for risk factors of hypertension such as tobacco smoking, being overweight or obese, physical inactivity and unhealthy diet at every visit. They should also have their blood pressure (BP) measurement at every clinic visit. Note that protease inhibitors can also contribute to high blood pressure. Persistently high resting BP defined as >140/90mmHg on at least two measurements five minutes apart with the patient seated should be managed as guided by the algorithm (Figure 21). People with any risk factor identified should be advised to modify lifestyle as described in Section 6.16 below.

Figure 21: Algorithm for diagnosis and management of hypertension



6.16 LIFESTYLE MODIFICATIONS TO PREVENT NON- COMMUNICABLE DISEASES AND THEIR COMPLICATIONS

Lifestyle modifications are the first line strategies to prevent and manage non-communicable diseases like hypertension and diabetes. These following strategies should be integrated into HIV service delivery:

1. Smoking cessation: HIV-infected persons who smoke should be encouraged to stop smoking. Ceasing to smoke reduces the risk of:
    - Respiratory infections and chronic lung disease.
    - Cancers of the lung, larynx, mouth, esophagus, throat, bladder, kidney, liver, stomach, pancreas, colon and rectum, and cervix.
    - Hypertension, diabetes, heart disease, and stroke.

2. Exercise: Clients should be advised to have aerobic exercises for at least 30 minutes a day, 5 days a week. Aerobic exercise has positive effects on blood pressure whether a person has hypertension or not, producing average reductions of 4 mmHg in systolic blood pressure and 3 mmHg in diastolic blood pressure. Health care workers should help patients find activities that they enjoy because this increases adherence.
3. Dietary changes/modifications: These should include:
    - Eating a diet high in fruits and vegetables and low in fat.
    - Limiting processed and fast foods.
    - Reducing sugar intake.
    - Reducing sodium intake to <1.5 g/day.
    - Reducing/ abstaining from alcohol.
4. Weight reduction: HIV clients should be advised to maintain a normal body weight by taking adequate exercise and overweight clients should be advised to reduce high-calorie food intake. Weight loss is an important lifestyle modification in reducing the risk of blood pressure and diabetes. A reduction of 4.5 kg can help reduce blood pressure or prevent hypertension. A reduction of approximately 9 kg may produce a reduction in systolic blood pressure of 5 to 20 mm Hg.

6.16.1 MANAGEMENT OF CLINIC REVIEWS FOR STABLE HIV PATIENTS WITH NCDS

HIV patients with diabetes and hypertension often have to attend separate HIV and NCD clinics on different days of the month. This comes at a cost to the patient; time off work, transport costs to the health facility and often affects their adherence to either ARVs or NCD drugs. Therefore:

- Stable HIV patients with NCDs and without any complications should be given same clinic appointment and seen by the same clinician (where possible).
- Provide comprehensive health education sessions that is inclusive of both HIV and NCD information during the clinic.
- Manage the patients' records/charts in the same location for easier access and retrieval when needed.
- Patients who develop NCD-related complications should be referred to higher level/specialists for further management.

6.16.1 ASSESSMENT AND MANAGEMENT OF DEPRESSION

PLHIV are at risk of mental and neurological disorders. About 10–20% of PLHIV have major depression. PLHIV with depression are less likely to achieve optimal ART adherence and could have poor treatment outcomes. Assessing and managing depression is important and should be an integral part of HIV care programs.

6.16.2 Screening for depression

Clinicians should screen for depression as part of the annual mental health assessment and when symptoms suggest its presence. It is particularly important to screen for depression during the following crisis points:

- When newly diagnosed with HIV or at disclosure of HIV status to family and friends.
- Occurrence of any physical illness, recognition of new symptoms/progression of

disease or hospitalization or diagnosis of AIDS.

- Initiation of medication.
- Death of a significant other.
- Necessity of making end of life and permanency planning decisions.
- Major life changes,e.g., childbirth, pregnancy, loss of a job, end of a relationship.

6.16.2.1Tools for screening for depression

Patient Health Questionnaire-2(PHQ-2)

The PHQ-2 tool is a two-item instrument that is recommended for use as a first- approach to detection of depression symptoms at the point of enrollment into care. The purpose of the tool is not to establish a diagnosis, but to improve case-detection of depression. The PHQ-2 score ranges between 0–6 and those with a score greater than 3 should be further evaluated using the longer version, the PHQ-9 in facilities where staff have been trained to use this tool.

Table 43: Patient Health Questionnaire-2 (PHQ-2)

PATIENT HEALTH QUESTIONNAIRE-2 (PHQ-2)				
Over the last two weeks, how often have you been bothered by any of the following problems? *(Use " ✓"to indicate your answer)*				
	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

Patient Health Questionnaire-9 (PHQ-9, see Annex 12)

PHQ-9 can be used both as a screening and diagnostic instrument. It can also be used to monitor symptoms during treatment of depression. It is preferable that the PHQ-9 is used by a trained health care worker, where necessary a mental health care worker should be consulted to help management of the patients.

6.16.2.2Interactions between ARVs and antidepressants

Interactions between ARVs and antidepressants are summarized in Table 44.

Table 44: Interactions between ARVs and common antidepressants, and recommended management

ARV	Antidepressant	Interaction	Management
Ritonavir	Amitriptyline	Increased amitriptyline levels/effect	Monitor and adjust amitriptyline dose as indicated
	Fluoxetine	Increased ritonavir effects	No dose adjustment required
Efavirenz	Bupropion	Decreased bupropion effects	Monitor for signs and symptoms of depression and titrate bupropion dose to effect

ARV	Antidepressant	Interaction	Management
Lopinavir/ ritonavir	Bupropion	Decreased bupropion effects	Monitor for signs and symptoms of depression and titrate bupropion dose to effect
	Trazodone	Increased trazodone levels/effects	Use with caution; if benefits outweigh risk, start with low dose of trazodone
Darunavir	Paroxetine	Decreased paroxetine levels	Titrate paroxetine dose to effect; monitor for response
	Sertraline	Decreased sertraline effects	Titrate paroxetine dose to effect; monitor for response
	Trazodone	Increased trazodone effects	Use with caution; if benefits outweigh risk, start with low dose of trazodone

6.17 VACCINES FOR PEOPLE LIVING WITH HIV

All HIV-exposed/ infected infants and children will receive the routine vaccinations as recommended by UNEPI.

6.17.1 BCG VACCINE

All HIV-infected and exposed children should be immunized as per EPI immunization schedule. However, when considering BCG vaccination at a later age (re-vaccination for no scar or missed earlier vaccination), exclude *symptomatic* HIV infection. Children with symptomatic HIV infection should not receive BCG.See Section 4.8.2.

6.17.2 HBV VACCINE

Offer HBV vaccine to all people regardless of HIV status in endemic areas. See Section 6.10.

6.17.3 HPV VACCINE

Adolescents aged 9 to 15 years will receive the HPV according to the national recommendation (See section Section6.14.2).

6.17.4 YELLOW FEVER

Yellow fever is endemic in most of sub-Saharan Africa. Yellow fever vaccine is a live attenuated vaccine. It can be given to HIV-positive patients with CD4 count >200 cells/mm^3.Itis recommended during yellow fever outbreaks and for those intending to travel to high risk areas for yellow fever. The single vaccine gives lifetime coverage.

Box 6: Key highlights in Care and Support for people living with HIV

- PLHIV should be educated, encouraged and supported to improve their nutrition, regularly assessed and screened for malnutrition and linked to appropriate management. PLHIV should be encouraged to practice proper personal and food hygiene and ensure water safety.
- PLHIV with Advanced HIV disease (CD4<200cells/mm3 , WHO stage 3 and 4) should be screened for OIs (especially TB and Cryptococcal Meningitis) and appropriately receive prophylaxis or treatment before initiation of ART. Initiate treatment for diagnosed OIs and defer ART initiation for at least 2 weeks to decrease risk of IRIS.
- TB/HIV co-infection: If patient is already on ART, start TB treatment and modify the ART regimen appropriately. If Patient is ART naïve, start TB treatment and initiate ART 2 weeks after (earlier than 2 weeks in adult patients with CD4 <50 cells/mm3).
- ARV and/or TB regimen adjustments may be made in the treatment of TB-HIV co-infection to address drug interactions and ensure optimization of both the ART and TB medication.
- TB Preventive Therapy (TPT): All PLHIV with a negative TB screen, and children and pregnant women/adolescent girls with history of TB contact should be given TPT. Do not initiate TPT and ART concurrently.
- In children and pregnant women/adolescent girls with exposure to person with active TB: Initiate TPT immediately and delay ART initiation or ART optimization.
- In pregnant women/adolescent girls without TB exposure, defer TPT until 3 months postpartum.
- In PLHIV initiating ART or optimizing ART regimens: defer TPT until 3 months after ART initiation or ART optimization.

7 PSYCHOSOCIAL CARE AND ADHERENCE SUPPORT FOR PLHIV

7.1 INTRODUCTION

With implementation of "test and treat", the need for psychosocial care and support is more critical to enhance adherence, retention and viral suppression. This section of the guidelines highlights the key interventions to guide adherence support and provision of psychosocial care. Psychosocial care and support, including support for behavior change and treatment adherence, is an essential component of HIV prevention, care and treatment. Those who are infected often must deal with anger, fear and self-stigmatization because HIV is a highly stigmatized and life-long, chronic disease. Their partners, children, and family frequently face grief, bewilderment and high levels of stress. Psychological and social needs vary, depending on sero-status, stage of disease, prognosis and other factors. Providing psychosocial support can bring about behavioral changes in support of prevention, care, and treatment among people living with HIV, their partners and families.

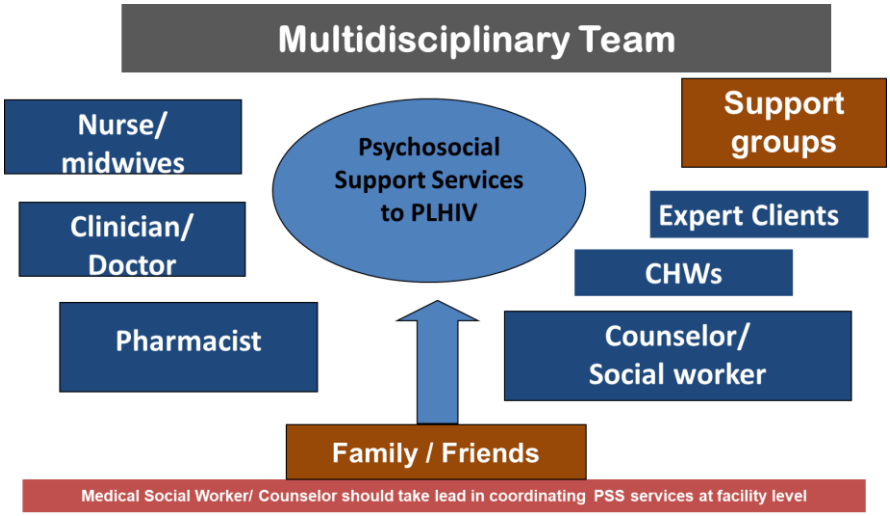
7.2 WHO SHOULD PROVIDE PSYCHOSOCIAL SUPPORT(PSS) TO PLHIV?

PSS should be provided at both facility and community levels. The medical social worker/ counsellor/nurse-counsellor shall be the PSS focal person and should take lead in coordinating PSS services both at facility and community level. The PSS focal person shall be responsible for:

1. Ensuring PSS services are well coordinated within the facility and community.
2. A strong and effective referral and linkage system is established and maintained
3. Documentation of PSS services is accurately done.
4. Ensuring routine reporting for PSS services.

PSS services should be provided by a multi-disciplinary team that interacts with the client throughout the process of care as shown in Figure 22 below.

Figure 22: Who to provide Psychosocial Support Services to PLHIV



For the facility to offer comprehensive PSS services, the health facility should ensure effective bi-directional linkages between the facility to the community and vice versa.

7.3 PSYCHOSOCIAL CARE AND SUPPORT SERVICE PACKAGE

The following package of services is recommended to ensure provision of comprehensive psychosocial care for PLHIV:

1. Psychosocial screening and assessment.
2. Health education.
3. Adherence preparation, monitoring and support.
4. Counseling and psychotherapy.
5. Mental health screening and support.
6. Positive Health Dignity and Prevention (PHDP).
7. Family /Social support.
8. Care and support for GBV Survivors.
9. Nutritional care and support.
10. Referral and Linkage:
    - Other specialized health care
    - Socio-economic support
    - Legal support and the fight against discrimination
    - Spiritual support
    - OVC services

This package should be offered in the context of clients' differences related to culture, gender, age, and the vulnerabilities of people with HIV-particularly among children, adolescents, and women.

7.4 MINIMUM STANDARDS FOR PROVIDING PSYCHOSOCIAL SUPPORT SERVICES

Table 45: Standards for Providing Psychosocial Support Services

Standard	What should be done
S1: All health facilities should provide a conducive environment both physical and social for providing psychosocial support	• Create space within the health facility to provide room for screening and provision of individual and group psychosocial support. • Ensure privacy. • Arrange the PSS service space to suit different population categories (adolescents, men, children, women). • Organize the HIV/ART care points client flow to include psychosocial support. • Ensure a safe and confidential filing, record keeping and storage system. • Provide relevant supplies and logistics for providing PSS (play materials, job aids, edutainment etc).

S2: All PSS service providers should have the competences to deliver quality PSS services	• The health facility management should ensure that:
	  ○ All PSS service providers are trained in PSS according to national standards.
	  ○ Health workers are mentored and supervised regularly to keep their skills updated.
	  ○ Health workers have the required job-aids and tools to enable them provide PSS to all categories of populations including children, adolescents, pregnant women, and key populations.
	• PSS should be provided following MOH approved standard approaches for different sub-populations
	  ○ Determine the relevant approaches for providing PSS (Individual, couple or group approach).
	  ○ Create or make referrals to peer support groups/clubs for provision of PSS.
	  ○ Integrate PSS services in all health-related plans and routine health care services.
	  ○ Offer PSS services in community settings following a targeted approach especially for priority populations.
	• Identify and support a focal person to oversee PSS service provision.

S3: All health care providers should routinely assess clients for PSS needs and provide appropriate care and support to PLHIV as an integral component of comprehensive HIV prevention, care, treatment and support	The health workers should assess clients PSS needs using standard screening and assessment tools. These include:
	  ○ PHQ-2 Depression screening tool
	  ○ GBV screening tool
	  ○ HEADSS tool
	  ○ OVC Screening tool

Standard	What should be done
S5: All Health Facilities shall use data collected to improve the quality of PSS services of HIV care services	• Document and report PSS services using MOH approved tools. Key tools include HIV Care/ART Card, ART Register, Linkage and Referral Register, Referral and Linkage form, Peer Psychosocial support Tracking Log and HMIS 106a. • Develop SOPs to guide documentation and reporting of PSS services. • Conduct periodic internal data reviews to ensure data quality. • Utilize PSS data for continuous quality improvement.
S4: All health facilities should establish and maintain an effective referral and linkage system for provision of a minimum package of PSS services for PLHIV	• Establish intra and inter facility referral and linkage systems for psychosocial issues which the provider may not have capacity to address. • Establish referral network from the facility to other community services. • Ensure availability of a service directory for different PSS services within the health facility catchment area. The directory should specify name of provider, services offered, contact person, address of provider, costs (if involved) and service time. • The PSS focal person remains the designated focal person for referrals and linkages. • Avail and mentor PSS providers on the use of approved documentation tools (Community-facility referral and linkage register and the Comprehensive HIV Referral Form). • Routinely document all facility-community and community-facility referrals and feedback in approved tools. • Establish and strengthen feedback mechanisms (phone calls, physical follow up, etc).

7.5 ADHERENCE PREPARATION, MONITORING AND SUPPORT

7.5.1 BACKGROUND

Good adherence to ART is key for sustained HIV viral suppression, reduced risk of drug resistance, improved overall health, quality of life, and survival, as well as decreased risk of HIV transmission. Conversely, poor adherence is the major cause of ART treatment failure. Adherence should be routinely assessed and reinforced by everyone in the clinical team (physicians, counselors, nurses, pharmacists, peer educators,etc.) at each of the patient's visits to the clinic. This section will cover how to prepare patients for ART, and monitor and support them to adhere to ART.

7.5.2 ADHERENCE PREPARATION

Preparing people to start antiretroviral therapy (ART) is an important step to achieving ART success. Healthcare providers should initiate a detailed discussion about the willingness and readiness of patients to initiate ART. However, the choice to accept or decline ART ultimately lies with the person or his or her caregiver. If they choose to defer initiation, ART can be offered again at subsequent visits.

Health workers should provide information on circumstances where delays in starting ART can have negative consequences, particularly for people with tuberculosis (TB), advanced immune suppression, and/or who are at high risk of death. The healthcare team should use the 5As principles for chronic care as a guide to offer pre-ART adherence counseling and psychosocial support. These are Assess, Advise, Assist, Agree and Arrange Table 46.

Table 46: 5As for adherence preparation support

Guide	Components
Assess	Goal: To assess patients' knowledge of HIV,ARVs and potential barriers to adherence • Knowledge about HIV and ARVs • Myths and misconceptions about HIV and ARVs • Potential barriers to adherence • Patient psychosocial concerns and needs that may hinder adherence to ART • Patient willingness and commitment to take medicines correctly • Patient readiness to honor subsequent appointment for treatment support • Patient's support systems at family and community level • Disclosure status and implications
Advise (information giving)	Goal: To provide the patient with knowledge about HIV/ARVs to enable themdecide to initiate treatment • Give information about HIV and ARVs • Provide information on adherence to ART. Include information on the 5 Rs (taking the right medicine, at the right time, right dose, right way, and right frequency) • Demonstrate how the ARVs are taken • Provide information about side effects of ARVs, improved quality of life while on ART, changes that may occur in a person's life once on treatment • Explain the benefits of disclosure and support systems to adherence • Explain to the patient how often they will be monitored once on treatment; other ways of assessing adherence and response to treatment including pill counts

Guide	Components
	• Emphasize the importance of attending all the clinic appointments for review and support • Discuss the Positive Health, Dignity, and Prevention package • Explain the implication of not adhering to ARV treatment • Explain what VL test is and the meaning of suppressed and unsuppressed viral load
Assist	Goal: To support client identify possible barriers and consider different options of dealing with the barriers. The client: • Evaluates the possible barriers to adherence and how to overcome them • Identifies the support systems that will enable the client to take his drugs and to regularly come to the facility such as treatment supporter, social support groups • Consider disclosing to a trusted person of their choice such as a treatment supporter, social support group, etc.
Agree on	Goal: To guide the client to develop a realistic individual adherence plan. The client considers and where possible documents: • An adherence plan (Table 47) • Family and community support systems (expert client in the community) • Possibility of home visit and consent • Possibility of testing other family members including sexual partner and children • Assess client's readiness to start ART (see Table 48: ART readiness assessment form)

Arrange for	• The patient to see a clinician for ARV prescription if they are ready to start ART
	• Follow-up adherence counseling and psychosocial support sessions
	  ○ At one month for patients who have initiated ART
	  ○ At agreed time but probably a week for those who were not ready for ART at theinitial visit
	• The patient to join psychosocial support groups and use support systems
	• Follow-up appointments (home visiting where appropriate, phone call reminders and text messages where appropriate)
	• Monthly counseling sessions for drug adherence.
	• Reviewing the action plans at every encounter
	• When to bring other family members for testing
	• Supported disclosure where it has not happened

Table 47: Checklist for developing an adherence plan

Question
1. How many pills of the medicine will you take/give per day? (client demonstrates as you observe)
2. What time will you take/give the medicine?
3. How will you remember to take/give the medicine?
4. Where will you keep the medicine?
5. What will motivate you to take/give the medicine?
6. Whom have you disclosed to/plan to disclose to?
7. Who is your or your child's treatment buddy?

Question
8. Who will pick your/your child's medicine if you cannot come to the clinic?
9. How will you ensure you keep your appointments as scheduled?
10. What challenges/factors may affect your adherence? (Explore for non-disclosure, alcohol and substance abuse, sexual partner(s), and stigma)

Table 48: ART readiness assessment checklist

A. Psychosocial/knowledge criteria (applies to patients and caregivers)	Yes	No
1. Understands how HIV affects the body and benefits of ART?		
2. Has screened negative for alcohol or other drug use disorder?		
3. Is willing to disclose/has disclosed HIV status to a sexual partner and significant other?		
4. Has received demonstration of how to take/administer ART and other prescribed medication?		
5. Has received information on predictable side effects of ART and understands what steps to take in case of these side effects?		
6. For patients dependent on a caregiver: caregiver is committed to long-term support of the patient, daily administration of ART, and meets the criteria above?		
7. 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.)?		
8. Patient/caregiver has provided address and contact details?		
9. Patient/caregiver feels ready to start ART today?		
10. Has identified convenient time/s of the day for taking ART?		
11. Has treatment supporter been identified and engaged in HIV education, or will attend next counseling session?		
12. Is aware of the support group meeting time/s?		
13. Has enrolled into SMS reminder system? (If facility has reminder system)		
14. Are other support systems in place or planned (e.g. setting phone alarm, pill box)?		
15. Patient newly diagnosed with TB: *Start TB treatment* *Defer ART until 2 weeks after starting TB treatment*		
16. Patient diagnosed with cryptococcal meningitis or has symptoms consistent with cryptococcal meningitis *(headache, the presence of seizures, altered consciousness, photophobia, neck stiffness, and a positive Kernig's sign):* *Treat cryptococcal meningitis* *Defer ART until 4-6 weeks after initiating treatment for cryptococcal meningitis*		

7.6 MONITORING ADHERENCE TO ART

Adherence to ART requires life-long assessment and monitoring and should be part of each clinic visit, as factors that influence adherence are dynamic and require different approaches to address them as they change over time. A combination of methods to assess adherence is recommended as below.

7.6.1 Viral Load Monitoring

Viral load monitoring is considered the gold standard for monitoring adherence and confirming treatment response. All HIV-infected patients should receive a viral load test 6 months after initiating treatment and annually thereafter. Following an initial high viral load (>1000 copies/mL), enhanced/intensive adherence counseling should be carried out before conducting a second viral load test.

7.6.2 Self-Reporting

Self-reportingisrapid, inexpensive, easily carried out in clinical settings and is frequently used in routine care. It involves asking questions regarding missed doses to establish adherence. It is essential that these questions be posed in as non-threatening and sensitive a way as possible. All patients, especially adolescents should be encouraged to speak openly,and they should be reassured that many people find it difficult to take all their medications. When using self-report, use the four guide questions to determine adherence and reasons for not adhering to ART (Table 49).

Table 49: Question guide for reviewing an adherence plan

Question
1. How many times do you take drugs in a day?
2. What time do you take it?
3. How many doses have you missed in the past month?
4. What are the reasons for missing your drugs?

- Use the number of missed ARV doses in the past month to determine adherence level and appropriate action (Table 50).

7.6.3 Pill Counting

This approach compares the actual to the expected consumption of ART since last dispensed by the pharmacy. The effectiveness of pill counting is limited by the fact that patients may discard tablets not taken before their routine clinic visit leading to overestimated adherence. Pill count performs better when combined with self-reported adherence.

Using pill counts to determine adherence levels

- Count the number of pills the patient has in the medicines bottle.
- Determine the number of pills the patient should have taken since the last clinic visit.
- Compute the percent adherence using the formula below:

$$\%\ \text{adherence} = \left(\frac{Number\ of\ pills\ taken}{Total\ number\ of\ pills\ expected\ to\ have\ been\ taken}\right) * 100\%$$

After computing % adherence, use Table 50 to determine the adherence level and support the client accordingly.

Table 50: Determining adherence levels from self-report and pill count and recommended action

Missed doses per months		Percent adherence	Adherence ranking	Recommended Action
Oncedaily dosing	Twice daily dosing			
<2 doses	≤ 2 doses	**≥95%**	Good	• Review adherence plan • Support to continue adhering well.
2-4 doses	4-8 doses	85–94%	Average	• Address the causes of average/poor adherence • Review adherence plan
≥5 doses	≥9 doses	<85%	Poor	
Note: Adherence >105% could imply potential drug sharing or other inconsistencies in dosing and should be investigated.				

7.6.4 Pharmacy Refill/Clinic Records

Adherence can also be assessed by viewing the patient's clinic and pharmacy records. Such records document if and when a patient or caregiver collected their ARVs; irregular collection may indicate adherence challenges. Additionally, computerized pharmacy records assist health managers to assess the overall adherence. Pharmacy records are more reliable than self-reporting if documentation is accurate.

7.7 ADHERENCE SUPPORT

Adherence support interventions should be provided to people on ART. The following interventions have demonstrated benefit in improving adherence and viral suppression:

- *Adherence counseling:* This is a one on one interaction between the client and health care provider aimed at helping the client identify barriers related to their adherence and develop strategies to overcome the identified barriers.
- *Peer support system:* This enables clients to learn from each other's experiences and to cope better with the disease. A peer is a person who shares similar characteristics with a particular group of people. In HIV care, peers include mentor mothers in the eMTCT program, adolescent peer supporters (YAPS), expert clients and other peers as patients and caregivers usually relate better to peers. Peer support can be provided either in form of peer counseling or peer support groups.
- *Mobile phone calls and text messages:* These should be used with the patient's or caregiver's consent. The patient or caregiver should provide the appropriate phone numbers to avoid accidental disclosure when messages are sent to a wrong person.
- *Reminder devices* like calendars, pill boxes, cell phone alarmsand diaries can be used by clients.
- *Behavioral skills training and medication adherence training*: These include module-based interventions and those designed to improve life skills, attitudes, behavior and knowledge.
- *Fixed-dose combinations and once-daily regimens:* When available, health-care workers should prescribe fixed dose combinations because they reduce the pill burden. If once daily regimens are available and recommended, they should be used.
- *Use of treatment buddies(supporters):* This is an individual identified by the client to take on the role of a treatment supporter. This person reminds/gives the client their medication whenever it is time and reminds them of their refill dates.

- *Peer-led dialogues:* These include group discussions among clients. They could discuss the challenges they face and come up with possible solutions.

7.8 INTENSIVE ADHERENCE COUNSELING AND SUPPORT FOR PATIENTS WITH DETECTABLE VIRAL LOAD.

7.8.1 Introduction

Intensive Adherence Counseling (IAC) and support refers to a *targeted and structured* counseling and support intervention offered to patients on ART with a non-suppressed viral load (patients with viral load >1000 copies/ml). IAC is offered systematically and routinely as per scheduled appointments; one month apart. IAC helps a client develop a comprehensive plan for adhering to ARVs by identifying their barriers to adherence, gaining insight of the barriers, exploring possible ways to overcome barriers and planning to adhere to medicine. Provision of IAC requires a multidisciplinary team including clinicians, nurses, counselors, family members, peers, etc. It may also require consultations from experts or referrals to address the issues related to stigma, disclosure, mental health and nutrition.

7.8.2 How to offer IAC

The 5As counseling framework applies to provision of intensive adherence counseling and psychosocial support. Key messages at every step are summarized below in Table 51 below.

Table 51: 5As for adherence support for people with non-suppressed viral load

Guide	Components
IAC Session 1	

Assess	• Explain purpose of session
	  ○ Disclose VL test results to client and explain the meaning of suppressed and non-suppressed VL
	  ○ Explain reasons for non-suppressed VL results (non-adherence to drugs or drugs may not be working well)
	  ○ Discuss implications of non-suppressed results to the client
	• Determine adherence levels
	  ○ Calculate the adherence score using the adherence percentage formula
	• Assess client's barriers to adherence
	  ○ Use the adherence assessment checklist to ascertain client's adherence practices.
	  ○ Identify barriers to client's adherence (arising from the assessment)

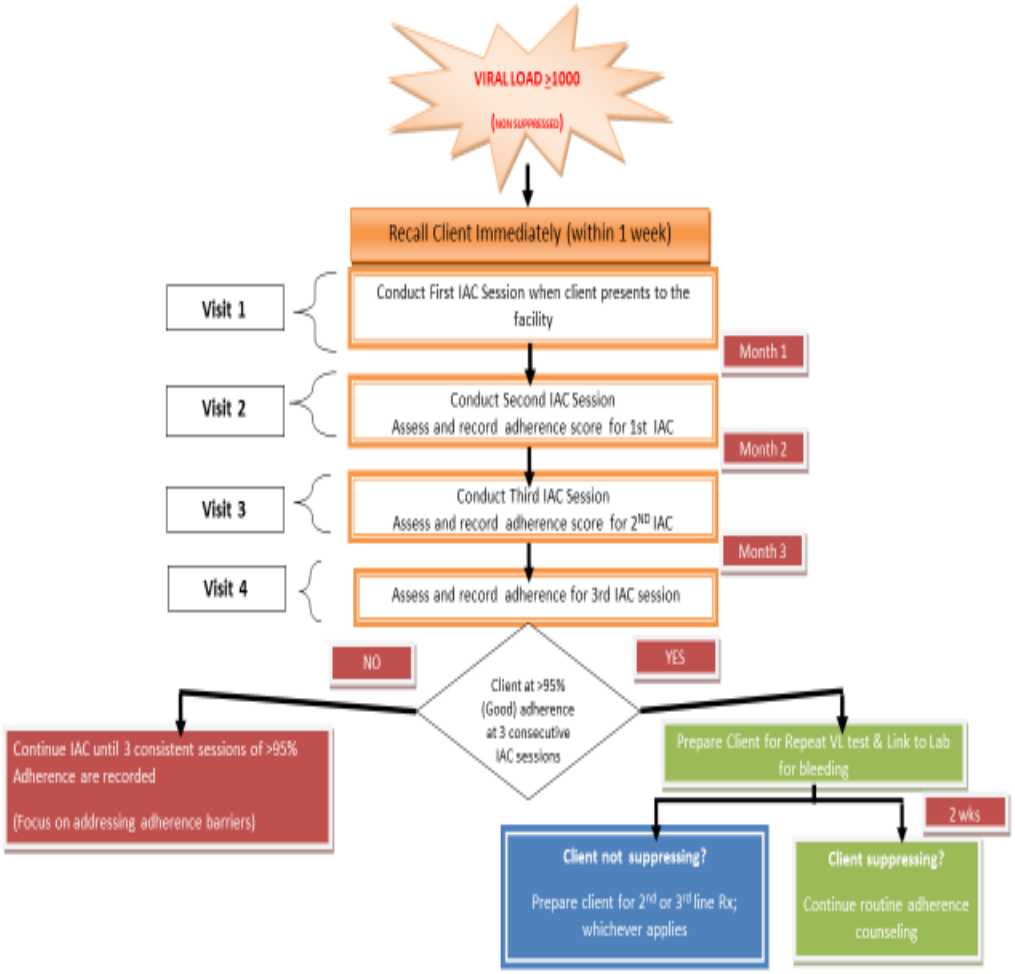
Advise	• Identify information gaps from assessment
	  ○ Educate client in relation to specific barriers identified
	• Review benefits of good adherence
	  ○ Assess client's knowledge of benefits
	  ○ Provide correct and complete information on
	• Discuss consequences of non-adherence
	  ○ Assess client's knowledge on the dangers of non-adherence
	  ○ Educate client on the consequences of non-adherence

Assist	• Evaluate the underlying causes of the identified barriers
	  • Prioritize the barriers
	  • Identify possible root causes of each barrier (where applicable)
	• Identify client specific strategies to overcome identified barriers

Guide	Components
	• Discuss possible options to address key barriers • Provide information about available support systems e.g. CBOs, peer support groups etc • Discuss the pros and cons of each strategy/option
Agree on	• Agree on client's action points to address the key barriers o Identify appropriate strategies o Provide relevant and necessary information • Evaluate each action point using the 5 Ws and 1H o What, where, when, who, which, how? • Document agreed upon action points on the IAC session form • Develop and document a new adherence plan on the IAC session form
Arrange	• Summarize the session • Review the action points • Review the new adherence plan • Arrange for ART refill • Explain the schedule for IAC intervention • Explain the number of sessions • Emphasize appointment keeping • Schedule the 2nd IAC session • Document the next appointment date on the IAC session form • Remind client to bring remaining pills at next visit • Refer and link to other services as appropriate
IAC Session 2	
Assess	Assess adherence levels • Document the adherence score • Compare current score with the previous Assess progress in dealing with barriers • Identify what worked • Identify what did not work • Discuss new strategies Assess compliance to adherence plan • Identify what worked • Identify what did not work • Discuss new strategies Assess for possible new barriers to adherence • Use adherence assessment checklist
Advise	Do as in IAC Session 1
Assist	Do as in IAC Session 1
Agree on	Do as in IAC Session 1
Arrange	Do as in IAC Session 1
IAC Session 3	
Assess	Do as in IAC Session 2
Advise	Do as in IAC Session 1
Assist	Do as in IAC Session 1

Guide	Components
Agree on	Do as in IAC Session 1
Arrange	Review adherence scores for 1st, 2nd and current IAC visits • If adherence score is consistently good (>95%) for three consecutive IAC visits, give 1month appointment for 2nd VL bleeding • If adherence score is not consistently good for three consecutive IAC sessions, give appointment for 4th IAC session Give appointment for 2nd bleeding for VL test (After 1 month) • Remind and emphasize to client to keep the next appointment. • Flag the client's file as due for repeat VL testing (indicate due date on the red sticker) Discuss reminder plans with clients who are due for bleeding • Provide ARV drugs for 1 month (strictly) • Call client 1 week to the due date to remind them of appointment

Figure 23: Flow-chart for offering IAC to non-suppressed Adult PLHIV



7.8.3 Providing Intensive Adherence Counseling and Support to non-suppressed children and adolescents

Due to the high levels of pre-treatment NNRTI resistance in Uganda (see Section 8.6.3.4), these guidelines recommend optimization of ART for children (Chapter 8). Children and adolescents whose viral load are not suppressed should receive IAC following the recommendations below:

- All children and adolescents on NNRTI-based regimens with a non-suppressed viral load:
    - Switch immediately to second line ART without waiting for a repeat viral load result.
    - IAC should be initiated immediately and provided monthly.
    - IAC should be continued until child/adolescents stabilizes on their new regimen for a maximum of 6 months.
    - Resume routine adherence support aligned to clinic appointments.
- Children and adolescents on DTG or PI-based regimens: DTG and PIs have a high barrier to resistance, so poor adherence is a more likely cause for an unsuppressed VL than resistance. Therefore, for children and adolescents on DTG or LPV/r-based first line regimens with non-suppressed VL:
    - Conduct IAC and repeat VL after 3 months.
    - If VL is still not suppressed after IAC interventions, switch to 2nd line ART.

7.9 POSITIVE HEALTH, DIGNITY AND PREVENTION (PHDP)

Positive health, dignity, and prevention (PHDP); also referred to as self-care, is a set of interventions PLHIV can undertake to keep physically, mentally and psychologically healthy and as well as prevent transmission of HIV. PHDP empowers PLHIV to take charge of their prevention, care and treatment responsibilities.

Table 52: Positive health, dignity, and prevention intervention

Intervention	Description
Preventing HIV transmission	PLHIV should be encouraged to adopt safer sexual practices including abstinence, correct and consistent condom use. Condom use prevents HIV transmission, reduces risk of other STIs, and prevents unintended pregnancies.
Disclosure and partner testing	PLHIV should actively explore ways of disclosing their HIV status to sexual partners, family members and significant others. Offer provider- and/or counselor-mediated or supported disclosure as options for those who do not feel comfortable disclosing on their own.
Family planning	Encourage PLHIV to discuss their reproductive choices and support them to adopt those which do not compromise their health. For women who choose to conceive, link them to eMTCT services.
Alcohol and other risk reduction	Educate on risks of alcohol abuse leading to poor treatment adherence resulting in disease progression, and the likelihood of engaging in risky sexual behaviours, placing themselves at increased risk for acquiring STIs and placing their negative partners at risk for infection.

