Ministry of Health

CONSOLIDATED GUIDELINES FOR PREVENTION AND TREATMENT OF HIV IN UGANDA

December 2016

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FOREWORD

The Government of Uganda promotes a combination of interventions to manage a generalized HIV epidemic in the country. Over the past ten years, the AIDS Control Program has integrated antiretroviral therapy (ART) into the comprehensive response to HIV prevention, care and support.

Since 2014, the Health Sector has been implementing HIV "test and treat" policy for all children, pregnant and breastfeeding women, HIV positive people with both TB or hepatitis B co-infection and the HIV-positive individuals in serodiscordant relationships. The "test and treat" policy involves providing lifelong ART to people living with HIV irrespective of CD4 or WHO HIV clinical staging. By the end of June 2016, out of an estimated 1.5 million individuals living with HIV, 898,197 individuals were already initiated on ART.

The 2016 version of the "Consolidated Guidelines for Prevention and Treatment of HIV in Uganda" now expands the HIV "test and treat" policy to all adolescents and adults diagnosed with HIV. In compliance with WHO recommendation, we have removed all limitations on eligibility for ART among all people living with HIV: all populations and age groups are now eligible for treatment. This is a significant policy change aimed at consolidating the gains made in the past decades to reverse AIDS as a public health problem in Uganda. In addition, these guidelines do recommend HIV pre-exposure prophylaxis for HIV-uninfected persons at substantial risk of HIV acquisition. Although we have made provisions for future use of new drugs, we have maintained the recommendation to use same once-per-day combination pill for all adults living with HIV, including those with tuberculosis, hepatitis and other co-infections.

In order to make service delivery easier, we have provided additional guidance on service delivery modalities for targeting different client categories. This will catalyze the pace towards achieving universal access to ARVs. With more targeted approaches for identifying and managing persons living with HIV, there will be efficiency gains thereby creating financial savings for use in procurement of more medicines thereby scaling up treatment for HIV prevention.

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

I would like to call upon all actors in the fight against HIV in Uganda, to support successful implementation of these guidelines.

Prof. Anthony K. Mbonye
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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 rapture of membranes

ART Antiretroviral therapy

ARV Antiretroviral

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 blood count

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

CHEWS Community Health Extension Workers

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 Dry blood spot

DM Diabetes mellitus

DNA Deoxyribonucleic acid

DRV/r Darunavir/ritonavir

DSD Differentiated service delivery

DTG Dolutegravir

E Ethambutol

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 Inpatient department

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-upper arm 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

PTT Prothrombin time

PWDs Persons with disabilities

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

YCC Young child clinic

Z Pyrazinamide

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 further expand access to antiretroviral therapy (ART), initiate treatment earlier and expand the use of ARV drugs for HIV prevention.

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 now expand 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. These guidelines also recommend pre-exposure prophylaxis for HIV-negative individuals at high risk of acquiring HIV including key population. In addition they also recommend dolutegravir, one of a newer class of ARV drugs as first-line treatment for adults and adolescents who do not tolerate efavirenz.

These guidelines also provide operational and service delivery guidance to districts and health facilities to implement new approaches including:

- Effective integration of elimination of mother-to-child HIV transmission (eMTCT) services into maternal, newborn, child and adolescent health services (MNCAH);
- Differentiated service delivery, which reduces clinic visits and allows community ART distribution to PLHIV who are stable on ART; and
- Retention, adherence to treatment, adolescent-friendly and responsive health services.

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 an updated, evidence-based and simplified guide to providing ARV drugs for HIV treatment and prevention to all age groups and populations.
3. To provide a standardized and simplified guide on infant and young child feeding for HIV-infected or exposed infants and children.
4. To provide guidance on key operational and service delivery issues that need to be addressed to increase access to HIV services and strengthen the continuum of HIV care.

1.3. TARGET AUDIENCE

The primary audiences for these guidelines are:

- Health care workers and district health teams
- Program managers of HIV, MCNH, reproductive health (RH), and TB programs as well as national medicines warehouses, and

- AIDS development partners, implementing partners, training institutions, researchers, civil society organizations and PLHIV

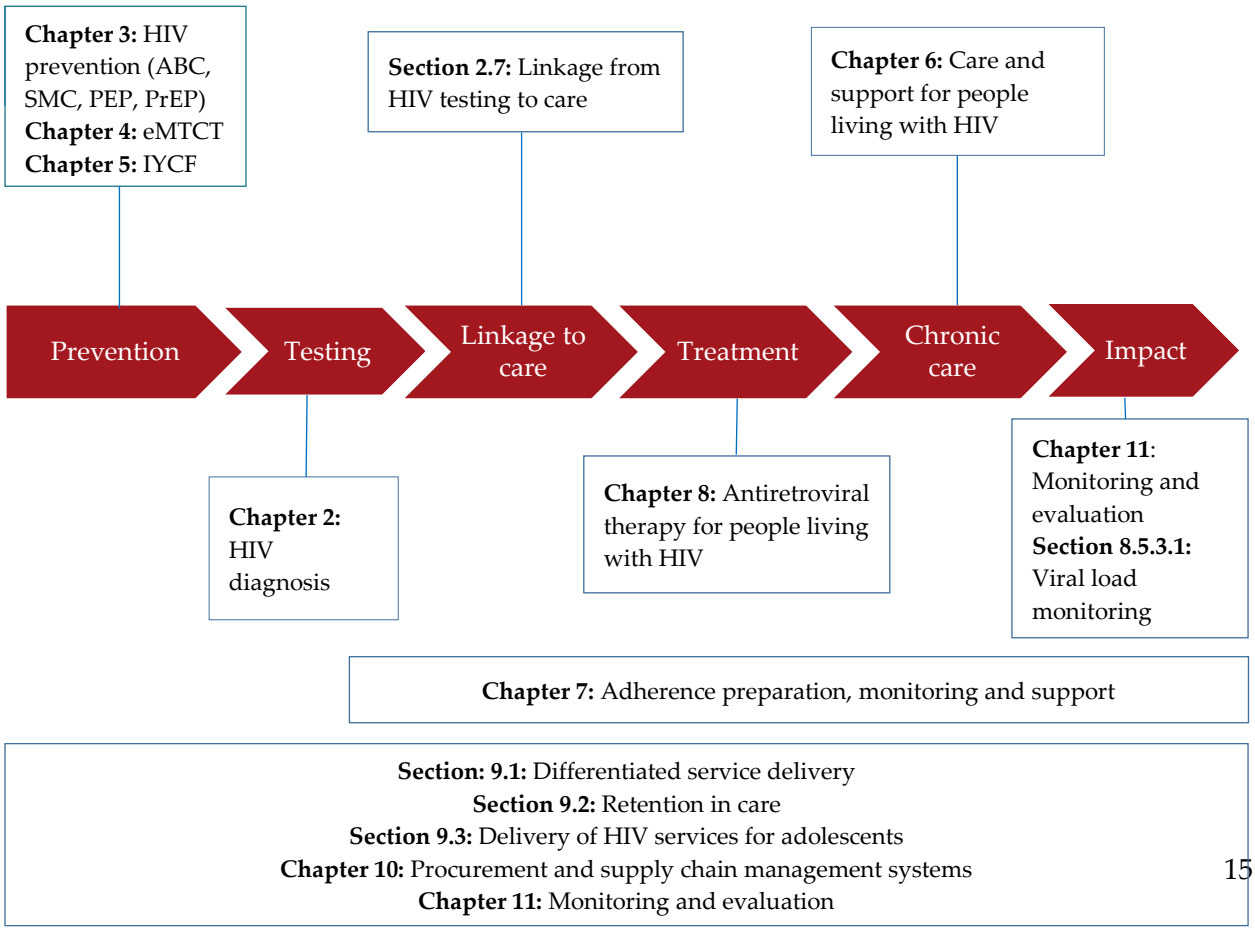
1.4. GUIDELINES DEVELOPMENT PROCESS

These guidelines were developed by a team of technical experts within the country including PLHIV and external experts. The guidelines development process was comprehensive and involved attending the WHO regional guidelines dissemination meeting, adaptation of the guidelines, approval of the adaptation by the National ART advisory committee, senior and top management of Ministry of Health and Health Policy Advisory Committee, writing the guidelines and peer review. The adaptation of the guidelines by different subcommittees involved review of evidence cited in the WHO guidelines, presentation and review of any local evidence, discussion and agreement on the adaptation. We also received technical support and peer review from external experts including those from the WHO, CDC, USAID, CHAI and EGPAF.

1.5. COMPONENTS OF THE GUIDELINES

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

Figure 1: HIV continuum of care and the relevant sections of the guidelines

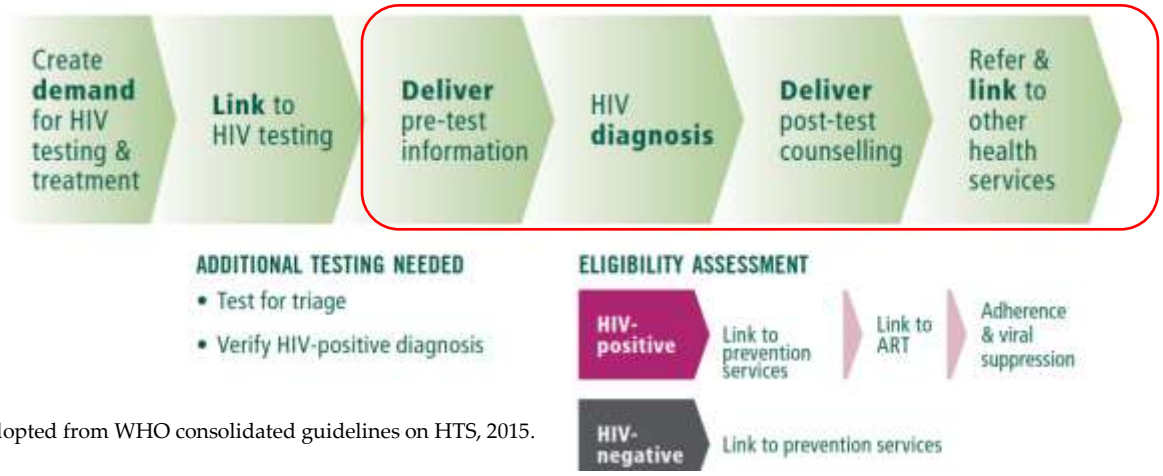


2. HIV DIAGNOSIS AND LINKAGE TO HIV CARE AND TREATMENT

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 and correctly to ensure early access to prevention, treatment and support services. By 2015, only 65% of the estimated 1.46 million HIV-positive persons in Uganda knew their HIV serostatus, and 51% of these were receiving antiretroviral treatment (MoH, 2015). 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. HTS delivery includes a range of activities and services that are described in the pathway in Figure 2 below. This section guides the provision of focused and targeted HTS for reaching populations at risk of HIV infection. Health workers should use this guidance alongside the national HTS policy and implementation guidelines (2016).

Figure 2: HTS pathway



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 human rights approach that observes the 5Cs (Confidentiality, Consent, Counseling, Correct test result and Connection to appropriate services). These principles are described below.

- **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.
- **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.
- **Counseling:** All persons accessing HTS should be provided with quality counseling before and after testing as per the approved HTS protocol.

- **Correct test result:** HTS providers should adhere to the national testing algorithm and **must** follow the SOP for HIV testing to ensure that clients receive correct HIV test results.
- **Connect to other services**: Providers should link HTS clients to appropriate HIV prevention, treatment, care and support services.

2.3. HIV TESTING SERVICE APPROACHES

To improve access and efficiency of HTS, a mix of health facility and community-based approaches should be utilized.

2.3.1. FACILITY-BASED APPROACHES

Facility-based HTS approaches include provider-initiated and client-initiated testing and counseling.

2.3.1.1. Provider-initiated HIV testing and counseling (PITC)

Under this approach, HTS should be initiated by the health worker as part of standard health care. Health workers should **routinely offer HTS** to all individuals attending health care services with the purpose of better patient management and early HIV diagnosis. This includes patients in all clinical settings in inpatient and outpatient departments and all patients whether symptomatic or not. Health workers should prioritize PITC for patients at maternal and child health clinics, adult and pediatric patient wards, TB clinics, family planning clinics, STI clinics, nutrition units, clinics managing survivors of sexual abuse and in HIV care clinics (for partners and family members). They should also assess all patients at OPD for HTS eligibility. PITC will be offered as an **'opt–out' HTS service.**

2.3.1.2. 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 including lay providers, counselors, laboratory personnel and medical workers at any entry point in the facility.

2.3.2. COMMUNITY HIV TESTING APPROACHES

Community-based HTS approaches are index client contact tracing, outreach or work-based HTS. All community HIV testing services should ensure that all clients diagnosed with HIV are effectively linked to HIV treatment and support services.

2.3.2.1. Index client contact tracing

In this approach, the index client is used to help identify subsequent clients for testing. Index client contact tracing is done either through home-based HTC or a snowball approach.

- ***Home-based HIV testing and counseling (HBHTC):*** 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 HBHTC should be prioritized for household members of all HIV-positive individuals in care as well as confirmed and presumptive TB patients.

- ***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.

2.3.2.2. Outreach HTS

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

- ***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.
- ***HTS integrated into health outreaches*** like immunization or VMMC.
- ***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.

2.3.3. WORKPLACE-BASED 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 serostatus is at the discretion of the employee.

2.3.4. HIV SELF-TESTING (HIVST)

Currently, self-testing is still under pilot studies and has not yet been included among the service delivery approaches for HIV testing in Uganda. In this approach, a client performs their own test and interprets the results. HIVST does not provide a diagnosis for HIV. All reactive self-test results should be confirmed using the approved national HIV testing algorithm. HIVST pilot projects should provide adequate information to individuals who test HIV positive to ensure linkage to confirmatory testing, HIV care, and support and prevention services. The MOH, upon availability of evidence, will develop guidelines for delivery of HIVST.

2.4. TARGET POPULATIONS FOR HTS

HTS providers should target populations with high HIV risk, high HIV burden and vulnerable/priority populations. Priority populations include: sex workers and their clients; long distance truck drivers; fisher folks; men who have sex with men; boda-boda drivers; uniformed forces; pregnant women and their sexual partners; discordant couples; infants and young children; sexually abused persons; children, adolescents and youth especially girls, young women, emancipated minors, orphans and vulnerable children (OVC); children out of school; mentally ill; persons with disabilities (PWDs); health workers; internally displaced persons; refugees; prison inmates; migrant workers; and TB patients. For guidance on the strategies and opportunities for reaching these different population groups, refer to Section 9.1.6.1 on differentiated HTS models and the *National HIV Testing Services Policy and Implementation Guidelines, 2016.*

2.5. HIV TESTING SERVICE PROTOCOLS

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

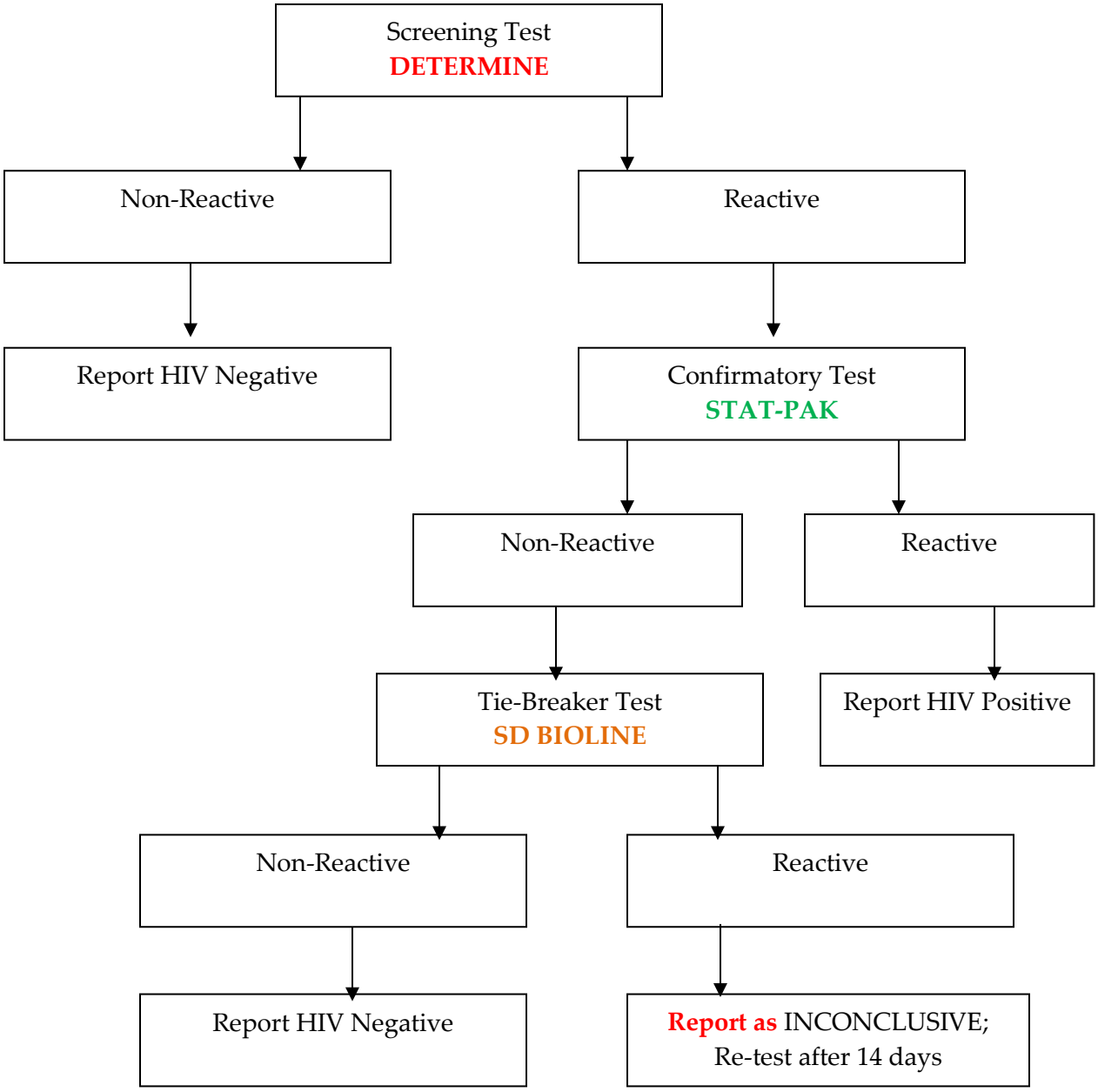
Table 1: HIV testing provision steps/protocol

Step	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.	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 (Section 2.5.1 and Section 2.5.2).
3.	Post-test counseling (individual/couple)	Assess readiness to receive results. Give results simply. Address concerns, disclosure, partner testing and risk reduction. Provide information about basic HIV care and ART care; complete the HTS card and HTS register.
4.	Linkage to other services	Provide information about services; fill the triplicate referral form. When the patient is enrolled, enter the pre-ART enrolment number into the HTS register and subsequently into the ART register when the patient is initiated on ART.

2.5.1. 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 3 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 six weeks after the child stops breastfeeding.

Figure 3: Serial HIV testing algorithm for persons above 18 months of age



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

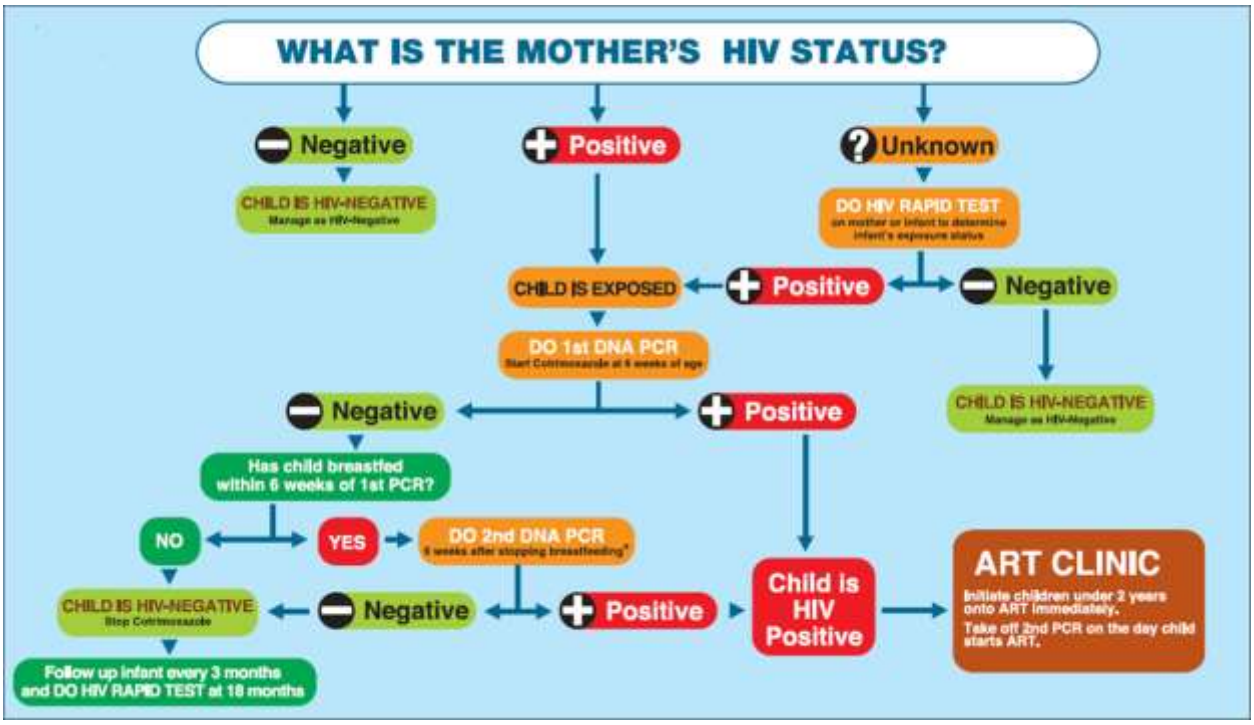
A virological test (DNA/PCR) is recommended for determining HIV status in infants and children below 18 months of age. The sample for testing should be collected using dried blood spot (DBS) specimens.

The 1st DNA/PCR test should be done at six weeks of age or the earliest opportunity thereafter. Interpretation of the results and further testing are guided by the testing algorithm in Figure 4 below.

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 1st DNA/PCR test** result means that child is **not infected**, but could become infected if they are still breastfeeding. Infants testing HIV negative on DNA/PCR should be re-tested using DNA/PCR six weeks upon cessation of breastfeeding. Infants with negative 2nd DNA/PCR test should have a final rapid antibody test performed at 18 months.

Figure 4: HIV testing algorithm for children <18 months of age



2.6. RE-TESTING FOR HIV

2.6.1. Re-testing for HIV-positive people before ART initiation

All HIV-positive individuals should be re-tested for HIV before initiating ART. Re-testing should be performed by a different tester using the approved national HIV testing algorithm at the ART initiation site/care point.

2.6.2. Re-testing all individuals with inconclusive results after 14 days

For individuals with repeatedly inconclusive results, further guidance will be provided by MoH.

2.6.3. 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.

2.6.4. Re-testing for HIV-negative individuals

The following population categories should be re-tested for HIV as summarized in Table 2.

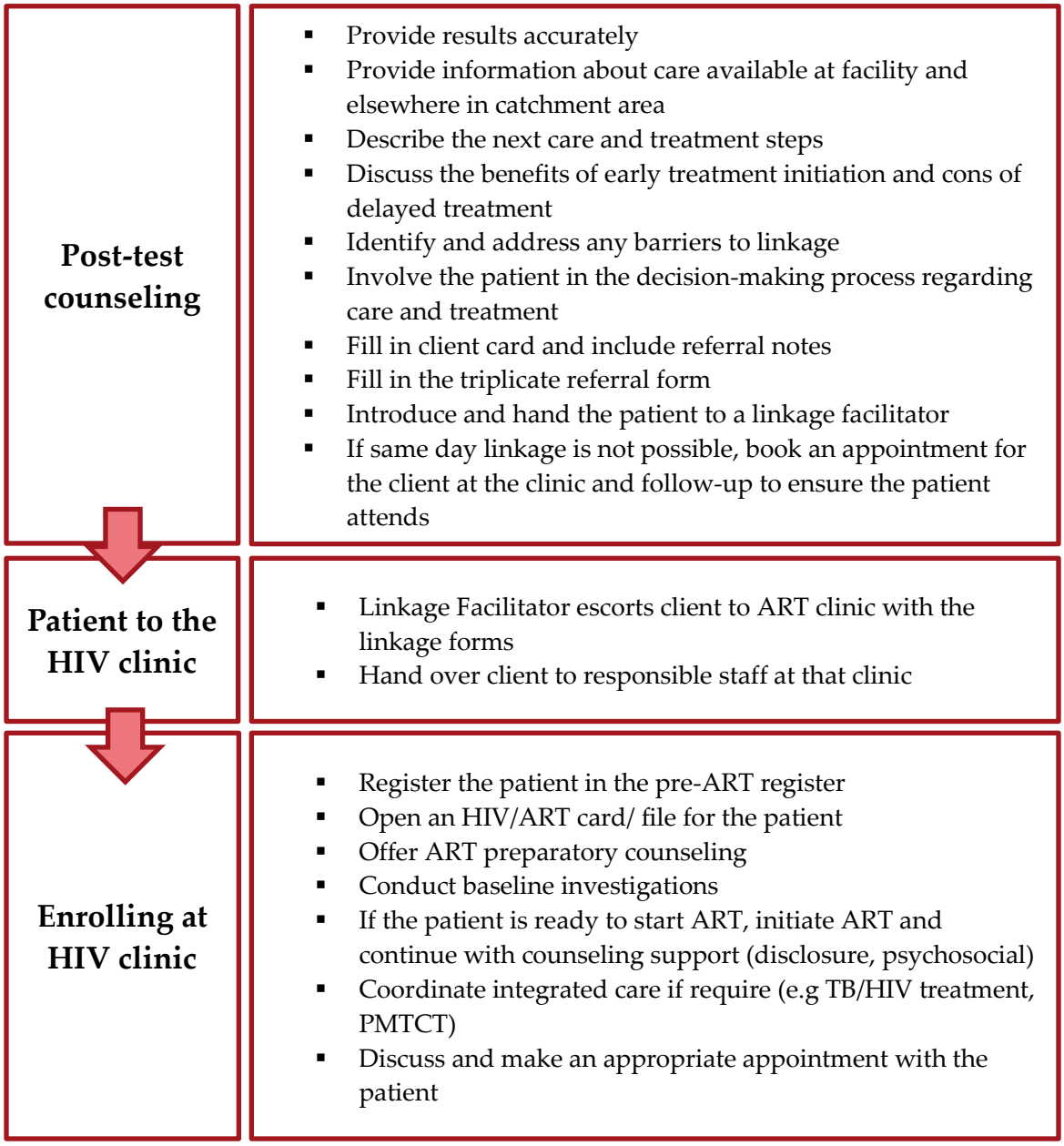
Table 2: Categories of HIV-negative persons to re-test at specified time points

Population category	When to re-test
Individuals exposed to HIV within four weeks before HIV testing	Four weeks after the 1st test
Key populations	Every three months
HIV-negative partners in discordant couples	Every three months
Pregnant women	1st trimester/1st ANC visit, then in the 3rd trimester/during labor and delivery
Breastfeeding women	Every three months until three months after cessation of breastfeeding
Confirmed and presumptive TB Patients	Four weeks after the 1st test
PEP clients	At one month, three month and six months after completing the PEP course
PrEP	As per the 2016 guidelines
STI patients	Four weeks after testing
HIV-exposed infants (HEIs)	Six weeks upon cessation of breastfeeding and at 18 months of age
Children >18 months still breastfeeding	Six weeks upon cessation of breastfeeding
INCONCLUSIVE results	14 days after the last test
General Population	Once a year

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

Linkage refers to the process of connecting individuals who have tested positive for HIV from one service point to another. Linkage to care is successful if the patient/client receives the services they have been referred to receive. For all clients who test HIV-positive, linkage should occur within seven days (within the same facility) and 30 days for inter-facility or community-to-facility referrals. It is recommended to use lay providers (community- and facility-based) as linkage facilitators. The process of linkage within the same health facility is described in Figure 5 below.

Figure 5: Internal linkage facilitation steps



2.7.1. 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 patients referred to other facilities and ensure they are enrolled in care and on ART within 30 days, using the follow-up/tracking schedule described in Table 3 below.

Table 3: Schedule for follow-up/tracking inter-facility linkages

Timeline	Action
Day 1 (referral day)	A client diagnosed HIV positive and referred to the preferred facility. 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.

2.7.2. COMMUNITY-FACILITY-COMMUNITY 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. HTS programs 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 who 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 4 below.

Table 4: 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.
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.

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

2.8. QUALITY ASSURANCE

HIV testing services should be delivered according to national standards. The main quality-assurance issues in HTS service delivery are:

- HTS should be performed by trained and certified providers. Providers should be assessed annually for competency.
- Standard operating procedures should be followed at all times.
- HTS data quality (data collection, analysis, reporting) should be maintained.
- Internal and external HIV test quality control processes should be performed and include supervision.

3. HIV PREVENTION

3.1. INTRODUCTION

In Uganda, the HIV epidemic is driven by multiple behavioral, biomedical and structural factors. There is thus no single HIV prevention intervention that is sufficient 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 so as to have the greatest possible impact on reducing new infections. This chapter will provide guidance on how to implement interventions that reduce the acquisition of new infections among HIV-uninfected youth and adults, 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 and multiple, especially concurrent sexual partnerships; and discourage cross-generational and transactional sex. See Table 5 for services for behavioral change and risk reduction.