7.10 OVC CARE AND SUPPORT

Programming for children orphaned and made vulnerable by HIV/AIDS contributes to the achievement of an AIDS-free generation by responding to the social, economic and emotional consequences of the disease on children, their families, and communities that support them.

Health workers therefore should screen all children and adolescents for vulnerability and appropriately link them to OVC services within the facility's catchment area.

A standardized screening tool for vulnerability within health facilities is provided in Table 53 below.

Table 53: OVC Vulnerability screening tool

No	Question	Y	N
1.	Is child/adolescent enrolled in an OVC Program?		
2.	Has child/ adolescent had less than two meals on any day in the last seven days?		
3.	If school-going, has child/adolescent missed school in the last 7 days?		
4.	Does child/adolescent have a non-suppressing Viral load?		
5.	Has child/adolescent missed appointment in the last 3 months?		
6.	Does child/adolescent have signs of abuse, exploitation and neglect?		
Action: If the response is 'Y' to any of the questions, link to OVC Program for an assessment using a Triplicate referral form and document appropriately			

7.11 DELIVERING HIV SERVICES FOR ADOLESCENTS

7.11.1 INTRODUCTION

An adolescent is a person aged 10–19 years. Adolescence is a period characterized by rapid physical, emotional, cognitive, and social changes. During this period, adolescents are at risk of poor health outcomes and acquisition of new HIV infections. Therefore, to improve access to HIV prevention, care and treatment services and improve their health outcomes, health care providers need to provide adolescent-friendly health services (AFHS). The WHO minimum standards for adolescent health service delivery and Uganda's minimum health care package consider health services adolescent friendly/responsive if they meet the minimum service standards i.e. Provide aadolescent literacy (information and education); engage community support (e.g. care giver involvement, linkages to community services); offer an appropriate service package; ensure provider competencies; offer favorable facility characteristics (space, flexible hours, separate clinics, privacy, attractiveness, branding); ensure equity and non-discrimination; monitor and ensure adolescent participation (peer-led). Adolescent responsive services should also be accessible, acceptable, appropriate, equitable and effective. Health facilities providing HIV/ART services should therefore ensure that services are provided within this framework to target adolescents as indicated in Table 54 below.

Table 54: Adolescent Friendly HIV Services

Guidance
1. Service delivery: The services offered should be adolescent-friendly so that they can meet the needs of this age group.
Adolescent Literacy: Adolescents should be provided with accurate and comprehensive information about HIV to help them protect themselves from HIV infection. Such information should include the meaning of HIV and AIDS, how HIV is transmitted and how HIV is prevented. Adolescents living with HIV should be disclosed to about their HIV status and given information about their treatment. Key information should include: the basic care package, meaning of ART, TPT, benefits of ART, importance of ART, side-effects of ARVs and basic clinic routines. Provide educational/information materials in the

Guidance

form of posters and brochures in a language best understood by the adolescents. Share available hotlines where the adolescents can access information or counseling off-site.

Community Engagement: The support of caregivers is important for positive outcomes for adolescents. Adolescents accessing HTS by themselves and testing HIV positive should be encouraged and supported to disclose to their parents or caregivers. Caregivers support adolescents to adhere to their medication, remind them about clinic appointments, provide life necessities and provide psychosocial support. In addition, vulnerable adolescents should be linked to other non-health community services to ensure comprehensive service provision and promote adherence as well as retention in care.

Adolescent service package in HIV settings: Health facilities should provide a comprehensive service package for adolescents to minimize missed opportunities. The recommended service package in HIV settings includes: Information and counseling on health especially growth and development; reproductive health issues; life skills education; GBV/VAC services; mental health screening and management; counseling on alcohol and substance abuse; pregnancy testing; nutrition services; HIV testing; ART/TB services; referral and follow up; sexual reproductive health services e.g. antenatal care, safe deliveries, post-natal care, STI prevention, screening and treatment; modern contraceptive methods and recreation facilities. Delivery of these services will follow a differentiated approach as described in Chapter 10.

Provider competencies:

- Health workers providing adolescent services need to be trained in adolescent health and HIV management using nationally approved training curricula. These should constitute a multi-disciplinary team including clinicians, counselors, nurses, and peer leaders.
- A designated health worker should be assigned to serve as an adolescent focal person.
- Use of job aids developed for adolescent service delivery during service provision.

Favorable facility characteristics:

- The facility should identify a convenient, comfortable, private, and accessible place/area with a separate waiting area to offer adolescent services.
- There should be branding right from the facility sign-post to show that the facility offers AFHS. Signs indicating the location of the adolescent space should be visible to guide the adolescents without the need for them to ask for directions.
- Where space is a problem, conduct separate adolescent clinic days using the available space.
- The dedicated adolescent space should be attractive to encourage them to keep clinic appointments e.g. provide play materials, initiate activities that keep them busy (drama, sporting, etc).
- Have flexible clinic hours that take care of both in-school and out-of-school adolescents including running clinics until late (after 5 pm) and/ or over weekends.

Equity and non-discrimination:

- HIV services should be made available to all adolescents irrespective of ethnicity, tribe, age, sex, or sexual orientation.
- Offer free or affordable services to adolescents.
- Offer services in line with the standard minimum care package for adolescents.
- Link adolescents to other services not provided by the facility to ensure comprehensive service delivery
- HIV services should be provided following a differentiated approach. Adolescents are a heterogenous group and therefore services should be tailored to the needs of various categories. For instance, health facilities should implement adolescent responsive MCH services for pregnant and breastfeeding adolescent girls e.g enrolment into Group ANC/PNC.

Guidance
Monitoring and Evaluation of Adolescent HIV services: • Adolescents' treatment outcomes across the clinical cascade should be monitored through routine data collection and reporting of the HIV indicators. These should be part of the facility report submitted routinely through the national reporting system. • Track and follow-up adolescents using the standard loss to follow-up protocols and tools *Adolescent participation (Peer-led):* Participation of adolescents in their care is an effective approach in delivering adolescent health services. Facilities should identify, train, and use peers to support the provision of services across the clinical cascade using the standardized national peer support guidelines. Activities implemented by adolescent peer supporters should be monitoring to ascertain their contribution to the clinical cascade. • **Note:** As much as possible, adolescent health/HIV services should be integrated into the already existing health service delivery systems making it 'a one-stop shopping center'.
2. HIV testing services (HTS): Access and uptake of HTS among adolescents is low partly due to their poor health seeking behavior as well as the absence of an enabling environment. HTS is an entry point to HIV prevention, care, and treatment services
HTS with linkage to prevention, treatment and care is recommended for all adolescents with a focus on those from key populations. Informed consent and HIV testing. Adolescents aged 12 years and above can consent on their own for HTS without the approval of their parent/guardian. Strategies for improving uptake of HTS among adolescents: • Use a peer-led approach where adolescent peers are trained to provide pre and post-test counseling as well as performing HIV tests. • Offer services at the convenience of adolescents through flexible working hours, walk-in services for those without an appointment, weekend or same-day appointments. • Offer services in a place that ensures privacy and confidentiality. • Provide age-appropriate information such as benefits of knowing one's HIV status. Generating demand for HTS Consider where the adolescents live (rural or urban). A wide range of approaches can be used including: • Peer-to-peer engagement. • Multimedia campaigns including TV, radio, billboards and brochures. • Social media: Facebook, Twitter, WhatsApp, Instagram, etc. • Phone technology: SMS messages with a platform that allows self-assessment for risk and determining whether to test. • Performing artists and celebrities. • Sports gala. • Music and drama festivals. • School extracurricular activities/clubs. • Community events such as promotions, meetings, bazaars.. • Health education. Providing opportunities for HIV testing. HTS services should be offered using facility or community service delivery approach as integrated or stand-alone services. For the facility approach, create HIV testing opportunities within existing service points where adolescents routinely receive care including: • OPD/YCC, ANC, maternity, family planning and sexual and reproductive health service delivery points.

Guidance
• Youth/adolescent information centers/corners. • Community-based/mobile outreach testing sites targeting key populations • examples include moonlight testing for out of school adolescents, bars, and brothels).
3. Prevention services for adolescents: Provide adolescent friendly risk-reduction interventions to prevent HIV, teenage pregnancy, and other STIs.
• Assess the sexual behavior of the adolescent. • Provide HTS to sexually active adolescents (test every three months for on-going risk, and once a year if exposed after last HTS). Messages should focus on avoiding cross generation sex, multiple partners, transactional sex and promote abstinence and delayed sexual activity. • Encourage condom use for those sexually active. • Screen for STIs and treat as appropriate. • Identify and link adolescents to other available services at the facility as appropriate (VMMC, ART). • Offer voluntary contraception options. • Assess for gender-based violence (GBV) and refer as appropriate. • Identify, refer and link adolescents to other available community programs.
4. Linkage to care and treatment.
A peer-led approach should be used to link adolescents living with HIV (ALHIV) into care and treatment services preferably on the same day. • Use community-based structures such as village health teams, and community health extension workers to complement peer leaders • Ensure complete linkage through establishing a feedback mechanism.
5. HIV care and treatment for adolescents
ART delivery for adolescents will mainly be facility-based using any of the three delivery approaches recommended for the facility-based model: • Fast-track drug pickup approach for stable clients picking their drugs quarterly. • Comprehensive clinical evaluation for all. • Facility-based treatment clubs/healthcare managed groups for drug refills within their groups/clubs, adherence support, peer support and psychosocial support.
6. Psychosocial support for adolescents.
All HIV positive adolescents should receive psychosocial assessment and support as part of their routine care. The assessment should be done using the Home, Education/ Eating/ Employment, Activity, Drugs, Sex, and Sexuality, Suicidal ideation/mental health (HEADSS) tool at each clinical visit (Annex 10). In addition, they should be assessed for adherence, mental health problems; social vulnerabilities and violence using standard national tools. Adolescents should be supported to deal with common psychosocial problems including disclosure of HIV status; stigma and discrimination; adherence, loss and bereavement as well as socio-economic challenges. All these singly or in combination affect the quality of treatment outcomes.
<u>Benefits of psychosocial wellbeing include:</u> • Improved adherence to medicines and access to essential services. • Reduced psychological distress. • Increased likelihood of appropriate disclosure to others. • Better engagement in HIV-related care. • A better understanding of HIV and related conditions. • Improved uptake of Positive Health Dignity and Prevention (PHDP) services.
7. Retention: Adolescents living with HIV may need additional support to remain engaged in care. Retention in ART care is critical for continued adherence to ART, monitoring for drug toxicity/resistance and successful viral suppression.

Guidance
• Offer adolescent-friendly services. • Form and use peer support groups. • Conduct special programs for adolescents including life skills training. • Regularly update contact information especially physical address and telephone contacts, use appointment calendars and send messages (SMS reminders for appointments). • Conduct activities such as games and sports, music, drama, etc. • Identify, refer and link adolescents to other available community programs. • Consider providing ART within community settings.
8. Transition: Purposeful and planned transition to adult-oriented services is an important factor in the long-term well-being of an adolescent.
The transition should depend on the service delivery approach at each health facility. Transitioning should consider the neurocognitive condition of the adolescent. In settings where there is an integrated clinic providing services for children, adolescents, and adults at the same facility the process should follow the steps below: • Identify and develop a transition team at the adolescent clinic. The team should include: a clinician, counselor, peer supporter, caregiver and adolescent. • Develop a transition plan when the adolescent turns 18 years or at the first encounter if older than that. • Update the transition plan and assess the adolescent's readiness at each clinical encounter over at least a two-year period. • Once the young adult is 20 years and older and is ready to transition, give them an appointment for the adult clinic. • On the same day that they express readiness to transition introduce the adolescent to the adult care team (who may be the same staff). However, for health facilities with a separate adolescent clinic from the adult one they should also: • Invite the adult transition team to meet at the adolescent clinic, the young person who is ready to transition and agree on an appointment date (if feasible). • Introduce the adult treatment team to the adolescent at the agreed appointment and hand them over.

7.12 RETENTION IN CARE

For the test and treat guideline implementation to contribute to the achievement of the 90-90-90 targets, patients must be retained in HIV care. Uganda will implement strategies to strengthen retention of patients in care and treatment. Some of these strategies are drawn from the lessons learned from the implementation of Option B+ guidelines and test and treat for HIV-infected children. During the implementation of Option B+ and the test and treat for HIV-infected children one-year retention rates were 60% and 75%, respectively. To mitigate such losses of patients from care during the test and start implementations the country will implement the strategies outlined in Table 55 below.

Table 55: Strategies for Improving Retention in Care

Strategy	Rationale
1. Decentralization of ART care and laboratory services	Decentralization improves retention by: • Taking services closer to the target population, lowering transport costs

Strategy	Rationale
• MOH and district health teams will work to decentralize ART services to all HCIIIs and eligible HCIIs. • Laboratory services will be decentralized to the appropriate health services. • Where specific labs services are not available, health facilities will be supported to access the services through the current transport hub and sample referral system.	for patients, and thereby increasing the likelihood that they stay in care. • Improving access to all HIV services. • Reducing patient burden at higher level facilities and may reduce waiting time at those facilities.
2. Implementing differentiated service delivery models • Health care workers will be trained and supported to implement DSD models starting at high volume sites. • For more details of the models refer to the DSD implementation manual.	• DSD will reduce frequency of clinic visits by dispensing medication for longer periods • Community models will take services closer to the clients and reduce transport costs for patients • Health worker time will be freed, and they can give sufficient time to the patients who require more care and time
3. Institute/strengthen comprehensive patient appointment and tracking systems. Will include: • Use of appointment books • SMS reminders and phone calls • Home visits • Partnerships with community-based service providers to support community follow-up, and patient tracking • Early retention and birth cohort control monitoring • All these strategies should be implemented through CQI initiatives	• Patients who miss appointments will be identified easily and will be followed-up and brought back into care if found.
4. Strengthening client counseling and education services at the health facilities • Health workers, counselors, VHTs, CHEWs, expert clients, peer mothers and lay testers will be trained to provide standardized patient counseling services including adherence and psychosocial support. • Patients will be initiated on treatment when they have been prepared and are ready to start ART.	When patients are educated and counseled well, they are empowered to support their care and are more likely to stay in care.
5. Implement evidenced based communication strategy The country will use a communication strategy that will address individual, interpersonal, organization, community and society barriers to retention in care.	Improving patient education and addressing barriers will improve health seeking behaviours.

Box 7: Key highlights in Psychosocial Care and Adherence Support for PLHIV

- Psychosocial care and support are an essential component of HIV prevention, care and treatment as it addresses fear, stigma and impacts on behavior change, access to services, adherence to medication and retention in care.
- Poor adherence is the major cause of ART treatment failure. Adherence to ART is therefore critical to viral load suppression, reduced risk of drug resistance development and improved treatment outcomes. Adherence should be routinely assessed and continuously reinforced. Intensive Adherence Counseling and support (IAC) is a targeted and structured counseling and support intervention and should be offered to patients on ART with a non-suppressed viral load (patients with viral load >1000 copies/ml).
- It is important to establish referral and linkage systems within facilities and in the communities for increased access and retention along the continuum of care.
- Establishing adolescent friendly service delivery in order to create demand and increase access to services among this population. Implementation of innovative approaches including peer-led approaches, social media, mobile phones technology, flexible clinic hours, dedicated spaces and community/school activities in prevention, care and treatment services are recommended.

8 ANTIRETROVIRAL THERAPY FOR PEOPLE LIVING WITH HIV

8.1 THE GOAL OF ART

The aim of antiretroviral therapy is to suppress viral load levels amongst PLHIV to undetectable levels, reduce the risk of morbidity and mortality associated with HIV, and reduce transmission of HIV.

8.2 COMPOSITION OF ART

Standard ART consists of a combination of at least 3 antiretroviral (ARV)drugs to maximally suppress the HIV and stop the prevention of HIV disease. ART regimens usually comprise a "Backbone" of 2 Nucleoside Reverse Transcriptase Inhibitors (NRTIs) and a 3rd "Anchor" ARV from another class (including Integrase Strand Transfer Inhibitors, Protease Inhibitors, Non-Nucleoside Reverse Transcriptase Inhibitors).

8.3 WHEN TO START ART

ART should be initiated at the earliest opportunity in all people with confirmed HIV infection, regardless of clinical stage or CD4 cell count.

Rationale for treating all people living with HIV

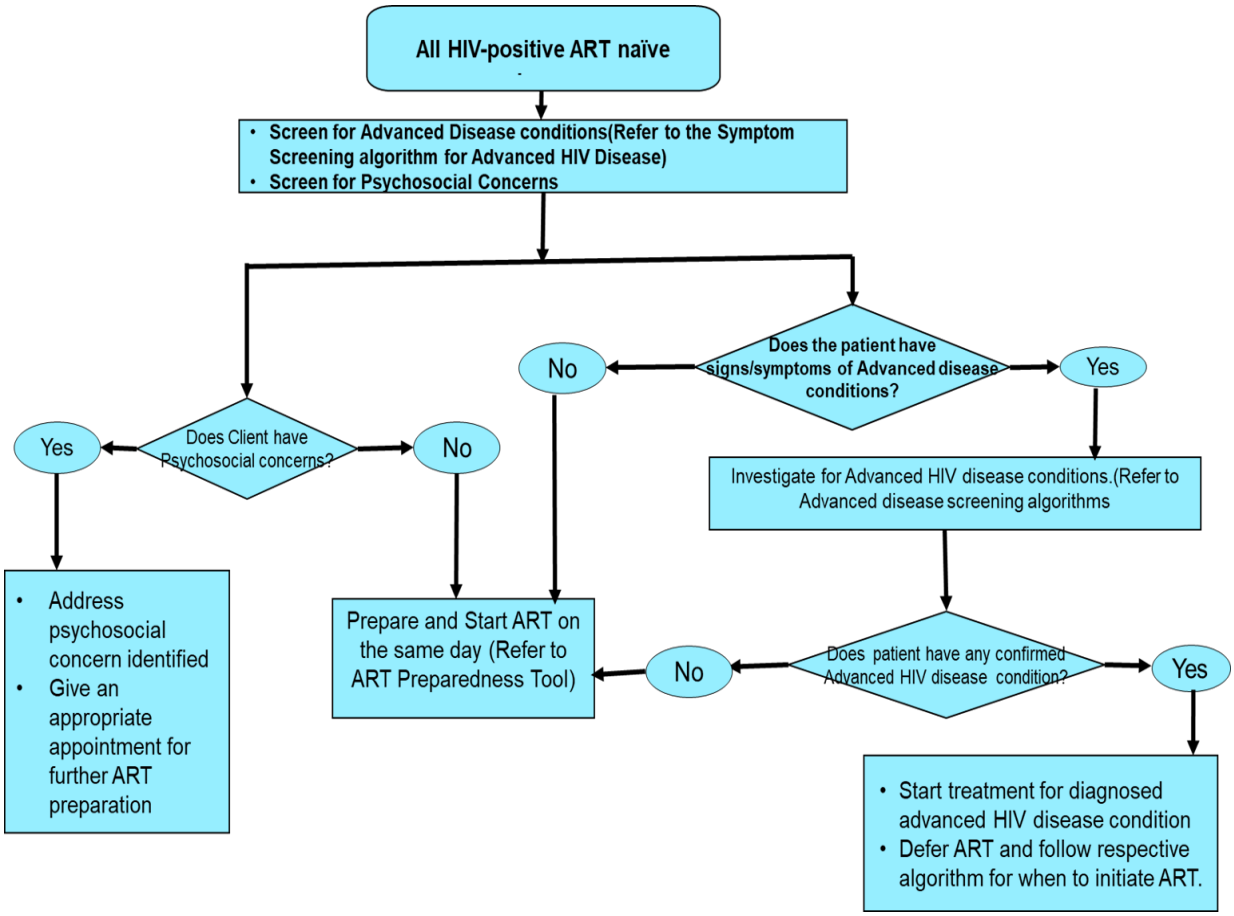
Since 2013, evidence and programmatic experience have continued to favour early initiation of ART because it results in reduced mortality, morbidity, and HIV transmission outcomes**.**

8.4 THE PROCESS OF STARTING ART

Although the program recommends starting all PLHIV on ART, health workers should do the following:

- Assess all clients with the Symptom Screen for Advanced Disease Pathway (Figure 14) any evidence of opportunistic infections (OIs) especially TB and cryptococcal meningitis. If the patient has TB or cryptococcal meningitis, ART should be deferred and initiated after starting treatment for these OIs as outlined in Chapter 6: Sections 6.5.1.3, 6.7 and 6.8). Treatment for other OIs and ART can be initiated concurrently.
- For patients without TB or cryptococcal meningitis, offer ART on the same day through an opt-out approach. In this approach, patients should be prepared for ART on the same day according to the guidelines in Section 7.5.2and assessed for readiness to start ART using the readiness checklist (Table 48).
- If a client is ready, ART should be initiated on the same day. If a client is not ready or opts out of same-day initiation, a timely ART preparation plan should be agreed upon with the aim of initiating ART within seven days for children and pregnant women, and within one month for adults. See Figure 24 for the process of evaluating patients for ART.

Figure 24: How to evaluate patients for ART initiation



8.5 FIRST-LINE ART REGIMENS FOR PATIENTS INITIATING ART

Principles for selecting the ARV regimens (treatment optimization):

The first-line ART regimens for treating HIV infection in Uganda were selected based on the universal principles:

- Toxicity: regimens with less toxicity are preferred.
- Palatability and pill burden; better palatability and lower pill burden preferred.
- Increased durability and efficacy.
- Sequencing: spares other available formulations for use in the 2nd line regimen.
- Harmonization of regimen across age and population.
- Lower cost.

DOLUTEGRAVIR (DTG) is an integrase inhibitor and is recommended for use as the anchor ARV in the preferred first and second-line treatment regimens for all HIV infected clients; children, adolescents, men, women (including pregnant women, breastfeeding women, adolescent girls and women of child bearing potential).

8.5.1 RATIONALE FOR USING DOLUTEGRAVIR (DTG)

a. High Circulating levels of resistance to NNRTI-containing First-line Therapy

NNRTI-containing combinations have been used as first-line regimens for adults in Uganda since the start of ART services in 2005. However, there are growing concerns of increasing levels of transmitted drug resistance, mostly to NNRTIs, in Uganda and

elsewhere. A recent study by the Uganda National Antiretroviral Drug Resistance Committee conducted in Uganda revealed high levels of pre-treatment drug resistance (PDR) estimated at 15.9% to NNRTIs, exceeding the threshold of 10.0% set by WHO for first line ARVs.

b. Superior Efficacy over Current Standard of Care Regimens

DTG is superior to alternative ARV options and patients can experience rapid viral suppression, thereby reducing risk of transmitting HIV while prolonging time on first-line treatment. It has been shown that patients who receive DTG achieve viral suppression faster as compared to those who receive EFV.

c. Better Tolerability

DTG shows improved tolerability versus current preferred regimens with substantial reductions in treatment-limiting adverse drug reactions. Specifically, patients can avoid some of the psychiatric adverse events of EFV (ie depression and suicidal tendencies). Overall, general patient feedback supports DTG as a highly tolerated medicine that is less likely to result in treatment discontinuation.

d. Higher genetic barrier to resistance

The higher genetic barrier of DTG means patients are less likely to develop resistance and therefore postponing the need for second-line treatment

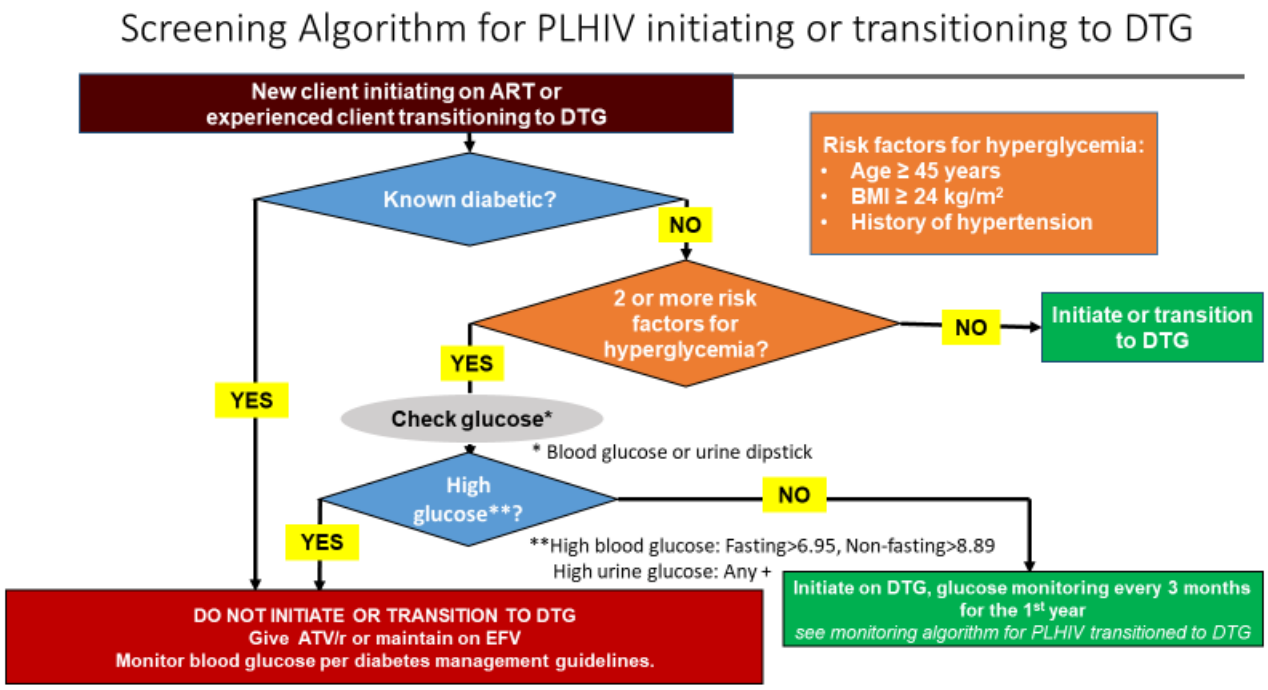
8.5.1.1 SCREENING FOR RISK FACTORS PRIOR TO INITIATING DTG

DTG is a very well-tolerated drug, with lower overall adverse effects when compared to other drugs like EFV. Hyperglycemia among previously non-diabetic adults and worsening of hyperglycaemia among diabetics has been reported among clients on DTG. Although the hyperglycaemia associated with DTG has been reported among clients newly initiated on ART as well as among those already on ART and transitioned to DTG-based regimens, the hyperglycaemia appears to occur more commonly among the latter group. Adults being initiated on DTG should be screened for risk factors for hypergylcaemia:

- Age ≥ 45 years
- BMI≥ 24 kg/m^2
- History of hypertension

1. Known diabetics should not be initiated or transitioned to DTG. Give an EFV400 or an ATV/r-based regimen.
2. Clients with 2 or more risk factors for hyperglyacaemia and a high baseline RBS or FBS should not be initiated/transitioned to DTG. Give an EFV400 or ATZ/r -based regimen.
3. Clients with 2 or more risk factors for hyperglyacaemia with normal baseline RBS or FBS: Initiate or transition to DTG and monitor RBS or FBS every 3 months for 6 months.

Figure 25: Screening Algorithm for PLHIV initiating or transitioning to DTG



8.5.2 RATIONALE FOR USING EFV400

Studies have shown that efavirenz at a dose of 400 mg is not only virologically non-inferior to Efavirenz 600mg but also has fewer adverse events which is the major limiting factor of efavirenz use. Fewer adverse events lower the risk of treatment discontinuation. EFV 400 mg can be co-administered with Rifampicin-containing anti-TB treatment, with co-administration well tolerated and plasma concentrations maintained above the levels considered to be effective. EFV400 is recommended for use as an alternative first line anchor ARV when DTG is contraindicated.

8.5.3 RECOMMENDED FIRSTLINE REGIMEN FOR INITIATING ART IN ADULTS AND ADOLESCENTS WEIGHING ≥30kg

All eligible HIV-infected adults and adolescents weighing ≥ 30kg should be initiated on Tenofovir, Lamivudine and Dolutegravir (TDF+3TC+DTG) as a once-daily fixed dose combination (Table 56).

8.5.3.1 WHEN TO USE ALTERNATIVE FIRST LINE REGIMENS

When to use TDF+3TC+EFV400

Adults and adolescents should only be initiated on TDF+3TC+EFV400 if they are ineligible for DTG i.e. Table 56.

1. If weight does not allow for use of the currently available DTG formulations (containing 50mg).
2. Diabetic patients.
3. An EFV based regimen may also be considered if the client needs concurrent TB treatment and doubling the dose of DTG is not an option (See Chapter 6, Table 30 and Table 31).

When to use TDF+3TC+ATV/r

Adults and adolescents should only be initiated on TDF+3TC+ATV/r if they are ineligible for DTG and EFV (Table 56).

When to use ABC+3TC+DTG

Adults and adolescents eligible for DTG should only be initiated on ABC+3TC+DTG if TDF is contraindicated (Table 56), including the following conditions:

1. Kidney disease and estimated glomerular filtration rate (GFR) below 60 ml/min.
2. Adolescents below 30kg of weight.

When to use ABC+3TC+EFV400

Adults and adolescents should only be initiated on ABC+3TC+EFV400:

1. If TDF is contraindicated and they are ineligible for DTG (Table 60).
2. If the client requires concurrent TB treatment and doubling the dose of DTG is not an option (Tables 30 and 31).

8.5.3.2 PREGNANT AND BREATSFEEDING WOMEN NEWLY INITIATING ON ART

Newly diagnosed HIV-infected pregnant and breastfeeding women will be initiated on Tenofovir, Lamivudine and Dolutegravir (TDF + 3TC + DTG).

8.5.3.2.1 WHEN TO USE ALTERNATIVE FIRSTLINE REGIMENS

When to use TDF+3TC+EFV400

Pregnant and breastfeeding women will only be initiated if DTG is contraindicated (Table 56).

When to use ABC+3TC+EFV400

Pregnant or breastfeeding women should only be initiated on ABC+3TC+EFV if TDF and DTG are contraindicated (Table 56).

When to use TDF+3TC+ATV/r

Pregnant or breastfeeding women should only be initiated on TDF+3TC+ATV/r if EFV and DTG are contraindicated (Table 56).

8.5.3.2.2 PREGNANT AND BREATSFEEDING WOMEN ALREADY ON FIRST LINE ART:

Do viral load test at the 1st ANC/PNC visit**:**

- If already on TDF+3TC+EFV and stable with suppressed VL, maintain on TDF+3TC+EFV400 until 6-9 months postpartum and then transition to TDF+3TC+DTG if VL within past 6 months is suppressed.
- If already on TDG+3TC+DTG and stable with suppressed VL, maintain this regimen.
- If on a first line regimen containing NVP, ABC or AZT and VL at ANC 1 is suppressed, maintain same regimen and switch to TDF+3TC+DTG at 6-9 months postpartum if VL within past 6 months is suppressed.
- ***Note: In the case of a pregnant or breastfeeding woman on Abacavir consider the possibility that she was given the Abacavir because of a contraindication to Tenofovir. Screen the women carefully for eligibility for TDF before initiating TLD.***

8.5.4 RECOMMENDED FIRSTLINE REGIMEN FOR INITIATING ART IN CHILDREN WEIGHING BETWEEN 20Kg TO LESS THAN 30KG (≥20Kg to <30Kg).

RECOMMENDED FIRSTLINE REGIMEN: ABC+3TC+DTG

All HIV-infected children weighing between 20kg to less than 30kg should be initiated on Abacavir + Lamivudine+ Dolutegravir (ABC+3TC+DTG) (Table 56)

Rationale for using ABC based regimen as recommended 1st line regimen

Using ABC in first-line regimens spares AZT for use in 2nd line. Also, ABC+3TC+DTG can be given as once a day dose which may improve adherence.

8.5.4.1 WHEN TO USE ALTERNATIVE FIRSTLINE REGIMENS

When to use ABC+3TC+LPV/r

Children who weigh between 20kg to <30kg should only be initiated on ABC+3TC+LPV/r if DTG is contraindicated or not tolerated (Table 60).

When to use TAF/3TC/DTG

Patients will be given TAF/3TC/DTG if ABC and AZT are contraindicated. TAF (when available) should be given to children who are older than 6 years and weigh ≥ 25kg.

8.5.5 RECOMMENDED FIRSTLINE REGIMEN FOR INITIATING ART IN CHILDREN LESS THAN 20KG

RECOMMENDED FIRSTLINE REGIMEN: ABC+3TC+DTG

All HIV-infected children weighing less than 20kg should be initiated on Abacavir + Lamivudine + Dolutegravir (ABC + 3TC + DTG) when appropriate DTG formulations and strengths (5mg, 10mg and 25mg) are available

(Table 56)

In the absence of DTG formulations initiate on Abacavir + Lamivudine+ Ritonavir-boosted Lopinavir (ABC+3TC+LPV/r).

LPV/r syrup, pellets or tablets should be prescribed/dispensed on the basis of the individual child's ABILITY to CORRECTLY take the specific formulation. As soon as the child is able to take pellets, these will be prescribed instead of syrup. Likewise, as soon as a child is able to swallow tablets without breaking, crushing or chewing them, these will be prescribed instead of pellets.

8.5.5.1 WHEN TO USE ALTERNATIVE FIRSTLINE REGIMENS

When to use ABC+3TC+RAL

Children who weigh less than 20kg should only be initiated on ABC+3TC+RAL if DTG formulations (10mg and/or 25mg) are not available or if LPV/r is not tolerated.

When to use ABC+3TC+EFV

Children who weigh less than 20kg should only be initiated on ABC+3TC+EFV if they are > 3 years and if they weigh more than 10kg and require concurrent TB treatment. (Chapter 6,

Table 30 and 31). On completion of TB treatment EFV should be substituted with DTG (if formulation is available) or LPV/r.

When to use AZT+3TC+DTG or LPV/r

AZT+3TC+ DTG or LPV/r should only be used in children who experience a hypersensitivity reaction to Abacavir (ABC).

Table 56: Recommended first-line ARV regimens in adults, adolescents, pregnant or breastfeeding women and children

Patient Category	Preferred regimens	Alternative regimens
ADULTS AND ADOLESCENTS		
Adults and adolescents ≥ 30Kg	**TDF + 3TC + DTG**	Pregnant and breastfeeding women: TDF + 3TC + EFV400
Pregnant and breastfeeding women	**TDF +3TC+ DTG[3]**	If DTG is contraindicated[1]: TDF + 3TC + EFV400 If TDF is contraindicated[2]: ABC + 3TC +DTG If both TDF and DTG are contraindicated: ABC +3TC +EFV400 If EFV and DTG are contraindicated: TDF +3TC + ATV/r or ABC + 3TC + ATV/r
CHILDREN		
Children ≥20Kg-<30Kg	**ABC + 3TC + DTG**	If DTG is contraindicated: ABC + 3TC + LPV/r (tablets) If ABC is contraindicated: AZT + 3TC + DTG or TAF + 3TC + DTG (TAF in children> 6 years and ≥25Kg)
Children<20Kg	**ABC + 3TC + DTG[3]**	If intolerant or appropriate DTG formulations are not available: ABC +3TC + LPV/r (syrup, pellets, or tablets)[4]. If intolerant to LPV/r: ABC + 3TC + RAL or ABC + 3TC + EFV (in children > 3 years and >10Kg) If ABC is contraindicated: AZT + 3TC + DTG or LPV/r

1. Contraindications for DTG (use DTG screening tool prior to DTG initiation) including: known diabetics, patients on anticonvulsants (carbamazepine, phenytoin, phenobarbital)
2. Contraindications for TDF: Renal disease and/or GFR <60ml/min, weight <30Kg
3. DTG is the preferred when appropriate formulations and dosages available.
4. Children will be assessed individually for ability to correctly take the different formulations of LPV/r and will be given syrup, pellets or tablets appropriately.