Table 5: 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 prevention services need to be trained • Peer-led model for priority and key populations • Outreaches for key and priority populations • Job aides to support standardization for quality assurance • Linkage and follow-up between facility and community is important
Risk assessment for client	• Offer HTS to sexually active clients who have not tested in the last 12 months or have had unprotected sex in last three months • 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 status about sexual behavior • Assess for STIs and link to treatment • Discuss sexual and reproductive health services and link to services as appropriate
Provide socio-behavioral change communication (SBCC) and link to services as appropriate	• Discuss delay of onset of sexual debut in children and adolescents (abstinence) • Discuss correct and consistent condom use and offer condoms as appropriate • Discourage multiple, concurrent sexual partnerships to promote faithfulness with a partner of known status • Discourage cross-generational and transactional sex • Discourage risky cultural practices such as widow inheritance, wife replacement and childhood marriages • Identify, refer and link clients to other available facility and community programs • Assess for violence, (physical, emotional, or sexual); if client discloses sexual violence, assess if the client was raped and act immediately (see Section 0 for GBV case management and Section 3.3.3 for PEP)

Area	Guidance
Condom promotion and provision	• Discuss condom use as an option for risk reduction • Discuss barriers to condom use • Clarify any questions and dispel myths around condoms • Demonstrate how to use condoms • Allow the client to role play • Practice how to introduce condoms in relationship • Provide condoms to client

3.3. BIOMEDICAL PREVENTION INTERVENTIONS

The key biomedical interventions include eMTCT, safe male circumcision (SMC), ART, PEP, PrEP, blood transfusion safety and STI screening and treatment. Key populations in particular should receive STI screening and treatment. This section will discuss SMC, PEP and PrEP. Selected other interventions will be discussed in other chapters including: eMTCT (Chapter 4), ART (Chapter 8) and STI screening and treatment (Section 6.6.1).

3.3.1. SAFE MALE CIRCUMCISION (SMC)

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 6 below describes the process involved in providing SMC.

Table 6: Process of providing safe male circumcision

Process	Description
Priority groups for SMC	• All males in reproductive age group (including adolescent boys)
Recommended methods for SMC	• Conventional surgery using the dorsal slit method • WHO pre-qualified devices
Eligibility Screening for SMC	• **Screen for STIs:** If STIs are present defer the circumcision and treat the STIs (see Section 6.6.1) • **Tetanus Immunization Status:** All persons undergoing circumcision should have at least one documented TT dose if undergoing the dorsal slit method and two doses given at least 28 days apart and not more than 6 months apart if WHO pre-qualified devices are used. ○ If there is no evidence of TT defer SMC and refer for TT • **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 and at six weeks • Following device circumcision: follow the manufacturer guidance for the device used

3.3.2. POST-EXPOSURE PROPHYLAXIS

Definition: Post-exposure prophylaxis (PEP) is the short-term use of ARVs to reduce the likelihood of acquiring HIV infection after potential occupational or non-occupational exposure.

Types of exposure:

- **Occupational exposures** occur in the health care or laboratory setting and include sharps and needlestick injuries or splashes of body fluids to the skin and mucous membranes.
- **Non-occupational exposures include** unprotected sex, exposure following assault like in rape and defilement, and road traffic accidents.

Steps in assessing a potential PEP recipient

Health facilities providing PEP must have trained health care workers on infection prevention and control, and management of PEP. The health care workers should use the steps in Table 7 to assess clients for PEP eligibility and provide PEP.

Table 7: 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 or mild disinfectant (chlorhexidine gluconate solution) • Use antiseptic hand rub/gel if no running 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 • Use antiseptic hand rub/gel if no running water • 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 52) • 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, not beyond 72 hours of exposure
	• Recommended regimens include:
	  ○ **Adults: TDF+3TC+ATV/r**
	  ○ **Children: ABC+3TC+LPV/r**
	• A complete course of PEP should run for 28 days
	• Do not delay the first doses because of lack of baseline HIV test
	• Document the event and patient management in the PEP register (ensure confidentiality of patient data)

Step 5: Provide follow-up	• Discontinue PEP after 28 days • Perform follow-up HIV testing three months after exposure • Counsel and link to HIV clinic for care and treatment if HIV-positive • Provide prevention and education/risk reduction counseling if HIV-negative

3.3.3. ORAL PRE-EXPOSURE PROPHYLAXIS (PrEP)

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, 2016*.

Definition: PrEP is the use of ARV drugs by people who are not infected with HIV to block the acquisition of HIV.

Where will PrEP services be offered? PrEP will initially be offered in a few accredited ART sites that have the capacity and funding to provide a complete package and whose outcomes will inform further roll out. PrEP is not yet being rolled out in all public health facilities. The Ministry of Health, AIDS Control Programme will provide guidance on further scale-up to all public health facilities. Table 8 describes processes involved in offering PrEP.

Table 8: The process of providing pre-exposure prophylaxis (PrEP)

Process	Description
Eligibility for PrEP	PrEP provides an effective additional biomedical prevention option for HIV-negative people at substantial risk of acquiring HIV infection. These include people who: • Have multiple sexual partners • Engage in transactional sex including sex workers • Use or abuse injectable drugs and alcohol • Have had more than one episode of an 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 • Are recurrent users of PEP (3 consecutive cycles of PEP) • Engage in anal sex • Are members of key populations who are unable or unwilling to achieve consistent use of condoms These risk factors are likely to be more prevalent in populations such as sex workers, fisher folk, long-distance truck drivers, men who have sex with men (MSM), uniformed forces, and adolescents and young women engaged in transactional sex.
Screening for PrEP eligibility	After meeting the eligibility criteria: • Confirm HIV-negative status • Rule out acute HIV infection • Assess for hepatitis B infection: if negative, patient is eligible for PrEP; if positive, refer patient for management • Assess for contraindications to TDF/FTC
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) • Initially, provide a 1-month TDF/FTC prescription (1 tablet orally, daily) together with a 1-month follow-up date • Counsel client on side effects of TDF/FTC
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 every three months • For women, perform a pregnancy test based on clinical history • Review the patient's understanding of PrEP, any barriers to adherence, tolerance to the medication as well as any side effects • 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 as needed
Guidance on discontinuing PrEP	• Acquisition of HIV infection • Changed life situations resulting in lowered risk of HIV acquisition • Intolerable toxicities and side effects • Chronic non-adherence to the prescribed dosing regimen despite efforts to improve daily pill-taking • Personal choice • HIV-negative in a serodiscordant relationship when the positive partner has achieved sustained viral load suppression (condoms should still be used consistently)

3.4. STRUCTURAL INTERVENTION

Structural interventions are the prevention interventions that reduce vulnerability to HIV infection. These could be social, political, cultural, orgnaizational etc. Gender based violence is one of the most common structural predisiposition to HIV.

3.4.1. PREVENTION AND MANAGEMENT OF GENDER-BASED VIOLENCE

Gender-based violence (GBV) has the potential to increase the risk of acquiring HIV. GBV can 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. Clients should therefore be assessed for GBV at least once every six months as part of the HIV program.

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

Table 9 describes the minimum package of post-rape care services and child protection after GBV.

Table 9: 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 3.3.2) • STI screening/testing and treatment (see Section 6.6.1) • 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

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

4.1. INTRODUCTION

Globally, about 90% of children get HIV from their mothers during pregnancy, delivery, and breastfeeding. For a long time in Uganda, vertical HIV transmission ranked second only to sexual transmission as the predominant mode of HIV infection in the country, accounting for about 18% of new infections. However, after implementing Option B+ since 2012, there has been a dramatic reduction in new vertical infections from 25,000 in the year 2000 to about 3,486 in 2015 (Spectrum estimates, 2015). In this section, guidance is provided for delivering eMTCT and HIV-exposed infant (HEI) services to achieve the elimination of mother-to-child transmission of HIV and syphilis in-line with the national 90-90-90 targets for HIV epidemic control by 2030. The section also provides technical guidance on how eMTCT and HEI services should be integrated into the maternal, newborn, child and adolescent health (MNCAH) service delivery platform.

4.2. eMTCT APPROACH

The eMTCT strategy comprises a package of interventions summarized in four approaches (see Table 10). These interventions must be offered simultaneously within the platform of MNCAH services throughout the continuum of eMTCT services as will be described in Figure 6.

Table 10: The eMTCT approach

Element	Target group	Additional information

Prong 1: Primary prevention of HIV infection	Women and men of reproductive age including adolescents	This prong aims to prevent HIV in women of reproductive age, adolescents 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 and GBV screening and management
		• STI and HBV screening and management

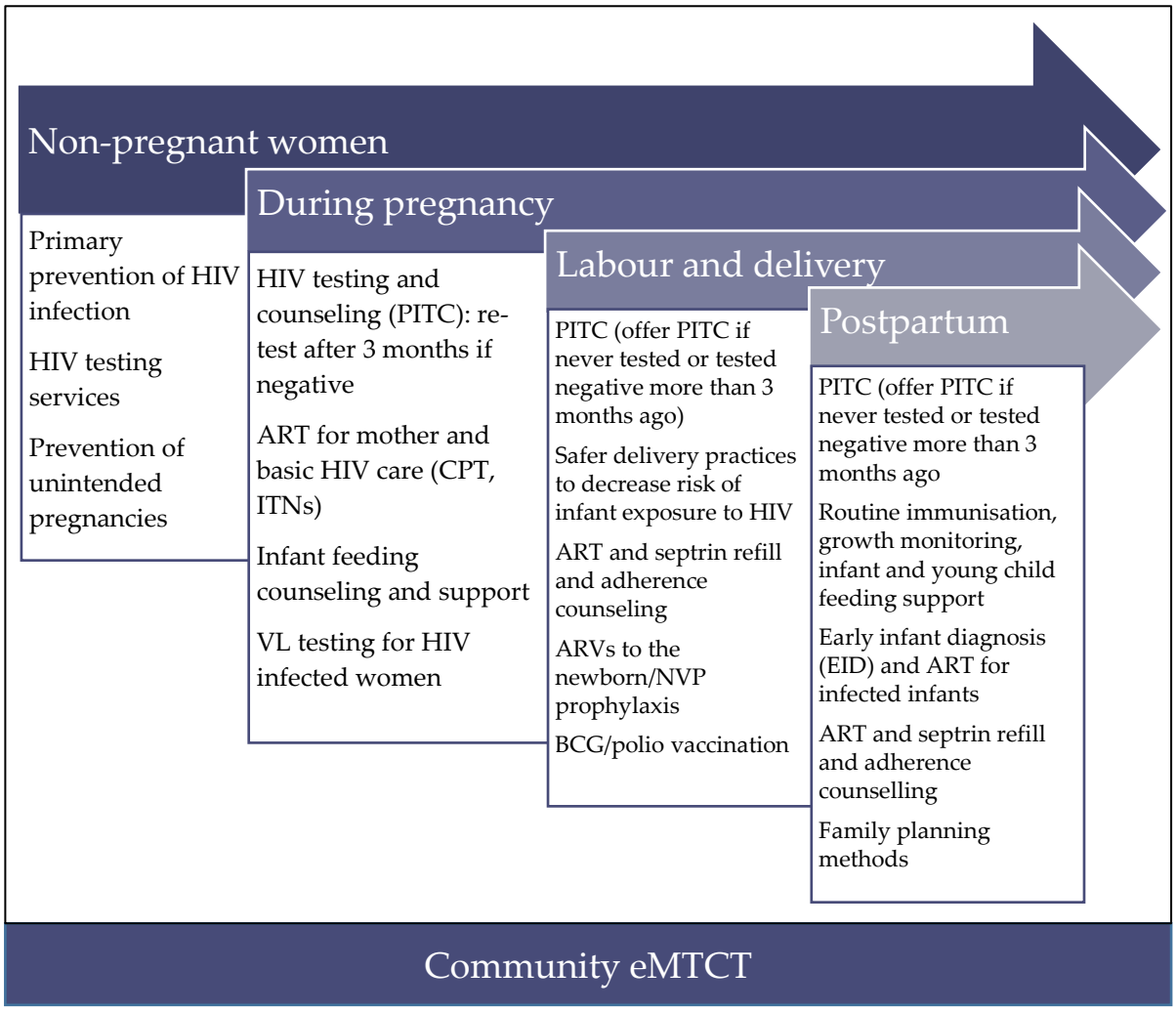
Prong 2: Prevention of unintended pregnancies among women living with HIV	Women including adolescents living with HIV and their partners	• Family planning (FP) counseling and voluntary services (informed decision) • HIV testing and counseling in sexual and reproductive health (SRH) and FP settings • Safer sex practices, including dual protection (condom use promotion) • Pre-conception counseling and referral for infertility investigation and treatment
Prong 3: Prevention of HIV transmission from women living with HIV to their infants	Pregnant and breastfeeding women including adolescents 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 • 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

Element	Target group	Additional information		
Prong 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 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	**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 • 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)	**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 • STI and 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

4.3. INTEGRATING eMTCT AND MNCAH SERVICES

eMTCT interventions should be integrated into the MNCAH services which include but not limited to the ANC, labour and delivery, postnatal care, 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 6).

Figure 6: The eMTCT continuum of services



4.4. SERVICES FOR NON-PREGNANT WOMEN

4.4.1. PRIMARY PREVENTION OF HIV INFECTION

Preventing HIV in women 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 of reproductive age are presented in Table 11.

Table 11: Services for preventing HIV infection in women of reproductive age

Service	Description
Routine HTS and syphilis testing in the MNCAH setting	Provide HTS to all women 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 (see Table 2).
BCC	Safer sex practices, including dual protection (condom promotion) and delay of onset of sexual activity (see Table 5).
Other prevention services	**SMC:** Offer and refer SMC services to male partners of the women **GBV:** Screen all women of reproductive age, including adolescents, for GBV and offer services within MCH including post exposure prophylaxis **PrEP**: Offer PrEP to eligible 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 7).
STI and HBV screening and treatment	Counsel and screen women for STIs including syphilis and HBV and manage the STIs (see 6.6.1).

4.4.2. PREVENTION OF UNINTENDED PREGNANCIES AMONG WOMEN LIVING WITH HIV

Family planning (FP) for 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 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 should not be coerced into FP; their sexual and reproductive choices should be respected and safeguarded.

Table 12 describes the process of offering FP.