Note: Refer to Chapter 6 Table 30 for concurrent TB treatment

*Refer to Table 60 for complete list of ARV adverse effects/toxicities and recommended drug substitutions.

8.6 MONITORING RESPONSE TO ART

8.6.1 INTRODUCTION

This chapter provides guidance on how to and when to use clinical assessment and laboratory monitoring tests to monitor response to ART, ART side effects and toxicity, and how to diagnose ART treatment failure. The purpose of monitoring patients on ART is to assess:

1. Response to ART and diagnose treatment failure
2. Safety of the medicines- side effects and toxicity.
3. Adherence to ART

Monitoring adherence to ART is covered in Chapter 7. The visit schedule and the recommended clinical and laboratory monitoring are in Table 59.

8.6.2 CLINICAL MONITORING

Clinical monitoring involves taking a medical history and doing a physical exam. In this section, we shall describe a comprehensive clinical assessment for patients who are well and are in the fast track model of differentiated service delivery.

Table 57: Components of a comprehensive clinical assessment of PLHIV

Components
• Demographics (age, sex etc.) • Symptom Screen and Advanced Disease Pathway-ask all patients all questions • Screen for signs and symptoms of Hepatitis B and C infections, malaria, and other infections • Screen for pregnancy (women of reproductive age) • Screen for co-morbidities • Screen for STIs • Screen for symptoms of depression • Obtain previous history of ART • Obtain previous history of chronic illnesses (hypertension, DM, COPD, kidney disease) • Obtain a list of current medication(s) • Screen for side/adverse effects of medications. • Establish family planning methods currently in use • Assess development, sexual awareness, and behavioral issues in adolescents • Assess school attendance (children of school-going age) • Determine progress with disclosure if not done already • Perform nutritional assessment: weight and height in all patients, plus mid-upper arm circumference (MUAC) in children 6-59 months • Assess growth and development in children under 5 years; monitor for changes • Ensure examination of vital signs, skin, eyes, oropharynx (presence of thrush), lymph nodes, lungs, heart, abdomen, genital tract (for STIs), extremities, nervous system • Determine WHO clinical staging

8.6.3 LABORATORY MONITORING

8.6.3.1 Viral load monitoring

Uganda adopted viral load monitoring as the preferred approach for monitoring response to ART and to diagnose/confirm ART treatment failure. Compared to clinical or immunological monitoring, virological monitoring provides an early and more accurate indication of treatment failure and the need to switch from first-line to second-line drugs, and form second-line to third-line drugs, hence reducing the accumulation of drug resistance mutations and improving clinical outcomes.

A patient who has been on ART for more than 6 months and is responding to ART should have viral suppression (VL <1000 copies/ml) irrespective of the sample type (either DBS or plasma). Facilities should constitute a multidisciplinary VL review committees to review, track, and make decisions about switching to 2nd line and 3rd line or a more potent regimen. At the minimum, the committee should consist of a healthcare worker and a lay provider (e.g. expert client, counselor, peer education, VHT) who know the client.

8.6.3.2 Frequency of viral load monitoring

- Adults: the first VL test should be done 6 months after initiation of ART. The second VL following the first suppressed viral load should be done at 12 months after initiation of ART and thereafter every 12 months, if it is suppressed. If not suppressed, follow the algorithm in Figure 26.
- Children and adolescents under 19 years of age: the first VL test should be done at 6 and 12 months after initiating ART, if it is suppressed, every 6 months thereafter. If not suppressed, follow the algorithm in Figure 26.
- HIV positive pregnant and breastfeeding women: If newly initiated on ART at ANC, conduct a VL test at 6 months on ART. If VL <1000 copies/ml repeat VL every 6 months throughout pregnancy and until cessation of breastfeeding. If not suppressed, follow the algorithm in Figure 27.
- HIV positive pregnant and breastfeeding women already on ART at ANC1 or MBCP: If HIV+ woman is already on ART at ANC1 or enrolled at MBCP, conduct a VL test at first ANC or MBCP visit. If VL <1000 copies/ml, repeat VL every 6 months throughout pregnancy until cessation of breastfeeding. If not suppressed, follow the algorithm in Figure 27.
- After every switch in treatment (after failure): The VL test should be done at 6 months after a switch to second- and third-line ART.
- Third line ART patients: The VL test should be done every 6 months. If a VL >1000 copies (un-suppressed VL) then genotype testing is recommended.

Figure 26: Viral load testing algorithm for children, adolescents and adults

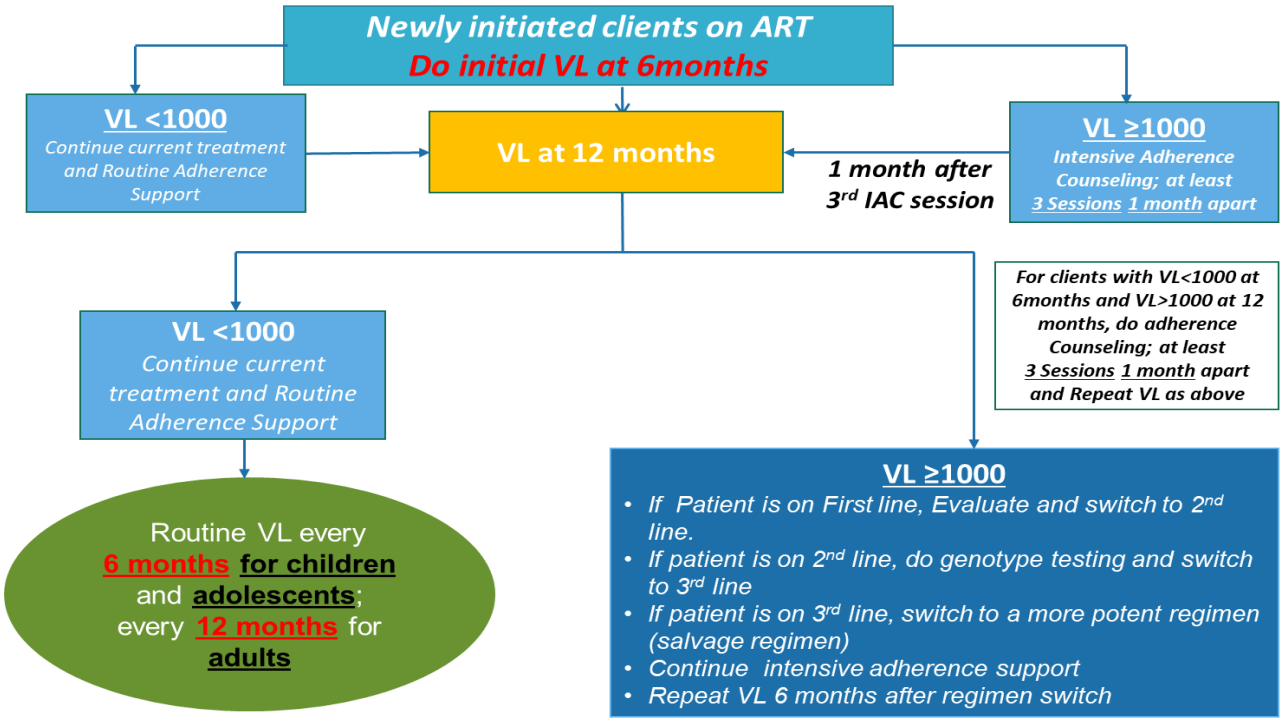
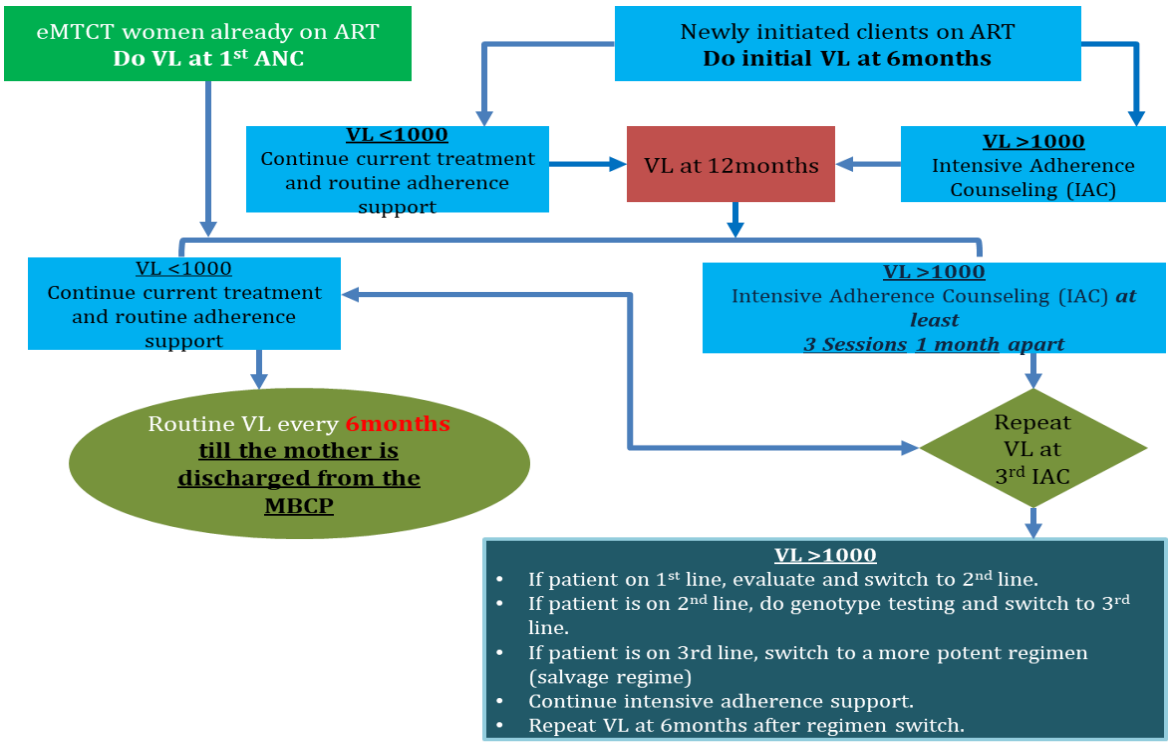


Figure 27: Viral load algorithm for pregnant and breastfeeding mothers



**In the case of pregnant women attending 1st ANC visit who are already on ART but only recently initiated (<6 months on ART), the VL may not be suppressed but this may not be due to poor adherence or treatment failure. Defer the VL test until 6 months since ART initiation.*

8.6.3.3 When viral load is not suppressed (VL>1000 copies per ml)

For PLHIV with non-suppressed viral load, the following 10- point package should be applied in all health facilities:

1. Sort viral load results from the laboratory as suppressed vs non-suppressed (NS) for rapid action by the ART clinic.
2. Apply the red stickers for non-suppressed clients to flag non-suppressed client files.
3. Conduct a first intensive adherence counselling within 7-30 days of result return.
4. Record IAC sessions on intensive adherence counselling forms to support completion of 3 IAC sessions.
5. Form viral load focal teams with clinical–lab interface for routine review of non-suppressed files.
6. Utilization of non-suppressed registers.
7. Engage multidisciplinary switch team at health facilities to discuss failing patients.
8. Integrate viral load monitoring talks into morning health education sessions.
9. Linkage with community structures for peer support and client tracking.
10. VL CQI site-level initiatives for managing non-suppressed patients.

8.6.3.4 Genotype testing

HIV genotypic resistance test is a qualitative test that detects mutations associated with ARV drug resistance. The test evaluates if the HIV strain infecting the individual has developed resistance to one or more ARV drugs. This is useful in identifying a combination of ARVs to which the HIV strain is susceptible. In addition to the documented high levels of pre-treatment drug resistance to Nevirapine and Efavirenz in Uganda (15.4% in the general population and 35.7% among infants of HIV infected mothers), there are also children who are failing on their first-line regimens and have been exposed to both AZT and Abacavir during the course of their first-line treatment. The probability of resistance to ABC therefore creates uncertainty of the effectiveness of an ABC/3TC NRTI backbone in a second line regimen in these children.

Genotype testing is expensive; therefore, a targeted approach is recommended. The following categories of patients will receive Genotype testing to identify optimal ART regimens:

- All children <15 years failing on 1st line ART:
    - Children exposed to both AZT/3TC and ABC/3TC NRTI backbone and are failing on their first-line ART treatment.
    - Infants born to mothers failing treatment (first, second or third line)
    - Children receiving Lopinavir/ritonavir or Dolutegravir on first-line ART and who have a repeat viral load result >1000 copies/ml following intensified adherence counselling.
- Patients failing on a PI-based regimen irrespective of line of care.
- Patients with a prior exposure to a PI and failing on a DTG based regimen and vice versa.
- All patients failing on their 2nd line ART.
- All patients failing on their 3rd line ART.

8.6.3.5 CD4 monitoring

CD4 cell count is recommended in the following scenarios:

- At baseline when initiating ART when available. Baseline CD4 helps to screen for risk for opportunistic infections, e.g. cryptococcal infection in patients with CD4 less than 100 cells/mm^3.
- ART patients with VL >1000 copies/ml and/or WHO clinical Stage 3 or 4 disease.
- PLHIV who are on treatment or prophylaxis for cryptococcal infection to inform decision on when to stop fluconazole.
- PLHIV re-engaging in care after interrupting treatment for 3 or more months.

8.6.3.6 Other laboratory tests

Other laboratory tests should be done when clinically indicated (Table 58).

Table 58: Follow-up lab tests and their clinical indication

Test	Indication
CrAg	(CD4<200cells/mm^3)
Urine TB LAM	(CD4<200cells/mm^3)
Complete blood count (CBC)	Patients at risk of anaemic conditions, e.g. patients on AZT, anti-cancer drugs, chronic renal disease, etc.
TB tests	If TB is suspected
RFTs: Serum creatinine	If PLHIV has comorbidities (DM, hypertension)
LFTs: ALT, AST	Compromised liver function, e.g. Hepatitis B or C infection, ART hepatotoxicity
Lipid profile and blood glucose	If PLHIV has comorbidities (diabetes mellitus, hypertension) or lifestyle risk factors or on ART for more than five years or is ≥ 45 years

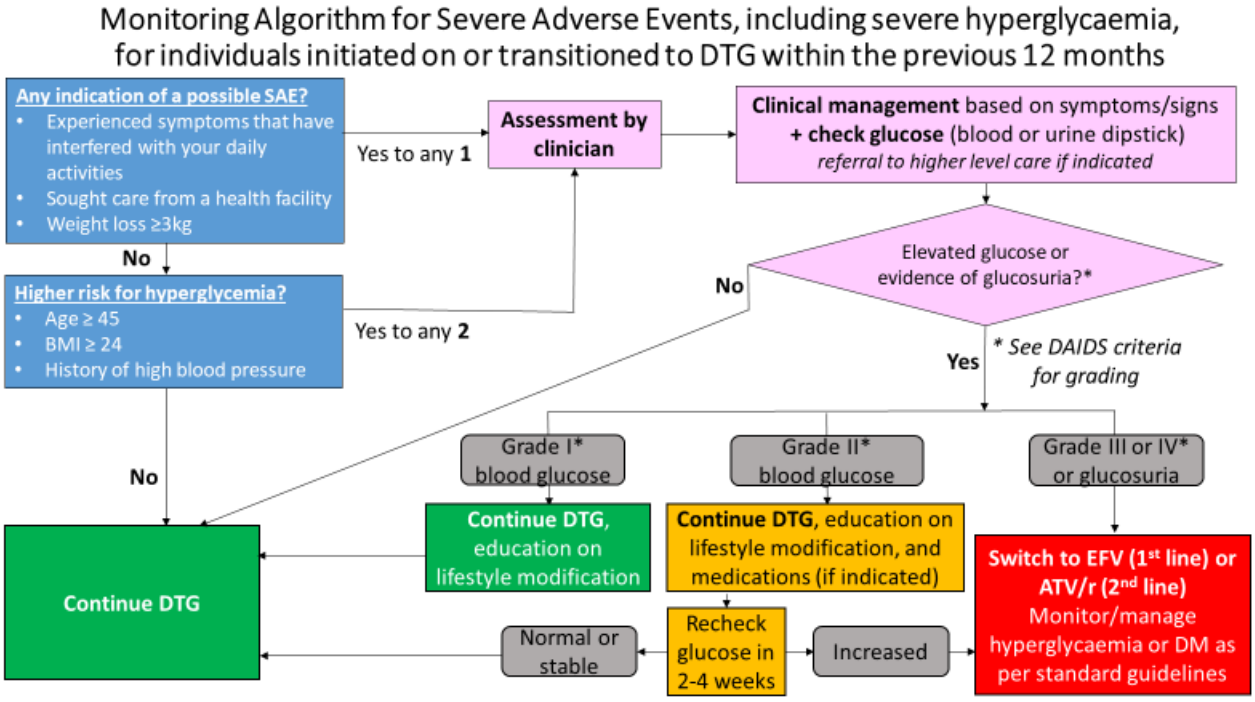
Table 59: Follow-up schedule for PLHIV and monitoring components

Time	Before ART	During ART								
					DSD from 6 months			After 12 months on ART		
	Baseline	1 month	2 months	3 months	6 months	9 months	12 months	3 monthly	6 monthly	12 monthly
Clinical assessment										
Comprehensive clinical assessment (Table57)	X	x	x	x	x	x	x	x	x	x
Prepare for ART (refer to Section 7.5)	X									
Assess readiness for ART (refer to Section 7.5)	X									
Provide CTX	X	x	x	x	x	x	x	x**	x**	x**
Provide FP if required	X									
Assess for drug intolerance, side effects/toxicities		x	x	x	x	x	x	x	x	x
Assess for Immune reconstitution inflammatory syndrome (IRIS)		x	x	x	x					
Adherence assessment, monitoring, and support		x	x	x	x	x	x	x	x	x
ART and CTX refill (***in children adjust dose based on weight)***		x	x	x	x	x	x	x	x	x
FP refill		x	x	x	x	x	x	x	x	x
TB Screening								x	x	x
Follow up review: If the patient is clinically well:										
Give **ONE month** refill and appointment		x	x	x						
Give **THREEmonths** refill and appointment					x	x	x	x		
Laboratory tests										
Viral Load					x*		x*		x**	x
CD 4	X									
HBsAg,	X									
CrAg if CD4 <100,	X									
TB LAM if CD4 <100,	X									
FBS/RBS (especially adults at risk on DTG)	X			x	x	x	X		x	
LFTs	X									
Do other lab tests if clinically indicated (Table 58)	X	x	x	x	x	x	X	x	x	x
Cervical cancer screening										x

x* If VL is not suppressed, call the patient back for intensive adherence counseling

x This is to be done in children, adolescents, pregnant and breastfeeding women**

Figure 28: Monitoring patients initiated or transitioned to DTG



8.6.4 WHAT TO EXPECT IN THE FIRST MONTHS OF ART

Although ART is a lifelong commitment, the first months of therapy are especially important.

- Clinical and immunological improvement and viral suppression are expected when individuals adhere to ART.
- Opportunistic infections (OIs) and immune reconstitution inflammatory syndrome (IRIS) may develop, as well as early adverse drug reactions, such as drug hypersensitivity, especially in the first three months of treatment.
- ART significantly decreases mortality overall, but death rates are also highest in the first three months of ART. These complications are most common when the people starting ART already have advanced HIV disease with severe immunodeficiency and existing coinfections and/or comorbidities, severely low hemoglobin, low body mass index, and very low CD4 cell counts or are severely malnourished.
- More frequent visits and monitoring can help reduce this mortality.
- Poor adherence in this period is also associated with the risk of early treatment failure and rapid development of drug resistance.

8.6.5 IMMUNE RECONSTITUTION INFLAMMATORY SYNDROME (IRIS)

IRIS is a spectrum of clinical signs and symptoms thought to be associated with immune recovery brought about by a response to ART. It is a widely recognized phenomenon that occurs among 10–30% of the people initiating ART, usually within the first 4–8 weeks after initiating therapy. IRIS should be considered only when the presentation cannot be explained by a new infection, the expected course of a known infection, or drug toxicity. The most serious and life-threatening forms of IRIS occur in patients co-infected with TB, Cryptococcus,

Kaposi's sarcoma and herpes zoster. BCG vaccine–associated IRIS (localized and systemic) may occur in infants infected with HIV in settings where BCG immunization is routine.

Risk factors for IRIS include a low CD4+ cell count (<50 cells/mm3) at ART initiation, disseminated opportunistic infections or tumors and/or a shorter duration of therapy for opportunistic infections before ART starts.

8.6.5.1 Managing IRIS

IRIS is generally self-limiting, and interruption of ART is rarely indicated. Treat any co-infections to reduce morbidity and symptoms. If the symptoms are protracted, reassure the patient to prevent discontinuation of, or poor adherence to ART.

8.6.5.2 Steps to reduce development of IRIS

Diagnose HIV early and initiate ART before CD4 declines to below 200 cells/mm^3. Screen and optimally manage opportunistic infections before initiating ART, especially TB and Cryptococcus. The timing of ART in people with opportunistic infections requires balancing a greater risk of IRIS after early initiation against continuing high mortality if ART is delayed.

Table 60: Toxicities/side effects of commonly used ARVs and recommended substitutions

	MAJOR ADVERSE/TOXICITY EVENTS	PRESENTING SIGNS/SYMPTOMS	SUGGESTED MANAGEMENT
REGIMENS FOR ADULTS AND ADOLESCENTS			
DTG	1. Hyperglycaemia 2. Insomnia 3. Hepatotoxicity 4. Hypersensitivity reactions	1. Excessive drinking/eating, excessive urination 2. Difficulty falling asleep 3. Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes 4. Skin itching (localized or diffuse), dizziness, faintness, difficulty breathing, nausea, vomiting, diarrhoea, and abdominal cramping	Do RBS to confirm hyperglycaemia then substitute with EFV Insomnia: Ensure patient is taking DTG during the day if it persists then substitute with EFV If EFV is contraindicated: Substitute with ATV/r
EFV	1. Persistent central nervous system toxicity 2. Convulsions 3. Hepatotoxicity 4. Severe skin and hypersensitivity reactions 5. Gynecomastia	1. Dizziness, insomnia, abnormal dreams, or mental symptoms (anxiety, depression, mental confusion, suicidality) 2. New-onset seizures 3. Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes 4. New-onset skin rash 5. Breast enlargement in men	In case on EFV 600mg • Lower the dose of EFV to 400mg. In case on EFV 400mg • Reassure, If symptoms persist • Substitute EFV with DTG If DTG is contraindicated: substitute with ATV/r
TDF	1. Chronic kidney disease, acute kidney injury and Fanconi syndrome 2. Decreased bone mineral density 3. Lactic acidosis or severe 4. Hepatomegaly with steatosis	1. Lower back pain, change in urine volume 2. Bone aches, spontaneous fractures 3. Exhaustion or extreme fatigue, muscle cramps or pain, headache. 4. Abdominal pain or discomfort, decrease in appetite.	Do LFTs and RFTs. If deranged (elevated liver enzymes and/or GFR is < 60mls/min) then substitute with ABC If ABC is contraindicated: substitute with AZT
ABC	1. Hypersensitivity reaction	1. Skin itching (localized or diffuse) dizziness, faintness, difficulty breathing, nausea, vomiting, diarrhoea, and abdominal cramping	Substitute with TDF If TDF is contraindicated: substitute with AZT
AZT	1. Severe anaemia, neutropenia 2. Lactic acidosis or severe hepatomegaly with steatosis 3. Lipoatrophy, lipodystrophy, myopathy 4. Severe vomiting	1. Easy fatigability, breathlessness, recurrent infections 2. Exhaustion or extreme fatigue, muscle cramps or pain, headache. 3. Abdominal pain or discomfort decrease in appetite. 4. Persistent vomiting resulting in severe dehydration	Do Hb (if < 8mg/dl): Substitute with TDF If TDF is contraindicated: substitute with ABC

	MAJOR ADVERSE/TOXICITY EVENTS	PRESENTING SIGNS/SYMPTOMS	SUGGESTED MANAGEMENT
NVP	1. Acute symptomatic hepatitis 2. Hypersensitivity reaction, Stevens-Johnson Syndrome (severe or life-threatening rash, mucosal involvement)	1. Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes 2. Severe or life-threatening rash with mucosal involvement (ulcers in the mouth or eyes)	Substitute or switch to appropriate regimen **NOTE: NVP is not recommended in ART regimens. NVP should be substituted even in absence of ARs/toxicity OR regimen switched if client is failing**
ATV/r	1. Electrocardiographic abnormalities (PR and QRS interval prolongation) 2. Elevated Lipid 3. Indirect hyperbilirubinemia (clinical jaundice) 4. History of nephrolithiasis	1. Dizziness or fainting 2. Refer to Blood Lipid levels in Table 68 3. Yellowing of eyes, dark yellow urine, yellow stools 4. Severe lower back pain that comes in waves and fluctuates in intensity, pain on urination, cloudy or foul-smelling urine.	Do ECG; Use with caution in people with pre-existing conduction disease or who are on concomitant drugs that may prolong the PR or QRS intervals, pre-existing coronary disease or previous stroke. Jaundice is clinically benign but potentially stigmatizing. Do LFTs and Lipid profile. If deranged: Substitute with DTG or LPV/r
DRV/r	1. Hepatotoxicity 2. Severe skin and hypersensitivity reactions	1. Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes 2. Skin itching (localized or diffuse) dizziness, faintness, difficulty breathing.	Do LFTs if deranged Substitute with ATV/r or LPV/r. When it is used in third-line ART, limited options are available. For hypersensitivity reactions, substitute with another therapeutic class.
ETV	1. Severe skin and hypersensitivity reactions	1. Skin itching (localized or diffuse) dizziness, faintness, difficulty breathing.	Substitute with another therapeutic class (integrase inhibitors or boosted PIs).
LPV/r	1. Electrocardiographic abnormalities (PR and QRS interval prolongation, torsades de pointes) 2. Hepatotoxicity 3. Pancreatitis 4. Dyslipidemia	7 Dizziness, fainting 8 Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes 9 Upper abdominal pain that feels worse after eating, fever, rapid pulse, nausea and vomiting. 10 Refer to Blood Lipid levels in Table 68. 11 ≥3 watery stool motions/ day.	Do ECG; Use with caution in people with pre-existing conduction disease or who are on concomitant drugs that may prolong the PR or QRS intervals, pre-existing coronary disease or previous stroke.

	MAJOR ADVERSE/TOXICITY EVENTS	PRESENTING SIGNS/SYMPTOMS	SUGGESTED MANAGEMENT
	5. Diarrhoea 6. Unable to tolerate taste		Do LFTs, Serum Amylase and Lipid profile: if deranged: Substitute with DTG or ATV/r
REGIMENS FOR CHILDREN 0-10 YEARS			
ABC	1. Hypersensitivity reaction	1. Skin itching (localized or diffuse) dizziness, faintness, difficulty breathing.	Substitute with AZT.
EFV	1. Persistent central nervous system toxicity (such as dizziness, insomnia, abnormal dreams) or mental symptoms (anxiety, depression, mental confusion) 2. Convulsions 3. Hepatotoxicity 4. Severe skin and hypersensitivity reactions 5. Gynecomastia	1. Dizziness, insomnia, abnormal dreams, or mental symptoms (anxiety, depression, mental confusion, suicidality) 2. New-onset seizures 3. Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes 4. New-onset skin rash 5. Breast enlargement	Reassure, If symptoms persist, substitute EFV with DTG or LPV/r (if appropriate DTG formulation is not available)
NVP	1. Acute symptomatic hepatitis 2. Hypersensitivity reaction, Stevens-Johnson Syndrome	1. Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes 2. Severe or life-threatening rash with mucosal involvement (ulcers in the mouth or eyes)	Substitute with DTG or LPV/r **NVP is not recommended in ART regimens. NVP should be substituted even in absence of ARs/toxicity OR regimen switched if treatment failure confirmed** **NOTE:** NVP will continue to be used for prophylaxis in EMTCT
LPV/r	7. Electrocardiographic abnormalities (PR and QRS interval prolongation, torsadesde pointes) 8. Hepatotoxicity 9. Pancreatitis 10. Dyslipidemia 11. Diarrhoea	12 Dizziness, fainting 13 Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes 14 Upper abdominal pain that feels worse after eating, fever, rapid pulse, nausea and vomiting. 15 Refer to Blood Lipid levels in Table 66. 16 ≥3 watery stool motions/ day 17 Changes in taste of food, low appetite	Do ECG; Use with caution in people with pre-existing conduction disease or who are on concomitant drugs that may prolong the PR or QRS intervals, pre-existing coronary disease or previous stroke. Do LFTs, Serum amylase and Lipid profile. If deranged: Substitute with DTG

	MAJOR ADVERSE/TOXICITY EVENTS	PRESENTING SIGNS/SYMPTOMS	SUGGESTED MANAGEMENT
	12. Unable to tolerate taste		If DTG contraindicated: (formulation not available): Substitute with RAL If RAL contraindicated and child is >3 years: Substitute with DRV/r
AZT	1. Severe anemia, neutropenia 2. Lactic acidosis or severe hepatomegaly with steatosis 3. Lipoatrophy, lipodystrophy, myopathy 4. Severe vomiting	1. Refer to Blood Counts. 2. Exhaustion or extreme fatigue, muscle cramps or pain, headache. 3. Abdominal pain, discomfort or decrease in appetite. 4. Persistent vomiting resulting in severe dehydration	Do Hb (if < 8mg/dl) Substitute with ABC
RAL	1. Rhabdomyolysis, myopathy, myalgia 2. Hepatitis and hepatic failure 3. Severe skin rash and hypersensitivity reaction	1. Severe muscle pain, muscle wasting 2. Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes 3. Skin itching (localized or diffuse) dizziness, faintness, difficulty breathing	Do LFTs if deranged and child is > 3 years: Substitute with DRV/r If child is <3 years: Substitute with LPV/r

8.7 PROGRAMMATIC SUBSTUTUTIONS (ART OPTIMIZATION) FOR PATIENTS ALREADY ON FIRST LINE ART

The ART optimization process for adults, adolescents, and children already on first line ART will involve single or double substitutions of specific ARVs in order to align to the recommended first-line regimens. Prior to ARV substitution the VL will be assessed for all patients. If a VL result within the last 6 months is not available, a VL test should be requested. Only clients with suppressed VL results (VL less than 1000copies/ml) will have their ART regimens optimized by drug substitution. If the VL is NOT suppressed (VL> 1000 copies/ml), ARV substitutions should NOT be done. These clients should be assessed and managed as treatment failure. If the VL remains unsuppressed after IAC interventions, the client should be switched to 2nd line ART. Note that for children and adolescents aged less than 19 years on NNRTI-based first line regimen whose VL is not suppressed, switch to second line ART without waiting for a repeat VL result but conduct IAC to improve adherence to the new regimen.

8.7.1 PROGRAMMATIC DRUG SUBSTITUTIONS IN ADULTS AND ADOLESCENTS ALREADY ON FIRST LINE ART

8.7.1.1 WHEN TO SUBSTITUTE NNRTI WITH DTG

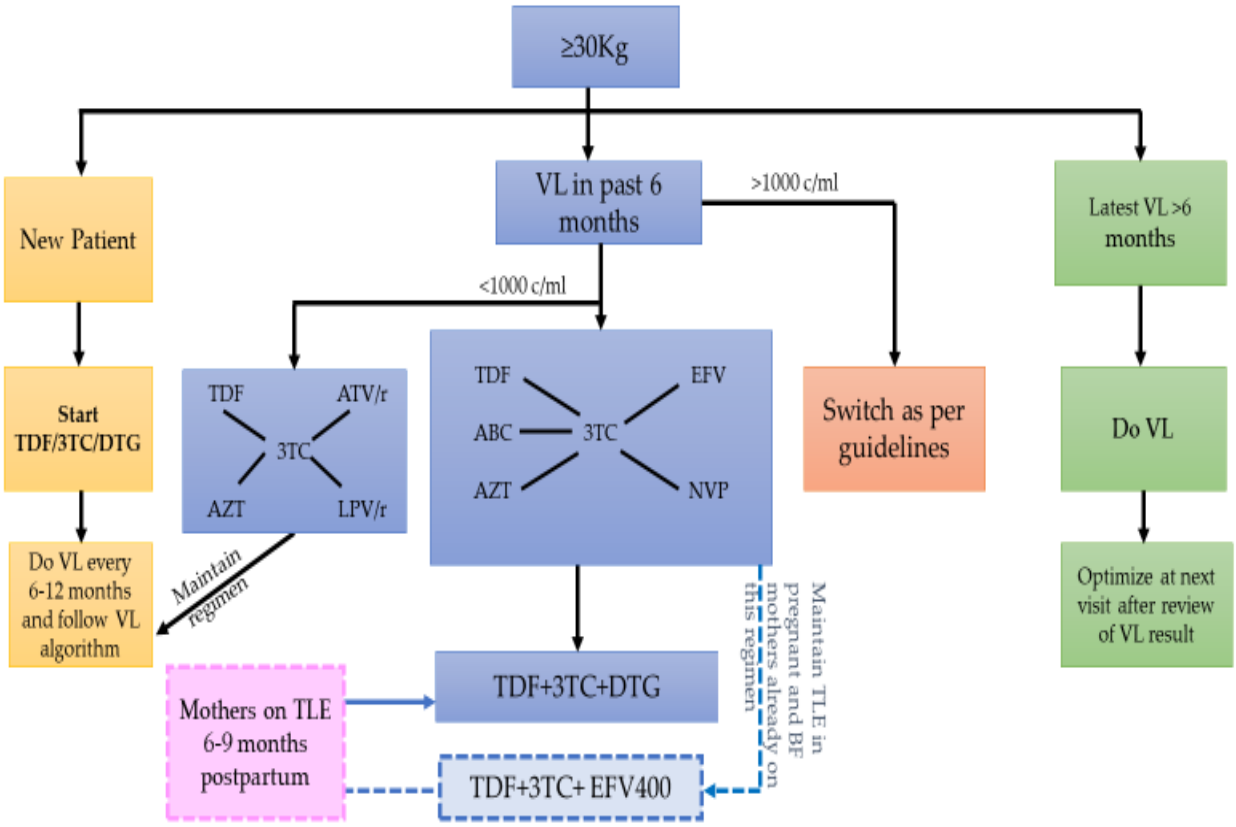
Patients on first line ART with a suppressed viral load result within the last 6 months, will have their NNRTIs substituted with DTG to optimize treatment. Adolescents on ABC based first line regimen who weigh ≥ 30kg, shall have their ABC substituted with TDF. The regimens should be aligned to the recommended first-line regimens. Alternative regimens will be used in case of contraindications to DTG as shown in Table 56.