Table 12: Process of providing family planning services to HIV-infected women

Service	Explanation
Counsel women routinely for FP	**Provide routine FP information and counseling to women attending ANC, PNC, YCC and ART services:** Encourage HIV-infected women to discuss their reproductive health choices and support them as appropriate. Information provided during counseling should cover: • Family planning methods, advantages and side effects • Common misconceptions about family planning • Advantages of dual protection and also how to negotiate condom use • 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. *"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.
After counseling, offer FP on a one-on-one basis	**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 **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 on ART (see Table 13)
Ongoing support for women when using FP	• Counsel and adherence support to 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

Table 13: Interactions between ART and contraceptives

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

4.5. DURING PREGNANCY

This section outlines ANC services for all pregnant women, specific services for the HIV-infected pregnant women and HIV-negative pregnant women. Table 14 describes services offered during pregnancy.

Table 14: 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:
	  ○ 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:
	  ○ STI, HBV or TB-infected pregnant women
	  ○ Those with a specific incident of HIV-exposure within the past three months
	• Provide risk reduction counseling to HIV-negative women.

Antenatal care package for all pregnant women (regardless of HIV status)	**General care:** • All pregnant women should have at least four 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 • 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 beginning AZT-based ART at baseline and four weeks after initiating ART. • For HIV-positive pregnant women already on ART, do VL test at first ANC visit, then follow the national VL testing algorithm (VL testing chart) • For newly diagnosed HIV-positive pregnant women, do VL test 6 months

Service	Description	
	after initiating ART and then follow the national VL testing algorithm (VL testing chart). ○ To interpret viral load results use algorithm in Figure 15: Viral load testing algorithm	
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 (see Section 6.5.2.10) • Screening and management of opportunistic infections (OIs)	
Assess risk of unborn baby among pregnant women with HIV at ANC 1	• 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	
ART	• All women 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+EFV (600mg) (see Section 8.4.2) • All women should receive Pre-ART adherence counseling before initiating ART and ongoing adherence support after that (see Chapter 1) • ART should be initiated and maintained in mother-baby care point in MCH	
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 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 • Not due for vital lab tests in the next two months, e.g., viral load • Has disclosed to significant other/ household member/ family member	**HIV-positive pregnant woman initiating ART in ANC (new clients): Unstable pregnant and breastfeeding women** • Recently initiated on ART (less than one year on ART) • Poor viral suppression: most recent VL of above 1000 copies/ml • Adherence less than 95% • 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

Service	Description	
		member
	• 4 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 1)

4.6. 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 15).

Table 15: 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 8.4.2)

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 Table 17)

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 Section 5.2)
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

Service	Description
	HIV care services at the facility of their choice using linkage guidelines in Section 2.7

4.7. DURING POSTPARTUM

Following delivery, address the treatment, care and support needs of HIV-infected women, their children and families (prong 4), provide family planning services (prong 2) and continue to prevent HIV in women 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 16). 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 16: 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 counseling and services (see Table 12) • Review of ART regimen and provide adherence support • Reinforce safe infant feeding practices • 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 women who have never tested and their partner • Provide repeat HIV testing to women who were negative at ANC, labour and delivery • Provide ART for all women newly diagnosed at PNC according to the guidance in Section 8.4.2 • Continue to provide risk-reduction counseling and support to HIV-negative women • Do repeat testing every three months during breastfeeding for all HIV negative women
HIV care and management for the HIV-infected mother and family	• Antiretroviral therapy (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 • Psychosocial support • Adherence counseling and support • Monitor retention in care • Assess all women 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 health care and psychosocial support to the family. The HEI should receive care together with their mother in the mother-baby care point in the MCH setting until the infant is 18 months of age. 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 and are in Annex 1.

4.8.2. HEALTH CARE SERVICES FOR THE HIV-EXPOSED INFANTS

Table 17 summarizes the services for HEI during the 18 months of follow-up.

Table 17: 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 4 to test and interpret the test results: • Provide 1st PCR within 6–8 weeks or the earliest opportunity thereafter • Provide 2nd PCR 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 or 2nd PCR
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:

Service	Description
	○ **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. ○ **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, weight and length/height should be taken and recorded on the growth monitoring card (see Annex 10). • 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 1. • 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.
NVP 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. • High-risk infants 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).
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. The dose is in Table 24. • 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

Service	Description
	100mg). **Isoniazid (INH) preventive therapy (IPT)** • 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, Newborn 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. • Provide key aspects of home-based care for the child, including: o Dispensing prophylaxis and treatment o Maintaining adherence o Complying with the follow-up schedule o Ensuring good personal and food hygiene to prevent common infections o 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 8.4.4.

4.9. COMMUNITY eMTCT

4.9.1. 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 eMTCT services.

4.9.2. 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 18 months 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.

4.9.3. ESTABLISHING/STRENGTHENING 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 a common 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.

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. DURING PREGNANCY

Nutrition counseling messages and services for HIV-infected pregnant women are in Table 18.

Table 18: Nutrition counseling messages and services for pregnant women

Service	Description
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

Service	Description
	overcome side effects. 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.
Malaria prevention	Malaria may cause anemia. Mothers should sleep under an insecticide-treated mosquito net; HIV-infected pregnant women on cotrimoxazole should not receive intermittent preventive treatment (IPT) for malaria with sulfamethoxazole-pyrimethamine (SP).
Attend ANC	Counsel and educate mothers to attend ANC at least four times during pregnancy and follow their health worker's recommendations.

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 particular attention to prevention of conditions such as cracked nipples or mastitis that increase the risk of HIV transmission.

5.3. DURING LABOUR AND DELIVERY

- Help mothers initiate breastfeeding within half an hour of birth including in cases of caesarean section.
- Newborn infants should be fed only colostrum (the first milk) and 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. DURING POSTNATAL PERIOD

5.4.1. FEEDING A CHILD 0–6 MONTHS

HIV-exposed but uninfected infants/unknown HIV status	• HIV-infected mothers should exclusively breastfeed (EBF) their infants for the first six months of life. Appropriate complementary foods should be introduced after six months of life. Mothers should be supported to fully adhere to ART and continue breastfeeding their infants for the first 12 months of life. • Breastfeeding should continue until a nutritionally adequate and safe diet without breastmilk can be provided. • Establish the HIV exposure status of those infants with unknown status.

HIV-infected infants	HIV-infected mothers should exclusively breastfeed (EBF) their infants for the first six months of life. Appropriate complementary foods should be introduced after six months of life. Mothers should be supported to fully adhere to ART and continue breastfeeding their infants for the first 24 months of life.

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.
- The mother should be encouraged to breastfeed as often as the infant wants (on demand).
- 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 different food groups (carbohydrates, plant/animal protein, vegetables, fruits and fats/oils).
A = Active/ responsive feeding	Mothers should be encouraged to patiently and actively feed their infants and young children 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 12 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 2–6 YEARS

- Encourage mothers to give a variety of foods prepared from the family meal (each meal should consist of a carbohydrate, protein, and vegetables) at least three times a day.
- Encourage caregivers to give nutritious snacks between meals e.g. fruit (banana, pawpaw, orange, 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.

6. CARE AND SUPPORT FOR PEOPLE LIVING WITH HIV

6.1. INTRODUCTION

The Ministry of Health 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 need. The package is summarized in Table 19.

Table 19: 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 6.4).
Opportunistic infection screening, prevention, and management	• Provide cotrimoxazole prophylaxis to every infected HIV patient for life • Provide INH prophylaxis if eligible • Screen and manage other OIs like TB and cryptococcal 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 6.7 for detailed guidance on screening and managing NCDs.
Sexual and reproductive health services	• Screen and manage sexually transmitted infections • Provide family planning and pre-conception services (see Table 12) • 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 6.6.2)
Adherence counseling	Do adherence preparation, monitoring and support (see Section 1)
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.
Orphans and vulnerable children (OVC)	• Conduct basic assessment for vulnerability (less than three meals/day, inconsistent or no school attendance, the existence of HIV-infected or affected person in the household, child abuse, widowed,

Service Area	Service Description
	elderly or child-headed household) • 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 2 and Annex 3 for staging in adults and adolescents, and in children respectively.

6.4. NUTRITION CARE AND SUPPORT FOR PLHIV

6.4.1. INTRODUCTION

Nutrition assessment counseling and support (NACS) is an important component of comprehensive care for PLHIV and/or TB/HIV because HIV increases energy requirements; can reduce dietary intake; can cause nutrient malabsorption and nutrient loss; and can result in complex metabolic alterations that culminate in weight loss and wasting. NACS, therefore, should be conducted in PLHIV from enrolment and extend throughout the care continuum.

6.4.2. STEPS IN IMPLEMENTING NACS

NACS should be implemented in HIV care settings using the "The Seven Steps" approach in Table 20.

Table 20: Seven steps approach for implementing NACS

Step	Activities
Step 1 Nutrition and health education	• Create awareness on benefits of proper nutrition • Sensitize clients on the benefits of proper nutrition and monitoring of nutritional status
Step 2: Nutrition assessment	**Anthropometry** Record weight, length/height, MUAC, and age Routinely monitor and promote growth for children <5 years
	Biochemical analysis Monitor micronutrient deficiencies such as haemoglobin level
	Clinical assessment Check for signs of undernutrition including bilateral pitting oedema, wasting, hair changes, anemia (pale conjunctiva, gums, nails, skin), breathlessness, and rapid pulse
	Dietary assessment Collect information about the types and amounts of food consumed, appetite, and eating behaviours
Step 3: Nutrition classification	Classify nutritional status and decide on care plan, see Figure 7
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) (Table 21)
	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 7: Community linkage	Link malnourished patients to livelihood and/or supplementary feeding programs where possible

Figure 7: Algorithm for nutrition assessment, classification, and care plan of acute malnutrition

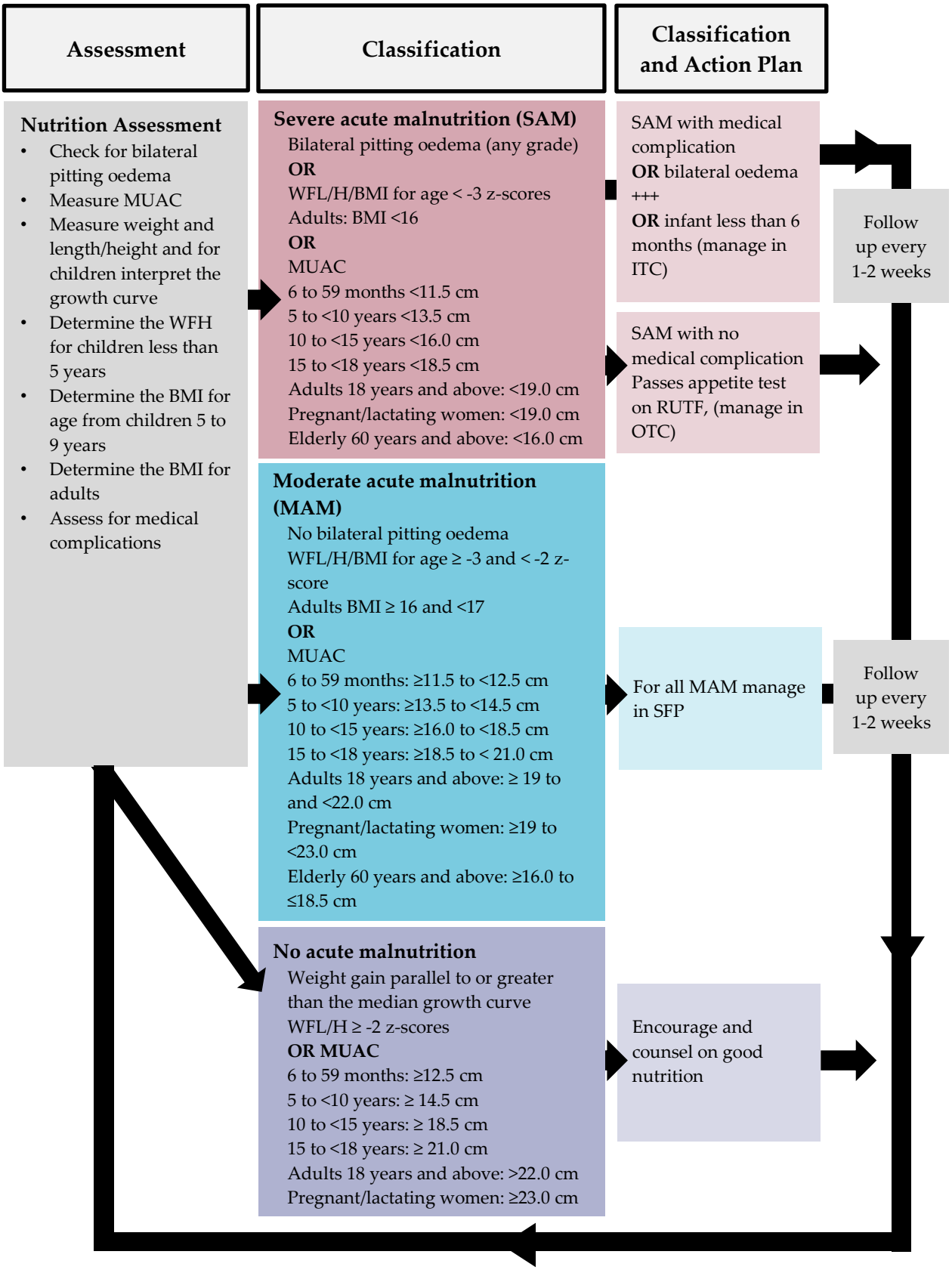


Table 21: Dosing of RUTF

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, 2016*.

Table 22: Rations of RUTF by age category

Age	Normal daily ration size (gms)	Daily ration +50% ration increase (gms)	Monthly ration size (kilograms)
6 - 11 months	100	150	5
12 - 23 months	100	150	5
2 - 5 years	100	150	5
6 - 9 years	150	225	7
10 - 14 years	200	300	9
14 years and above	300	450	14

Table 23: Criteria for discharge from outpatient therapeutic care

Category of Discharge	Discharge Criteria	Action
Cured	Patient is clinically well and alert and has no bilateral pitting oedema for 2 weeks **PLUS** Weight For Length/Height or ≥ -2 z-scores (6-59 months) Body mass index (BMI) for-age ≥ -2 z-scores (5-19 years) BMI >18kg/m2 (adults >18years) **OR** MUAC: • ≥12.5 cm (6 months to <5 years) • ≥14.5cm (5 to <10 years) • ≥18.5cm (10 to <15 years) • ≥21.0cm (15 to <18 years) • >22.0 cm (pregnant and lactating women with infant less than 6 months) • ≥22.0 cm (adults)	Record in Integrated Nutrition Register as "Cured" Link caregivers/ patients to other primary health care services or initiatives at facility/or community including • YCC or growth monitoring and promotion (GMP) program • SFP or other livelihood programs where available • HIV/AIDS/TB care and treatment
Non-respondent	Has not reached discharge criteria after three months (four months for the HIV/TB patients)	Refer to ITC for re-evaluation If HIV/TB status is known: Assess on a case-by-case basis and take action after discussion with the patient's HIV/TB treatment provider
Defaulted	Absent (not reported or followed up in the community) for two consecutive visits	Make a follow-up home visit to assess situation to support the family in monitoring the patient progress On return, the patient may re-enter OTC if he or she meets the admission criteria Follow the criteria for registering the patient as a re-admission using the number previously given
Transferred to ITC	Condition has deteriorated and requires ITC Not responding to treatment	Fill a referral slip with information (including medicines) and the reason for transfer Record in INR where the client has been transferred too.

6.5. PREVENTION, SCREENING AND MANAGEMENT OF CO-INFECTIONS

This section will provide guidance on how to prevent, screen and manage co-infections. Only a few co-infections will be described here including: TB, cryptococcal meningitis, *Pneumocystis jiroveci* pneumonia (PJP), hepatitis B and C virus infection and STIs. Management of other co-infections like oral candidiasis, oesophageal candidiasis, toxoplasmosis and chronic diarrhea can be found in "*The Uganda Clinical Guidelines 2016*."

6.5.1. COTRIMOXAZOLE PREVENTIVE THERAPY (CPT)

- Cotrimoxazole preventive therapy (CPT) can reduce the risk of malaria, diarrhea and pneumonia caused by bacterial infections; hospitalization; and mortality. It is also the mainstay of prevention of PJP.
- **All PLHIV should receive CPT** for life unless they have allergy to sulphur-containing drugs or toxicity to cotrimoxazole.
- **All pregnant women should receive CPT irrespective of gestation age** and should continue through breastfeeding and thereafter for life. Additional intermittent preventive treatment for malaria using sulfadoxine-pyrimethamine (SP) is **not required** for pregnant women on CPT.

Table 24: Cotrimoxazole dosing table

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

6.5.1.1. Cotrimoxazole toxicity

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

Table 25: Guidance on how to manage cotrimoxazole hypersensitivity manifested in skin reactions

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**

Contraindications to CPT

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

6.5.1.2. 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 IPT with SP.

Dapsone dosing

- Weight of 25–34.9kg: 100 mg once per day
- Weight of >35kg: 100mg once a day

6.5.2. TUBERCULOSIS (TB) SCREENING, TREATMENT AND PREVENTION

6.5.2.1. 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 42% 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 MoH further recommends that management of TB/HIV co-infected patients be provided at the same time and location.

6.5.2.2. 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 4). 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, screening by chest X-ray is recommended for HIV-positive TB contacts.

6.5.2.3. 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 HIV-infected infants and children (Annex 5) and adolescents and adults (Annex 6) with presumptive TB. 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.

In addition to the Xpert MTB/RIF, chest radiography is another useful investigation for patients with presumptive TB. The lateral flow urine lipoarabinomannan assay (LF–LAM) may be used to assist in the diagnosis of TB in seriously ill PLHIV and those with CD4 less than or equal to 100 cells/μL. If the Xpert MTB/RIF is positive and indicates rifampicin resistance, refer the patient to an MDR-TB treatment site.

6.5.2.4. 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

Site of TB disease	Regimen	
	Intensive phase	Continuation phase
All forms of TB (excluding TB meningitis and bone TB)	2RHZE	4RH
TB meningitis Bone (osteoarticular) TB	2RHZE	10RH
For previously-treated TB patients (relapse, LTFUP, failure) 1. Xpert +ve/Rif sensitive: Treat as a new patient 2. Xpert +ve/Rif resistant: Refer to MDR-TB treatment site for further management		

6.5.2.5. 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.

6.5.2.6. When to start 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 28).
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.

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

Table 27: First-line ART regimen for TB/HIV co-infected patients initiating ART

Age group	Recommended Regimen
Adults, pregnant and breastfeeding women and adolescents	TDF+3TC+EFV
Children aged 3 to ≤12 years	ABC+3TC+EFV
Children aged 0 to ≤3 years	ABC+3TC+AZT

6.5.2.8. 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 28).

Table 28: ARV regimen substitutions for patients initiating TB treatment while on ART

Age Group	Regimen when diagnosed with TB	Recommended action/substitution
Adults, pregnant and breastfeeding women, and adolescents	If on EFV-based regimen	Continue with the same regimen and dose
	If on DTG-based regimen	Continue the same regimen but increase the dose of DTG (give DTG 50mg twice daily instead of once daily)
	If on NVP-based regimen	Substitute NVP with EFV If EFV is contraindicated, give a triple NRTI regimen (ABC+3TC+AZT)
	If on LPV/r or ATV/r-based regimen	Continue the same regimen and substitute rifampicin with rifabutin for TB treatment
Children aged 3 to ≤12 years	If on EFV-based regimen	Continue the same regimen
	If on NVP or LPV/r-based regimen	Substitute NVP or LPV/r with EFV If EFV is contraindicated, give a triple NRTI regimen (ABC+3TC+AZT)
Children aged 0 to ≤3 years	If on LPV/r or NVP-based regimen	Give triple NRTI regimen (ABC+3TC+AZT)
Note: *Patients who have been substituted should revert to their original regimen once TB treatment is completed*		

6.5.2.9. TB prevention

TB prevention should follow principles:

- Vaccination with BCG to prevent severe forms of TB in children
- Early identification and prompt treatment of TB patients
- Providing isoniazid preventive therapy
- Implementation of infection control practices within the health facility and household settings

6.5.2.10. Isoniazid preventive therapy (IPT)

IPT prevents the progression of TB infection to active TB disease. All PLHIV with a negative TB symptom screen should be offered IPT for six months (Table 29). IPT is not recommended for contacts of patients with MDR-TB.

Eligibility for IPT

- 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 IPT dose.

See *Izoniazid Preventive Therapy in Uganda, January 2015* for more information on determining eligibility for IPT.

Table 29: Isoniazid dosing table

	3–5.9 kg	6–9.9 kg	10–13.9 kg	14–19.9 kg	20–24.9 kg	≥25 kg
INH 100 mg (tablet, once daily)	0.5	1	1.5	2	2.5	nr
INH 300 mg (tablet, once daily)	Not recommended (nr)	nr	nr	Nr	Nr	1

6.5.2.11. 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 due to associated BCG disease among HIV-infected children.

6.5.3. CRYPTOCOCCAL INFECTION

6.5.3.1. Introduction

In Uganda, cryptococcal meningitis (CM) is associated with mortality of up to 39%. Patients with a CD4 cell count of <100 cells/mm^3 are at the highest risk of CM. This section describes screening and management of early cryptococcal disease.

6.5.3.2. Screening and management of early cryptococcal disease

Screening for cryptococcal disease

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 screening for cryptococcal disease.

Who should be screened for cryptococcal disease?

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

- All HIV-infected but ART-naïve patients with CD4 <100 cells/mm^3
- All PLHIV on ART who are suspected or confirmed to have treatment failure (i.e. viral load >1,000 copies/ml with stage III or IV disease)

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 stick whole blood.
- The process of screening patients for cryptococcal meningitis is guided by the algorithm in **Figure 8**.
- After doing a serum CrAg test, the test results (negative or positive) determine the next steps.

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

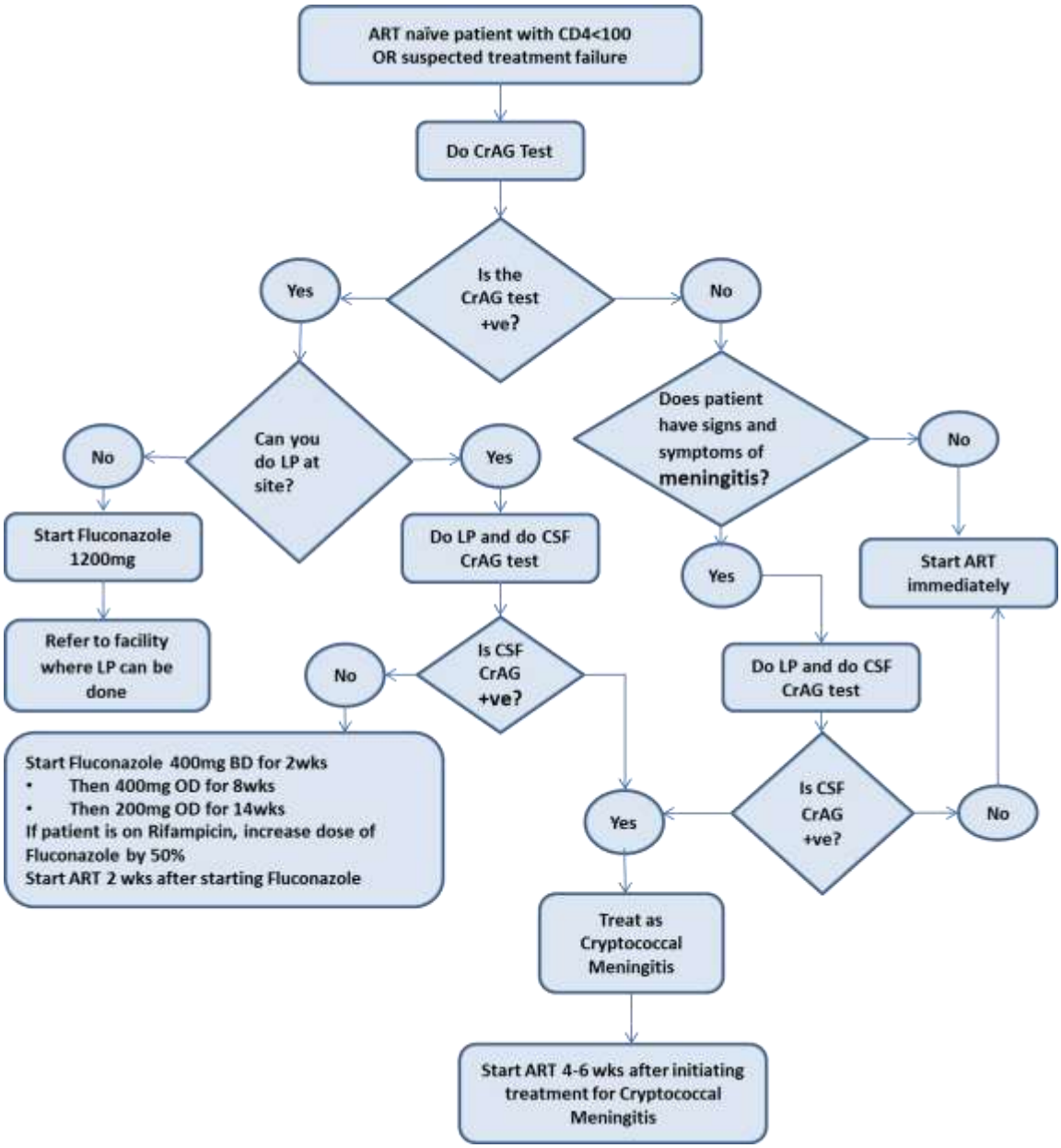
- Patients with a positive CrAg should be assessed for signs and symptoms of CM including headache, presence of seizures, altered consciousness, photophobia, neck stiffness, or a positive Kernig's sign.
- Patients with a positive CrAg are at high risk of having CM even in the absence of symptoms. Therefore, 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 cryptococcal disease but without CNS involvement and the patient should be started on pre-emptive therapy (see

- Table 30).
- If the CSF CrAg test is positive, the patient has CM and should be treated for cryptococcal meningitis (see Table 31: Management of cryptococcal meningitis).

Table 30: 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 patients below 19 years	Fluconazole 400 mg (or 6 mg/kg/day up to 400mg) for 8 weeks	Fluconazole 200 mg for 14 weeks

Figure 8: Algorithm for screening and managing cryptococcal disease



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 meningeal signs should be started on daily fluconazole 1200mg, counseled and referred to a site where LP can be done.

For serum CrAg-negative patients
- Assess the patient for signs and symptoms of cryptococcal meningitis including a headache, presence of seizures, altered consciousness, photophobia, neck stiffness, and a positive Kernig'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 serum CrAg test and manage accordingly.

6.5.3.3. 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 cryptococcal meningitis and a lumbar puncture cannot be performed for any reason, it is recommended to perform a rapid serum CrAg using the LFA to diagnose cryptococcal meningitis.

6.5.3.4. 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 31.

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 cryptococcal 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 31: 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 0.7–1mg/kg/day + flucytosine (100mg/kg/day in four divided doses)
or
Amphotericin B 0.7–1mg/kg/day + high-dose fluconazole 800mg/day
or
Amphotericin B short course (1mg/kg/day) for 5-7 days + 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>If amphotericin B is used in induction phase: fluconazole 400-800mg/day (or 6-12 mg/kg/day in children and adolescen t <19 yr)

If high short dose amphotericin or high dose fluconazole used in induction phase: fluconazole 400-800mg/day (or 12 mg/kg/day in children and adolescent < 19 yr)</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 (1 year)</td><td>Fluconazole 200mg/day (or 6 mg/kg/day up to 200mg in children and adolescent <19 yr)</td><td>Criteria to stop after a minimum of 1 year of maintenance phase
Adults
VL< 1,000 copies/mm^3 & CD4 ≥ 100 for 6 months or CD4 ≥200 if viral load not available
Children: If CD4 >25% or viral suppressed</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:
o Send CSF to microbiology reference laboratory at the College of Health Sciences, Makerere University 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>
</table>

• Other options for treatment are a combination of flucytosine (100mg/kg/day in four divided doses) and fluconazole 800-1200mg daily. For patients on rifampicin increase fluconazole dose by 50%.
Adequate control of elevated CSF pressure
• Control of increased intracranial pressure improves survival by 25% in persons with cryptococcal meningitis. • All patients with a CSF Pressure > 250 mm 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. • Removing 20-30 mL of CSF (even in the absence of a manometer) may be adequate to decrease CSF pressure. Most patients will need 2-3 LPs during the induction phase.

6.5.4. 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 32 describes the signs, symptoms and management of PJP.

Table 32: 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 perihilar region or hyperinflation • 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) for 21 days **Adjunctive therapy:** Use corticosteroids only in patients with severe PJP
Prevention	Initiate all HIV-infected people on cotrimoxazole preventive therapy

6.5.5. HIV/HEPATITIS B VIRUS CO-INFECTION

Hepatitis B virus (HBV) is the leading cause of chronic liver disease among HIV patients in Uganda. In Uganda, the prevalence of hepatitis B among HIV patients is estimated to be 17%. See Table 33 for signs, symptoms, and management of HBV infection.

Table 33: 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

6.5.6. 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.

6.5.7. 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.

6.6. SEXUAL AND REPRODUCTIVE HEALTH SERVICES

6.6.1. SCREENING AND MANAGEMENT OF SEXUALLY TRANSMITTED INFECTIONS (STIS)

6.6.1.1. Introduction

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.

6.6.1.2. STI 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 34).

Table 34: 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 has a fishy odor
LOWER ABDOMINAL PAIN (PID)	☐ Dull pain in the stomach or lower abdomen ☐ Pain during sex

6.6.1.3. STI management

Uganda adopted the syndromic approach to the management of STIs, *National STI Treatment Guidelines, 2009/2010* (see Annex 7).