8.7.1.2 WHEN TO SUBSTITUTE NNRTIs WITH DTG AMONG PREGNANT AND BREASTFEEDING WOMEN ALREADY ON FIRST LINE ART

Do VL test at the 1st ANC/PNC visit:

- Pregnant and breastfeeding women who are on EFV-based first-line regimens and are virologically suppressed will remain onEFV400-based regimens throughout pregnancy until 6-9 months post-partum when EFV400 should be substituted with DTG if the VL within the past 6 months is suppressed.
- Pregnant and breastfeeding women who are on first line regimens containing NVP, AZT or ABC and are virologically suppressed will remain on the same regimens throughout pregnancy until 6-9 months post-partum when they shall be transitioned to TDF+3TC+DTG if the VL within the past 6 months is suppressed.
- ***Note: In case of a pregnant or breastfeeding woman on Abacavir consider the possibility that she was given the Abacavir because of a contraindication to Tenofovir. Screen the women carefully for eligibility for TDF before initiating TLD.***

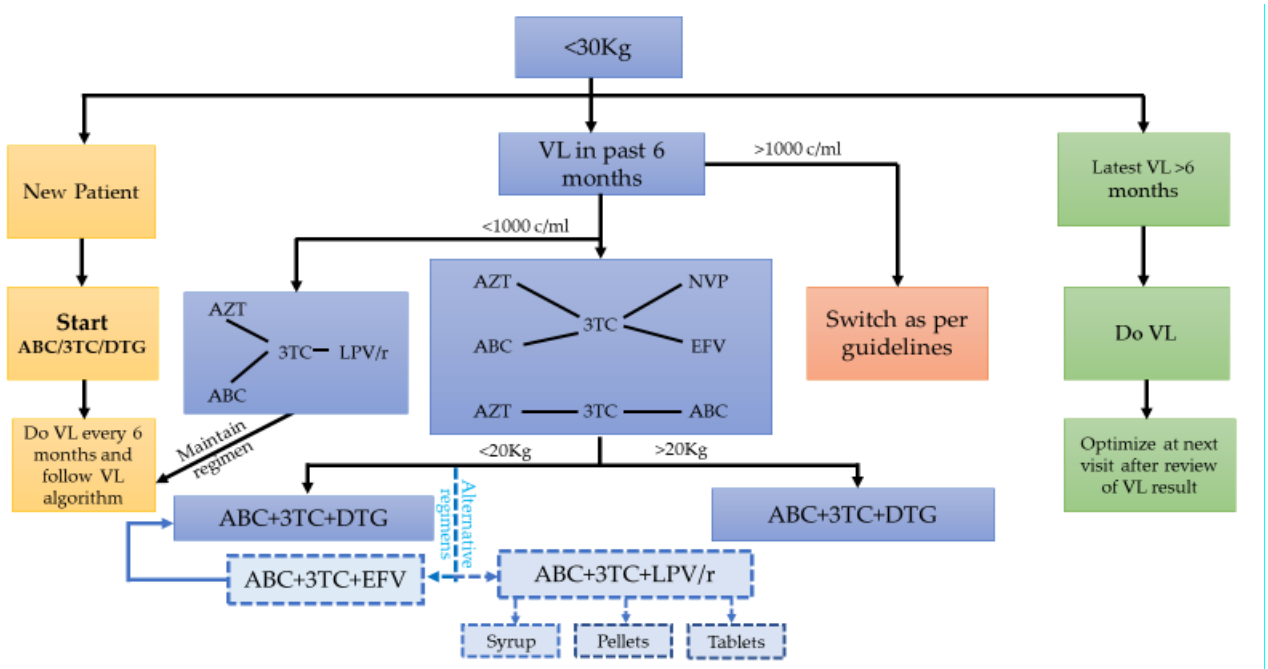
Figure 29: Recommended programmatic drug substitutions in adults and adolescents



8.7.2 PROGRAMMATIC DRUG SUBSTITUTIONS FOR CHILDREN ON FIRSTLINE ART

All children on NNRTI- based regimens should have the NNRTI substituted with DTG (Table 56 and Figure 30). In the absence of appropriate DTG formulations at the time of treatment optimization, children<20Kg on EFV-based regimens who are virally suppressed should be maintained on the same regimen until the appropriate dose of DTG is available or until they attain weight of 20Kg when they can be transitioned to DTG. Children <20kg on Nevirapine should be given a LPV/r-based regimen. As children grow their LPV/r formulations should be appropriately adjusted from syrups to pellets and finally to tablets. Children already on LPV/r-based regimens with suppressed VL shall be maintained on these regimens. Alternative regimens are recommended in case of intolerance to DTG or LPV/r (see Table 56 and Figure 30).

Figure 30: Recommended programmatic drug substitutions in children



8.8 WHEN TO SWITCH ART DUE TO TREATMENT FAILURE

Poor adherence, inadequate drug levels or prior existing drug resistance can all contribute to ARV treatment failure. An individual must be taking ART for at least six months before you can determine that a regimen has failed. To diagnose treatment failure, use virological and/or clinical criteria (Table 61). Although immunological data were included in past guidelines, it is not recommended for monitoring response to ART in these guidelines. When treatment failure is confirmed, the patient should be switched to a new ARV regimen; 2nd line regimen for those failing on the 1stline regimen; and 3rd line regimen for those failing on 2nd line regimen. Before switching therapy, it is essential to assess and address adherence issues.

Table 61: Criteria for switching ART due to treatment failure

Failure	Definition	Comments
Each criterion below can be used independently to determine treatment failure. You do not need to have both to diagnose treatment failure.		
Virological failure	Two consecutive viral loads above 1000 copies/ml, done at least 3-6months apart, with adherence support following the 1st VL test.	The patient should have been on ART for at least six months
Clinical failure	Adults, adolescents and children: New or recurrent WHO clinical stage 3 or stage 4 event (except TB) in a patient who has been on effective ART regimen for at least six months.	The condition must be differentiated from IRIS occurring after initiating ART

8.9 CHILDREN WITH A NON-SUPPRESSED VIRAL LOAD

If the child is on an NNRTI regimen and VL is not suppressed, switch to 2nd line immediately and do IAC simultaneously. Do not postpone switch.

If the child is on a DTG or LPV/r-based first line ART regimen, conduct IAC and repeat VL after 3 months. DTG and PI have high resistance barrier so poor adherence is a more likely cause for an unsuppressed VL than resistance. If VL is still not suppressed after IAC interventions, switch to 2nd line ART. For children and adolescents, this switch will be guided by an HIV drug resistance test.

8.10 WHAT REGIMEN TO SWITCH TO (SECOND LINE AND THIRD LINE ART)

Second line for adults, adolescents and children will be either PI-based or DTG-based depending on what anchor ARV was used in the first line regimen. The choice of the NRTI backbone for the 2nd line regimen will also depend on what was used for the 1st line NRTI backbone:

Table 62: Recommended NRTI sequence from first-line to second-line

First line NRTIs	Second line NRTIs
Adults and adolescents ≥30Kg	
TDF+3TC	AZT+3TC
ABC+3TC	TDF+3TC
AZT+3TC	TDF+3TC
Children <30Kg	
ABC+3TC	AZT+3TC
AZT+3TC	TAF*+3TC
AZT+3TC	ABC+3TC

*TAF is recommended for children >6 years and >25Kg.

8.10.1 SECOND LINE ARVS IN ADULTS AND ADOLESCENTS ≥30Kg, INCLUDING PREGNANT AND BREASTFEEDING WOMEN

RECOMMENDED 2nd line REGIMEN:

2NRTIs + DTG

(if client failed on a PI- or NNRTI-based 1st line ART regimen)

or

2 NRTIs + ATV/r

(if client failed on a DTG-based or NNRTI-based 1st-line ART regimen)

The choice of NRTI should be determined based on the NRTI the patient was previously on (For NRTI sequencing see Table 62 and for 2nd line regimens see Table 63

Rationale for using ATV/r

Atazanavir is preferred over LPV/r because it offers an option of once daily dosing with lower pill burden and better GI tolerability as compared to LPV/r which is taken twice daily and has higher pill burden. Furthermore, ATV/r is more affordable than LPV/r ($2 less per patient per month). Therefore, ATV/r is the preferred PI when DTG was used in the first-line regimen.

WHEN TO USE ALTERNATIVE 2ND LINE REGIMEN: 2NRTIs +LPV/r
LPV/r should only be used for second line in adults and adolescents if ATV/r or DTG are contraindicated.

8.10.2 SECOND LINE ARVS IN CHILDREN ≥20Kg – 30Kg

RECOMMENDED 2nd line REGIMEN:
2NRTIs + DTG*

(If child failed on a PI- or NNRTI-based 1st line ART regimen)

Or

2NRTIs + LPV/r

(If child failed on a DTG- or NNRTI-based 1st line ART regimen)

The choice of NRTI should be determined based on the regimen the patient was previously on(For NRTI sequencing see Table 62 and for 2nd line regimens see Table 63).

**DTG in the preferred anchor ARV for 2nd line ART for children switching from an NNRTI-based regimen. However, if DTG formulations are not available, opt for an LPV/r-based regimen.*

WHEN TO USE ALTERNATIVE 2ND LINE REGIMEN: TAF+3TC+ DTG or LPV/r
For children who have failed on AZT+3TCNRTI backbone, give TAF+3TC NRTI backbone as part of second line ART regimen.

WHEN TO USE ALTERNATIVE 2ND LINE REGIMEN: 2NRTIs + DRV/r
DRV/r -based regimens will be used for children who failed on a DTG- or LPV/r- based first line regimen and in whom the preferred 2nd line regimen anchor ARV (LPV/r or DTG) is contraindicated or unavailable.

8.10.3 SECOND LINE ARVS IN CHILDREN <20Kg

RECOMMENDED 2nd line REGIMEN:

2NRTIs + DTG*

(If child failed on a PI- or NNRTI-based 1st line ART regimen)

or

2NRTIs + LPV/r

(If child failed on a DTG-based or NNRTI 1st line ART Regimen)

The choice of NRTI should be determined based on the regimen the patient was previously on (For NRTI sequencing see Table 62 and for 2nd line regimens see Table 63).

**DTG in the preferred anchor ARV for 2nd line ART for children switching from an NNRTI-based regimen. However, if DTG formulations are not available, opt for an LPV/r-based regimen.*

WHEN TO USE ALTERNATIVE 2ND LINE REGIMEN: 2NRTIs + LPV/r

LPV/r is recommended in children who have used NNRTI in their first line regimen and for whom DTG formulation is unavailable**.**

WHEN TO USE ALTERNATIVE 2ND LINE REGIMEN: 2NRTIs + DRV/r

DRV/r -based regimens will be used for children who failed on a DTG- or LPV/r- based first line regimen and in whom the preferred 2nd line regimen anchor ARV (LPV/r or DTG) is contraindicated or unavailable.

Table 63: Second- and third-line ART regimens for patients failing on treatment

Population	Failing first line regimens	Recommended second line regimen	Alternative second line regimen	Third line regimens[1,2]
Adults and adolescents ≥ 30Kg, including pregnant and breastfeeding women	TDF + 3TC+EFV TDF+3TC+NVP	**AZT+3TC+DTG**	**AZT+3TC+ATV/r**	**All 3rd line regimens to be guided by resistance testing** ***NOTE: For details on the third-line ART, please see the third-line ART implementation guides.***
	TDF+3TC+DTG	**AZT+3TC+ATV/r**	**AZT+3TC+LPV/r**	
	AZT+3TC+NVP AZT+3TC+EFV ABC/3TC/NVP ABC+ 3TC+ EFV	**TDF+3TC+DTG**	**TDF+3TC+ATV/r**	
	AZT+3TC+DTG ABC+3TC+DTG	**TDF+3TC+ATV/r**	**TDF+3TC+LPV/r**	
Children ≥ 20Kg - <30Kg	ABC+3TC+EFV ABC+3TC+NVP	**AZT+3TC+DTG**	**AZT+3TC+LPV/r**	
	ABC+3TC+LPV/r	**AZT+3TC+DTG**	**AZT+3TC+DRV/r**	
	ABC+3TC+DTG	**AZT+3TC+LPV/r**	**AZT+3TC+DRV/r**	
	AZT+3TC+EFV AZT+3TC+NVP	**TAF or ABC+3TC+DTG**	**TAF or ABC+3TC+LPVr**	
	AZT+3TC+LPV/r	**TAF or ABC+3TC+DTG**	**TAF or ABC+3TC+DRV/r**	
	AZT+3TC+DTG	**TAF or ABC+3TC+LPV/r**	**TAF or ABC+3TC+DRV/r**	
Children <20Kg	ABC+3TC+EFV ABC+3TC+NVP	**AZT+3TC+DTG**	**AZT+3TC+LPV/r**	
	ABC+3TC+LPV/r	**AZT+3TC+DTG**	**AZT+3TC+DRV/r**	
	ABC+3TC+DTG or RAL	**AZT+3TC+LPV/r**	**AZT+3TC+DRV/r**	
	AZT+3TC+EFV AZT+3TC+NVP	**ABC+3TC+DTG**	**ABC+3TC+LPV/r**	
	AZT+3TC+LPV/r	**ABC+3TC+DTG**	**ABC+3TC+DRV/r**	
	AZT+3TC+DTG	**ABC+3TC+LPV/r**	**ABC+3TC+DRV/r**	

1-All PLHIV should receive resistance testing to inform the prescription of 3rd-line medicines.
2-Since all 3rd-line PLHIV will have prior PI Exposure, DRV/r will be taken twice a day.
3-For children aged less than 10 years on NNRTI-based First Line regimen whose VL is not suppressed, switch without a second VL but conduct IAC to improve adherence to new regimen.
4- For all children < 15 years failing first-line ART, optimize the second-line ART using HIVDR test

8.10.4 PROGRAMMATIC DRUG SUBSTITUTION ON 2ND LINE REGIMENS

Adults on ATV/r or LPV/r-based 2nd line regimens who are virally suppressed (basing on VL result within the past 6 months) and who did not receive DTG in their 1st line regimens should have ATV/r or LPV/r substituted with DTG.

Pregnant and breastfeeding women on ATV/r or LPV/r-based 2nd line regimens who are virally suppressed and who did not receive DTG in their1stlineregimens should be maintained on the same regimens. At 6-9 months postpartum, if their VL is suppressed (basing on VL result within past 6 months), ATV/r or LPV/r should be substituted with DTG.

Although simplification of regimens including once-a-day dosing is a main goal of ART optimization, children and adolescents who are virally suppressed and stable on 2nd line regimens containing twice-daily LPV/r will be maintained on their regimens so as to preserve their options for 3rd line regimens. Drug substitutions may be considered on a case by case basis especially in children and adolescents in whom twice-daily dosing may hinder adherence.

8.11 THIRD-LINE ART REGIMENS

8.11.1 Eligibility for Third-Line ART

Patients on second-line ART who meet the following criteria are eligible for third line ARVs:

a. If they have a detectable viral load test result >1000 copies/ml at the repeat viral load test following intensified adherence counseling.
b. The patient should have had three intensified adherence counseling sessions one month apart after the initial detectable viral load.
c. The patient has three consecutive scores of adherence >95% as determined by adherence support team.

8.11.2 What to do when a patient on second line has suspected resistance to secondline ART:

When a patient on second-line ART is suspected to be failing on second-line ART following the first unsuppressed viral load, and the adherence scores are > 95% for three consecutive IAC sessions, the following should be done:

a. Two samples of venous blood should be taken off and sent to CPHL (Central Public Health Laboratories). This is for both plasma and DBS samples.
b. The samples should be accompanied by the combined viral load and HIV drug resistance form. The first sample will be used by CPHL to conduct the repeat viral load test. Once the result is > 1000 copies/ml, CPHL will send the second sample to the resistance testing laboratories at Joint Clinical Research Centre and Uganda Virus Research Institute.
c. All samples will be sent to CPHL. CPHL will be responsible for transporting samples to the resistance testing laboratories.
d. The resistance test results will be returned to CPHL and CPHL will forward them to the national third-line ART clinical team. The team will review the results alongside the patient details and make the decision to switch or not to switch the patient to third-line ART. Please refer to Figure 31 for the third-line ART flow chart.

e. Through the Implementing partner, the decision made by the national third-line ART clinical team will be sent to the regional/district and health facility teams.
f. The health facility team will follow up the patient to initiate them on third-line ART.

8.11.3 Recommended third-line regimens for adults, adolescents and children

The recommended anchor drug for third-line regimens for adults, adolescents and children will be **ritonavir-booster Darunavir (DRV/r)**. DTG will be considered for children <20Kg who utilized DRV/r for their second-line regimen. However, selection of third-line ART regimens will be guided by resistance profiling of the antiretroviral drugs. In the initial phase of implementation of the third-line ART program within the national system, the drugs will be kept at the regional referral hospitals to which the health facilities will make their orders. For details on guidance on how to order for and report on third-line ART, refer to Chapter 11.

Figure 31: Third-Line ART Flow Chart

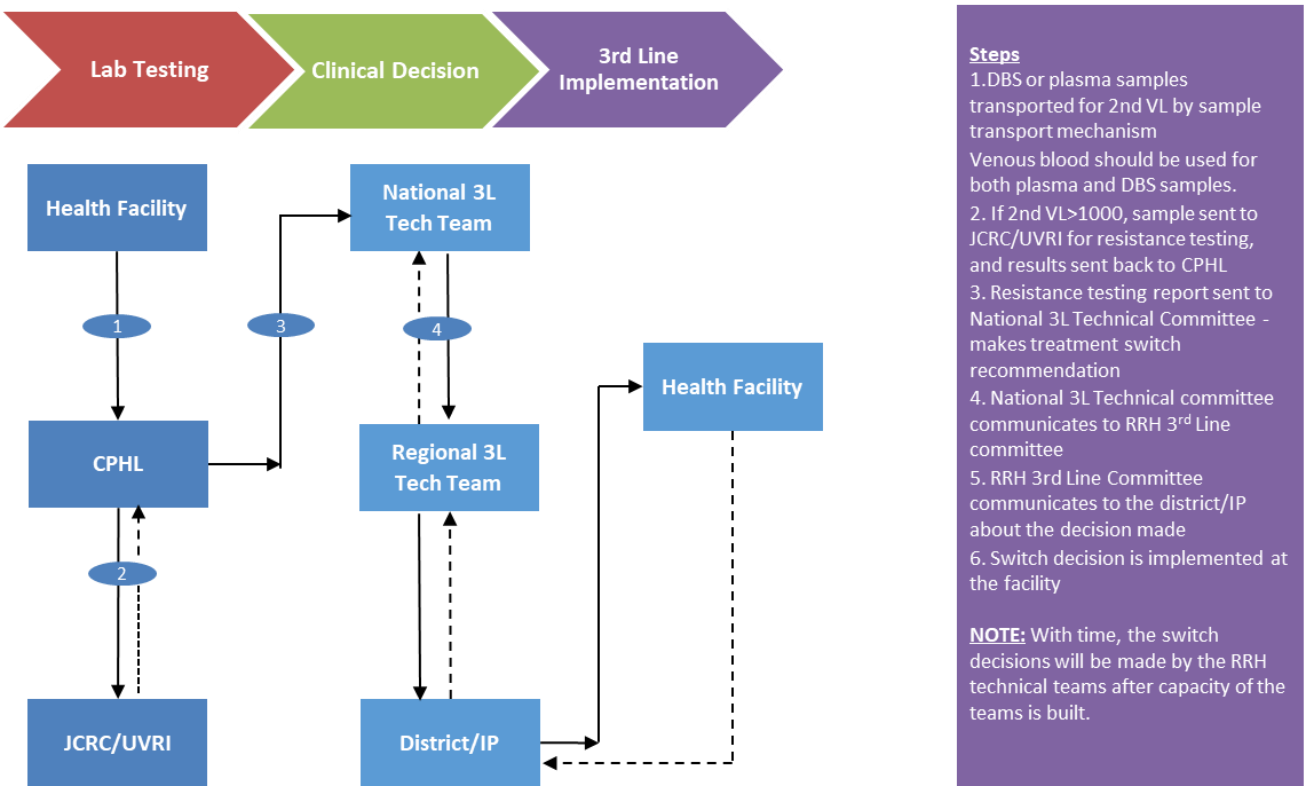


Table 64: Drug interactions

Drug Family	ARV Drug	Interaction	Action
Anti-TB medicines	NVP	Rifampicin decreases NVP concentrations in blood. Could cause liver toxicity	Do not co-administer NVP and rifampicin See Table 30 and Table 31 for TB/ARV co-management

Drug Family	ARV Drug	Interaction	Action
	DTG	Rifampicin lowers DTG levels	Adjust DTG dose to twice daily
	ATV/r, LPV/r, DRV and RTV	Rifampicin boosts metabolism of PIs	If given together with LPV/r increase the dose of RTV to achieve 1:1 ratio
Combined oral contraceptive pills, hormonal implants (etonogestrel)	EFV or ATV/r, LPV/r, DRV and RTV	Risk of contraceptive failure due to increased metabolism of contraceptives	Use additional barrier method or Use Depo-Provera or IUDs
Anxiolytics, e.g. midazolam, diazepam	ATV/r, LPV/r, DRV and RTV	Risk of respiratory depression (midazolam) Increased sedation (diazepam)	Reduce dose of midazolam or diazepam
Antifungals, e.g. ketoconazole	NVP	Risk of hepatotoxicity	Use fluconazole
Simvastatin, rosuvastatin, atorvastatin	ATV/r, LPV/r, DRV and RTV	Inhibition of CYP450 3A4 (reduced metabolism of statins)	Use atorvastatin with lowered dose and monitor for side effects like muscle pains
Anti-epileptics, e.g. carbamazepine, phenobarbital, and phenytoin	EFV, DTG, Etravirine,	Carbamazepine decreases DTG levels by 30-70%	Use valproic acid
Drugs for acid reflux or ulcers, e.g. omeprazole, esomeprazole, lansoprazole, pantoprazole	ATV/r	Reduced concentrations of Atazanavir	Use alternatives like ranitidine, cimetidine, etc.
Polyvalent cation products containing Mg, Al, Fe, Ca, Zn (e.g. vitamin supplements and antacids)	DTG	Reduce DTG levels	Use DTG 2 hours before or 6 hours after the product to avoid interaction
Antimalarial drugs: artemether/lumefantrine, halofantrine	ATV	Both could prolong QT interval	When given with artemether/lumefantrine monitor closely for undesired effects Halofantrine: do not give together (contraindicated)
Metformin	DTG	DTG increases metformin levels. May increase risk of hypoglycaemia and metabolic acidosis	Close follow-up (routine electrolytes, BUN and Creatinine, Random Blood Sugar tests) recommended

Box 8: Key highlights in Antiretroviral Therapy for people living with HIV

- Optimization of ART regimens with more efficacious and durable drugs and simplified dosing is recommended for improved long-term viral suppression.
- The preferred first-line ART for all adults, adolescents and children is Dolutegravir-based.
- PLHIV on NNRTI-based first-line regimens should have their viral loads assessed. If virally suppressed, their ART should be transitioned to optimal preferred first-line regimens. If not suppressed, the patients should be switched to second-line ART with IAC.
- PLHIV initiated on DTG should be longitudinally monitored for adverse effects following recommended pharmacovigilance protocols.
- Newly diagnosed pregnant and breastfeeding women shall be initiated on TDF+3TC+DTG. Pregnant and breastfeeding women already on TLE should be maintained on this regimen until 6-9 months postpartum when they should be transitioned to TLD if the VL within the past 6 months is suppressed. Women becoming pregnant while on DTG-based regimens shall be maintained on the regimen.
- Treatment should be monitored by measuring viral load 6 months after initiation of ART and every 6-12 months or when clinically indicated. A viral load of >1000cells/mm^3 suggests treatment failure and is indication for switch of ART.
- The preferred second-line ART for adults, adolescents and children are either DTG-based or PI-based, depending on the first-line regimens.
- Third-line regimens shall be guided by genotype (resistance) testing.

9 PHARMACOVIGILANCE

9.1 INTRODUCTION

Pharmacovigilance (PV) is defined by the World Health Organization (WHO, 2006) as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects of medicines or any other medicine related problem.

This section recommends heightened pharmacovigilance, re-emphasizes the systems in place for reporting and monitoring drug safety.

9.1.1 Importance of PV

Approval of new medicines for use is based on the information from the pre-approval studies. However, these studies cannot identify all the possible adverse outcomes that a drug may cause, and several unexpected side effects manifest during clinical use which must be monitored, and managed. Health workers must therefore make effort to monitor/detect, understand causes, report, manage and mitigate these reactions (pharmacovigilance).

Toxicities many occur at any time during treatment. Toxicities or adverse drug reactions refer to unintended harmful events due to exposure to medicines. They may be mild to severe and should be anticipated and monitored in a timely manner to avoid severe morbidity and mortality outcomes. Adverse drug reactions may negatively affect treatment uptake, adherence and retention in care.

9.1.2 The major aims of PV are:

a) Early detection of previously unknown adverse reactions and interactions.

b) Detection of increase in known adverse drug reactions.

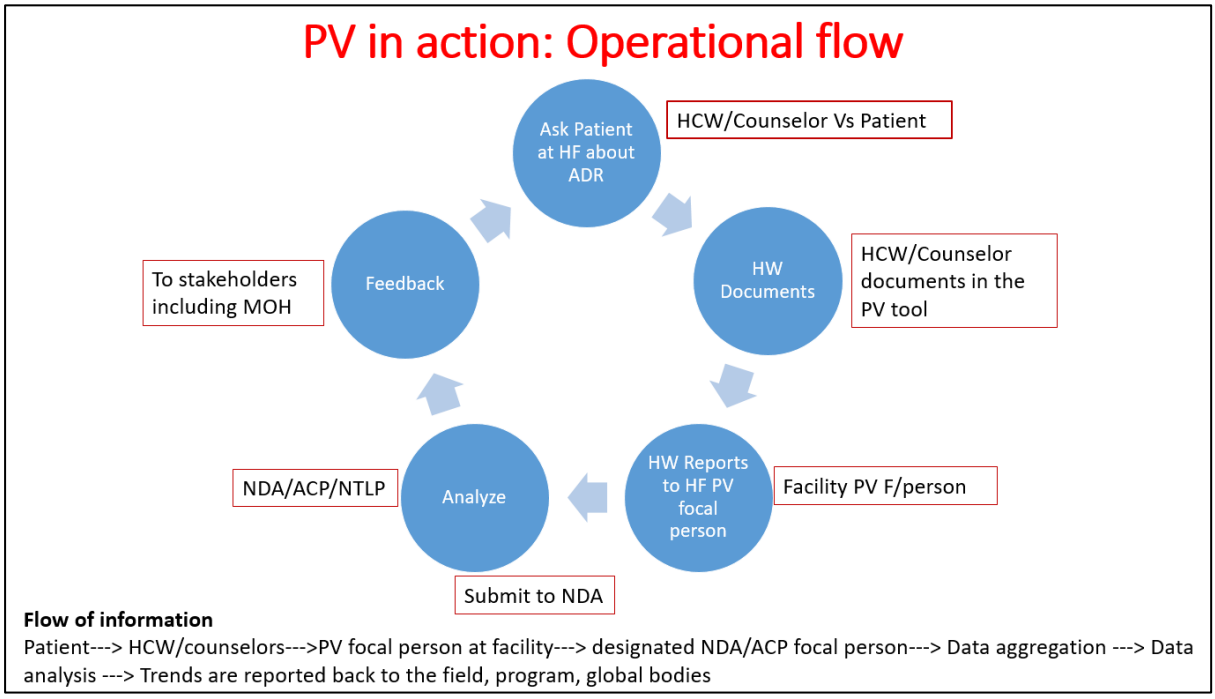
c) Identification of predisposing risk factors and possible mechanisms underlying adverse reaction.

d) Estimation of quantitative aspects of risk/ benefits analysis and dissemination of needed information to improve drug prescribing, use and regulation.

9.1.3 Methods of pharmacovigilance

There are different methods of PV which include Spontaneous reporting and Active pharmacovigilance however, the method approved for HIV and TB implementing site is active pharmacovigilance.

Figure 32: Steps and key players in Pharmacovigilance



9.2 PHARMACOVIGILANCE STRATEGY FOR THE ART PROGRAM IN UGANDA

The program has adopted active PV as part of the routine standard of care in all HIV and TB facilities. Active PV implementation process will be as follows:

a) All sentinel sites shall conduct baseline and routine laboratory investigations for suspected adverse drug event in addition to clinical screening which form, shall be in the patient file. Both laboratory and clinical screenings shall be done even when the patient has no signs and symptoms of ADRs.
b) Non- sentinel sites shall conduct risk-based screening to determine what laboratory tests are to be done. For patients who screen positive to a minimum of two questions on the screening tool shall be eligible for relevant laboratory tests.

9.2.1 ACTIVE PHARMACOVIGILANCE

Active PV, in contrast to spontaneous PV, seeks to ascertain completely the extent of adverse events through a continuous systematic process. To complement spontaneous reporting, sentinel sites were selected to implement active PV in order to pro-actively follow-up patients and detect drug reactions. Patients will undergo proactive clinical and laboratory assessment during treatment to detect ADRs and AEs even when the patient has no signs or symptoms. Active PV will involve the following processes:

1) For each encounter, the health worker should screen for any suspected ADRs as per screening tool above at triage.

2) Clinicians should further evaluate reported signs and symptoms.
3) Where applicable the clinician should request for additional tests (including laboratory and radiological) for patients with signs or symptoms suggesting ADRs.
4) Routine Screening for active PV: At all sentinel sites, the clinician should request for tests at baseline (before starting DTG or INH) and periodically thereafter as described in Table 64 below. These are recommended to be conducted even when the patient has no signs and symptoms.
5) All AEs detected should be managed according to severity in accordance to the guidelines
6) All suspected ADRs should be recorded on the DSM form, reviewed at the site by the facility pharmacovigilance team, and relayed to the NDA either online or through the reporting form to NDA (Annex 15).
7) Data on ADRs is regularly analysed by the NDA with co-opted members as agreed upon by the pharmacovigilance technical working group.

9.2.1.1 Procedure of reporting an adverse drug reaction

As soon as an ADR is suspected/detected, the clinician/doctor should:

1) Adequately assess the patient immediately
2) Record the diagnosis in the OPD/IPD register.
3) The clinician or doctor or Nursing Officer making the diagnosis shall fill the ADR form, the pharmacist or dispenser shall collect filled forms, make tallies, and enter them into HMIS database.
4) The suspected ADR should concurrently be recorded on the Adverse Drug Reaction (ADR) form in Annex 15. The ADR form should be filled in duplicates; - Original copy submitted to the National Pharmacovigilance Centre at the NDA secretariat, the duplicate (blue copy) stays at the Health Unit/Facility. A valid report should have the following minimum information a) Source of information b) Patient details c) Drug details d) Reaction details.
5) Ensure relevant tests are conducted
6) The report is then submitted to the pharmacovigilance focal person within the facility, or if no such person exists, to the regional referral within your catchment area or to the nearest NDA office, or directly to the national Pharmacovigilance Centre at the NDA head office;
    a. For reports on serious adverse events, within 24 to 48 hours of detection/diagnosis.
    b. For non-serious adverse events report as soon as possible but, in any case, not later than 15 days.
7) Follow up of the ADR should be done appropriately and any emerging supplementary/additional information should be forwarded immediately. The tally data for the previous month (collected from HMIS 105 and HMIS 108) should be entered into the HMIS database. NB: – Use a separate form for each event.

9.2.1.2 Alternative methods of reporting may include:

1) Telephone/WhatsApp line; a reporter can call the National Drug Authority or Regional Pharmacovigilance Centre or send a WhatsApp message. The essential information is captured or transcribed on to the suspected ADR reporting form for follow-up.
    - Toll free line: 0800101999
    - WhatsApp: on 0791-415555
2) The internet: A web-based database (Vigiflow) is available at the regional centres.
3) Mobile application. The Medsafe mobile app is available for both patients and health workers to report side effects and receive official news and alerts medicines in Uganda.
4) An online reporting platform for active pharmacovigilance is being planned.

9.2.1.3 Screening tool for Active Pharmacovigilance

This tool (see below) is to be placed in the recipient of care's file to be used as a checklist to screen for side effects of TLD/DTG or INH/TPT at the triage point.

Figure 33: Screening tool for Active Pharmacovigilance

Screening tool for Active Pharmacovigilance

To be placed in the recipient of care's file to be used to screen for side effects of TLD/DTG or INH/TPT at the triage point

Recipient of Care's n(RoC) names…….. Patient clinic #. ……

Sex Age Medication (Tick) DTG based ☐ regimen INH/TPT DTG based ☐ regimen and ☐ INH/TPT

Date of assessment

Since you began taking the NEW medication (TLD/DTG or INH/TPT), have you noticed any changes in the following? (Ensure to ask about all side effects)
Actions to take:

- Record any side effects present & refer (RoC) to clinician to manage them.
- For females on/due for DTG, record if pregnant and refer to clinician to manage.

Month		1	2	3	4	5	6	7	8	9	10	11	12	Remarks
1	**Neuropsychiatric side effects.** Does the client have any of the following (Y/N)?(Bad Dreams, Trouble sleeping/insomnia, headaches, Anxiety or nervousness, change in memory, Change in mood)? Younger children: Ask for irritability (in addition to the above symptoms)													
2	**Hepatotoxicity.** Does the client have any of the following (Y/N)? (Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes).													
3	**Peripheral Neuropathy.** Does the client have any of the following in the hands or feet (Y/N)? (Numbness, tingling, burning sensation). If any is present, record side effect in patients' file and refer to clinician. Younger children: Ask for pain in hands and feet, regression in motor milestones - refusal to crawl, walk or run, reduced playfulness (in addition to the above symptoms)													
4	**Hyperglycemia or diabetes.** Does the client have any of the following (Y/N)? (Increased appetite, increased thirst, and excessive urination). Younger children: Ask for irritability (in addition to the above symptoms)													
5	**Other Abdominal symptoms.** Does the client have any of the following (Y/N)? (Diarrhea, generalized abdominal pain).													
6	**Skin rash.** Does the patient have any new skin rash (Y/N)?													
7	**Musculoskeletal symptoms.** Does the client have any of the following (Y/N)? (Muscle or joint aches, tiredness).													
8	**General SEs.** Does the client have any of the following (Y/N)? (fever, body swelling)													
9	**Other side effect (Please specify): _____**													
	For Females on DTG, review LNMP to rule out pregnancy.													

Send a report on any side effect identified to national drug authority (NDA)

Table 65: Laboratory monitoring for Active Pharmacovigilance in non-sentinel sites

Category of Patient	Drugs	Screening procedures
ART naïve or experienced patient being initiated or switched to DTG or starting Isoniazid preventive therapy	At the time of starting/switching to DTG or starting INH	
	DTG	1. Review eligibility for DTG (Figure25) 2. Perform Baseline Random or Fasting Blood Glucose for those eligible according to the DTG eligibility screening tool (Figure 22).
	Isoniazid	1. Review eligibility for INH 2. Perform risk-based baseline Liver Function Tests checked against any previous values (Minimum AST and ALT) 3. Hepatitis B test
	After initiating/switching to DTG or starting INH	
	DTG	1. Screen using screening tool to identify any developing signs and symptoms. 3. Perform RBS every 3 months for those at high risk for hyperglycaemia in the first 12 months, then thereafter use clinical indication to determine need for tests.
	Isoniazid Prophylaxis	1. Screen using screening tool to identify any developing signs and symptoms. 2. Do Liver Function Tests based on clinical indication.
Patients on other regimens and not on INH	Any ART	1. Screen using screening tool to identify any developing signs and symptoms. 2. Perform laboratory and radiological investigations based on clinical indication.

Table 66: Laboratory monitoring for Active Pharmacovigilance in sentinel sites

Category of Patient	Drugs	Screening procedures
ART naïve or experienced patient being initiated switched to DTG or starting Isoniazid preventive therapy	At the time of starting/switching to DTG or starting INH	
	DTG	1. Review eligibility for DTG (Figure25) 2. Perform Baseline Random or Fasting Blood Glucose checked against any previous values
	Isoniazid	1. Review eligibility for INH 2. Baseline Liver Function Tests checked against any previous values (Minimum AST and ALT) 3. Hepatitis B test
	After initiating/switching to DTG or starting INH	
	DTG	1. Screen using screening tool to identify any developing signs and symptoms.

Category of Patient	Drugs	Screening procedures
		3. Routine RBS every 3 months in the first 12 months, then thereafter use clinical indication to determine need for tests.
	Isoniazid Prophylaxis	1. Screen using screening tool to identify any developing signs and symptoms. 2. Routine Liver Function Tests at 3 months after initiating INH
Patients on other regimens and not on INH	Any ART	1. Screen using screening tool to identify any developing signs and symptoms. 2. Perform laboratory and radiological investigations based on clinical indication

*Unavailability of laboratory tests should not prevent transition. Use clinical screening to assess for adverse effects.