6.6.2. CERVICAL CANCER SCREENING

Women living with HIV have a higher risk for cervical cancer. Cervical cancer screening using visual inspection with acetic acid (VIA) is recommended for all HIV-positive sexually active girls and women at enrolment into HIV care. The VIA should be repeated annually. Patients with pre-cancerous cervical lesions should be managed using cryotherapy as guided by the eligibility criteria (Table 35).

Table 35: 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 2 mm 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 2 mm beyond the cryoprobe edges* • The lesion extends into the endocervix* • Pregnancy* • Pelvic inflammatory disease (until treated) • Active menstruation

* Refer for further management

Prevention of cervical cancer

Cervical cancer is caused by the HPV. 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. Figure 9 describes the available HPV vaccine.

Figure 9: 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

6.7. SCREENING AND MANAGEMENT OF NON-COMMUNICABLE DISEASES

6.7.1. INTRODUCTION

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

6.7.2. DIABETES MELLITUS (DM)

HIV-infected adults experience more chronic metabolic complications as a result 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.

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

In addition to the usual risk factors for development of DM, there are a number of 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 after the sickness, co-infection with hepatitis C, dyslipidemia, and lipodystrophy.
- Anti-retroviral drugs are the 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 (other ARVs like NNRTIs and integrase inhibitors can be used safely).

6.7.2.2. Screening and diagnosis

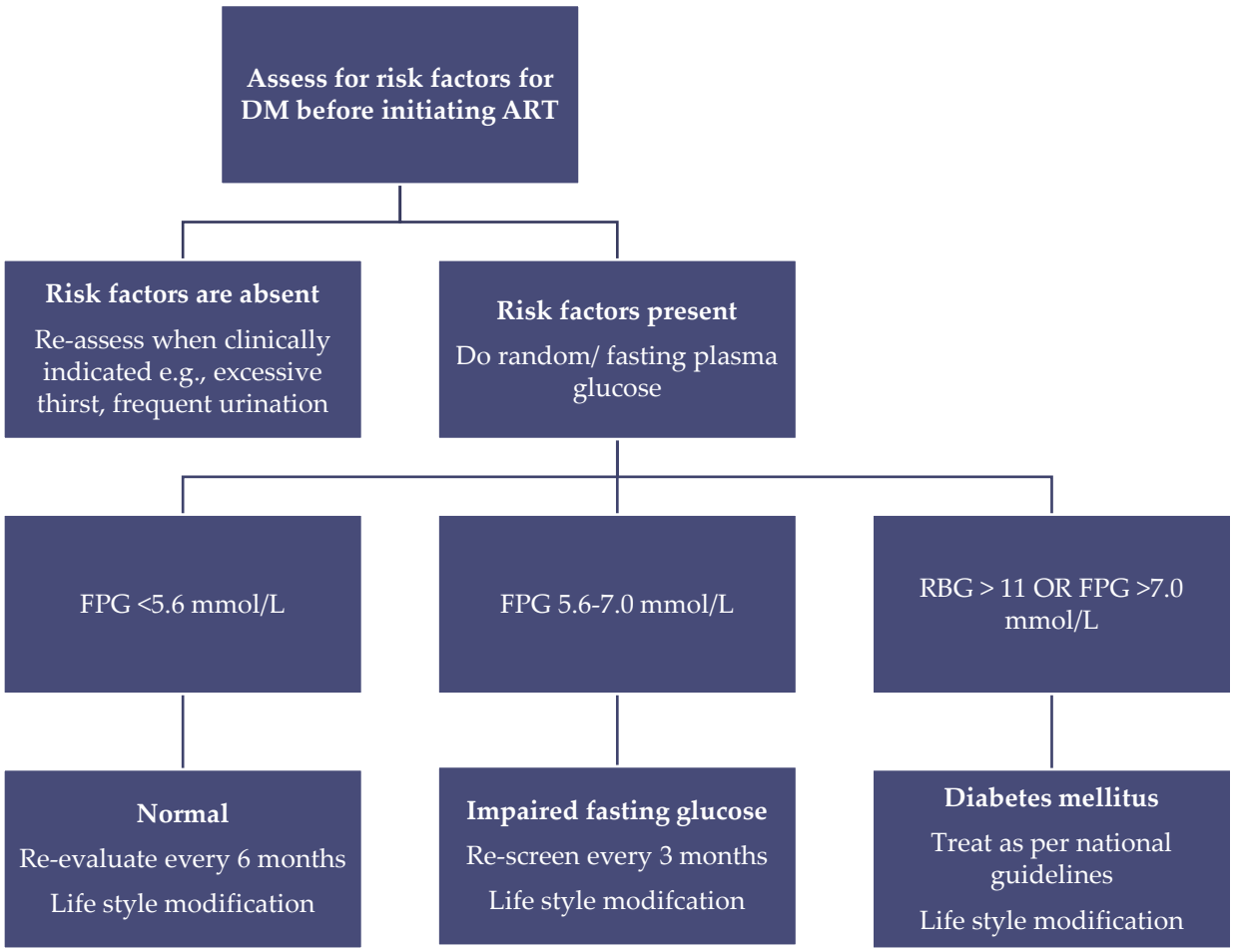
Patients should be assessed for risk factors for DM before initiation of ART and when clinically indicated. Those with risk factors should thereafter be re-evaluated every six months as shown in Figure 10.

6.7.2.3. 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.
- Metabolically neutral ARVs should be prescribed for patients at risk of developing DM. These include ABC, TDF, ATV/r, and DRV/r.
- Exclude HIV-associated nephropathy before initiating metformin because lactic acidosis can occur.
- 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 can be used with close monitoring.

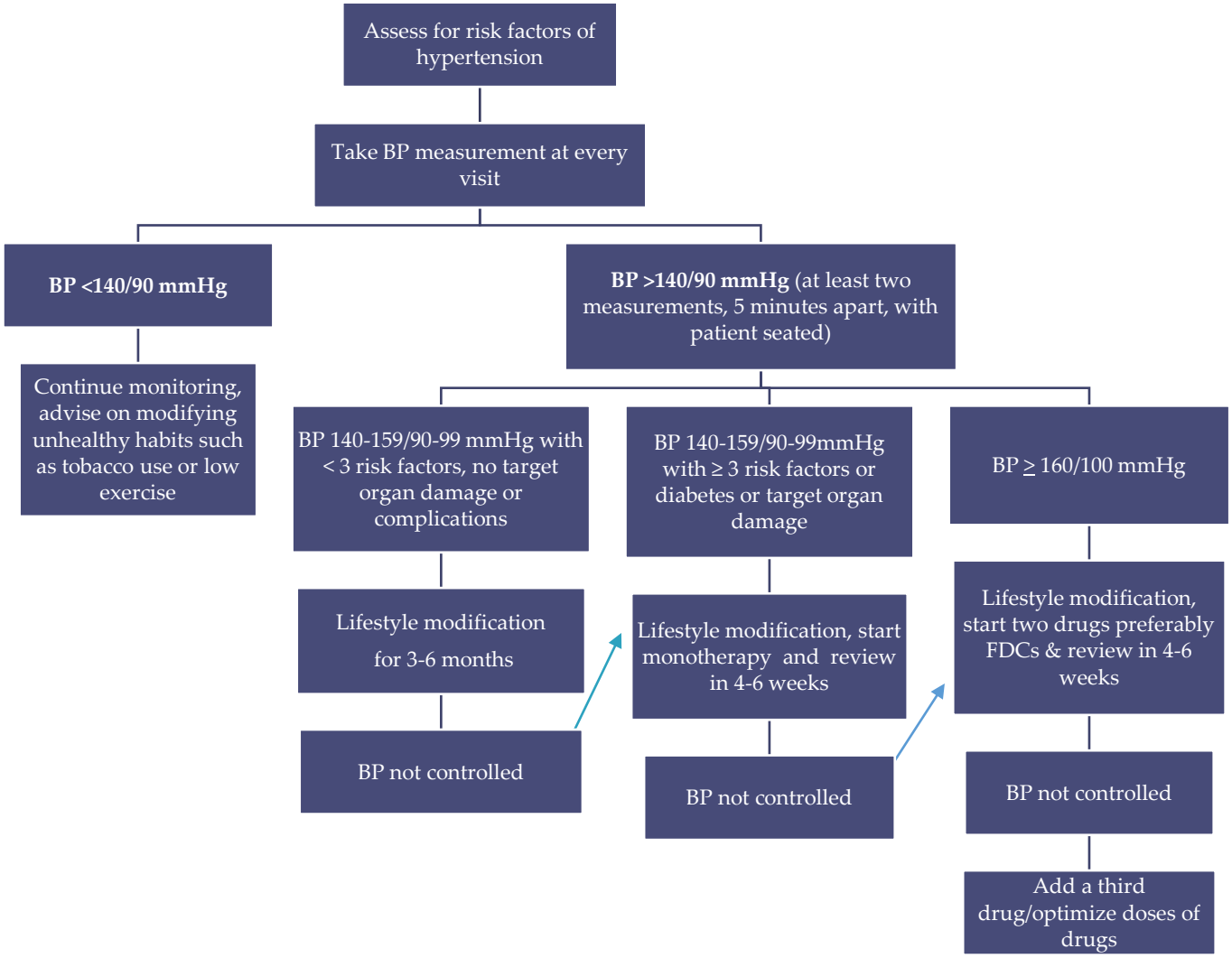
Figure 10: Algorithm for diagnosis and management of diabetes



6.7.3. 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. 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 11). People with any risk factor identified should be advised to modify lifestyle as described in Section 6.7.4.

Figure 11: Algorithm for diagnosis and management of hypertension



6.7.4. LIFESTYLE MODIFICATIONS TO PREVENT NON- COMMUNICABLE DISEASES

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 or not a person has hypertension, 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.

6.7.5. 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.

6.7.5.1. 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
- Introduction to medication
- Death of a significant other
- Necessity of making end of life and permanency planning decision
- Major life changes, e.g., childbirth, pregnancy, loss of a job, end of a relationship

6.7.5.2. Tools for screening for depression

Patient Health Questionnaire-2 (PHQ-2)

The PHQ-2 tool (Figure 12) 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 (Figure 13) in facilities where staff have been trained to use this tool.

Figure 12: Patient Health Questionnaire-2 (PHQ-2)

PATIENT HEALTH QUESTIONNAIRE-2 (PHQ-2) *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)*				
	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)

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.

The guide for diagnosis and management based on scores in the tool are summarized in Table 36.

Figure 13: 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 your family down	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 difficult ☐ Very difficult ☐ Extremely difficult ☐

Table 36: Guide for diagnosis and management of depression based on PHQ-9 tools

PHQ-9 score	Provisional diagnosis	Treatment recommendation
5-9	Minimal symptoms	Support, educate to call if worse, return in a month
10-14	Major depression, mild	Antidepressant or psychotherapy
15-19	Major depression, moderately severe	Antidepressant or psychotherapy
>20	Major depression, severe	Antidepressant or psychotherapy

6.7.5.3. Interactions between ARVs and antidepressants

Interactions between ARVs and antidepressants are in Table 37.

Table 37: 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
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

6.8. VACCINES FOR PEOPLE LIVING WITH HIV

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

6.8.1. BCG VACCINE

See Section 6.5.2.11.

6.8.2 HBV VACCINE

See Section 6.5.5.

6.8.3 HPV VACCINE

Adolescents aged 10 to 14 years will receive the HPV according to the national recommendation (see Figure 9).

6.8.4 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. It is recommended during yellow fever outbreaks and for those intending to travel to high risk areas for yellow fever. The single vaccine gives lifetime coverage.

6.9. POSITIVE HEALTH, DIGNITY, AND PREVENTION

Positive health, dignity, and prevention (PHDP) is a set of HIV prevention interventions for PLHIV with a focus on keeping PLHIV physically, mentally and psychologically healthy and as well as prevent transmission of HIV (Table 38).

Table 38: Positive health, dignity, and prevention intervention

Intervention	Description
Support and promote adherence	See Chapter 1.
Preventing HIV transmission	Encourage safer sexual behaviours 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	Discuss strategies for disclosing HIV status to sexual partners and family members. 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. For pregnant women who choose to conceive, link to eMTCT services (Table 12).
Referral to community-based programs	Refer and link them to community-based programs like adherence groups and income generation activities (IGAs).
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. ADHERENCE PREPARATION, MONITORING, AND SUPPORT

7.1. 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.

7.2. ADHERENCE PREPARATION

Preparing people to start antiretroviral therapy (ART) is an important step to achieving ART success. Health care 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 immunosuppression, and/or who are at high risk of death. The health care team should use the 5 As principles for chronic care as a guide to offer pre-ART adherence counseling and psychosocial support. These are **Assess, Advise, Agree, Assist** and **Arrange** (Table 39).

Table 39: 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 (see • • Table 41) • 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 them to enroll for treatment (Table 40)** • 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

Guide	Components
	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 • 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
Agree on	• An adherence plan (Table 42) • Family and community support systems (expert client in the community) • Possible home visit and consent • Possibility of testing of other family members including sexual partner and children Assess client's readiness to start ART (see Table 43: ART readiness assessment form)
Assist	The client to: • Evaluate the possible barriers to adherence and how to overcome them • Identify 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 • Disclose to a trusted person of their choice such as a treatment supporter, social support group, etc. • Develop an individual support adherence plan • Document the agreed-upon options on the ART card

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 the initial 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 40: Basic questions and answers about HIV and ARVs

Questions	Answers
What does it mean to be HIV positive?	It means your body has the HIV. This virus destroys your immune system and causes AIDS.
How does HIV affect your body?	It destroys CD4 cells in your blood and leaves your body defenseless against opportunistic infections.
What are ARVs?	These are drugs that are used to treat HIV. There are several of them, and they work in different ways.

Questions	Answers
How do ARVs work?	Its stops the virus from multiplying in the body resulting in an increase in CD4 cells which helps the body to fight opportunistic infections.
What are the benefits of taking ARVs?	ARVs: • Suppress the multiplication of the virus in the body. • Cause your CD4 count to increase, and you will fight disease better and reduce your risk of falling sick. • Promote growth and better development in children. • Increase your life span since you will not be falling sick often ○ Because you are not sick often, you will be able to work and provide for yourself and your family. • Reduces the risk of transmitting HIV to your uninfected partners or baby.
When should an HIV-infected person start ARVs?	As soon as one is confirmed to be HIV-infected and is ready to start treatment. However, the health worker should ensure that you have been prepared enough to start ARVs using the 5 As approach.
How much ARVs should I take daily and how often?	Although these are all ARVs, they are of different types and therefore you should take your medicine according to the health worker's prescription. Drug sharing should be prevented as it affects adherence. Patients qualify for different ARV drug regimens depending on age, type of job, weight (in children), and prevailing clinical condition(s). Therefore ARVs should be taken on prescription only.
What are some of the side effects of ARVs?	Severe anemia, vomiting, skin rash, diarrhea, nightmares, convulsions, hypersensitivity, etc.
How can I know that I have side effects and what should I do?	If you experience conditions that were discussed as side effects of the drugs given during adherence counseling, you should report to the health facility that provided the treatment • If away from the facility, you should go to the nearest health facility along with your patient prescription book • If not sure of what to do contact the expert client in your area for support • Call the health facility line for support
How often should I return for HIV care?	• You should always return for care and monitoring as scheduled by the health worker. • When you experience a side effect or a psychosocial challenge • When you feel sick, e.g., when you have malaria
Why should I start ART when I don't feel sick?	• HIV harms you on the inside even when it is not seen on the outside. It destroys cells that help your body fight diseases. Soon you may start falling sick often. • When you (your child) take ARVs now, the medicines reduce the amount of HIV in your blood and as a result your body will be able to fight diseases better, and you will be healthy. • Starting ARVs early helps to prevent TB, heart disease and HIV-related cancer and other infections that may occur if your immunity is low. **For children and adolescents** • You will not fall sick often, will grow and develop well, attend school and achieve their future dreams. ○ **When you (your child) is not sickly,** you will be able to carry on with

Questions	Answers
	your other duties normally and may save money on hospital bills. **Adults and sexually active adolescents** • When the amount of virus in your blood is reduced, the chances that you will transmit HIV to others are significantly reduced. **For key populations and discordant couples** • ARVs will prevent your sexual partner(s) from HIV infection. Also use other prevention methods like condoms. **Pregnant women** • Reduce the chances of transmitting HIV to your baby *Starting you on ART early will help you to have a better quality of life as you will not fall sick often, you will live healthy and stronger and have an HIV-free baby.*
Benefits of adhering to ARVs	• Suppresses the multiplication of the virus in your body • The CD4 count will increase, and you will be protected from other illnesses • Reduces the risk of developing ARV drug resistance • The risk of transmitting HIV to your HIV-uninfected sexual partners may be reduced • Reduces the risk of infecting your born or unborn baby • In children, they will grow and develop better • In adolescents, they will look healthy
Consequences of not adhering to ARVs	• You may not be able to suppress viral multiplication in your body • The virus will continue to destroy your immune system and decrease your CD4 count • When your CD4 count is low, you will be prone to opportunistic infections, and you will develop more severe disease • The virus in your body may also become resistant to ARVs • You will have limited options for treatment and require more costly ARVs for your treatment which may not be readily available in the country • Become less productive resulting in loss of economic activity • May succumb to life-threatening conditions of AIDS which leads to death • The chances are high that pregnant and breastfeeding women will transmit HIV to their born and unborn babies • Adolescents might not realize their future dreams

Table 41: Barriers to adherence

Population	Barriers
Infants and Children	• Lack of a committed, involved and responsible caregiver • HIV infected caregiver/parent with ill-health/adherence/emotional challenges • Caregiver's job obligations • Child may refuse to take the medicine • Multiple caregivers for the child • Poor palatability of some medicines • Difficulty in swallowing medicines • High pill burden • Frequent dosing changes

Population	Barriers
	• Limited choice of pediatric formulations • Child abuse and neglect • Stigma and discrimination • Non-disclosure to the child and family members

Adolescents	• Psychosocial issues such as peer pressure, the perceived need to conform
	• Inconsistent daily routine
	• Child abuse and neglect
	• Stigma and discrimination
	• Left out of decisions and have limited opportunities to discuss their concerns
	• Limited availability of adolescent-specific treatment literacy and adherence counseling tools
	• For adolescents who are transitioning from pediatric to adolescent care, additional challenges may include:
	  o Assuming increased responsibility for their care
	  o Issues relating to disclosure to peers or partners
	  o Difficulties in navigating the health care system
	• Lack of links between adult and pediatric services and inadequately skilled health workers
	• The adolescent stages of growth and development
	• Alcohol and substance abuse

Pregnant or breastfeeding women	• Pregnancy-related conditions such as nausea and vomiting may negatively affect treatment adherence
	• Other individual factors include suboptimal understanding of HIV, ART, and eMTCT
	• Lack of partner disclosure and support,
	• Fear of stigma and discrimination,
	• Non-disclosure
	• GBV
	• Drug sharing
	• Service delivery barriers including:
	  o Poor-quality clinical practices
	  o Gaps in provider knowledge and training
	  o Poor access to services

Adults	• Social barriers (e.g. long work schedules/job time/nature of Job) • Forgetfulness • Lack of trust in providers or medicines • Stigma and discrimination • Lack of social support • Non-disclosure • Drug side effects • Pill burden • Inadequate information about ARVs • Alcohol and substance abuse
Key populations	• Stigma and discrimination • Provider attitude • Alcohol and substance abuse

Population	Barriers
	• Nature of job/engagement • High mobility • GBV • Lack of peer support • Lack of knowledge by health workers of KPs
People with mental health conditions and substance abuse	• Uncontrolled depressive symptoms • Forgetfulness • Poor organization • Poor comprehension of treatment plans

Table 42: Ten questions guide for developing an adherence plan

Question	Patient/caregiver response
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?	
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 43: ART readiness assessment form

A. Psychosocial/knowledge criteria (applies to patients and caregivers)	Yes	No	Comment
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?			
B. Support systems criteria (applies to patients and caregivers)			
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)?			
C. Medical criteria			
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*			
• *The only absolute criteria for deferring ART is yes to question 15 and 16* • *If the response to any question in Section A or B is "No," develop a strategy to address the issue as quickly as possible, and consider assigning an expert client to follow up. ART may be initiated with adequate adherence support while the criteria are being addressed, or ART may be deferred until the criteria are met, on a case-by-case basis.*			
This tool has partly been adapted from the "Guidelines for the use of ARVs for treating and preventing HIV infection in Kenya".			

7.3. 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.

7.3.1 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 (see Section 8.5.3.1, Viral load monitoring). Following an initial high viral load (>1000 copies/mL), enhanced/intensive adherence counseling should be carried out before conducting a second viral load test.

7.3.2 SELF-REPORTING

Self-reporting is rapid, 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 44).

Table 44: Four question guide for reviewing an adherence plan

Question	Client Response
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 45).

7.3.3 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 45 to determine the adherence level and support the client accordingly.

Table 45: Determining adherence levels from self-report and pill count and recommended action

Missed doses per months		Percent adherence	Adherence ranking	Recommended Action
Once daily 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.				

7.3.4 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.

7.4. ADHERENCE SUPPORT

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

- **Peer counselors:** These include peer mothers in the eMTCT program, adolescent peers, expert clients and other peers as patients and caregivers usually relate better to peers.
- **Mobile phone calls and text messages:** These should be used with the patient or caregiver 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 and 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:** 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 also 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.

7.5. INTENSIVE ADHERENCE COUNSELING FOR PATIENTS WITH UNSUPRESSED VIRAL LOAD

Intensive adherence counseling (IAC) is the counseling offered to patients with a non-suppressed viral load. IAC helps a client develop a comprehensive plan for adhering to ARVs by identifying their barriers to adherence, gaining insight of the barriers, and exploring possible ways to overcome barriers and making a plan to adhere to medicine. 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, and nutrition.

The multidisciplinary team should use the 5 As to offer intensive adherence counseling and psychosocial support. These are; **Assess, Advise, Agree, Assist** and **Arrange** and are summarized in Table 46 below.

Table 46: 5As for adherence support for people with non-suppressed viral load

Guide	Components
Assess	• Client's adherence history • Patient's psychosocial concerns and needs • Patient's willingness and commitment to take medicines correctly • Patient's understanding of the implications of a non-suppressed viral load • Barriers to ART adherence • Patient's readiness to receive comprehensive counseling on a monthly basis • Patient's psychological state in the past two weeks

Advise (information giving)	• Explain what VL test is and results (suppressed and non-suppressed viral load)
	• Explain that non-suppressed viral load means:
	  ○ Either the ARVs are not working well, or patient is not taking medicine well
	  ○ The amount of virus in the patient's blood is high and is going to destroy their CD4 cells quickly, leading to a lack of protection from infections
	• Emphasize that the patient will receive adherence counseling sessions monthly for at least 3 or more months at agreed service points as per the identified concern
	• Repeat viral load will be taken one month after the third counseling session
	• Discuss positive health, dignity, and prevention (PHDP) package

Assist the client to:	• Evaluate the possible underlying causes of the non-suppressed viral load. • Develop an adherence plan to achieve viral load suppression with regards to their adherence barriers. • Identify the support systems that will enable the client to take his or her drugs as prescribed. These should include treatment buddy, peer support groups, and

Guide	Components
	family members. • Brainstorm on strategies to facilitate good adherence e.g. appointment keeping for refills, treatment buddies, social support groups, joining, and linkage to CBOs. • Disclose to a trusted person of their own choice and significant other. • Document the agreed upon options on the HIV/ART card, and routine/intensified adherence counseling form.
Agree on	• An action plan on how to achieve viral suppression including using the principles in Table 42 to develop an adherence plan. • The support systems to help the client implement the agreed upon action plan. • ***Supporting the patient's choices and help them own the action plan***
Arrange	Arrange for follow up intensive adherence counseling and psychosocial support sessions. Emphasize that the patient will receive adherence counseling sessions monthly for at least 3 or more months. The following are the actions to be followed: • Joining psychosocial support groups and other support systems • Home visiting • Sending SMS and phone call reminders • Monthly counseling sessions targeting drug adherence • Following up the PHDP Care Package for PLHIV • Review of the action plans at every encounter

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 all PLHIV to undetectable levels, and reduce the risk of morbidity and mortality associated with HIV, as well as reduce transmission of HIV.

8.2. 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 with HIV

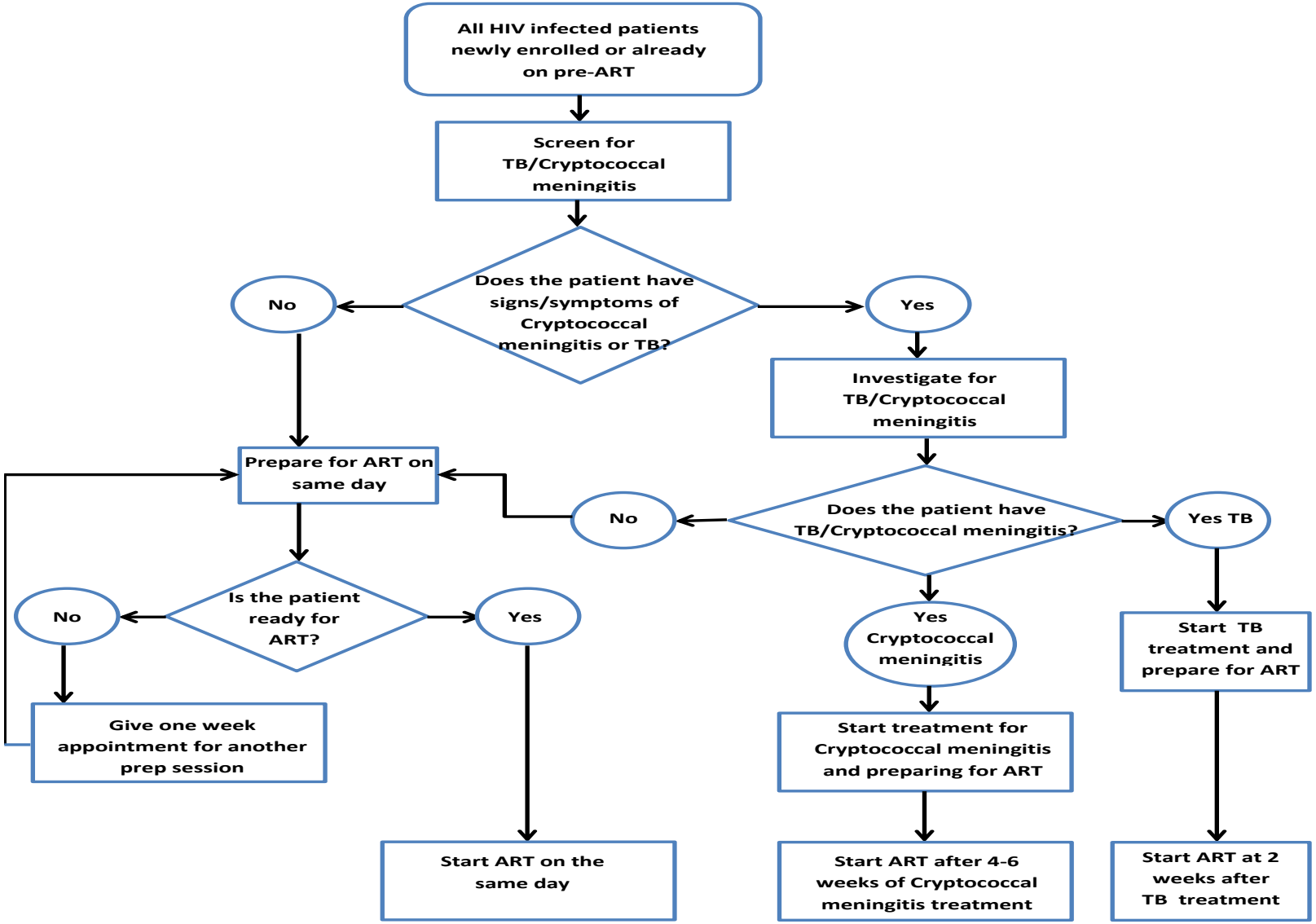
Since 2013, evidence and programmatic experience have continued to favour earlier initiation of ART because it results in reduced mortality, morbidity, and HIV transmission outcomes.

8.3. THE PROCESS OF STARTING ART

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

- Assess all clients for opportunistic infections 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. 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, the patients should be prepared for ART on the same day according to the guidelines in Section 7.2 and assessed for readiness to start ART using the readiness checklist (Table 43).
- 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 14 for the process of evaluating patients for ART.

Figure 14. How to evaluate patients for ART initiation



8.4. WHAT ARV REGIMEN TO START WITH (FIRST-LINE ART)

Principles for selecting the ARV regimens

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

- Regimen with lower toxicity
- Better palatability and lower pill burden
- 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
- Help the country to achieve a recommended regimen for the vast majority of PLHIV

8.4.1. RECOMMENDED FIRST-LINE REGIMEN FOR INITIATING ART IN ADULTS AND ADOLESCENTS AGED 10 AND ABOVE

The first-line ART regimen for adults and adolescents aged ten years and above consists of 2 nucleoside reverse transcriptase inhibitors (NRTI) plus a non-nucleoside reverse transcriptase inhibitor (NNRTI).

RECOMMENDED FIRST-LINE REGIMEN: TDF+3TC+EFV

All HIV-infected adults and adolescents aged 10 years and above should be initiated on tenofovir, lamivudine and efavirenz (TDF+3TC+EFV) as a once-daily fixed dose combination (Table 47).