9.3 COMMON DRUG TOXICITIES IN HIV CARE

Antiretroviral drugs and other drugs used in HIV care can cause a wide range of toxicities, from low-grade intolerance that may be self-limiting to life-threatening side effects. Differentiating between ART toxicity (also known as adverse reactions) and complications of HIV disease is sometimes difficult. An observed toxicity could be due to a concurrent infectious process or due to a reaction to medications other than ARVs such as Isoniazid–induced hepatitis in a child on treatment for TB or a rash induced by Cotrimoxazole.

Drug-related side effects while on ART can occur immediately (soon after a drug has been administered), early (within the first days or weeks of treatment) or late (after months or years of treatment). Adverse reactions may be specific to a particular drug, or they may be generic to the class of drugs in use. Toxicity is a concern because it can be life-threatening, can cause non-adherence to ARVs, and may be disfiguring like lipodystrophy. See Table 60 for common ARV side effects and toxicities.

9.3.1 Managing ARV and TB Drug Toxicity

Healthcare workers should assess patients on ART and TB medicines for side effects and toxicities at every clinic visit. If the patient has side effects or toxicity do the following:

1. Determine the seriousness of the toxicity.
2. Evaluate concurrent medications and establish whether the toxicity may be attributable to an ARV or TB medicine, or to any other medication taken at the same time.
3. Consider other disease processes. Not all problems that arise during treatment are caused bymedicines.
4. Manage the side effects and toxicities according to severity (Table 67).
5. Report the event using the Adverse Drug Reaction form.

Table 67: Management of ARV side effects/toxicities

Category	Action
Severe, life-threatening reactions	Immediately discontinue all ARV drugs, manage the medical event and substitute the offending drug when the patient is stable.

Category	Action
Severe reactions	Substitute the offending drug without stopping the ART.
Moderate reactions	Substitute with a drug in the same ARV class but with a different toxicity profile, or with a drug in a different class. Do not discontinue ART. Continue ART as long as feasible. If the patient does not improve on symptomatic therapy, consider single –drug substitution.
Mild reactions	Do not discontinue or substitute ART. Reassure the patient or caregiver that while the reaction may be bothersome, it does not require a change in therapy; provide support to mitigate the adverse reactions as well as counseling about the events.

Table 68: Symptomatic and Laboratory Severity Grading for common ADRs

Parameter	Grade 1: Mild	Grade 2: Moderate	Grade 3: Severe	Grade 4: Potentially life threatening
Note: For all symptoms reported as potential ADRs, grade them according to the criteria above.				
Symptomatic grading	Mild symptoms causing no or minimal interference with usual social & functional activities with intervention not indicated	Moderate symptoms causing greater than minimal interference with usual social & functional activities with intervention indicated	Severe symptoms causing inability to perform usual social & functional activities with intervention or hospitalization indicated	Potentially life-threatening symptoms causing inability to perform basic self-care functions with intervention indicated to prevent permanent impairment, persistent disability, or death
Note: Use the reference ranges below to grade the severity of events where laboratory investigations are available. For laboratory investigations not included, refer to DAIDS Grading tables for grading: https://rsc.niaid.nih.gov/clinical-research-sites/daids-adverse-event-grading-tables				
Random Blood Sugar	116 to 160 mg/dL 6.44 to < 8.89 *mmol/L*	> 160 to 250 mg/dL 8.89 to < 13.89 *mmol/L*	> 250 to 500 mg/dL 13.89 to < 27.75 *mmol/L*	≥ 500 mg/dL ≥ 27.75 *mmol/L*
Fasting Blood Sugar	110 to 125 mg/dL 6.11 to < 6.95 *mmol/L*	> 125 to 250 mg/dL 6.95 to < 13.89 *mmol/L*	> 250 to 500 mg/dL 13.89 to < 27.75 *mmol/L*	≥ 500 mg/dL ≥ 27.75 *mmol/L*
Glycosuria (random collection tested by dipstick)	Trace to 1+ or ≤ 250 mg	2+ or > 250 to ≤ 500 mg	> 2+ or > 500 mg	N/A
LFTs (Transaminases) ALT or SGPT and AST or SGOT	1.25 to < 2.5 x ULN (For any) *ULN=Upper limit of Normal	2.5 to < 5.0 x ULN (For any)	5.0 to < 10.0 x ULN (For any)	≥ 10.0 x ULN (For any)
RFTs (Creatinine)	N/A	< 90 to 60 ml/min or ml/min/1.73 m2 OR 10 to < 30% decrease from participant's baseline	< 60 to 30 ml/min or ml/min/1.73 m2 OR 30 to < 50% decrease from participant's baseline	< 30 ml/min or ml/min/1.73 m2 OR ≥ 50% decrease from participant's baseline or dialysis needed
Cholesterol, Fasting, High ≥ 18 years of age	200 to < 240 mg/dL; 5.18 to < 6.19 mmol/L	240 to < 300 mg/dL; 6.19 to < 7.77 mmol/L	≥ 300 mg/dL; ≥ 7.77 mmol/L	N/A

Parameter	Grade 1: Mild	Grade 2: Moderate	Grade 3: Severe	Grade 4: Potentially life threatening
LDL, Fasting, High ≥ 18 years of age	130 to < 160 mg/dL; 3.37 to < 4.12 mmol/L	160 to < 190 mg/dL; 4.12 to < 4.90 mmol/L	≥ 190 mg/dL; ≥ 4.90 mmol/L	NA
Triglycerides, Fasting, High	150 to 300 mg/dL; 1.71 to 3.42 mmol/L	>300 to 500 mg/dL; >3.42 to 5.7 mmol/L	>500 to < 1,000 mg/dL; >5.7 to 11.4 mmol/L	> 1,000 mg/dL; > 11.4 mmol/L

9.3.2 Drug substitutions for ARV drug toxicity

Substitution is the process of replacing one ARV drug with another. The duration on ART is important when doing ARV substitution. If substitutions are being done within six months of starting ART, it is not necessary to perform a viral load test.

However, after six months on ART, a viral load test may be required to rule out treatment failure before a drug is substituted in a failing patient. If the viral load is not suppressed, it is possible the patient may be failing on treatment. Follow the viral load algorithm to rule out treatment failure. In a failing patient, the ART regimen should be switched to 2nd line. See Table 60 for side effects of commonly used ARVs and recommended substitutions.

9.4 HYPERGLYCAEMIA FOLLOWING DTG INITIATION

9.4.1 Screening for DTG eligibility

Before initiating on or substituting a patient to a regimen containing DTG, screen for eligibility using the flow chart (refer to Figure 25).

9.4.2 Management of hyperglycaemia following DTG initiation

The diagnostic criteria for Hyperglycemia/DM are as follows:

1) **Random Blood Glucose (RBG) >11.0mmol/l**
    - This is the most convenient
    - It must always be followed by a fasting blood sugar except in presence of grade III and Grade IV hyperglycemia.
- **Fasting Blood Glucose (FBG) >7.0mmol/l**
    - Preferred in the absence of the OGTT.
- **Oral Glucose Tolerance Test (OGTT)**
    - This is the gold standard. However, it is not commonly available.
- **HBA1c >6.5%**
    - This is recommended for follow up of Diabetic patients to assess control while on hypoglycemic agents. Not to be used for screening.

Table 69: Management of Hyperglycaemia following DTG initiation

Management of Hyperglycemia following DTG initiation.

Hyperglycemia grading	Management	Comments
Grade I >117- <160mg/dl (6.5-8.9 mmol/l)	Encourage diet modification and exercise control Perform Fasting blood sugar after 1 week	For all patients: • Encourage diet modification and exercise for better glycemic control • Encourage regular monitoring of blood sugar while at home. • Encourage foot care. • Stop smoking and reduce alcohol intake • Counsel on symptoms of hypoglycemia. • Do lipid profile • Serum creatinine, Urea and Electrolytes. • Do regular screening for macro and microvascular complications of DM. • Consider stopping DTG.
Grade II 160-250mg/dl (8.9-13.9 mmol/l)	Encourage diet and exercise control Initiate oral hypoglycemics Start with metformin 500mg daily increase as needed to a maximum of 2000mg daily.	
Grade III 250-500 mg/dl (13.9-27.8 mmol/l)	Refer for specialist management and consider admission if RBS> 20mmol/l Counsel patient on signs and symptoms of hypoglycemia Ensure close monitoring of Fasting Blood Glucose.	
Grade IV >500mg/dl (>27.8mmol/l) or Life threatening complications like HHONK, DKA	Refer for admission If possible, Institute IV fluids(crystalloids – normal saline) immediately while preparing for transfer or give ORS if there is likely to be delay in accessing care.	

9.5 HEPATOTOXICITY FOLLOWING CO-ADMINISTRATION OF ART AND TPT /TB MEDICINES

Co-administration of ART and TPT/TB medicines increases the likelihood of toxicities especially hepatotoxicity. Health workers should therefore take care to adequately screen patients for TPT eligibility prior to initiation of TPT. Once toxicity occurs, it should be managed appropriately according to the grading (refer to Table 68 for grading).

9.5.1. Contraindication for TPT

- Presence of acute liver disease
- History of alcohol abuse
- Known hypersentivity to INH
- Presence of mental illness
- Presence of seizures
- Presence of severe neuropathy
- Newly initiated on DTG (within the last 3 months)
- Co-administration with Nevirapine. Note, for patients transitioning from NVP, ensure to wait for at least 2 weeks before starting TPT.

Box 9: Key highlights in Pharmacovigilance

Key Highlights

- These guidelines emphasize the importance of pharmacovigilance for the early identification and management of adverse effects of medications especially HIV and TB medicines.
- Method of pharmacovigilance adopted for all HIV and TB facilities will be Active pharmacovigilance.
- All facilities, as part of routine care will routinely screen, investigate, manage and report adverse drug reactions as they present at the facility. Healthcare workers should assess patients on HIV and TB medicines for side effects and toxicities at every clinic visit.
- Active pharmacovigilance involves pro-active investigation of patients during treatment and follows them up to detect adverse drug reactions and adverse events even when the patient has no signs or symptoms.
- Reports from active PV should be submitted to the National Drug Authority through the Regional Referral Hospital and NDA Regional Offices.
- Side effects and toxicities of ARVs and TB medicines should be managed according to severity. For moderate and severe reactions, the responsible ARV or TB medicine should be substituted following the specific substitution guidance. For life-threatening reactions, ART and/or TB medication should be discontinued, and the event managed. ART and TB medication should be resumed with substitution of the responsible ARV or TB medication when the patient is stable.

10 SERVICE DELIVERY APPROACHES

This chapter will discuss differentiated service delivery, HIV service delivery to adolescents, the comprehensive community service delivery approach and continuous quality improvement.

10.1 DIFFERENTIATED SERVICE DELIVERY (DSD)

10.1.1 Introduction

Differentiated service delivery refers to various ways of providing HIV prevention, care and treatment services that are tailored to the needs and preferences of PLHIV with the aim of maintaining good clinical outcomes and improving efficiency in service delivery.

Differentiated service delivery will improve the efficiency of existing approaches. It addresses individuals' needs, informs targeted interventions with better outcomes among clients; improves access, coverage and quality of services and lead to efficient utilization of resources.

This section presents the recommended differentiated service models for HTS, care and treatment for PLHIV and TB for adoption by the facilities and communities managing PHLIV. The details on how the differentiated care models will be implemented in Uganda are described in the Implementation guide for Differentiated Service Delivery Models (DSDM) for HIV and TB services in Uganda (version March 2020).

10.1.2 CORE PRINCIPLES OF DIFFERENTIATED SERVICE DELIVERY

The core principles of differentiated care are client-centered and improved health system efficiency.

a) Client-centred care

The core principle for differentiating care is to provide ART delivery in a way that acknowledges specific barriers identified by clients and empowers them to manage their disease with the support of the health system. WHO highlights the need for client-centred care to improve the quality of HIV care services.

b) Health system efficiency

With the population of PLHIV having increasingly diverse needs, it is acknowledged that health systems will have to adapt away from a "one-size-fits-all" approach. DSD supports shifting resources to clients who are the most in need by supporting stable clients to have fewer and less intense interactions with the health system.

10.1.3 WHY DIFFERENTIATED SERVICE DELIVERY IS NEEDED

Differentiated service delivery can improve the efficiency of existing approaches. It shall address individuals' needs, inform targeted interventions with better outcomes among clients, improve coverage and quality of services, and lead to efficient utilization of resources. It will allow health providers to better identify and categorize PLHIV early on, streamline care and treatment services for stable clients, and focus more time and attention on the clients requiring more attention. The recommended differentiated service delivery models in most cases will not require significant policy changes or additional resources since they are mainly streamlining what is already being implemented.

10.1.4 THE TARGET GROUPS FOR DIFFERENTIATED SERVICE DELIVERY

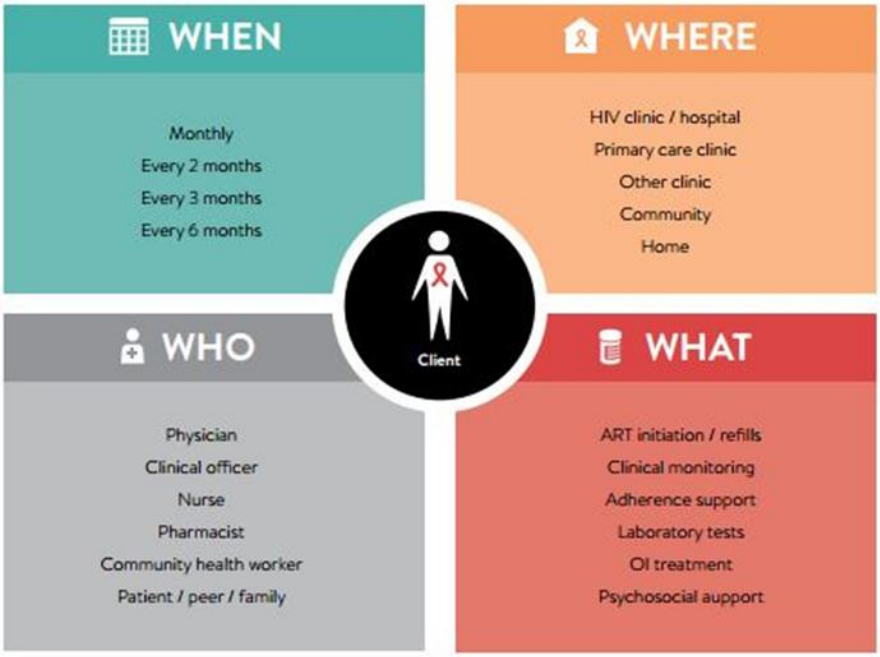
The DSD will meet the different care and treatment needs of different groups of clients including clients newly initiating ART, children, adolescents, pregnant and lactating women, adult men and women, key populations and patients with advanced disease. All the above will be categorized as stable or unstable.

10.1.5 BUILDING BLOCKS

There are four building blocks or delivery components that facilities need to address when considering the different models to adopt for specific client groups or populations. Figure 34 below summarizes these building blocks which include:

- The type of services delivered – WHAT
- The location of service delivery - WHERE
- The provider of the services – WHO
- The frequency of the services – WHEN

Figure 34: The building blocks for differentiated service delivery



In all models of service delivery, the client is at the centre. The stakeholders must balance the goal of improving client outcomes with their ability to utilize the available health system resources.

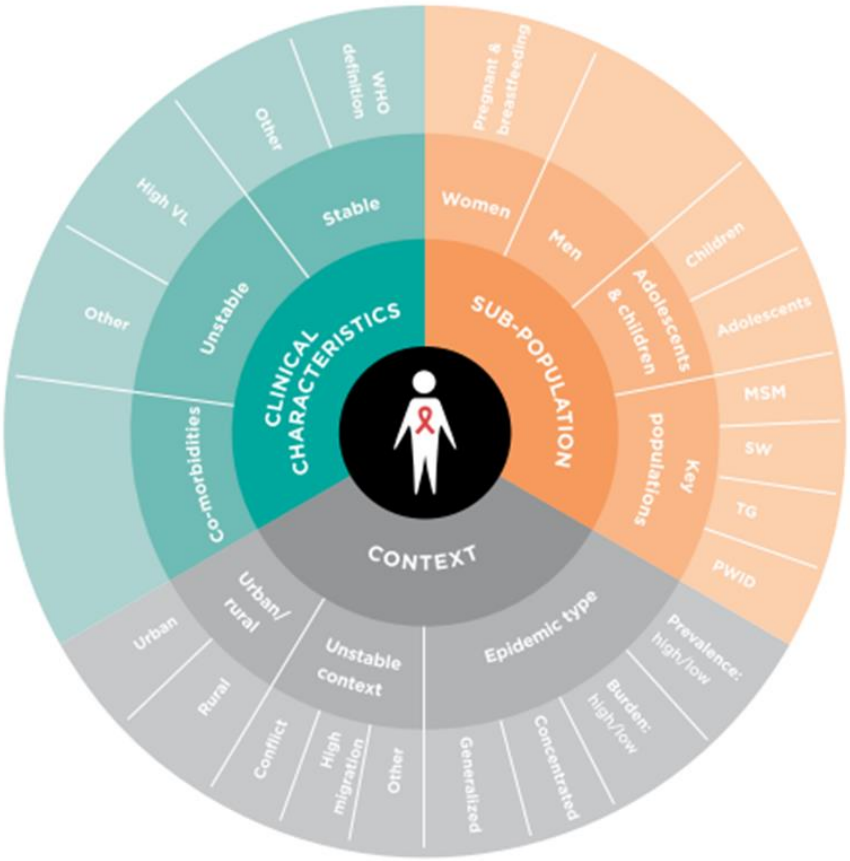
10.1.6 THE ELEMENTS TO CONSIDER IN DIFFERENTIATED CARE

In order to provide client-centred care, there is a need to consider the following:

- The clinical characteristics of the client (stable, unstable or complex).
- The specific populations (e.g., adults, children and adolescents, pregnant and breastfeeding women, key populations, men).
- The context (e.g., urban/rural, unstable context, epidemic type.)

This will allow you to build appropriate models of HIV Testing and Screening and HIV Treatment and Care using the building blocks described earlier. The elements are presented in Figure 35.

Figure 35: The three elements to consider while differentiating care



10.1.7 RECOMMENDED DIFFERENTIATED SERVICES

The two services for adopting differentiated models are:

1. Differentiated HIV testing services.
2. Differentiated HIV care and treatment services.

10.1.8 Differentiated HIV testing services

This section discusses the differentiated HTS approaches with the aim of helping health facility managers, facility in-charges, health care workers (HCWs), community- based health service providers and other stakeholders to adopt efficient HTS approaches for reaching the undiagnosed PLHIV.

Definition

Differentiated HIV Testing Services are service-delivery models that are adapted to address the specific barriers or bottlenecks requirements of a subgroup of individual clients to enable them to know their HIV status.

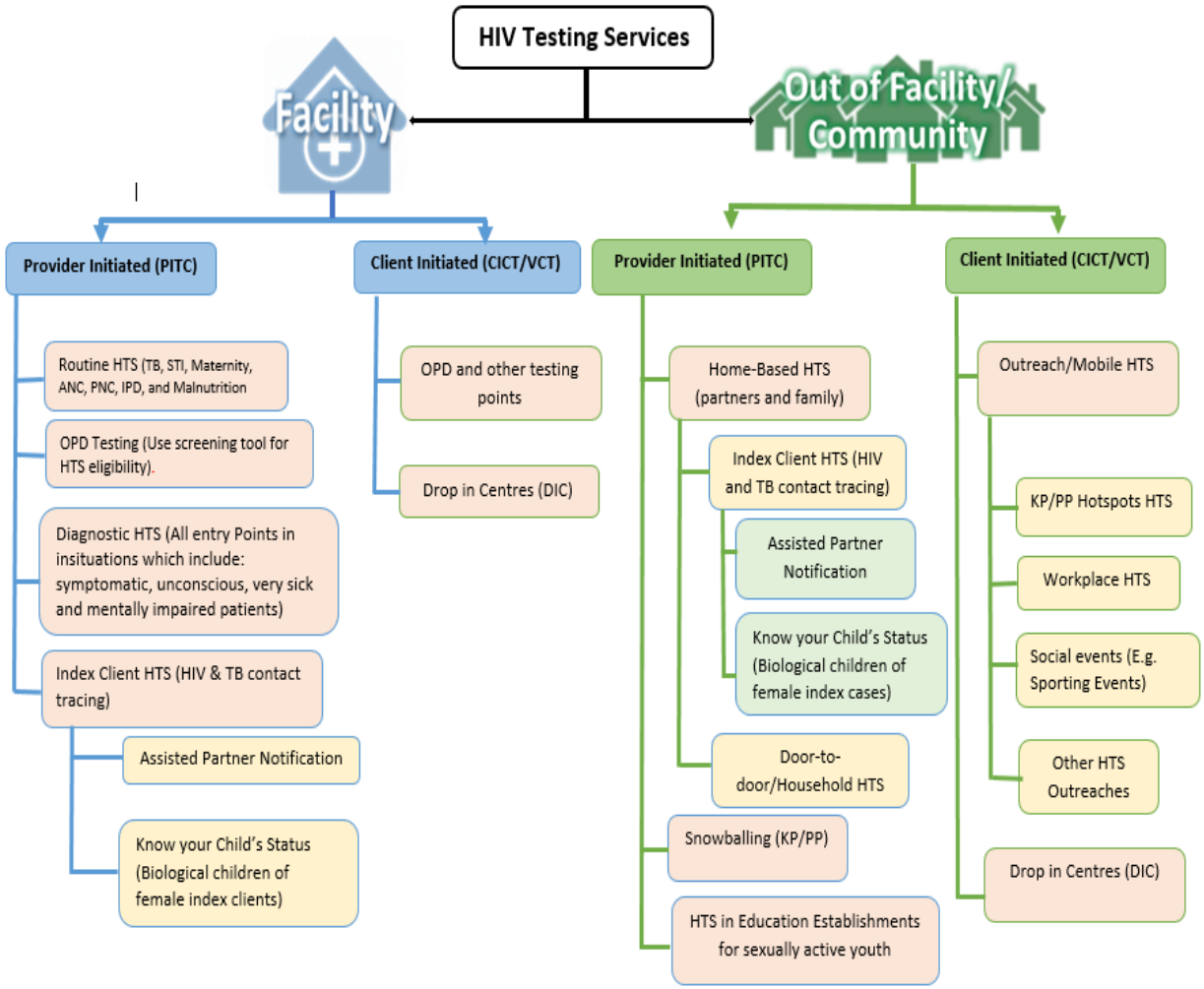
10.1.9 The recommended models and approaches

The recommended ways of differentiating HIV testing and screening include 1) facility-based models and 2) community-based models, summarized under Section 2.1.1 and 2.1.2as well as in Figure 36 below.

HTS services will be offered in the facility (facility-based HTS model) or in the community (community-based HTS model) (Figure 36).

- Facility-based HTS shall include provider-initiated HTS (i.e. Routine HTS, OPD testing, Diagnostic HTS and Index client HTS) and client-initiated counseling and testing (i.e.at OPD and other testing points or Health Facility based Drop in Centres).
- Community-based HTS shall include provider-initiated HTS (i.e. Home based HTS, Snowballing and HTS in Education Establishments for sexually active youth) and Client-initiated counseling and testing (i.e. outreach/mobile HTS and HTS at Community Drop in Centres).

Figure 36: Recommended differentiated HTS delivery models



10.1.9.1Differentiated care and treatment services

Differentiated HIV treatment and care refers to a strategic mix of approaches to address the specific requirements of a subgroup of clients living with HIV. It includes approaches aimed

at modifications of client flow, schedules and location of HIV treatment and care services for improved access, coverage, and quality of care.

The recommended models and approaches
The recommended ways of differentiating HIV treatment and care include 1) facility-based models and 2) community-based models, summarized in the Figure 37.

10.1.10 CATEGORIZATION OF THE CLIENT CHARACTERISTICS FOR DIFFERENTIATED SERVICE DELIVERY

There are two categories of clients (1) Stable and (2) Unstable/complex. The Table 70 below summarizes the minimum characteristics for categorization:

Table 70: The differentiated client categories and their characteristics

Stable Clients	Unstable/Complex Clients
• PLHIV (Children, Adolescents, Pregnant and lactating women and adults) on current ART regimen for more than 6 months*. • On 1st or 2nd line ART regimens. • Virally suppressed: Most recent viral load result suppressed and still valid as per the viral load algorithm. • WHO stages 1 or 2. • Demonstrated good adherence (over 95%) in the last 6 consecutive months. • TB clients who have completed 2 months intensive phase treatment and are sputum negative for PTB.	• PLHIV (Children, Adolescents, Pregnant and lactating women and adults) on current ART regimen for less than 6 months. • On 3rd line ART regimen. • Not virally suppressed or with a valid suppressed viral load result. • Has current or history of WHO stages 3 or 4 opportunistic infections within the past one year. • Poor adherence (less than 95%). • TB clients in intensive phase of treatment (< 2 months) or who are still sputum positive after intensive phase treatment for PTB. • MDRTB/HIV co-infected clients.

All stable clients transitioned to new regimen due to policy changes (e.g. ART optimization) shall be retained in their current DSD approaches if all other factors stay constant however pharmacovigilance MUST be emphasized. See section on DSD implementation in the context of ART optimization for details.

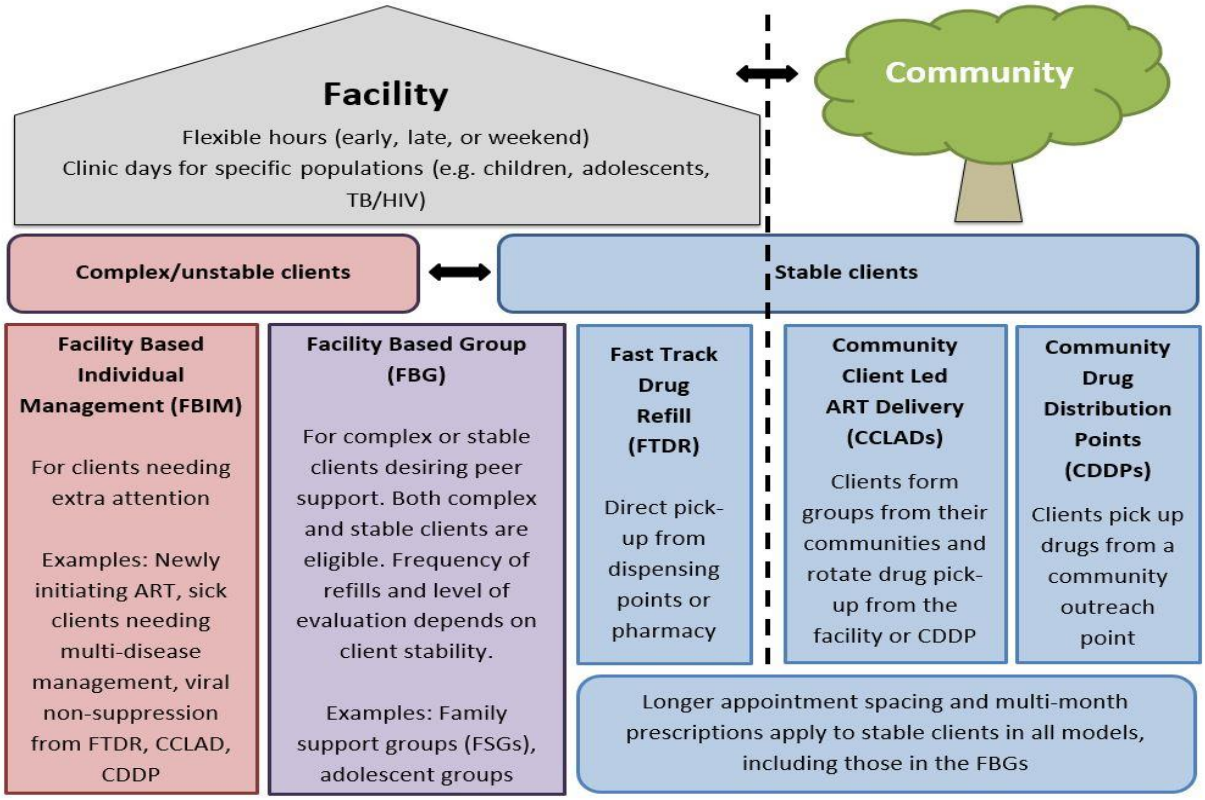
Clients must first be categorized as either stable or unstable/complex. This will determine the model and approach that they will be differentiated to.

KEY CONSIDERATIONS:

1. For a client to be stable, must meet all the above criteria for stable clients.
2. Clients with uncontrolled chronic co-morbidities (e.g. Hypertension, Diabetes, Cardiac diseases, and renal diseases) should be considered unstable until control is achieved.

3. Pregnant women can fall in either stable or unstable/complex categories, depending on their characteristics. They are, however, differentiated to only facility-based approaches.
4. Health workers may take into consideration other issues not included in the lists above, e.g. psychosocial problems/issues, family support, etc. to determine whether a client is stable or not.

Figure 37: Recommended differentiated care and treatment service delivery models and their respective target populations



10.1.11 MULTI- MONTH PRESCRIPTIONS

Multi-month prescriptions apply to stable clients in stable approaches. This is defined as prescriptions for 3- or 6-months. Previous guidelines recommended 3 months prescriptions for stable clients on stable approaches i.e. FTDR, CDDP and CCLAD. These guidelines recommend the introduction of 6 months prescription for high risk clients in whom frequent drug pickups may compromise their adherence to ART. Only stable clients will be considered for 6-month refills of ART in addition to meeting all the following criteria:

- ≥15 years
- Not pregnant or breastfeeding
- Repeat VL not due in less than 6 months
- Not TB/HIV co-infected
- No regimen switch or substitution in the last 6 months
- Completed INH prophylaxis

Six-month refills can be provided through FTDR or CDDP approaches.

10.1.12 Recommended HIV Care and Treatment models for select sub-populations:

Clients receiving HIV care and treatment under the facility- and community-based models can be summarized in the table below.

Table 71: Client categories for HIV Care and Treatment services under the various differentiated categories

Categories	Qualifying Clients								
	Stable* Client	Complex Unstable**/ New/ Transfers in	Children		Adolescents		PMTCT (ANC→3 months postpartum)	PMTCT (Mother-Baby Pair 3-18 months)	Key Populations
			<2 years	2-<10 years	10-14 years	15-19 years			
Facility Based Individual Management (Comprehensive clinical evaluation)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Facility Based Group	✓	✓	✓	✓	✓	✓	✓	✓	✓
Fast track drug pick-up	✓			✓ 1	✓	✓			✓
Community Client Led ART Distribution (CCLAD)	✓				✓ 3	✓ 5			✓
Community Drug Distribution Points (CDDPs)	✓			✓ 2	✓ 4	✓ 6			✓

10.1.13 DSD for children and adolescents

Previous guidelines restricted differentiation of HIV/TB services for children to FBIM or FBG while the adolescents were restricted to FBIM, FBG or FTDR. These guidelines recommend the expansion of DSD approaches for children and adolescents as per the guidance in the table above and the notes below.

Notes

- **1 and 2**, Stable children 2 - <10years can join FTDR or CDDP if their parents/care givers are stable and choose to join these approaches.
- **3 and 4**, Stable adolescents 10 – 14years can join CCLADs or CDDP if their parents/care givers are stable and choose to join these approaches.
- **3**, Stable adolescents (10 – 14years) can be CCLAD members if their parents/care givers are stable and choose to join CCLADs but they cannot pick drugs on behalf of the other members. The responsibility of picking drugs will be for the parent/care giver in each CCLAD group.
- **5 and 6**, Stable adolescents 15 – 19years can join CCLADs or CDDPs if they choose to.
- **5**, Adolescents 15 – 19years can form an adolescent only group if they choose to.

10.1.14 Early Differentiation

At 6 months after initiation of ART, a client can be classified as stable and qualify to be differentiated into approaches for stable clients in the facility and the community.

10.1.15 DSD implementation in the context of ART optimization

All stable PLHIV transitioning to other regimens due to policy changes (e.g. ART optimization) shall be retained in their current DSD approaches if all other factors stay constant. Efforts should be made to strengthen pharmacovigilance in all DSD models and approaches. The following are recommended as health workers optimize ART for the PLHIV enrolled onto FBIM, FBG, FTDR and CCLAD:

- Providing one-month refill at regimen change
- Providing patient education about side effects and when to return to facility
- Scheduling a clinical review one-month post regimen change
- If no major concerns are identified during the clinical review one-month post regimen change, stable clients can resume multi-month refills (MMRs)

Clients enrolled onto Community Drug Distribution Point (CDDP) approach shall have their regimen optimization done as follows:

- Regimen change done by clinician at the CDDP
- Patient education about side effects and when to return to facility provided at the CDDP
- 3-months refill provided
- Clinical review scheduled at 1 month after regimen change at the facility.
- If no major concerns identified the client is referred back to the CDDP for the next scheduled visit.
- If no major concerns are identified during the clinical review one-month post regimen change, the client is referred back to the CDDP for the next scheduled visit.

10.1.16 Provision of TB Preventive Therapy (TPT) to clients in the various DSD models and approaches

TB Preventive Therapy (TPT) is recommended for specific sub-populations who are at an increased risk of getting TB disease as per details in Chapter 6. The following should be followed while providing TPT in the context of DSD:

10.1.16.1 TPT initiation

- TPT should be initiated by a clinician regardless of which DSD approach the client is on. Efforts should be undertaken to have baseline tests done (i.e. LFTs) prior to initiation of TPT.
- TPT should be initiated at the health facility for all clients receiving ART services through FBIM, FBG, FTDR and CCLAD.
- For clients enrolled onto CDDPs, TPT should be initiated from the CDDP during the clinicians visit. Efforts should be undertaken to have baseline tests done (i.e. LFTs) at the time of initiation of TPT.
- Patient education about side effects and when to return to the facility should be provided at the time of TPT initiation regardless of DSD approach.
- TPT and ART refills should be aligned

10.1.16.2 Monitoring clients on TPT

- Clinical monitoring of clients on TPT should be done at every clinical encounter regardless of DSD approach the client is on:
  - Monitoring can be done through history taking and physical examination for signs suggestive of hepatic injury (i.e. Yellowing of eyes, body itching, body rash)
  - Monitoring can also be done through follow up phone calls to the clients. During the phones calls health workers should explore for signs of liver injury, adherence to treatment and provide client education.
  - LFTs should be done at baseline and at 3 months
- Clients in more intensive approaches (i.e. FBIM and FBG) should be reviewed every month for TPT and ART toxicities
- Clients in less intensive approaches (i.e. FTDR, CDDP and CCLAD) should be reviewed at least once every three months. Review at 3- and 6-months post TPT initiation should happen at the facility for clients enrolled onto FTDR and CCLAD. Review at 3- and 6-months post TPT initiation for clients enrolled onto CDDP should happen at the CDDP.

10.1.17 Differentiation of HIV services for special sub-populations.

10.1.17.1 Group ANC and PNC for Adolescent Girls and Young Women (AGYW)

This is where pregnant and breastfeeding AGYW receive MCH/PMTCT health services and education in a group setting together with other peers characterized by similar gestation ages or age groups irrespective of HIV status. After the initial individual ANC/PNC visit, all subsequent MCH/PMTCT care is provided in a group setting with most of the time dedicated to facilitated discussions. Additionally, individual clinical care is provided at a private space which is set up within the group setting. Individualized care includes physical examination and assessment for additional health care needs or specialized care. Upon identification, mothers are effectively referred to receive the identified services e.g. DREAMS, OVC and KP/PP services.

10.1.17.2 Young People and Adolescent Peer Support (YAPS)

The Young people and Adolescent Peer Support (YAPS), is an example of differentiated service delivery for adolescents and young people living with HIV. It is peer-led programming for adolescents and young people in line with WHO guidance for adolescent health programming. The adolescent peer support strategy is hinged on the community strategy placing the care giver/ parents/ family members at the centre of the intervention. The goal of the YAPS intervention is to contribute to reduction of HIV related morbidity and mortality among adolescents and young people living with HIV (AYPLHIV)through increasing identification, ART treatment coverage, viral load suppression and general wellbeing through psychosocial support.

Successful implementation of the YAPS model is hinged on the following:

1. Concept of differentiated service delivery models of care. This model highlights the "what, when, where, who and how" of service delivery by adolescent YAPS.
2. Functional adolescent-responsive services with involvement and support from all health facility staff and community.
3. Effective referrals and linkages to appropriate services.
4. Meaningful collaborations and networks with other units at the health facility and community-based service providers.

Details of implementing the YAPS model is contained in the National YAPS Implementation Guide.

10.1.18 How to Introduce Differentiated Service Delivery Models

Health care workers and other service providers in direct contact with clients need to be familiar with DSDM and therefore need to be trained to implement the selected approaches, and to enter data and maintain records that will help in future analysis of results.

During and immediately following the training of health care workers on DSD, MoH recommends the stepwise approach detailed in Table 72 to be followed in your facility to introduce differentiated models of service delivery. This approach will facilitate effective implementation and coordination of DSDM.

Table 72: Stepwise approach to introduce differentiated models of service delivery

Step 1: Establish a committee to coordinate DSDM activities

1. Strengthen an existing committee to undertake DSDM activities. At a minimum they should include:
    - ART In Charge
    - HTS Focal Person
    - HMIS/Data Clerk
    - Logistics Focal Person
    - QI Focal Person
    - PMTCT/EID Focal Person
    - Community Representative (Health Assistant, CDO, VHTs, CHEWs)
    - TB Focal Person
    - Laboratory Focal Person

NOTE:

- ✓ This team should be supervised by the Health Facility In-charge

2. To ensure buy-in and facilitate quick and easy DSDM implementation in the facility, the established committee will be in charge of coordinating the development and implementation of the work plan

Step 2: Conduct assessments to:

1. Determine the current practices i.e. what models and approaches are being implemented in the facility and community based on the building blocks and the elements.
2. Define the priority sub populations receiving services in your facility and communities. These will be the populations for whom both HTS and Care and Treatment services will be differentiated.
3. Determine the characteristics of each of the identified sub populations above.
4. Engage with community members and volunteers.
5. Determine the challenges by service providers in delivering different services to specific groups.

Step 3: Review results from the various assessments to determine the appropriate model(s) and approach(es) for your facility both HTS and Care and Treatment

Step 4: Assess resource needs

The approaches do not require additional resources in the run phase. However, they will require upfront investments. The facility needs to have a clear understanding of resource requirements before starting. Resources may include human resources, extra materials/equipment, and financial support.

Step 5A: Devise a clear work plan and implement selected model(s), with key milestones. Designate responsible persons

Step 5B: Implement and Monitor the model(s)

1. Refer to details for each model and approach on how to implement (Differentiated HTS and differentiated HIV Care and Treatment sections)
2. Utilize relevant SOPs, job aides, tools and registers for each model
3. Monitor set indicators for each model and approach (Refer to M&E section)
4. Review progress through CMEs, review meetings, etc.
5. Identify areas for improvement and use QI approach to address them (Refer to QI section)
6. Assess impact of the QI interventions and make necessary adaptations

7. Report (Refer to M&E section)

NOTE:

- ✓ At the end of each month report how many new approaches (by model) have been formed

Step 6: Document best practices

Documentation for best practices should be detailed enough, addressing aspects such as:

- ✓ Processes that were undertaken
- ✓ Structures/systems that were developed and/or strengthened
- ✓ Positions that were designated for key DSD activities
- ✓ Resources used, including how they were mobilized - from who or which organization and whether they fostered TB/HIV collaboration efforts
- ✓ Networks that were developed – within the community, across facilities etc. and how this was done
- ✓ Successes attained
- ✓ Challenges encountered and how they were addressed or attempted to be address (if the challenges still exist); etc.

Refer to the Implementation guide for Differentiated Service Delivery for HIV and TB Services in Uganda for details.

10.2 WORKING WITH COMMUNITY SYSTEMS AND STRUCTURES TO OPTIMIZE DELIVERY OF HIV SERVICES

10.2.1 INTRODUCTION

The rationale for community engaged health programming is rooted in the recognition that lifestyle, behavior and incidence of illness are all shaped by social and physical environment. Establishing and sustaining community structures and systems at all levels of the health system is critical in completing the HIV continuum of prevention, care and treatment. The National Community Strategy provides guidance to all stakeholders on the strategic direction and implementation of evidence based high impact interventions to improve HIV outcomes.

Collaboration between health facilities and community structures is critical in realizing the desired outcomes in the various areas including identification of positives, linkages to prevention, care and ART services, retention in care, viral load suppression as well as reduction in morbidity due to opportunistic infections.

The community structures and systems will play a key role in completing the continuum of care by increasing demand, uptake and continuous utilization of HIV prevention, HTS, care and treatment services both in facilities and community.

Meaningful involvement of community structures and systems empowers communities to be resilient; with capacity to take charge of their own health (self-care), participate in service delivery, demand for and advocate for improved services. This contributes to increased demand and uptake of HIV and other health related services.

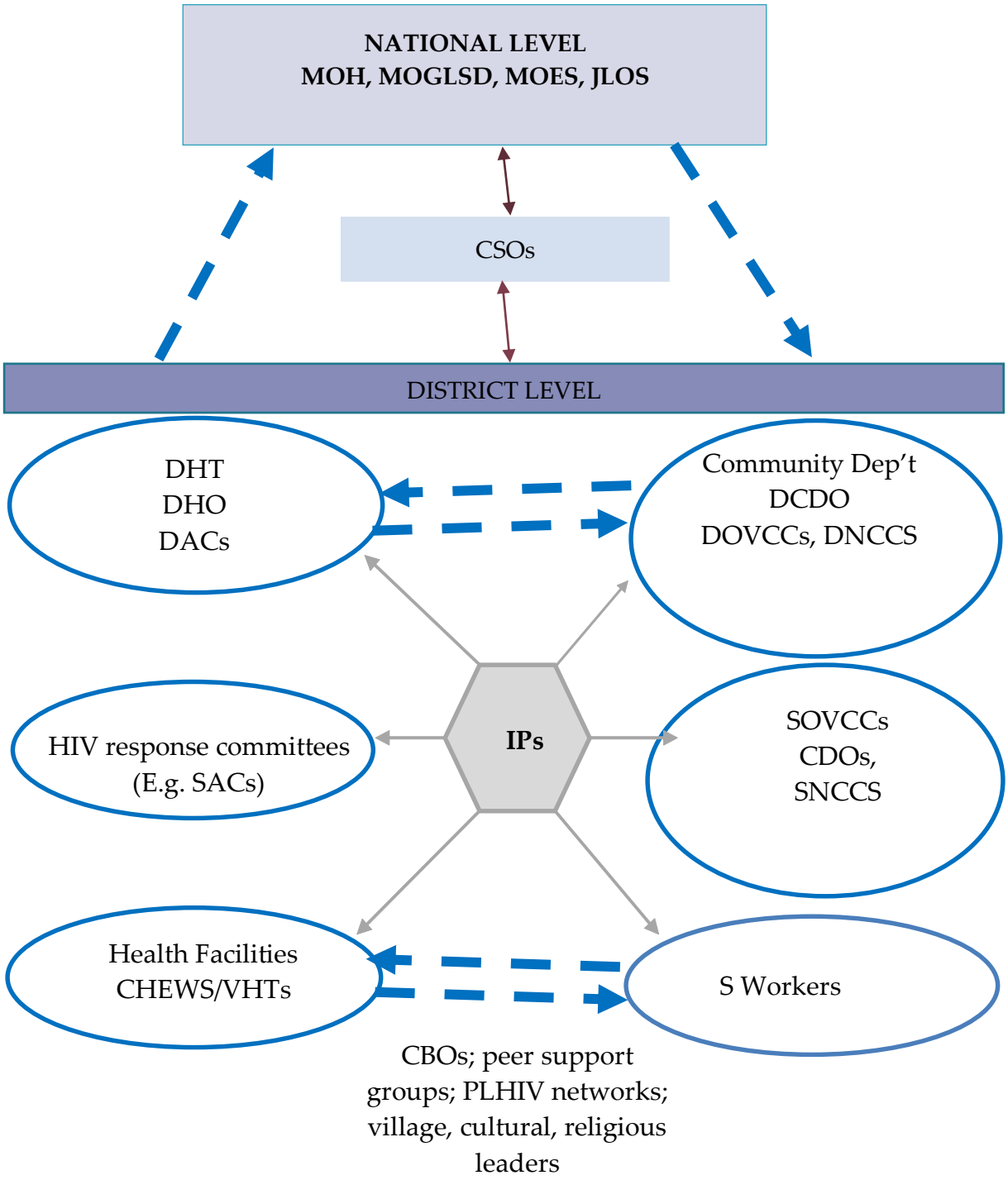
This guidance therefore describes strategic interventions that address patient literacy, participation in service delivery and demand creation. It follows a systems strengthening approach focusing on governance, leadership and coordination; service delivery; human resources for health, health information management; essential health commodities and financing.

10.2.2 STRATEGIC INTERVENTIONS

10.2.2.1Governance, leadership, and coordination:

The roles and responsibilities of the various stakeholders are outlined to strengthen two-way linkage between the community structures and formal health system structures at all levels including the district and the sub county. Figure 38 below conceptualizes the relationships between the various stakeholders to demonstrate anticipated coordination and collaboration. Standardizing roles and responsibilities should help ensure consistency of services and strengthening of linkages at sub-national level.

Figure 38: Coordination of the Community engagement



10.2.2.1.1 At national level

The ministry of Health will provide overall strategic policy direction and guidance together with key line Ministries and other national level stakeholders. Additionally, mobilization and allocation of resources, dissemination of guidelines are other key roles at national level. This

will be achieved through coordination meetings with stakeholders at national and regional levels.

10.2.2.1.2 At district level

The districts' health and community development offices will spear head planning, coordination, monitoring and supervision of the implementation of the community interventions. Regularly update CSO directories and mobilization for integration of community-based care into the district's HIV/AIDS programming. The District should monitor and supervise activities that provide an enabling environment for smooth implementation of the community interventions. The District should also ensure the functionality of district HIV&AIDS Committees at both sub-county, parish and community levels.

10.2.2.1.3 Health facility

The health facility is responsible for implementation. Facilities should establish a functional community referral focal desk operated by the community resource persons to ensure documentation, completion and timely feedback. The referral focal desk through the referral focal person will be the site of engagement between health workers and lay counselors, addressing challenges, defining priorities and responding to challenging cases requiring coordinated interventions. The health facility should orient community resource persons (VHT, peer educators, mentor mothers, and male champions) as well as compiling and reporting on the community-based care activities and indicators.

10.2.2.1.4 Community Level

Community based organizations and other organized groups including PLHIV networks, peer support groups, male action groups, youth and adolescent groups provide services to the target populations as guided by the core package of community-based services and establish Memorandum of Understanding with implementing partners and facilities as needed/appropriate. They should periodically compile and report on the community- based care activities to the district. The Community service providers are supposed to monitor the implementation of the community-based interventions, create demand for the HIV/AIDS prevention care and treatment services that lead to attainment of the 95-95-95 country targets as well as strengthen the existing referral systems within the community.

10.2.2.2. Human resources for health

Community cadres to support HIV prevention, care, treatment and support services will include:

- Community leaders such as local council leaders, religious leaders and cultural leaders. These are the community gate keepers who influence the demand and uptake

of services at community level. They will be engaged to disseminate correct policy guidelines; and technical information aimed at demystifying myths and misconceptions that hinder service uptake.

- PLHIV networks such as district-based networks of people living with HIV including young people. These will take lead in demand creation through patient literacy campaigns as well as service quality monitoring. They will also support follow up to ensure continued engagement of recipients of care with the health facilities.
- Peer support structures for different populations such as adolescents and young people, pregnant and breastfeeding women as well as key populations. These include expert clients, peer leaders (YAPS & G-ANC), mentor mothers and will provide differentiated HIV prevention, care, and support services at both facility and community

10.2.2.3. Community health information management (community monitoring) systems

The monitoring of community interventions will be done using the new Community Linkage and Referral Register that will be placed at the facility and community level. The Community Linkage and Referral Register has been incorporated under the HMIS tools, (HMIS 033) will be used to collect data to be put under the DHIS2. This data should be collected on a quarterly basis and shared at the national level.

10.2.2.4. Financing community services

Providing financial, organizational and technical capacity to community-based organizations and PLHIV networks to facilitate service delivery.

10.2.2.5. Service delivery

Key outcomes that the community systems will contribute to are patient literacy, demand creation, service uptake and robust referral and linkages to services. These will be achieved through implementation of a comprehensive service package as described in the National Community Strategy.

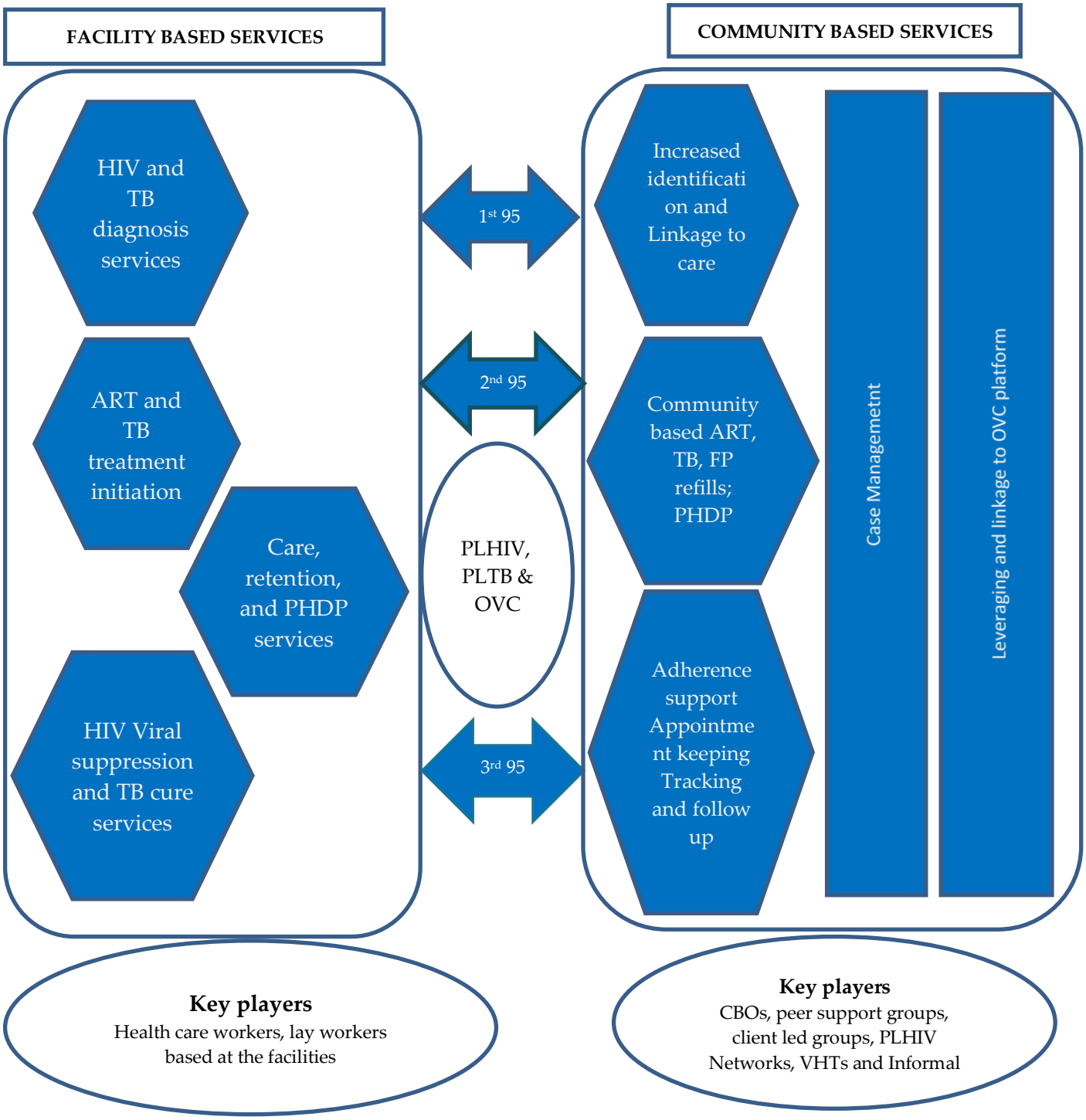
10.2.2.6. Commodities and essential supplies

Logistics to support effective community service delivery will include bicycles, uniforms, stationery, etc.

10.2.3 THE FACILITY –COMMUNITY SERVICES COLLABORATION FRAMEWORK

The services that are performed at the facility level should be linked to the community based services through effective collaborations between the key players at both service ends as shown in Figure 39.

Figure 39: Facility- Community Collaboration Framework



10.2.4 PACKAGE OF FACILITY-COMMUNITY COLLABORATION SERVICES ACROSS THE 90; 90; 90 CASCADE

Key considerations for establishment of collaborations between health facilities and community structures:

- The process should be participatory involving all relevant stakeholders at the district level including the Health facility staff, the DHT, the DCDO, and other stake holders in the districts
- The district's health and community development offices should spearhead the planning, coordination, monitoring and supervision of the implementation of the facility-community linkages.
- The process should include establishment of clear roles and responsibilities of all actors at all levels including MOH, ADPs, District local governments, health facilities, implementing partners and the community-based institutions.
- The community-based services should be integrated into the existing health services to avoid duplication of services.

10.2.4.1 1st 90 - Index client contact tracing to identify PLHIV and TB in the communities

Through effective collaboration with the health facilities in the catchment area, community structures may contribute, support and participate in activities that are aimed at identifying PLHIV through tracing contacts (sexual contacts/partners, household members) of HIV positive index clients and patients on TB treatment (Refer to the Community Strategy). These activities may include:

- Mapping and follow up of contacts of index HIV infected clients for HIV testing and TB screening services.
- Mapping and follow up of household contacts of index TB patients for TB screening and HIV testing.
- Targeted home visits with consent and appropriate support
    - Targeted home-based HCT and TB screening, focusing on men, children and adolescents.
    - Supported disclosure (anticipating and addressing potential risks such as gender-based violence because of disclosure by HIV positive women, including pregnant women and girls)
    - Integrated stigma reduction activities at the households, community and facility levels.
- Targeted community based HTS in hot spots and referral of all identified as HIV positive for care and follow up until achieving successful referral.
- Immediate linkage of HIV-negative clients at substantial risk of infection to HIV prevention services and related services, including VMMC, PrEP, condoms, treatment of sexually transmitted infections, and family planning services.

10.2.4.2 2nd 90 – Quality care and treatment through differentiated service delivery

Provision of this core package of services will be premised on the differentiated service delivery approach recommended by the Ministry of Health and these will largely hinge on an effective community platform. The community structures will support and contribute to various interventions which may include:

- Facilitating linkage to treatment of all identified HIV positive people or TB suspects with ongoing frequent contact until linkage is achieved.
- Supporting ART initiation of all identified positives in the community
- The community structures will support differentiated service delivery models as they serve as consistent points of ARV drug initiation and subsequent drug pick-ups.
- Provision of community based integrated health education, messaging and referral for appropriate services.
- Community based nutritional assessment counselling and support (NACS) and referral to the health facilities for treatment of malnutrition and household nutrition support through use of garden demonstrations or other interventions.
- GBV screening and post GBV care
- Psychosocial support by peer support groups, including family and PMTCT support groups
- Conducting TB DOTs in the community (peer-led, family supervised) or support monthly community drug delivery.
- Conducting referrals and linkages from community to facilities and from facilities to communities

10.2.4.3 3rd 90 – Supporting adherence and retention

These are services that foster adherence among clients on ART to achieve viral suppression. These will include:

- ART and TB adherence education and counseling by lay counselors
- Psychosocial support at community level by peer support groups
- Community-based follow up including phone calls by lay counselors to remind patients about appointments
- Community based tracking and follow up by lay counselors of those who do not keep appointment including loss to follow up/transfers
- Ongoing community based psychosocial support and counseling and linkage to support services
- Conducting community-based ART refills through well-organized community client groups.
- Emphasis on follow-up and tracking clients at higher risk of attrition and/or virologic non-suppression, such as adolescents, mother-baby pairs

for appointment keeping for completion of the EID cascade, and key populations.

10.2.5 LEVERAGING AND LINKAGE TO THE OVC PLATFORM

The community-based structures will leverage OVC programs (household economic strengthening, social protection, education, and case management) as appropriate:

OVC Package 1: Community to Facility linkages and collaborations

- Link the community OVC to the health facilities for HIV testing and counseling services (Knowing their HIV status) or TB evaluation.
- Support OVC to access HIV and TB care and treatment at the health facilities including ART or TB initiation and retention on ART or TB medications (Follow up appointments).
- Support OVC to access Sexual and Reproductive Health (SRH) services at health facilities including Antenatal care, contraceptive services and STI diagnosis and treatment.
- Support OVC to access young childcare (YCC) clinics and services including immunizations, growth and nutrition monitoring, including assessing early childhood development.
- Support OVC to access to post rape/defilement services and follow up.

OVC Package 2: Facility to Community linkages and collaborations

- Use HIV or TB positive child or adult as entry point for household HIV testing, TB screening, and assessment for OVC services
- Assess HIV or TB infected children for OVC service needs (could be done in facility or community)
- Link the OVC that qualify to relevant services in the community which may include
    - Healthy
        - Temporary food consumption support
        - Home visits for assessment & psychosocial support
        - Reminder calls/visits for clinic appointments
    - Schooled
        - Education (school fees/scholastic materials)
        - Vocational skills training/entrepreneurship
        - Referral from schools to Health Facilities
    - Stable
        - Cash transfer programs/VSLA/savings groups
        - Life skills
    - Safe
        - Legal support and Legal representation in courts of law.
        - Psychosocial support for GBV
        - Birth Registration
    - Case Management
        - Development of case management plans
        - Follow up and tracking of the case management plans

Note: More information and guidance will be found in the National Community Strategy to fast track the 90; 90; 90 goals.

10.3 INTEGRATING CONTINUOUS QUALITY IMPROVEMENT INTO HIV CARE SERVICES

10.3.1 INTRODUCTION

The Ministry of Health recommends the use of continuous quality improvement (CQI) as means to ensure the provision of high-quality health services and attainment of the 90-90-90 HIV targets. CQI is an approach to improvement of service systems and processes through the routine use of health and program data to meet patient, and program needs. The basis of CQI is a continuous measurement of the actual performance against the desired performance as per set national standards. The Ministry of Health recommends a combination of work environment organization using 5Ss (Sort, Set, Shine, Standardize, Sustain) and CQI methodologies to achieve Total Quality Management (TQM).

The health sector quality improvement framework clearly spells out quality improvement roles and responsibilities at the different levels of the health system from national level through regional, district, health sub-district, health facility to work improvement team levels.The functionality of these structures is crucial to the integration of CQI in health care services. This chapter will describe the process of using CQI to improve HIV service delivery through addressing the service delivery gaps.

10.3.2 STEPS TO USE CQI TO ADDRESS HIV SERVICES DELIVERY GAPS

CQI embraces five principles of client focus, teamwork, review of processes and systems, use of data to make decisions, and effective communication. Table 73below describes the steps involved in using CQI to address HIV service delivery gaps. Steps 1 and 2 describe the process of forming teams while steps 4 and 5 describe how the teams implement CQI. Steps 3–5 should be followed for each performance gap and regularly repeated (at least monthly) until the performance gap has been closed.

Table 73: Steps to use CQI to improvement HIV service delivery gaps

Step	Description
1. Establish the health facility QI team	• Team should have leader. • They will supervise the HIV work improvement teams (WIT) for different care processes.
2. Set up HIV work improvement teams (WIT)	• WIT should be set up for the different care processes along the HIV continuum of care. • They will dedicate time to understanding their current process for providing HIV care services, identify gaps and bottlenecks. • They will use the CQI approach through applying the principles of an iterative cycle of improvement (Plan, Do, Study, Act [PDSA] Cycle).
3. Identify gaps	• WIT should regularly review performance and HIV QI indicators. • WIT should analyze the data and identify performance gaps by comparing current performance to set targets.

Step	Description
4. Gap analysis to get root causes	• Use QI tools such as brainstorming, flow charting, five whys, cause and effect analysis to identify the root causes of the performance gaps.
5. Develop possible solutions	• Use QI tools like the driver diagram to develop possible solutions to address the performance gaps
6. Prioritizing solutions to address performance gaps	• Use a prioritization matrix to prioritize the solutions to be implemented. • Look for solutions that give maximum benefit at relatively low cost.
7. Developing improvement projects using the documentation journal	WIT will: • Develop improvement aims from the prioritized gaps. • List all the activities in a particular process targeted for improvement. • Use the activities to develop a flow chart for the process. • Use the flow chart to identify the individuals who will perform the different activities and include them in the WIT for the process. • Develop an improvement objective from the prioritized performance gap with the aid of the HIV QI indicator manual. • Document the data in the graph template of the documentation journal. • Develop an action plan indicating the changes that the team agreed to test or redesigning the service delivery model.

10.3.3 MONITORING OF CQI IMPLEMENTATION

- Work improvement teams working on a particular improvement project should regularly review performance data (in the documentation journals) resulting from the implementation of changes targeting the improvement.
- Health facility QI teams and QI focal person should jointly review the teams' documentation journals and provide guidance as necessary regularly (at least monthly).
- District QI committees should supervise and guide QI implementation at health facilities.
- Regional QI Committees should mentor and supervise district and selected facility QI implementation.

The following documents provide more guidance on implementing CQI:

- Health Sector Development Plan (HSDP) 2015/16-2019/20 (Ministry of Health)
- Health Sector Quality Improvement Framework and Strategic Plan (QIF & SP) 2015/16 - 2019/20 (Ministry of Health).
- CQI training curriculum for health workers 2020.

Box 10: Key highlights in Service Delivery Approaches

- The core principle for differentiating care is to make it client-centered by providing ART service delivery in a way that acknowledges specific barriers identified by clients and empowers them to manage their disease with the support of the health system.
- Determining the type of DSD bases on the category of patients (adults, adolescents, children, pregnant and breastfeeding women, key and priority populations), clinical status of patients (stable or unstable) and the context (rural or urban).
- DSD may be provided in the facility and in the community. Unstable patients will receive facility-based DSD interventions while stable patients may receive community-based DSD interventions.
- Multi-month prescriptions for ART and other medications for up to 6 months are recommended for eligible stable clients in whom frequent drug pickups may compromise their adherence to ART including key populations, migratory and those in hard to reach settings.
- Community structures and systems play a key role in completing the continuum of care by increasing demand, uptake and continuous utilization of HIV prevention, HTS, care and treatment services both in facilities and community. A coordinated system of referral and linkage between community structures and health facilities should be established to ensure access to services and optimal outcomes.

11 PROCUREMENT AND SUPPLY CHAIN MANAGEMENT SYSTEMS

11.1 INTRODUCTION

This section describes the supply chain management components that support the scale-up of HIV prevention, care and treatment services for Uganda to attain the 90-90-90 targets.

11.2 SELECTION OF HEALTH PRODUCTS AT THE FACILITY

- In general, all health facilities should select antiretroviral drugs and related commodities for both existing and new patients in line with these treatment guidelines (see Chapter8).
- It is recommended that the overall selection of HIV-related commodities and regimens be minimized to optimize treatment and product sourcing. Only health facilities designated by MOH to provide third-line treatment should select third-line ARVs.
- HIV-related commodities include: ARVs, Isoniazid, Co-trimoxazole, Dapsone, HIV test kits, fluconazole and other laboratory diagnostics.

11.3 PRODUCT QUANTIFICATION, ORDERING AND REPORTING

11.3.1 Quantification and forecasting

The Pharmacy departments' quantification and supply planning unit (QPPU) with guidance from ACP is responsible for that national level quantification and supply planning and ensuring reliable and uninterrupted supply at the warehouses.

All facilities are required to estimate the amounts of HIV commodities required for all existing and anticipated new patients. Facility patient numbers and consumption should inform the quantity to be ordered.

Following the rationalization guidelines in 2012, the MOH allocated every ART-accredited health facility to one central warehouse. The central warehouses include National Medical Stores (for all government facilities), Joint Medical Stores (PNFPS and PFPS), and Medical Access Uganda Limited (PNFPS and PFPS). Newly accredited facilities should refer to the accreditation letter for information on warehouse allocation.

11.3.2 Ordering of ART commodities

- Ordering and reporting of medicines and HIV test kits at health facilities is a multi-disciplinary task that should involve pharmacists, dispensers, clinicians, the laboratory officer, the M&E officer, and store managers.
- Ordering processes should be coordinated and led by a pharmacist or a dispenser or a person designated to manage medicines and health supplies in the facility.
- Facilities should order for medicines and HIV test kits on a bi-monthly basis following schedules provided by their respective central warehouses.
- Health facilities will use the ARV order and report form for ARVs, Fluconazole, Cotrimoxazole and Dapsone.

- Isoniazid for prevention of TB in HIV-positive patients should be ordered using the TB order form.
- HIV test kits should be ordered using the HIV test kit order form.
- Other laboratory commodities should be ordered using the general laboratory commodities form.
- The Ministry of Health revised all logistics management information system (LMIS) tools to accommodate changes in the 2018 treatment guidelines. Health facilities should obtain copies of updated LMIS from the warehouses.

11.3.3 Preparing bi-monthly orders and reports

When making bi-monthly orders and reports, health facilities should prepare and use the following information:

- Consumption data obtained from dispensing logs or electronic ordering tools for ARVs and the daily activity register for HIV test kits.
- Stock on hand of commodities from the stock cards/ stock books.
- Facility patient data including:
    - The number of existing patients on treatment aggregated by age and treatment regimens at the beginning of the reporting period.
    - The number of new patients enrolled in the reporting period including ART-naïve patients initiated on first-line treatment and those switched to second- or third-line regimens.

Further information to consider when ordering is:

- The amount of stock currently available
- The minimum and maximum stock levels
- The required delivery date for new orders
- Any anticipated risk of expiry

11.3.4 Submitting the bi-monthly order

Health facilities should submit all HIV commodity orders and reports to the appropriate warehouse in line with their delivery schedules. Orders can be submitted electronically through the DHIS2 web-based ordering system (WAOS) at the facility or through the district. Where it is not possible to submit an electronic order, facilities should submit paper-based orders through the district biostatistician.

11.3.5 Guidance on ordering and reporting for third-line ART medicines

Ordering and reporting for third line ARVs is currently restricted to regional referral hospitals and selected centers of excellence. This means only referral hospitals and these centers of excellence will be ordering and reporting on the consumption and usage of third line ARVs The referral hospitals and centers of excellence will use the standard ARV ordering and reporting forms to order and report on third line ARV following the bi monthly ordering and

reporting cycle. This should be done alongside other ARVs. Orders should be submitted through the web-based ARV ordering and reporting system (WAOS) before the order deadline.

11.3.5.1 Issuing third-line ARVs to follow up facility

11.3.5.1.1 At the regional referral hospital

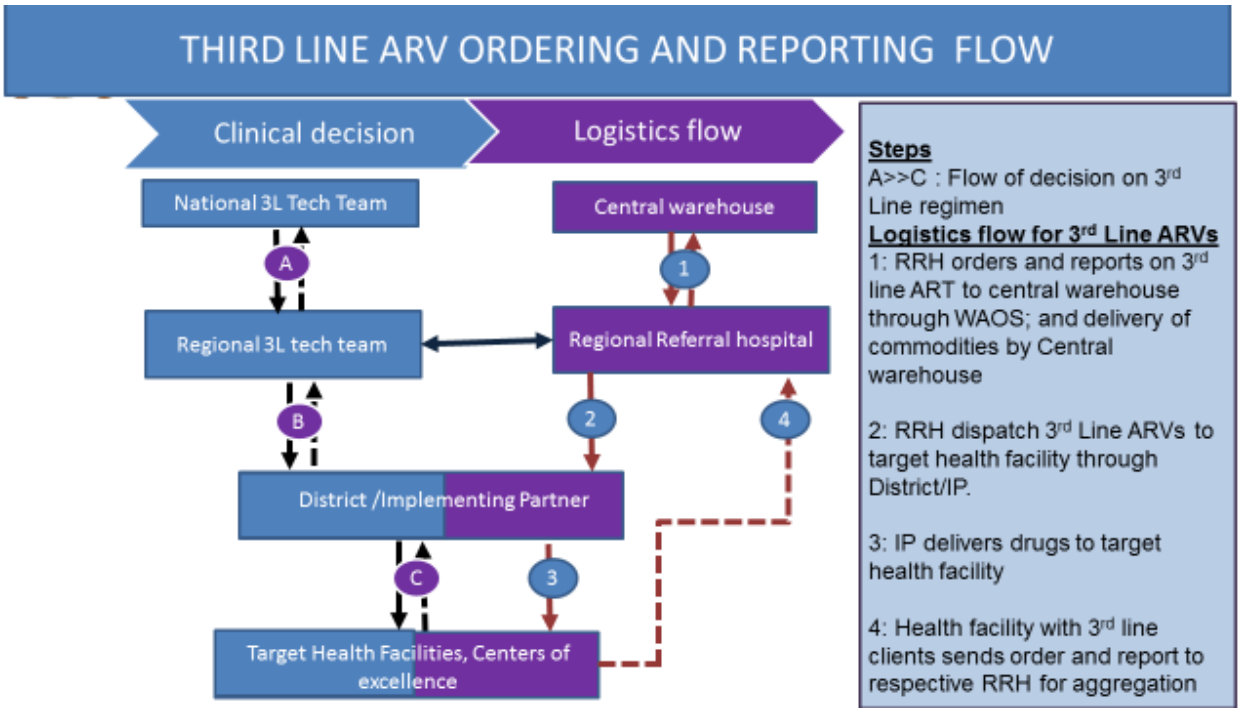
The regional referral hospital will be responsible for issuing third line ARVs to all lower level health facilities having third line patients within the region even when their other ARVs are provided through a different warehouse. Once resistance results and regimens prescribed have been communicated to the regional referral hospital and the responsible implementing partner, the regional referral hospital should use the issue and requisition voucher to send third line ARV to the parent facility. The implementing partner should facilitate the movement of the ARVs from the RRH to the lower facility. The RRH should consider ARVs issued to the lower level facility as consumed and therefore should proceed and update the stock card. This information should be used to prepare the next ARV order and report.

11.3.5.1.2 At the facility

Once the third line ARVs have reached the lower facility where a third line patient has been accessing care, the received quantity of medicine should be entered into a stock card. The facility should then follow the issuing procedures prescribed in the MOH medicines and health supplies management manual 2012. Once the medicine is dispensed to the patient, the dispensing log should be updated immediately. Refer to Figure 40 below.

Note: Lower facilities are currently not authorized to order for third line ARVs through WAOS. The regional referral is responsible for consolidating all orders for them. Lower facility requiring 3rd ARVs should send a copy of page 2 and patient summary page of the order form to their respective regional referrals.

Figure 40: Guidance on ordering for third-line ART commodities



11.4 GUIDANCE FOR STOCK MANAGEMENT AT HEALTH FACILITY

Medicines and medical supplies should be received at the facility store according to the recommended receipt procedure by MOH medicines and health supplies management manual 2012. The person receiving the supplies should enter them into the facility stock books and stock cards and store them under recommended storage conditions. Stock books and cards should be updated whenever stock is issued from the health facility main store. Monthly physical counts should be done and reasons for any discrepancy noted.

11.5 DISPENSING MEDICINES

Health care workers should do the following while dispensing ARV medicines:

- Ensure availability of dispensing tools at all dispensing points
- Ensure medicine shelf life is long enough to cover the treatment duration
- Dispensing to all patients should preferably be done using the primary packaging
- Record all transactions in the medicine dispensing log

11.6 STOCK REDISTRIBUTION

Redistribution should be triggered if the facility has more than four months of stock, risk of expiries or medicine stock out.

The stock should be redistributed in line with the *Ministry of Health Commodity Redistribution Strategy, 2012*/oras amended. It is important to note that redistribution does not lead to financial loss to the affected health facility. It however mitigates financial loss due to expiries

and additional cost of treatment incurred due to stock outs. Stock monitoring and reporting in real time is recommended to inform redistribution.

11.7 RATIONAL MEDICINES USE

Rational medicines use ensures patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements for an adequate period, and at the lowest cost to them and their community.

11.7.1 Principles of rational medicines use

11.7.1.1 Rational prescribing

Healthcare workers should prescribe medicines according to the following principles:

- Prescribe medicines according to the treatment guidelines
- Use the correct combination of drugs
- Prescribe medicines for the correct treatment duration
- Counsel patients on how to take the medicines
- Counsel patients on substituting or switching treatment regimens
- Counsel patients on safety and use of medicines

11.7.1.2 Rational dispensing

Healthcare workers should dispense medicines according to the following principles:

- Dispense the correct quantity, dose and dosage formulation to the correct patient. Fixed-dose combinations are preferred.
- Provide explanation on how patients should take their medicines.
- Appropriately label the medicine packs to include the patient's name and dose.
- Package and label medicines for individual patients that are for distribution under the community drug delivery points.
- Offer further explanation/counseling to patients on multiple medicines because of other co-morbidities. Communicate possible drug interactions and adverse effects.
- Effectively introduce new formulations to patients while taking into consideration medication branding.
- Counsel patient to adhere to medicine.

11.7.2 Dispensing of medicines to patients

11.7.2.1 Health facility-based clients

These are the clients who are receiving ARVs and other form of care from the health facility. Health care workers should do the following while dispensing ARV medicines to health facility-based clients:

- Ensure adequate medicines are requisitioned from facility store for dispensing
- Medicines shelf life should be long enough to cover duration of use by the client
- Preferably issue 3 months of stock to stable patients.
- In some stable patients who fit eligibility criteria (see section 10.1.11), 6 months of stock of drugs may be prescribed and dispensed
- Supply medicine to new patients for a duration determined by the clinician.
- Appropriately record all medicines issued in appropriate logistics HMIS tools.

11.7.2.2 Community-based clients

These are the clients who are receiving ARVs and other form of care from the communities where they live. Health care workers should:

- Take into consideration recommendations under section 11.7.2(dispensing medicines to facility-based clients).
- Dispense medicines to the CCLAD representative
- Use the ART medicines return forms and the CCLAD monitoring forms to ensure traceability.
- Ensure that medicines for CDDP are prepacked, labeled according to the expected client refill list for each of the CDDP. These medicines should be given to the health worker or the peer leader for that CDDP.

Efforts should be made by the ART focal person to ensure that all CCLAD members receive their medicines within the appropriate time.

12 MONITORING AND EVALUATION

12.1 INTRODUCTION

A comprehensive and well-functioning monitoring and evaluation (M&E) framework is essential to ensure that Uganda's program to prevent and treat HIV using ART is effective and efficient. This module provides a highlight of the HIV/AIDS programme monitoring and plan for monitoring the roll out of the revised guidelines.

The module is aligned to the guidance contained in the *National HIV and AIDS Strategic Plan 2015/2016–2019/2020, Health Sector HIV and AIDS Strategic Plan (HSHASP)2018/19 -2022/23 and Health Sector HIV and AIDS Monitoring and Evaluation Plan 2018/19 – 2022/2023.*

12.2 OVERVIEW OF HIV/AIDS PROGRAMME MONITORING

12.2.1 Patient Data Recording

The current patient monitoring system uses paper-based tools and electronic medical records system. However, the primary data collection method at facilities is paper-based, and includes pre-primary, primary and secondary tools as detailed in the *Ministry of Health HMIS Manual, 2020*. Paper-based records are used to update electronic medical record systems where they exist.

12.2.2 Patient Data Reporting

Health facilities should submit timely reports of aggregated patient data on a weekly, monthly and quarterly basis. The monthly and quarterly reports shall be consolidated and entered into DHIS-2. Table 74 below shows the different reports and frequency of submission.

An online dashboard to track the implementation of the consolidated guidelines will be developed.

Table 74: Routine reports and their frequency

Report	Description	Source documents	Frequency
HMIS 106A: Health Unit Quarterly Report	Reports the quarterly attendance figures for HIV care/ART, ART outcomes, nutrition, and TB services	Registers: Linkages and Pre-ART, ART, PEP, EID, TB, DSD, SMC, PrEP, CrAg, Viral Load .	Quarterly
HMIS 105: Health Unit Outpatient Monthly Report	Reports the monthly attendance figures for OPD, OPD diagnoses, MCH, HIV/AIDS service data, EID, laboratory data, stock-out of essential drugs and supplies and financial data	HCT Register, EID Register, Safe Male Circumcision Register, Laboratory Tests Daily Summary	Monthly
HMIS 033B: Health Unit Weekly Epidemiological Surveillance Report	Reports cases of notifiable diseases after the first few cases have been notified.	HIV Laboratory Tests Log and eMTCT Drug Dispensing Log	Weekly

Note: Indicators for routine monitoring have been updated and can be found in the Monitoring plan for the HSHASP 2018-2023. Facility ARV stock and orders shall be monitored via the Web-Based ARV Ordering System (WAOS).

12.2.3 Other programme data sources

The following sources complement the data generated from routine HIV/AIDS programme data

1. Surveys (population based, ANC surveillance, case-based surveillance, other special surveys including size estimations, modes of transmission, etc.)
2. Programme Evaluations (PMTCT Impact evaluation, eMTCT validation, etc.)
3. Operational research
4. Special studies and assessments (Cohort studies, HIV drug resistance, etc.)

12.2.4 Programme Data Quality and Use

The programme has institutionalised interventions that geared to ensure that programme data is of high quality to inform planning and decision making. These include but not limited to; standardised HMIS manual with indicator descriptions and definitions, annual data quality assessments, integrated and technical supervisions.

At national, sub national (region and district) and health facility levels, use of programme data generated from HMIS is emphasised. This is done through;

- Dashboards – tools that summarize and display aggregated data (VL, EID, B+, HIV stituation room, WHO DHIS2 App, etc.)
- Routine data/performance reviews
- Continous Quality Improvement projects

12.3 MONITORING ROLL OUT OF REVISED GUIDELINES

12.3.1 Tracking progress of roll out

Rolling out of the revised guidelines at health facilities and training of Health workers to ensure effective utilization of the guidelines will be tracked using the training reports, that will be entered into the online training database.

Data will be summarized as follows; weekly for the first three months and bimonthly thereafter. Summaries generated will be disseminated to key stakeholder to provide an update on the roll out of the guidelines.

12.3.2 Supervision on implementation of revised guidelines

This will be conducted at the following planned intervals;

- 3 months from onset of roll out amongst the health facilities that would have rolled out;
- One month after completion of national roll out of the revised guidelines at health facilities

This supervision exercises are aimed at assessing whether the HIV/AIDS services are provided based on the revised guidelines as well as identifying challenges encountered during in the utilization of the revised guidelines.

12.3.3 Review of the guidelines

The process of reviewing these guidelines will be informed by new emerging facts mainly from recommendations from WHO, results of operational research, programme evaluations and revised national strategic plans.

12.3.4 Indicator matrix

The Health Sector HIV and AIDS M&E plan 2018/19 – 2022/23 provides a comprehensive plan that tracks programme implementation and sustainable HIV control at national and sub national levels. Whereas a number of indicators pertaining to the revised guidelines are already covered in the sector HIV AIDS M&E plan, there are some process indicators, key to monitoring this roll out that are not catered for by the broader M&E plan. A list of indicators has been developed to track efficient implementation of the revised guidelines.

Annex 1: SUMMARY OF CHANGES IN THE 2020 GUIDELINES

The major updates and additions to the 2018 version of the Consolidated Guidelines for Prevention and Treatment of HIV and AIDS in Uganda include the following:

Chapter	Unit	Changes
Chapter 1: Introduction		No changes
Chapter 2: HIV diagnosis and linkage to HIV Care and Treatment	**2.3**	In Uganda, Targeted HIV testing is being offered in various ways and is also referred to as ''Risk Based Testing''. The forms of Targeted HTS include the following: • Index client Testing (including Social Networks Testing, APN) • HIV Self Testing (HIVST) through ''focused'' distribution of Self-Test Kits It is important that all HTS providers offer targeted HTS since it maximizes identification of PLHA, saves resources, reduces workload.
	2.6.3	• Categories of HIV Negative persons to re-test at specified time points • Children >18 months who are still breastfeeding should be re-tested 3 months after cessation of breastfeeding
Chapter 3: HIV Prevention	**3.3.3**	• TDF prescriptions for children and adolescents should be weight-based. • The TDF-based regimens are recommended for adolescent ≥ 30Kg and the ABC-based regimens recommended for children <30Kg.
	3.3.4	• PrEP eligibility has extended to include adolescents and young women including pregnant and lactating AGYW who are at substantial risk of acquiring HIV.
Chapter 4: Elimination of Mother-to-Child Transmission of HIV (eMTCT) and Improving Maternal, Newborn, Child and Adolescent Health (MNCAH)	**4.5**	Updated the guidelines for the treatment of Syphilis in ANC and eMTCT services for pregnant women: • Pregnant women/girls with early syphilis: give Benzathine penicillin G 2.4 million units intramuscularly once. Early syphilis for this guideline is: (primary, secondary, and early latent syphilis of not more than two years' duration). • In late syphilis or unknown stage of syphilis: give Benzathine penicillin G 2.4 million units intramuscularly once weekly for three consecutive weeks. Late syphilis for this guideline is defined as infection of more than two years' duration without evidence of Treponema infection. • Note: Adequate maternal treatment for prevention of congenital syphilis is defined as at least one injection of 2.4 million units of intramuscular Benzathine penicillin at least 30 days prior to delivery. • Alternative treatment with procaine penicillin or erythromycin, azithromycin and ceftriaxone if allergic to penicillin.
	4.5	Updated the ART regimens for HIV infected pregnant women and adolescent mothers attending ANC and eMTCT services:

		• Initiate newly identified pregnant and breastfeeding women on once-daily FDC of TDF+3TC+DTG with pharmacovigilance. • If a pregnant woman is already on TDF/3TC/EFV and is virally suppressed, she should be maintained on the same ART regimen until 6-9 months after delivery and then substitute EFV with DTG if VL within past 6 months is suppressed. • If a pregnant woman is already on ART on a non-TLE or non-TLD regimen (i.e with NVP, ABC or AZT) with a suppressed VL, maintain the same regimen until 6-9 months postpartum and then transition to TLD if the VL within the past 6 months is suppressed. Caution should be taken in transitioning pregnant and breastfeeding women on Abacavir to Tenofovir as there may be contraindications for Tenofovir. Screen for TDF eligibility prior to transition. • If she is already on ART and VL is not suppressed, manage as treatment failure and switch to DTG-based 2nd line regimen. • If she is already on a DTG-based 1st-line regimen and virally suppressed, maintain on the same regimen. • If she is on 2nd line ART with ATV/r or LPV/r and virally suppressed, maintain on the same regimen until 6-9 months after delivery and then substitute PI with DTG if VL within the past 6 months is suppressed and no previous exposure to DTG.
	4.5	Test pregnant women/girls and their partners for Hepatitis B during antenatal • For patients who are HBsAg positive assess the HBeAg and HBV viral load. Patients who are HBeAG negative with HBV VL of <200,000 IU/ml should be monitored with CBC, LFTs and VL at 6 and 12 months. • For patients who are HBsAg positive assess the HBeAg and HBV viral load. Patients who are HBeAg positive with HBV VL of >200,000 IU/ml should initiate prophylactic treatment at 24 weeks gestation or at the earliest contact. Discontinue medication at the end of 3 months. After starting treatment, LFTs should be monitored at 4, 8, 12 and 24 weeks and thereafter annually. Monitor HBV viral load at 6 and 12.
	4.8.2	ARV prophylaxis for HEI; What to do if baby presents after 6 weeks: • Do first PCR • Give ART (ABC/3TC/LPV/r bd; give weight appropriate dose) for 6weeks • If PCR results are negative, give NVP for 6 weeks (after completing the 6 weeks of ABC/3TC/LPV/r) • If PCR results are positive, continue with ABC/3TC/LPV/r as first line ART. • Irrespective of timing, the mother should be started on ART as soon as possible for her own health and to decrease risk of transmission to breastfeeding baby.
Chapter 5: Maternal, infant,		No Changes

and young child feeding guidelines		
	6.5.1.1.	Identify people with Advanced HIV Disease by performing a CD4 cell count for • Newly initiating patients. • Patients re-engaging in care after more than 90 days. • Patients who are not virologically suppressed. • Patients presenting with symptoms suggesting WHO Stage 3 or 4 disease.
	6.5.1.2	The CD4 eligibility criteria for conducting a Urine TB LAM and Cryptococcal Antigen (CrAg) screening is ≤ 200 cells/mm^3.
	6.7.3	Dosage of Anti TB medicines for children in the 25-32Kg weight band: • Intensive phase: RHZ (75/50/150)- 4 Tablets E (100)- 4 Tablets • Continuation phase: RH (75/50) -4 Tablets
	6.7.3.3	**ART regimens for TB/HIV co-infected patients initiating First-line ART** Adults and adolescents ≥30Kg, including pregnant and breastfeeding women: • Preferred regimen: TDF +3TC+DTG (double the dose of DTG) • Alternative regimens: o Use ABC where TDF is contraindicated o EFV400-based regimen o ATV/r-based regimen (substitute Rifampicin with Rifabutin) Children ≥ 20Kg- <30Kg: • Preferred regimen: ABC+3TC+DTG (double the dose of DTG) • Alternative regimens: o Use AZT or TAF where ABC is contraindicated o LPV/r-based regimen (substitute Rifampicin with Rifabutin or double dose LPV/r) o EFV-based regimen (children >3 years) Children <20Kg: • Preferred regimen: ABC+3TC+DTG (double the dose of DTG) • Alternative regimens: o Use AZT where ABC is contraindicated o LPV/r-based regimen (substitute Rifampicin with Rifabutin or double dose LPV/r) o EFV-based regimen (children >3 years or weighing >10Kg) o RAL-based regimen (double dose of RAL) o ABC+3TC+AZT (children <3 years or weighing <10Kg)

		ART regimens for TB/HIV co-infected patients initiating Second-line ART Adults and adolescents ≥30Kg, including pregnant and breastfeeding women: • Preferred regimens: AZT or TDF +3TC+DTG (double dose of DTG) AZT or TDF +3TC+ATV/r (substitute Rifampicin with Rifabutin) • Alternative regimen: o LPV/r -based regimen (substitute Rifampicin with Rifabutin or double the dose of LPV/r) Children ≥ 20Kg- <30Kg • Preferred regimens: TAF or AZT or ABC+3TC+DTG (double dose of DTG) TAF or AZT or ABC+3TC+LPV/r (Substitute Rifampicin with Rifabutin or double dose of LPV/r) • Alternative regimens: o LPV/r -based regimen (Substitute Rifampicin with Rifabutin or double the dose of LPV/r) o RAL-based regimen (double the dose of RAL) o DRV/r-based regimen (Substitute Rifampicin with Rifabutin) Children <20Kg • Preferred regimens: AZT or ABC+3TC+DTG (double dose of DTG) AZT or ABC +3TC+LPV/r (Substitute Rifampicin with Rifabutin or double the dose of LPV/r) • Alternative regimens: o LPV/r- based regimen (substitute Rifampicin with Rifabutin or double the dose of LPV/r) o RAL -based regimen (double the dose of RAL) o DRV/r-based regimen (substitute Rifampicin with Rifabutin) **After TB treatment the regimens should be optimized.**

	6.7.3.4	**ARV regimen substitutions for patients initiating TB treatment while already on ART** Adults and adolescents ≥30Kg including pregnant and breastfeeding women: • If on EFV based regimen: Continue with the same regimen and dose. • If on DTG-based regimen: Continue the same regimen but double dose of DTG • If on NVP-based regimen: Substitute NVP with EFV. • If on ATV/r-based regimen: Continue the same regimen but substitute Rifampicin with Rifabutin. If on 2nd line, substitute ATV/r with LPV/r and double the dose of LPV/r. If on an ATV/r-based 1st line regimen and EFV is not contraindicated, substitute ATV/r with EFV for the duration of TB treatment. • If on LPV/r -based regimen: Continue the same regimen but either substitute Rifampicin with Rifabutin or double the dose of LPV/r. Children ≥ 20Kg- <30Kg • If on DTG-based regimen: Continue the same regimen but double the dose of DTG. • If on EFV-based regimen: Continue the same regimen. • If on NVP -based regimen: Substitute NVP with EFV (if >3 years) or if EFV is contraindicated, give a triple NRTI regimen (ABC+3TC+AZT). • If on LPV/r-based regimen: Continue the same regimen but either substitute Rifampicin with Rifabutin or double the dose of LPV/r. If the child cannot tolerate double dose of LPV/r, substitute LPV/r with Raltegravir and double the dose of Raltegravir. Return to LPV/r after completion of TB treatment. • If on DRV//r-based regimen: Substitute Rifampicin with Rifabutin. Children <20Kg • If on DTG-based regimen: Continue the same regimen but double the dose of DTG. • If on LPV/r- based regimen: Continue the same regimen but either substitute Rifampicin with Rifabutin or double the dose of LPV/r. If the child cannot tolerate double dose of LPV/r, substitute LPV/r with Raltegravir. Double the dose of Raltegravir. Return to LPV/r after completion of TB treatment. • If on NVP-based regimen: If >3 years and >10Kg substitute NVP with EFV. If EFV is contraindicated, give a triple NRTI regimen (ABC+3TC+AZT). If <3 years and <10Kg give triple NRTI regimen (ABC+3TC+AZT). • If on DRV/r-based regimen: Substitute Rifampicin with Rifabutin **After TB treatment optimize ART regimen if virally suppressed. If not virally suppressed switch to 2nd or 3rd line ART.**

	6.7.4.1	The following regimens could be used for TPT: • 6H: Daily Isoniazid for 6 months. Note: Isoniazid may be available in combination with co-trimoxazole and pyridoxine as a fixed dose combination referred to as Q-TIB: In this case, Q-TIB is also administered daily for 6 months. • Rifapentin-Isoniazid based regimens: Weekly Isoniazid and Rifapentine for 3 months (3HP): recommended for patients aged more than 2 years. • 3RH: Daily Rifampicin and Isoniazid for 3 months (Recommended for children less than 15 years).
	6.7.4.1.1	**Eligibility for TPT** • HIV-positive children (≥one year of age), adolescents and adults with no signs and symptoms of TB. • HIV-positive infants and children <5 years with a history of TB contact who have no signs and symptoms of active TB disease, irrespective of previous TPT • HIV-positive pregnant mothers with evidence of exposure to active TB disease after ruling out active TB • HIV-positive pregnant mothers with a WHO Stage 3 or 4 event and/or CD4<200 without active TB Note: • For HIV-positive pregnant mothers without evidence of exposure to active TB disease, TPT will be deferred until 3 months after delivery • For HIV positive+ adolescent girls and women on TPT who get pregnant, continue and complete the TPT while closely monitoring for side effects
	6.7.4.1.2	**Timing of TPT in children** • Contacts of known TB patients: Initiate INH immediately (or within 2 weeks of ART initiation if newly identified HIV positive) • Virally suppressed children currently on NNRTI: Initiate INH as soon as possible and complete course before ART optimization. • Virally suppressed children currently on PI or DTG: Initiate INH if the child has been on ART for at least 3 months. • Newly initiating ART: Initiate INH prophylaxis after 3 months on ART.
	6.7.4.1.3	**Co-administration of DTG and TPT** Although studies have found that the co-administration of DTG and INH is well tolerated, liver injury is a recognized adverse effect of each of these drugs. Since there is potential for hepatotoxicity, the following are recommendations for co-administration. • For newly identified patients, start on TLD with active symptomatic monitoring for adverse events. Initiate TPT after 3 months. These 3 months allow time for potential unmasking of TB and to monitor any toxicities that may arise from DTG, prior to initiation of TPT.

		• For stable patients already transitioned to DTG: If patient has been on TLD for 3 months or more, initiate TPT immediately • Stable patients for DTG transition and have not received TPT before: o In case TLE stock is available: First complete TPT and then transition to DTG o In case TLE stock is not available: Transition to DTG and initiate TPT after 3 months Note: All patients receiving INH prophylaxis and DTG+INH should be closely monitored for signs and symptoms of liver toxicity as specified in the pharmacovigilance guidelines.
	6.8.2.3	**Management of Cryptococcal Meningitis** Induction phase of treatment: Recommended: • Amphotericin B liposomal (3mg/kg/day)/ deoxycholate (1mg/kg/day) + Flucytosine (100mg/kg/day in four divided doses) for 1 week, followed by 1 week of fluconazole (1200 mg/day for adults, 12 mg/kg/day for children and adolescents). Or • Fluconazole (1200 mg daily for adults, 12 mg/kg/day for children and adolescents) + Flucytosine (100 mg/kg/day, divided into four doses per day. Or • Amphotericin B deoxycholate (1mg/kg/day) + high-dose Fluconazole 1200mg/day. Alternative: Fluconazole 1200mg/day (or 6-12mg/kg/day in children)
Chapter 7: Psychosocial care and Adherence support for PLHIV		No changes
Chapter 8: Antiretroviral Therapy for People Living with HIV	**8.5.1.1**	Adults being initiated on DTG should be screened for risk factors for NCDs: • Age over 40 years • Overweight (BMI 25-30kg/m^2) or Obese (BMI >30kg/m^2) • Duration on ART (>5 years) 1. Known diabetics should not be initiated or transitioned to DTG: Give EFV400 or a PI. 2. Clients with 2 or more risk factors for NCDs and a high baseline RBS or FBS should not be initiated or transitioned to DTG: Give EFV400 or PI. 3. Clients with 2 or more risk factors for NCDs with normal baseline RBS or FBS: Initiate or transition to DTG and monitor RBS or FBS every 3 months for 6 months.

	8.5.3	**The Preferred First-line ARV regimen in adults, adolescents, pregnant or breastfeeding women and children initiating ART is DTG based.** Adults and adolescents ≥ 30Kg, including pregnant and breastfeeding women • Preferred 1st line regimen: TDF+3TC+DTG • Alternative regimen: o Use ABC where TDF is contraindicated o EFV400-based regime o ATV/r-based regimen Children ≥ 20Kg-<30Kg • Preferred 1st line regimen: ABC+3TC+DTG • Alternative regimen: o Use AZT or TAF where ABC is contraindicated (TAF in children> 6 years and ≥25Kg) o LPV/r-based regimen Children <20Kg • Preferred 1st line regimen: ABC+3TC+DTG • Alternative regimen: o Use AZT where ABC is contraindicated o LPV/r-based regimen o EFV-based regimen (Children >3 years and >10Kg) o RAL-based regimen
	8.6.3.2	**Frequency of viral load monitoring** The following criteria were added to the previous guidelines • After every switch in treatment (after failure): The VL test should be done at 6 months after a switch to second- and third-line ART. • Third line ART patients: The VL test should be done every 6 months. If a VL >1000 copies is detected (un-suppressed VL) then genotype testing is recommended.
	8.6.3.4	**Genotype testing** The following categories of patients will receive Genotype testing to identify optimal ART regimens: • Children exposed to AZT/3TC and ABC/3TC NRTI backbone and are failing on their first-line ART treatment. • Infants born to mothers failing treatment (first, second or third line)

		• Patients failing on a PI-based regimen irrespective of line of care. • Children receiving Lopinavir/ritonavir or Dolutegravir on first-line ART and who have a repeat viral load result >1000 copies/ml following intensified adherence counselling. • Patients with a prior exposure to a PI and failing on a DTG based regimen and vice versa. • All patients failing on their second line ART. • All patients failing on their third line ART.
	8.7.1.1	**When to substitute NNRTIs with DTG among adults and adolescents already on first line ART** Patients on first line ART with a suppressed viral load result within the last 6 months, will have their NNRTIs substituted with DTG to optimize treatment. Adolescents on ABC based first line regimen who weigh ≥ 30kg, shall have their ABC substituted with TDF. The regimens should be aligned to the recommended first-line regimens. Alternative regimens will be used in case of contraindications to DTG.
	8.7.1.2	**When to substitute NNRTIs with DTG among pregnant and breastfeeding women already on first line ART** Pregnant and breastfeeding women already on EFV-based first-line regimens will remain on EFV400 based regimens throughout pregnancy until 6-9 months post-partum when EFV should be substituted with DTG if VL within past 6 months is suppressed.
	8.7.1	**Recommended programmatic drug substitutions in adults and adolescents** All adults and adolescents on NNRTI-based first line ART with suppressed VL will have their regimens transitioned to TDF+3TC+ DTG (TLD). Pregnant and breastfeeding women on TDF+3TC+EFV (TLE) will maintain this regimen and transition to TLD 6-9 months post-partum if the VL within the past 6 months is suppressed. Clients on PI-based regimens with suppressed VL will be maintained on the same regimens.
	8.7.2.	**Programmatic drug substitutions for children on first line ART:** NNRTIs will be substituted with DTG. In the absence of DTG formulations at the time of substitution, Ritonavir-boosted Lopinavir should be given for children < 20kg. As children grow their LPV/r formulations should be appropriately adjusted from syrups to pellets and finally to tablets. Alternative regimens are recommended in case of intolerance to DTG or LPV/r. Refer to the Recommendations for first line ART.
	8.7.2	**Recommended programmatic drug substitutions in children:** All children on NNRTI-based first line ART with suppressed VL will have their regimens transitioned to ABC+3TC+DTG. In the absence of appropriate DTG formulations, children <20Kg should receive ABC+3TC+LPV/r. Children on PI-based regimens with suppressed VL will be maintained on the same regimens.
	8.9	**CHILDREN WITH A NON-SUPPRESSED VIRAL LOAD** • If the child is on an NNRTI regimen and VL is not suppressed, switch to 2nd line immediately and do IAC simultaneously. Do not postpone switch. • If the child is on a DTG or LPV/r-based regimen as part of first line ART, conduct IAC and repeat VL after 3 months. DTG and PI have high resistance barrier so poor adherence is a more likely cause for

		an unsuppressed VL than resistance. If VL is still not suppressed after IAC interventions, switch to 2nd line ART. For children and adolescents, this switch will be guided by an HIV drug resistance test.
	8.10	**Second- and Third-line ART regimens are selected based on previous ARV exposure with the aim to avoid the use of ARVs to which the client is likely to be resistant to in subsequent regimens.** Adults and adolescents ≥ 30Kg, including pregnant and breastfeeding women • Preferred 2nd line regimens: DTG-based or ATV/r-based • Alternative 2nd line regimens: ATV/r-based or LPV/r-based Children ≥ 20Kg- <30Kg • Preferred 2nd line regimens: DTG-based or LPV/r-based • Alternative 2nd line regimens: LPV/r-based or DRV/r-based Children <20Kg • Preferred 2nd line regimens: DTG-based or LPV/r-based • Alternative 2nd line regimens: LPV/r-based or DRV/r-based **All 3rd line regimens to be guided by resistance testing**
	8.10.4	**Programmatic drug substitution in 2nd line regimens** Adults on ATV/r or LPV/r-based 2nd line regimens who are virally suppressed (basing on VL result within past 6 months) and who did not receive DTG in their 1st line regimens should have ATV/r or LPV/r substituted with DTG. Pregnant and breastfeeding women on ATV/r or LPV/r-based 2nd line regimens who are virally suppressed and who did not receive DTG in their 1st line regimens should be maintained on the same regimens. At 6-9 months postpartum, if their VL is suppressed (basing on VL result within past 6 months), ATV/r or LPV/r should be substituted with DTG. Although simplification of regimens including once-a-day dosing is a main goal of ART optimization, children and adolescents who are virally suppressed and stable on 2nd line regimens containing twice-daily LPV/r will be maintained on their regimens so as to preserve their options for 3rd line regimens. Drug substitutions may be considered on a case by case basis especially in children and adolescents in whom twice-daily dosing may hinder adherence.
Chapter 9: Drug toxicity and Pharmacovigilance		This chapter has been introduced to emphasize the importance of timely screening, monitoring, investigating and management of adverse effects and toxicity of medications especially ARVs and anti-TB. This section provides guidance for the procedures for active pharmacovigilance including standard operating procedures for the management of hyperglycaemia following DTG initiation.

	9.2.1	**Laboratory Monitoring for Active Pharmacovigilance in non-sentinel sites** Non- sentinel sites shall conduct risk-based screening to determine what laboratory tests are to be done. For patients who screen positive to a minimum of two questions on the screening tool shall be eligible for relevant laboratory tests.
	9.2.2	**Laboratory Monitoring for Active Pharmacovigilance in sentinel sites** All sentinel sites shall conduct baseline and routine laboratory investigations for suspected adverse drug event in addition to clinical screening which form, shall be in the patient file. Both laboratory and clinical screenings shall be done even when the patient has no signs and symptoms of ADRs.
Chapter 10: Service Delivery Approaches	**10.1.10**	**Classification of clients for differentiated service delivery approaches** **Stable clients** • PLHIV (Children, Adolescents, Pregnant and lactating women and adults) on current ART regimen for more than 6 months*. • On 1st or 2nd line ART regimens. • Virally suppressed: Most recent viral load result suppressed and still valid as per the viral load algorithm. • WHO stages 1 or 2. • Demonstrated good adherence (over 95%) in the last 6 consecutive months. • TB clients who have completed 2 months intensive phase treatment and are sputum negative for PTB. **Unstable/Complex Clients** • PLHIV (Children, Adolescents, Pregnant and lactating women and adults) on current ART regimen for less than 6 months. • On 3rd line ART regimen. • Not virally suppressed or with a valid suppressed viral load result. • Has current or history of WHO stages 3 or 4 opportunistic infections within the past one year. • Poor adherence (less than 95%). • TB clients in intensive phase of treatment (< 2 months) or who are still sputum positive after intensive phase treatment for PTB. • MDRTB/HIV co-infected clients.

Chapter 10: Service Delivery Approaches	**10.1.11**	Multi-month prescriptions apply to stable clients in stable approaches. These guidelines recommend the introduction of 6 months prescription for high risk clients in whom frequent drug pickups may compromise their adherence to ART. Only stable clients will be considered for 6-month refills of ART in addition to meeting all of the following criteria: • ≥15 years • Not pregnant or breastfeeding • Repeat VL not due in less than 6 months • Not TB/HIV co-infected • No regimen switch or substitution in the last 6 months • Completed INH prophylaxis Six-month refills can be provided through FTDR or CDDP approaches.
	10.1.13	**DSD for children and adolescents:** These guidelines recommend the expansion of DSD approaches for children and adolescents • Stable children 2 - <10years can join FTDR or CDDP if their parents/care givers are stable and choose to join these approaches • Stable adolescents 10 – 14years can join CCLADs or CDDP if their parents/care givers are stable and choose to join these approaches • Stable adolescents (10 – 14years) can be CCLAD members if their parents/care givers are stable and choose to join CCLADs but they cannot pick drugs on behalf of the other members. The responsibility of picking drugs will be for the parent/care giver in each CCLAD group. • Stable adolescents 15 – 19years can join CCLADs or CDDPs if they choose to. • Adolescents 15 – 19years can form an adolescent only group if they choose to.
	10.1.14	**Early Differentiation:** At 6 months after initiation of ART, a client can be classified as stable and qualify to be differentiated into approaches for stable clients in the facility and the community.

	10.1.16	**Provision of TB Preventive Therapy (TPT) to clients in the various DSD models and approaches** The following should be followed while providing TPT in the context of DSD: **a. TPT initiation** • TPT should be initiated by a clinician regardless of which DSD approach the client is on. Efforts should be undertaken to have baseline tests done (i.e. LFTs) prior to initiation of TPT. • TPT should be initiated at the health facility for all clients receiving ART services through FBIM, FBG, FTDR and CCLAD. • For clients enrolled onto CDDPs, TPT should be initiated from the CDDP during the clinicians visit. Efforts should be undertaken to have baseline tests done (i.e. LFTs) at the time of initiation of TPT. • Patient education about side effects and when to return to the facility should be provided at the time of TPT initiation regardless of DSD approach. • TPT and ART refills should be aligned **b. Monitoring clients on TPT** • Clinical monitoring for of clients on TPT should be done at every clinical encounter regardless of DSD approach the client is on: o Monitoring can be done through history taking and physical examination for signs suggestive of hepatic injury (i.e. Yellowing of eyes, body itching, body rash) o Monitoring can also be done through follow up phone calls to the clients. During the phones calls health workers should explore for signs of liver injury, adherence to treatment and provide client education. o LFTs should be done at baseline and at 3 months • Clients in more intensive approaches (i.e. FBIM and FBG) should be reviewed every month for TPT and ART toxicities • Clients in less intensive approaches (i.e. FTDR, CDDP and CCLAD) should be reviewed at least once every three months. Review at 3- and 6-months post TPT initiation should happen at the facility for clients enrolled onto FTDR and CCLAD. Review at 3- and 6-months post TPT initiation for clients enrolled onto CDDP should happen at the CDDP.
Chapter 11: Procurement and Supply Chain Management Systems		No Changes
Chapter 12: Monitoring and Evaluation		No changes

Annex 2: HIV-exposed infants visit schedule and care package

Visit schedule	Birth	6wks	10wks	14wks	5mo	6mo	9mo	12mo	15mo	18mo	24mo
Immunization	X	X	X	X	.		X		.		.
Clinical assessment	X	X	X	X	X	X	X	X	X	X	X
Growth and development	X	X	X	X	X	X	X	X	X	X	X
CTX and ARV prophylaxis	Stable mother[c]- Give baby Nevirapine prophylaxis for 6weeks Unstable mother[d] – Give baby Nevirapine prophylaxis for 12 weeks Cotrimoxazole should be started at six weeks of age or thereafter and continued until infant is determined to be HIV-negative										
Infant diagnosis testing[e]	None	Do 1st PCR at 6 weeks of age or as soon as infant is identified Do 2nd PCR at 9 months Do 3rd PCR 6 weeks after cessation of breastfeeding								Do antibody test at 18 months	
Counseling and feeding advice	X	X	X	X	X	X	X	X	X	X	X
Mother's care and treatment	X	X	X	X	X	X	X	X	X	X	X

a - At every visit, the EID card, EID register, mother's HIV care/ART card and ART register should be updated as well the Open MRS/EID database where it exists
b – The standard is starting Nevirapine at birth and cotrimoxazole at 6 weeks of age
c – Stable mother
d – Unstable mother
e - Infants should come every month until test results are given to the caretaker

Annex 3: WHO staging for HIV infection and disease in adults and adolescents

Clinical Stage I:

1. **Asymptomatic**
2. **Persistent generalized lymphadenopathy**

Performance Scale 1: Asymptomatic, normal activity

Clinical Stage II:

1. **Moderate weight loss (less than 10% of presumed or measured body weight)**
2. **Minor mucocutaneous manifestations (seborrhoeic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular stomatitis)**
3. **Herpes zoster within the last five years**
4. **Recurrent upper respiratory tract infections, e.g., bacterial sinusitis, tonsillitis, otitis media and pharyngitis**

And/or Performance Scale 2: Symptomatic but normal activity

Clinical Stage III:

1. **Severe weight loss (more than 10% of presumed or measured body weight)**
2. **Unexplained chronic diarrhea for more than one month**
3. **Unexplained prolonged fever, intermittent or constant, for more than one month**
4. **Oral candidiasis**
5. **Oral hairy leukoplakia**
6. **Pulmonary tuberculosis (current)**
7. **Severe bacterial infections such as pneumonia, pyomyositis, empyema, bacteremia or meningitis**
8. **Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis**
9. **Unexplained anemia (<8gm/dl), neutropenia (<0.5× 10^9 per liter), or chronic thrombocytopenia (<50× 10^9 per liter)**

And/or Performance Scale 3: Bed-ridden for less than 50% of the day during the last month

Clinical Stage IV:

1. **HIV wasting syndrome – weight loss of more than 10%, and either unexplained chronic diarrhea for more than onemonth or chronic weakness or unexplained prolonged fever for more than one month**
2. **Pneumocystis pneumonia (PCP)**
3. **Recurrent severe bacterial pneumonia**
4. ***Toxoplasmosis* of the brain**
5. **Cryptosporidiosis with diarrhea for more than one month**
6. **Chronic Isosporiasis**
7. **Extrapulmonary Cryptococcosis including meningitis**
8. **Cytomegalovirus infection (retinitis or infection of other organs)**
9. **Herpes simplex virus (HSV) infection, mucocutaneous for more than one month, or visceral at any site**
10. **Progressive multifocal leukoencephalopathy (PML)**
11. **Any disseminated endemic mycosis such as histoplasmosis, coccidioidomycosis**
12. **Candidiasis of the oesophagus, trachea, bronchi or lungs**
13. **Atypical mycobacteriosis, disseminated**
14. **Recurrent non-typhoid salmonella septicemia**
15. **Extrapulmonary tuberculosis**
16. **Lymphoma**
17. **Invasive cancer of the cervix**
18. **Kaposi's sarcoma**
19. **HIV encephalopathy – disabling cognitive and/or motor dysfunction interfering with activities of daily living, progressing slowly over weeks or months, in the absence of concurrent illness or condition other than HIV infection that could account for the findings**
20. **Atypical disseminated leishmaniasis**
21. **Symptomatic HIV-associated nephropathy or symptomatic HIV-associated cardiomyopathy**

And/or Performance Scale 4: Bed-ridden for more than 50% of the day during the last month

Annex 4: WHO staging for HIV infection and disease in infants and children

Clinical Stage I: **1. Asymptomatic** **2. Persistent generalized lymphadenopathy**
Clinical Stage II: **1. Unexplained persistent hepatosplenomegaly** **2. Papular pruritic eruptions** **3. Extensive wart virus infection** **4. Extensive molluscum contagiosum** **5. Recurrent oral ulcerations** **6. Unexplained persistent parotid enlargement** **7. Linear gingival erythema** **8. Herpes zoster** **9. Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis)** **10. Fungal nail infections**
Clinical Stage III: **1. Unexplained moderate malnutrition not adequately responding to standard therapy** **2. Unexplained persistent diarrhea (14 days or more)** **3. Unexplained persistent fever (above 37.5 ºC, intermittent or constant, for longer than one month)** **4. Persistent oral candidiasis (after first six weeks of life)** **5. Oral hairy leukoplakia** **6. Acute necrotizing ulcerative gingivitis/periodontitis** **7. Lymph node TB** **8. Pulmonary TB** **9. Severe recurrent bacterial pneumonia** **10. Symptomatic lymphoid interstitial pneumonitis** **11. Chronic HIV-associated lung disease including bronchiectasis** **12. Unexplained anaemia (<8.0 g/dl), neutropenia (<0.5 x 109/L^3) or chronic thrombocytopenia (<50 x 109/ L^3)**
Clinical Stage IV: **1. Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy** **2. Pneumocystis pneumonia (PCP)** **3. Severe recurrent bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)** **4. Chronic herpes simplex infection; (oral, labial or cutaneous of more than one month's duration, or visceral at any site)** **5. Extrapulmonary TB** **6. Kaposi's sarcoma** **7. Oesophageal candidiasis (or Candida of trachea, bronchi or lungs)** **8. *Toxoplasmosis* of the brain (after the neonatal period)** **9. HIV encephalopathy** **10. Cytomegalovirus (CMV) infection (retinitis or infection of other organs) with onset at age over one month** **11. Extrapulmonary cryptococcosis (including meningitis)** **12. Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiomycosis)** **13. Chronic cryptosporidiosis (with diarrhea)** **14. Chronic isosporiasis** **15. Disseminated non-tuberculous mycobacteria infection** **16. Cerebral or B-cell non-Hodgkin lymphoma** **17. Progressive multifocal leukoencephalopathy** **18. HIV-associated cardiomyopathy or nephropathy**

Annex 5: Intensified TB case finding guide

Ministry of Health

Intensified TB Case Finding Guide

Use the guide to identify presumptive TB:

In HIV Clinic, OPD, IPD and Congregate settings

This guide should be administered by either a health care provider or lay provider at the health facility

STEP 1: The person conducting the assessment asks the following questions:

1.	Has the patient been coughing for 2 weeks or more? ***(for known HIV patients assess cough regardless of duration)***	**Yes**	**No**
2.	Has the patient had persistent fevers for 2 weeks or more?	**Yes**	**No**
3.	Has the patient had noticeable weight loss (more than 3 kg)	**Yes**	**No**
4.	Has the patient had excessive night sweats for 3 weeks or more? ***(for adults)***	**Yes**	**No**
5.	Has the child had poor weight gain in the last one month*? ***(ask for children < 5 years)***	**Yes**	**No**
6.	Has the child had contact with a person with Pulmonary Tuberculosis or chronic cough? ***(ask for children < 5 years)***	**Yes**	**No**

****poor weight gain*** *(Weight loss, **or** very low weight (weight-for-age less than –3 z-score), **or** underweight (weight-for age less than –2 z-score), **or** confirmed weight loss (>5%) since the last visit, **or** growth curve flattening)*

STEP 2: Guide for Actions to take

- If **yes to question 1** request for sputum test and refer to clinician for further investigations. ***Direct the patient to a designated area for people with chronic cough.***
- **If no to question 1 and yes to any other question;** refer to clinician for further investigations
- If **no to all questions:** repeat TB Assessment at subsequent visits

**For Children who are unable to produce sputum, refer to clinician for further investigations*

STEP 3: Record of Information at Health facility level

1. If you are in a clinic attending to patients enrolled in HIV care record this information on the comprehensive ART card; this information should then be transferred to the Pre ART or ART register.
2. If you are in a clinic setting (not attending to patients enrolled in HIV care e.g. OPD) and presumptive TB case is found, record the information in a presumptive TB register.

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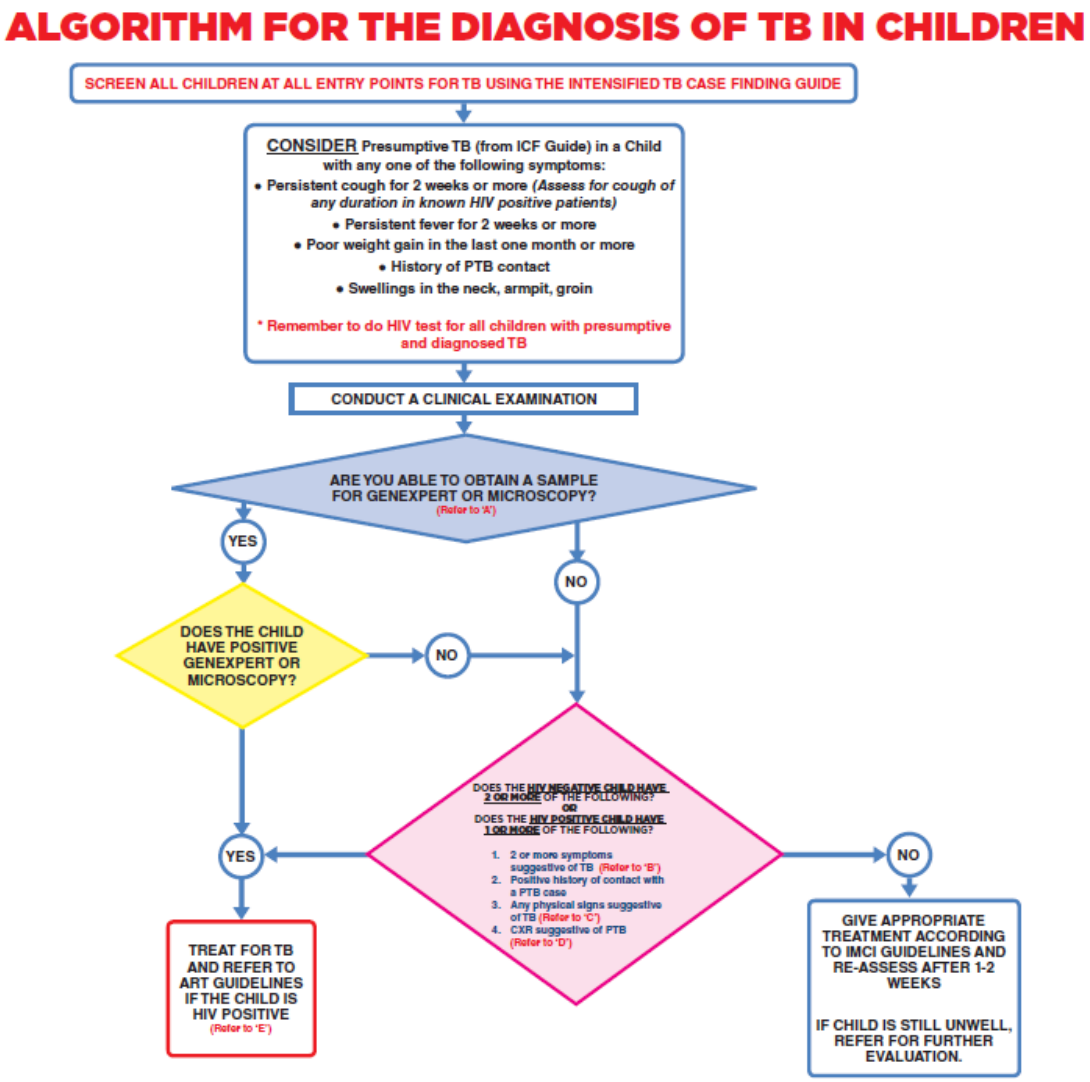
Annex 6: Algorithm for TB diagnosis in children



A SAMPLES FOR GENEXPERT

- Sputum (Expectorated/ Induced)
- Gastric Aspirates
- Cerebral Spinal Fluid (CSF)
- Lymph node Aspirates

B SYMPTOMS SUGGESTIVE OF TB

- Persistent cough for 2 weeks or more
- Persistent fever for 2 weeks or more
- Poor weight gain in the last one month or more

D CXR FINDINGS SUGGESTIVE OF PTB INCLUDE:

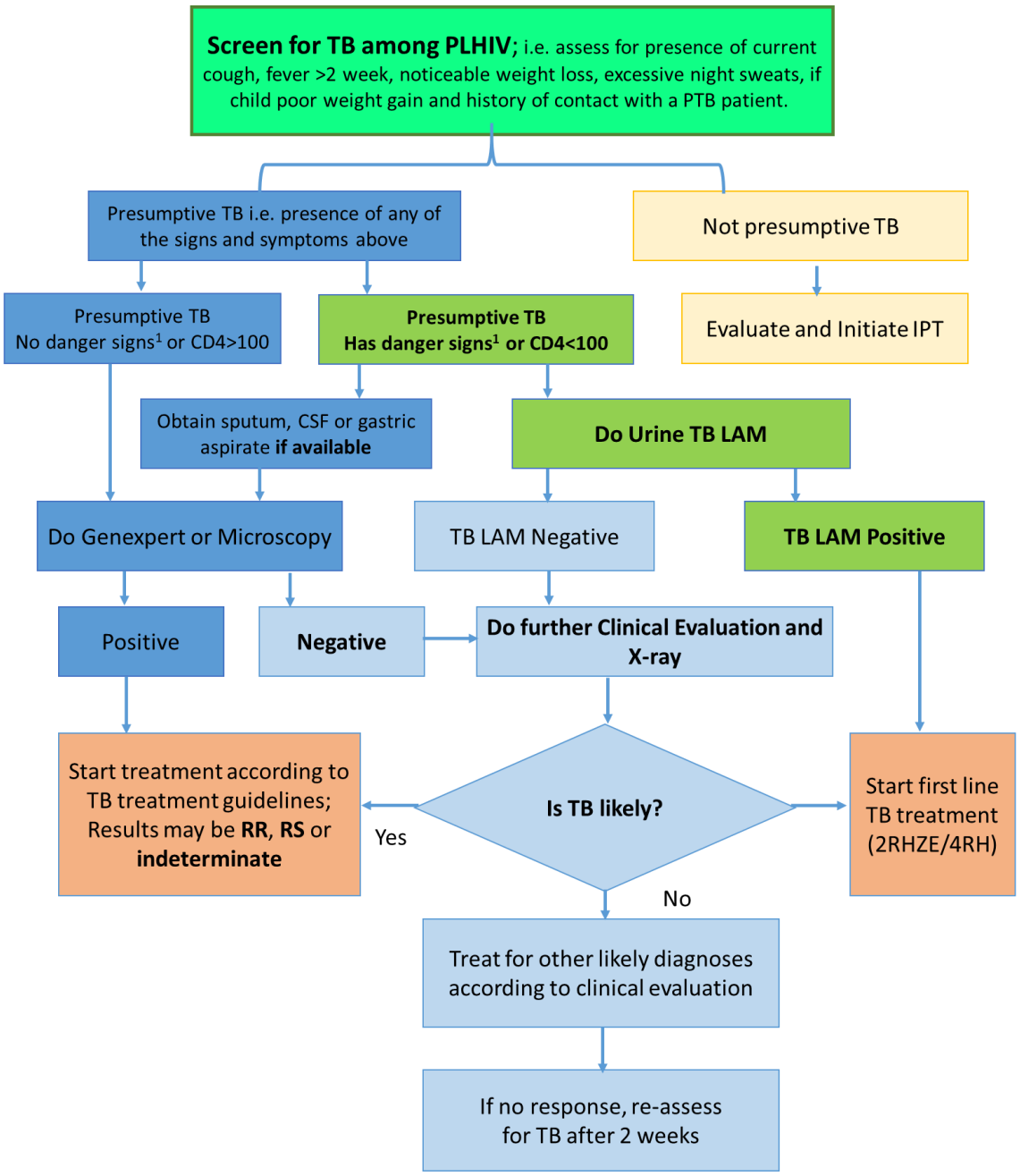
- Miliary picture
- Hilar adenopathy
- Cavitation

C PHYSICAL SIGNS SUGGESTIVE OF TB

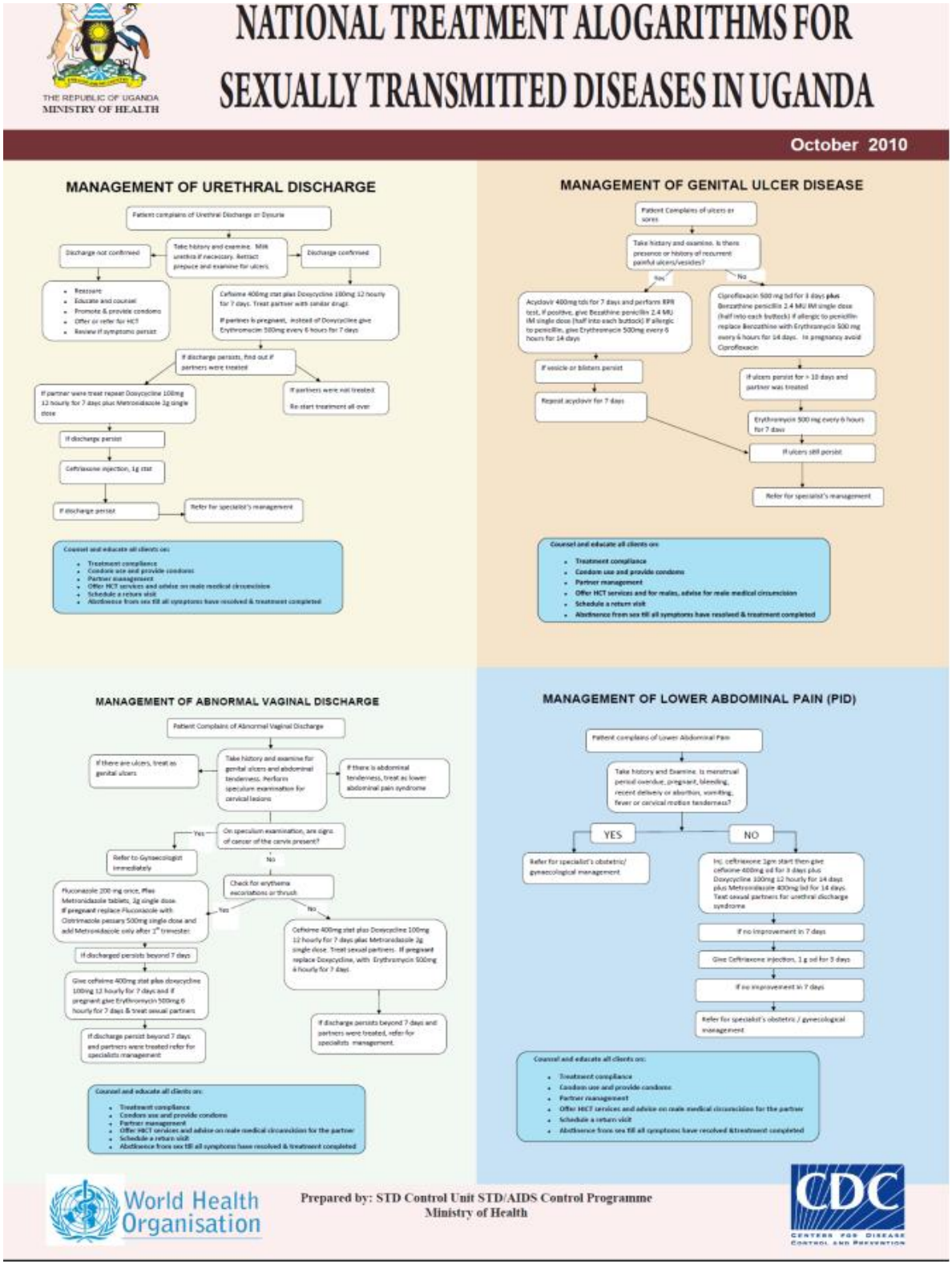
- Severe malnutrition
- Enlarged lymph nodes around the neck or the arm pit (TB adenitis).
- Acute pneumonia not responding to a complete course of appropriate broad spectrum antibiotics.
- Recurrent pneumonias (defined as at-least 2 episodes of pneumonia in a year with at-least 1 month of clinical recovery between episodes)
- Persistent wheeze not responding to bronchodilators (usually asymmetrical).
- Presence of a swelling on the back (Gibbus)
- Signs of meningitis in a child with symptoms suggestive of TB

E A child with a positive GeneXpert test and Rifampicin Resistance should be referred to the nearest MDR TB treatment site for further management; A child with a prior history of TB treatment and a child with a positive history of MDR TB contact should have a sample taken for GeneXpert test and referred to the nearest MDR TB treatment site for further evaluation and managemen

Annex 7: Algorithm for TB diagnosis in HIV positive adults and adolescents



Annex 8: Treatment algorithms for sexually transmitted diseases in Uganda



Annex 9: Human resources for differentiated service delivery and their roles

	Doctor/ Clinical Officer	Nurse/ Midwives	Trained Nursing Assistants	Pharmacists/ Pharm Technicians/ Dispensers/ Nurses/ storekeepers	Laboratory Technicians/ Laboratory Assistants	Lay providers (Expert Clients, VHTs, CHEWS, Mentor Mothers), CBOs and CSOs working with PLHIV/AIT	Health Information Assistants/ Data Clerk
Comprehensive clinical services including, NACS, symptom screening for NCDs, TB, STIs and hepatitis	X	X					
Prescription of ART, initiation and follow up for adults, adolescents and children	X	X					
Switching and substituting ART regimens by a multidisciplinary 'switch team'	X						
Management of complicated cases(e.g. cryptococcal meningitis (CCM); second line treatment failure etc.)	X						
TB initiation of smear or gene X-pert positive cases for adults, adolescents and children	X	X					
TB initiation for adults and adolescents requiring chest x-ray (CXR) interpretation, and for children where no sputum is available	X						
HIV testing services	X	X	X	X	X	X	X
Health Education	X	X	X			X	
Registration and filling of appointment diaries		X	X	X	X		
Performing vital signs (triage)	X	X	X				
Dried blood spot (DBS), VL sample collection, testing and results delivery	X	X	X		X	X	
Coordinating and supervising the community groups	X	X	X				
Linkage facilitation	X	X	X			X	
Pre-packing medicines, picking drug refills, distribution of refills, Forecasting and ordering of commodities from the warehouses, Dispensing, Filling/updating the dispensing log and tracking tools		X	X			X*	X
ART preparation and adherence counselling for adults, adolescents, children and pregnant women including treatment failure	X	X	X		X	X	X
Defaulter tracing		X	X		X	X	X
Client records management/data entry & updating registers (for area of service)		X	X		X	X	X
Phlebotomy	X	X			X		
Reporting on community activities/client groups, support; coordinate and supervise their peers						X	
Community – facility referrals and vice versa						X	

**These service providers will be supervised while undertaking these tasks*

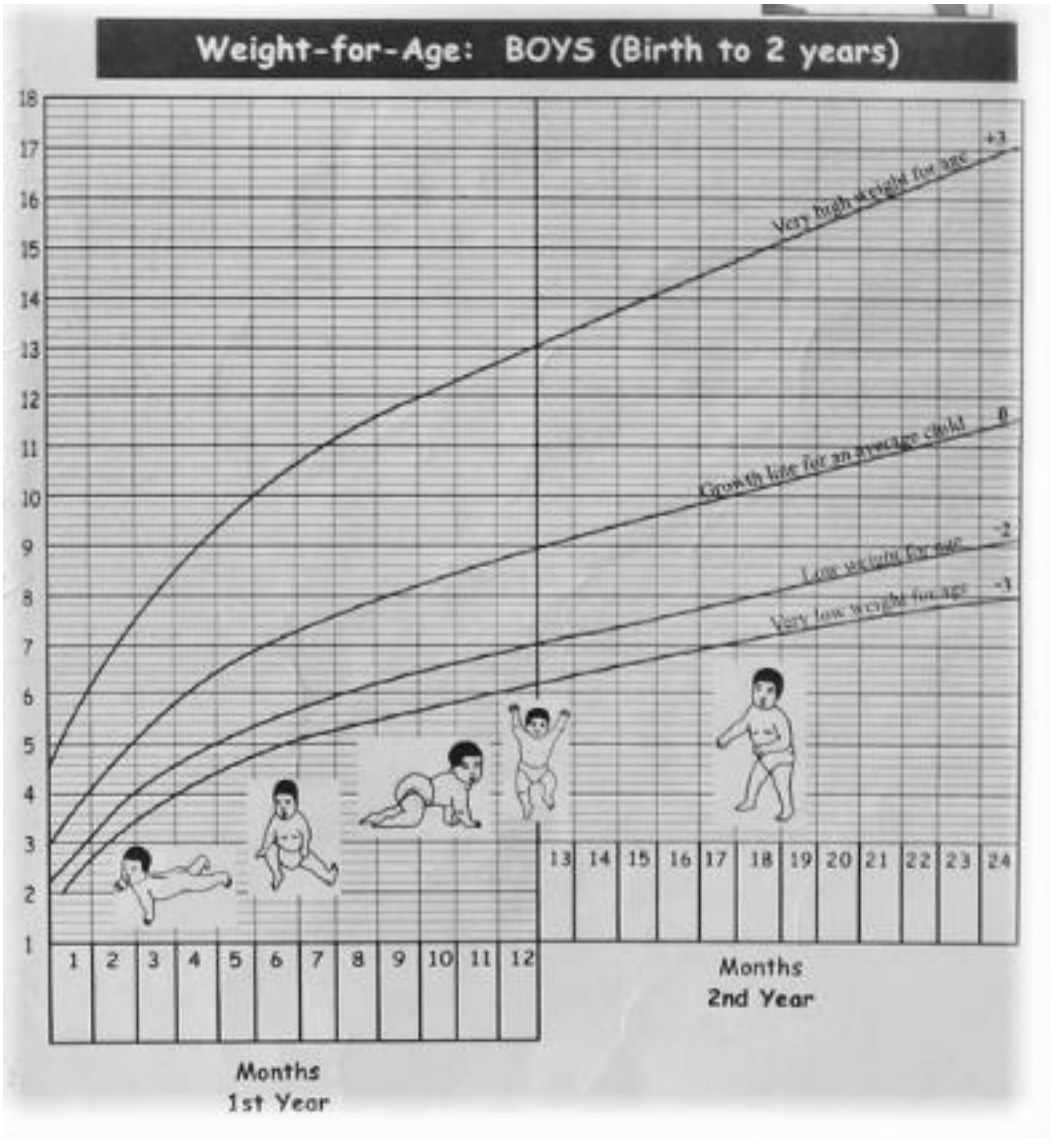
***Lay clients include; expert clients, VHTs, CHEWS, andmentor mothers*

Annex 10: Home education/eating/exercise activities drugs/depression sexuality suicidality/safety assessment tool in adolescents

HEADSS ASSESSMENT TOOL		
Component	**Area of assessment**	**Assessment results**
Home, situation, family	• Who lives with the young person? Where? • Do they have their room? • What are relationships like at home? • What do parent and relatives do for a living? Ever institutionalized? Incarcerated? Recent moves? Running away? • New people in ahome environment? • Have they disclosed their HIV status? If yes, with whom? If not, what are the reason?	
Education and employment	• School/grade performance--any recent changes? Any past dramatic changes? • Favourite subjects--worst subjects? (include grades) • Any years repeated/classes failed? • Suspension, termination, dropping out? • Future education/employment plans? • Any current or past employment? • Relations with teachers, employers--school, work attendance?	
Activities	• On own, with peers (what do you do for fun? where? when?) • With family? • Sports--regular exercise? • Religious attendance, clubs, projects? • Hobbies--other activities? • Reading for fun--what? • TV--how much weekly--favourite shows? • Favourite music? • Doestheyoung person have acar, use seat belts? • History of arrests--acting out--crime?	
Drugs /tobacco/alcohol	• Use by peers? Use by a young person? (include tobacco, alcohol) • Use by family members? (include tobacco, alcohol) • Amounts, frequency, patterns of use/abuse, and car use while intoxicated? • Source—how theypaid for them?	

HEADSS ASSESSMENT TOOL		
Component	**Area of assessment**	**Assessment results**
Sexuality	• Orientation? • Degree and types of sexual experience and acts? • The number of partners? • Masturbation? (normalize) • History of pregnancy/abortion? • Sexually transmitted diseases--knowledge and prevention? • Contraception? The frequency of use? Comfort with sexual activity, enjoyment/pleasure obtained? History of sexual/physical abuse?	
Suicide /Depression	• Sleep disorders (usually induction problems, also early/frequent waking or greatly increased sleep and complaints of increasing fatigue) • Appetite/eating behavior changes • Feelings of 'boredom' • Emotional outbursts and highly impulsive behaviour • History of withdrawal/isolation • Hopeless/helpless feelings • History of past suicide attempts, depression, psychological • History of suicide attempts in family or peers • History of recurrent serious 'accidents' • Psychosomatic symptomology • Suicidal ideation (including significant current and past losses) • Decreased affect at theinterview, avoidance of eye contact--depression posturing • Preoccupation with death (clothing, media, music, art)	

Annex 11: Child health card



Annex 12: Patient Health Questionnaire-9 (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9) *Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.*				
Over the last two weeks, how often have you been bothered by any of the following problems? *(Use "✓" to indicate your answer)*				
Question	**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 have let yourself or yourfamilydown	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	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
	Column total	_____	+_____	+_____
Add totals together = _____				
10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people? Not difficult at all ☐ Somewhat difficul☐ Very difficult ☐ Extremely difficul☐				

Annex 13: ARV Dosing Tables

	Formulations and strengths	3.0–5.9kg		6.0–9.9kg		10.0–13.9kg		14.0–19.9kg		20.0–24.9kg		25.0–34.9kg		Adolescents and adults >35kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Fixed Dose Combination Tablets/Granules	**ABC/3TC** 120/60mg	–	1	–	1.5	–	2	–	2.5	–	3	-	-	-	-
	ABC/3TC 600/300mg	-	-	-	-	-	-	-	-	-	-	–	1	–	1
	AZT/3TC 60/30mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	-	-	-	-
	AZT/3TC/NVP 60/30/50mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	-	-	-	-
	AZT/3TC 300/150mg	-	-	-	-	-	-	-	-	-	-	1	1	1	1
	AZT/3TC/NVP 300/150/200mg	-	-	-	-	-	-	-	-	-	-	1	1	1	1
	TDF/3TC 300/300mg	-	-	-	-	-	-	-	-	-	-	-	-	–	1
	TDF/3TC/EFV 300/300/600mg	-	-	-	-	-	-	-	-	-	-	-	-	–	1
	TDF/3TC/EFV 300/300/400mg	-	-	-	-	-	-	-	-	-	-	-	-	-	1
	TDF/3TC/DTG 300/300/50mg	¬-	-	-	-	-	-	-	-	-	-	-	-	1	-
	ABC/3TC/DTG 60/30/5mg	2	-	3	-	4	-	5	-	6	-	-	-	-	--
	ABC/3TC/LPV/r 30/15/40/10mg	2	2	3	3	4	4	5	5	6	6	-	-	-	-

	Formulations and strengths	3.0–5.9kg		6.0–9.9kg		10.0–13.9kg		14.0–19.9kg		20.0–24.9kg		25.0–34.9kg		Adolescents and adults >35kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Fixed Dose Combination Tablets/Pellets/Syrups	DTG 50mg	-	-	-	-	-	-	-	-	-	-	-	-	1	1
	DTG 10mg	1	-	1.5	-	2	-	2.5	-	3	-	-	-	-	-
	ABC 60mg	1	1	1.5	1.5	-	-	-	-	-	-	-	-	-	-
	EFV 200mg	-	-	-	-	–	1	–	1.5	–	1.5	–	2	-	-
	EFV 600mg	-	-	-	-	-	-	-	-	-	-	-	-	-	1
	NVP 200mg	-	-	-	-	-	-	-	-	-	-	-	-	1	1
	LPV/r Syrup 80/20mg per ml	1 ml	1 ml	1.5 ml	1.5 ml	2 ml	2ml	2.5 ml	2.5 ml	3 ml	3 ml	-	-	-	-
	LPV/r pellets 40/10mg[1]	2	2	3	3	4	4	5	5	6	6	–	–	-	-
	LPV/r 100/25mg[2]	-	-	-	-	2	1	2	2	2	2	-	-	-	-
	LPV/r 200/50mg	-	-	-	-	-	-	-	-	-	-	2	1	2	2
	ATV/r 300/100mg	-	-	-	-	-	-	-	-	-	-	-	-	–	1
	Raltegravir 25mg Chewable Tablet	-	-	-	-	3	3	-	-	-	-	-	-	-	-
	Raltegravir 100mg Chewable Tablet	-	-	-	-	-	-	1	1	1.5	1.5	-	-	-	-
	Raltegravir 400mg	-	-	-	-	-	-	-	-	-	-	1	1	1	1
	DRV 75mg Tablets[3]	-	-	-	-	3 +RTV 0.5ml	3 +RTV 0.5ml	5 +RTV 50mg	5 +RTV 50mg	5 +RTV 50mg	5 +RTV 50mg	-	-	-	-
	DRV 150mg	-	-	-	-	-	-	-	-	-	-	4 +RTV 100mg	4 +RTV 100mg	4 +RTV 100mg	4 +RTV 100mg

	DRV 600mg[4]	-	-	-	-	-	-	-	-	-	-	1 +RTV 100mg	1 +RTV 100mg	1 +RTV 100mg	1 +RTV 100mg
	RTV 25mg	-	-	-	-	-	-	2	2	2	2	3	3	-	-
	RTV 100mg	-	-	-	-	-	-	-	-	-	-	-	-	1	1
	ETV 200mg	-	-	-	-	-	-	-	-	-	-	-	-	1	1
	SQV 500mg[5]	-	-	-	-	-	-	-	-	-	-	-	-	2 +RTV 100mg	2 +RTV 100mg

1. For children≥10kg that are able to swallow tablets, give LPV/r 100/25mg tablet.
2. tablets of LPV/r 100/25mg can be substituted with 1 tablet of LPV/r 200/50mg in order to reduce the pill burden. These tablets should be administered fully intact/whole i.e. not cut or crushed.
3. DRV must be administered with 0.5mL of RTV 80mg/mL oral suspension in children <15kg, with 2 tab of RTV 25mg in children 15 to 25kg and 3 tab of RTV 25mg in children above 25kg. DRV is always taken with food.
4. DRV 600mg must be co-administered with RTV 100mg.
5. SQV 500mg must be co-administered with RTV 100mg and should only be used in adolescents and adults above 16 years.

Annex 14: Dosing of RUTF

Weight (kg)	Sachets/day	Sachets/week	Sachet/two weeks	Sachets/month
3.0 - 3.4	1.25	9	18	35
3.5 - 3.9	1.5	11	22	44
4.0 - 5.4	2	14	28	56
5.5 - 6.9	2.5	18	35	70
7.0 - 8.4	3	21	42	84
8.5 - 9.4	3.5	25	49	98
9.5 - 10.4	4	28	56	112
10.5 - 11.9	4.5	32	63	126
≥ 12.0	5	35	70	140
14 years and above	6	42	84	168

Source: *Integrated Management of Acute Malnutrition Guidelines,*

Annex 15: Suspected Adverse Drug Reaction Reporting form

CONFIDENTIAL

REPUBLIC OF UGANDA
MINISTRY OF HEALTH

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

A. PATIENT DETAILS

Patient name	Patient Number	Sex: M/F*
Age at time of onset(yrs)*	Health Facility	Last Menstrual Period
Weight (kg)	District	Trimester (if pregnant)

B. SUSPECTED DRUG (S) DETAILS

Generic Name*	Brand Name	Dose ,Route Frequency	Date* started	Date stopped	Prescribed for	Expiry date	Batch No

C. SUSPECTED REACTIONS

Please describe the reaction as observed and any treatment given to manage the reaction

Outcome

Recovered ☐ Recovering ☐ Continuing ☐ Death due to reaction ☐

Date reaction started*	Date reaction stopped	Date of notification

SERIOUSNESS OF THE REACTION

Patient died ☐ Prolonged inpatient Hospitalization ☐ Involved disability ☐ Life Threatening ☐
Congenital abnormality ☐

D. CONCOMITANT DRUGS

Please give information on the drug(s) the patient has been taking together with the suspected drug including those taken for chronic diseases (include self medication and herbal preparations)

Generic Name	Brand	Dosage	Date started	Date stopped	Indication(prescribed or OTC)

Relevant laboratory tests including dates	**Additional relevant information (medical history, allergies, failure of efficacy)**

E. REPORTER'S DETAILS

Name/designation*	Telephone and Email Address	Date of reporting	Health facility

* Mandatory field