WHEN TO USE ALTERNATIVE FIRST LINE REGIMENS

When to use TDF+3TC+DTG

Adults and adolescents aged 12 years and above should only be initiated on TDF+3TC+DTG if they have a condition where EFV is contraindicated including:

- Severe clinical depression, psychosis or suicidal tendencies
- Ongoing complications of neurological disease that block the prescriber's ability to assess side effects of EFV
- Use of anxiolytics especially benzodiazepines or carbamazepine.
- Severe hepatic impairment
- HIV/TB co-infected PLHIV using Bedaquiline
- Situations where the only available FP method is hormonal contraception containing levonorgestrel, ethinyl estradiol, or etonogestrel

Rationale for using dolutegravir (DTG)

Dolutegravir has a low potential for drug interactions, shorter mean time to viral suppression, higher genetic resistance barrier, a long half-life and low cost. However information about its efficacy/safety during pregnancy and in TB/HIV is still limited.

When to use ABC+3TC+DTG

Adults and adolescents aged 10 years and above should only be initiated on ABC+3TC+DTG if TDF is contraindicated, including the following conditions:

1. Kidney disease and estimated glomerular filtration rate (GFR) below 60 ml/min
2. Adolescents below 35 kg of weight

8.4.2. RECOMMENDED FIRST-LINE REGIMEN FOR INITIATING ART IN PREGNANT OR BREASTFEEDING WOMEN

PREFERRED FIRST-LINE REGIMEN: TDF+3TC+EFV

All HIV-infected pregnant, and breastfeeding women should be initiated on tenofovir, lamivudine, and efavirenz (TDF+3TC+EFV) (Table 47)

WHEN TO USE ALTERNATIVE FIRST LINE REGIMENS

ABC+3TC+ATV/r

Pregnant and breastfeeding women should be initiated on ABC+3TC+ATV/r only when TDF or EFV are contraindicated (Section 8.4.1.).

8.4.3. RECOMMENDED FIRST-LINE REGIMEN FOR INITIATING ART IN CHILDREN 3 to <10 YEARS OF AGE

RECOMMENDED FIRST-LINE REGIMEN: ABC+3TC+EFV

All HIV-infected children aged 3 to <10 years of age should be initiated on abacavir + lamivudine+ efavirenz (ABC+3TC+EFV) (Table 47).

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+EFV can now be given as once a day dose which may improve adherence.

WHEN TO USE ALTERNATIVE FIRST-LINE REGIMENS

ABC+3TC+NVP

Children aged 3 to <10 years should only be initiated on ABC+3TC+NVP if EFV is contraindicated in the following conditions:

1. Diagnoses with severe clinical depression or psychosis
2. Ongoing complications of neurological disease that block ability to assess side effects
3. The use of benzodiazepines or carbamazepines

8.4.4. RECOMMENDED FIRST-LINE REGIMEN FOR INITIATION OF ART IN CHILDREN UNDER 3 YEARS OF AGE

RECOMMENDED FIRST-LINE REGIMEN: ABC+3TC+LPV/r

All HIV-infected children under 3 years should be initiated on abacavir + lamivudine + ritonavir-boosted lopinavir (ABC+3TC+LPV/r) (Table 47).

Rationale for using an LPV/r based regimen as recommended 1st line regimen

Children younger than 36 months have a reduced risk of discontinuing treatment, viral failure or death if they start on an LPV/r based regimen instead of the NVP-based regimen. Also, surveillance of drug resistance among vertically infected children younger than 18 months in Uganda has revealed high levels of resistance to NNRTIs and LPV/r is known to have a high barrier to resistance.

WHEN TO USE ALTERNATIVE FIRST-LINE REGIMENS

AZT+3TC+LPV/r
AZT+3TC+ LPV/r should only be used in children who experience a hypersensitivity reaction to abacavir (ABC), however, this is rare in African populations.

Table 47: Recommended first-line ARV regimen in adults, adolescents, pregnant or breastfeeding women and children

PATIENT CATEGORY	INDICATION	ARV REGIMEN
Adults and adolescents aged 10 years and older and ≥35kg	**RECOMMENDED 1ST LINE REGIMEN** • Adults and adolescents initiating ART	**TDF+3TC+EFV**
	If EFV is contraindicated[1]	TDF+3TC+DTG
	If TDF is contraindicated[2]	ABC+3TC+EFV
Pregnant and breastfeeding women	**RECOMMENDED 1ST LINE REGIMEN** • Pregnant or breastfeeding women initiating ART	**TDF+3TC+EFV**
	If EFV[1] is contraindicated	TDF+3TC+ATV/r
	If TDF[2] is contraindicated	ABC+3TC+EFV
Children 3-<10 years old (Under 35kg)	**RECOMMENDED 1st LINE REGIMEN** • Children 3-<10 years initiating ART	**ABC+3TC+EFV**
	If EFV is contraindicated[1]	ABC + 3TC+NVP
Children <3 years of age	**RECOMMENDED 1st LINE REGIMEN** • Children <3 years initiating ART	**ABC+3TC+LPV/r**

1. Contraindications for EFV

- Severe clinical depression or psychosis
- Patient receiving benzodiazepines or carbamazepine.
- Ongoing complications of neurological disease that block ability to assess side effects of EFV

2. Contraindications for TDF

- Renal disease and/or GFR <60 ml/min
- Weight <35kg

Note: No substitutions should be done for stable patients including those currently on AZT 3TC NVP as their first line regimen.

8.5. MONITORING RESPONSE TO ART

8.5.1. INTRODUCTION

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

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. Monitoring adherence to ART is covered in Chapter 7. The visit schedule and the recommended clinical and laboratory monitoring are in Table 50.

8.5.2. 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 48: Components of a comprehensive clinical assessment of PLHIV

Components
• Demographics (age, sex etc.) • Screen for signs and symptoms of OIs (e.g. TB, cryptococcal meningitis), 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) • 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

8.5.3. LABORATORY MONITORING

8.5.3.1. 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, hence reducing the accumulation of drug resistance mutations and improving clinical outcomes.
- Can also help to distinguish between treatment failure and non-adherence.

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. At the minimum, the committee should consist of a health care worker and a lay provider (e.g. expert client, counselor, peer education, VHT) who know the client.

Frequency of viral load

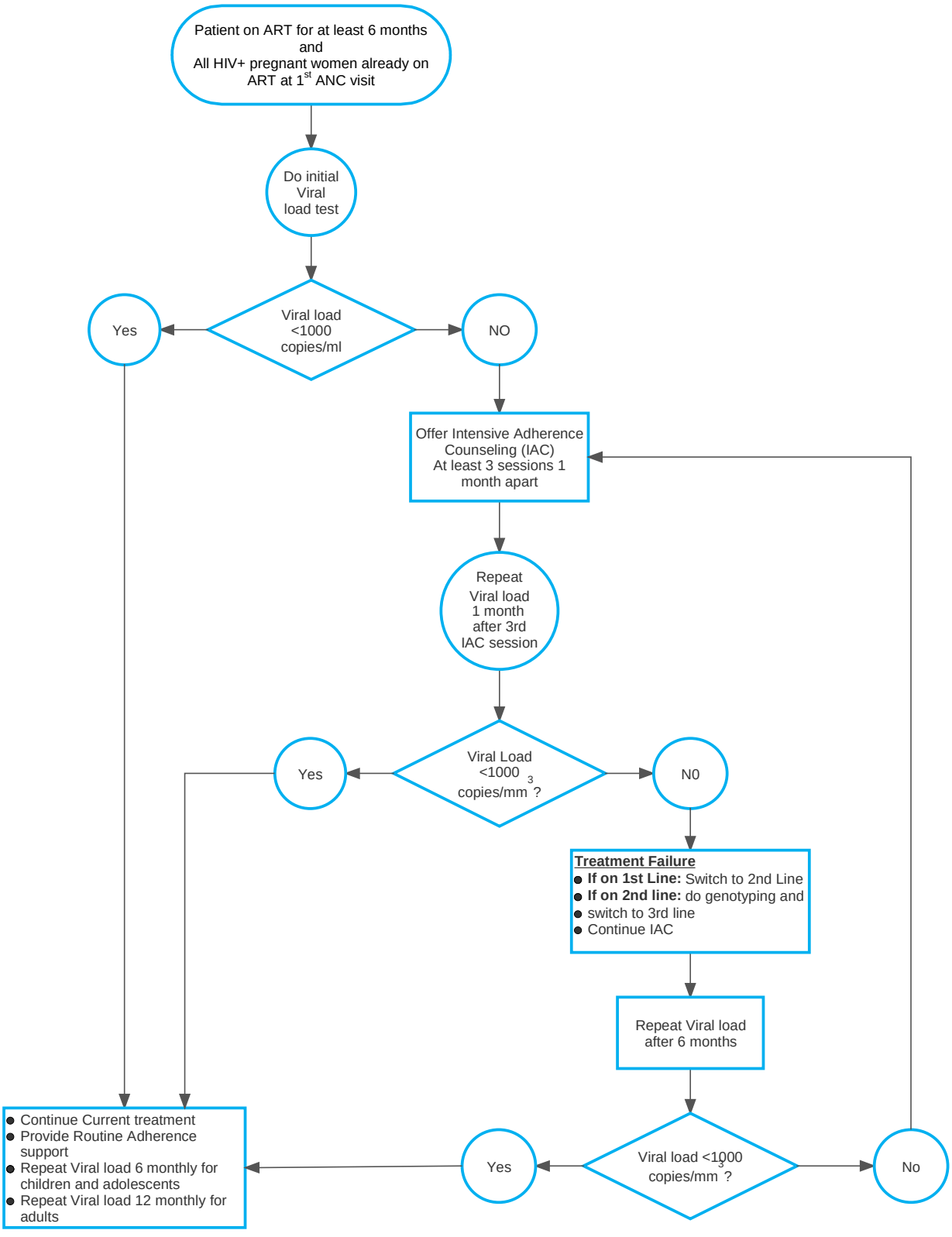
- **Adults:** the first VL test should be done at six months after initiating ART, and thereafter, annually, if it is suppressed. If not suppressed, follow the algorithm in Figure 15.
- **Children and adolescents under 19 years of age:** the first VL test should be done at six months after initiating ART, and if it is suppressed, do VL every six months.
- **Pregnant women:**
  - If newly initiating ART, follow the standard algorithm like adults;
  - If already on ART, a VL test is done at ANC 1, irrespective of when the last VL test was done, then follow the standard VL algorithm.

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

For non-suppressed PLHIV, the following should be done:

- Contact the patient to return to facility within one week after facility receives results.
- Ensure that facility ART team holds case discussions on patients with non-suppressed VLs to determine possible causes of non-suppression.
- Discuss results with the patient and assess for barriers to adherence.
- Do intensive adherence counseling support monthly for three months (see Table 46).
- Repeat VL test one month after the last (3rd) intensive adherence counseling session (the repeat viral load test should be done within 6 months of the last unsuppressed VL test).
- If the repeat VL is suppressed, follow the standard algorithm.
- If repeat VL is not suppressed, and the ART team is confident that the patient is adherent, then the patient is failing on the current ARV regimen and should be switched according to the guidance in Table 54.

Figure 15: Viral load testing algorithm



8.5.3.2. CD4 monitoring

Although CD4 cell count is no longer the mainstay for ART response monitoring and is not a precondition for initiating ART, it is still recommended in the following scenarios:

- At baseline when initiating ART. 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

8.5.3.3. Other laboratory tests

Other laboratory tests should be done when clinically indicated (Table 49).

Table 49: Follow-up lab tests and their clinical indication

Test	Indication
CrAg	(CD4 <100 cells/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
Serum creatinine	If PLHIV has comorbidities (DM, hypertension)
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 50: Follow-up schedule for PLHIV and monitoring components

Time	Clinical assessment	Laboratory tests
	Before ART	
Baseline	• Comprehensive clinical assessment (Table 48) • Prepare for ART (refer to Section 7.2) • Assess readiness for ART (refer to Section 7.2) • Provide CTX • Provide FP if required	• CD 4, HBsAg, CrAg if CD4 <100, VL test for pregnant women at first ANC **Do tests below if clinically indicated** • CBC (if the patient is at risk of anaemia) • TB tests (if TB is suspected) • RFTs (for hypertensive and DM patients) • LFTs (HBV or HCV infection) • Lipid profile and blood glucose • HCV antibody test

Time	Clinical assessment	Laboratory tests
During on ART		
1 month	• Comprehensive clinical assessment (Table 48) • Assess for drug intolerance, side effects/toxicities, and immune reconstitution inflammatory syndrome (IRIS) • Adherence assessment, monitoring, and support • ART and CTX refill ***(in children adjust dose based on weight)*** • FP refill **If the patient is clinically well, give one month refill and appointment**	Do other lab tests if clinically indicated (Table 49)
2 months	• Comprehensive clinical assessment (Table 48) • Assess for drug intolerance, side effects/toxicities, and IRIS • Adherence assessment, monitoring, and support • ART and CTX refill ***(in children adjust dose based on weight)*** • FP refill **If patient is clinically well, give one month refill and appointment**	Do other lab tests if clinically indicated (Table 49)
3 months	• Comprehensive clinical assessment (Table 48) • Assess for drug intolerance, side effects/toxicities, and IRIS • Adherence assessment, monitoring, and support • ART and CTX refill ***(in children adjust dose based on weight)*** • FP refill **If patient is clinically well, give three months refill and appointment**	Do other lab tests if clinically indicated (Table 49)
During ART		
6 months	• Comprehensive clinical assessment (Table 48) • Assess for drug intolerance, side effects/toxicities, and IRIS • Adherence assessment, monitoring, and support • ART and CTX refill ***(in children adjust dose based on weight)*** • FP refill **If patient is clinically well, give three months refill and appointment**	Do VL test If VL is not suppressed, call the patient back for intensive adherence counseling. Do other lab tests if clinically indicated (Table 49)
9 months	• Comprehensive clinical assessment (Table 48) • Assess for drug intolerance and side effects/toxicities	For VL suppressed PLHIV, give VL results Do other lab tests if clinically

Time	Clinical assessment	Laboratory tests
	• Adherence assessment, monitoring, and support • ART and CTX refill ***(in children adjust dose based on weight)*** • FP refill • **Determine eligibility and prepare for differentiated service delivery models DSDM** **If patient is clinically well, give three months refill and appointment**	indicated (Table 49)
12 months	• Comprehensive clinical assessment (Table 48) • Assess for drug intolerance and side effects/toxicities • Adherence assessment, monitoring, and support • ART and CTX refill ***(in children adjust dose based on weight)*** • FP refill **If patient is clinically well, give three months refill and appointment**	2nd VL in children Do other lab tests if clinically indicated (Table 49)
After 12 months on ART following DSDM		
3 monthly	• Comprehensive clinical assessment (Table 48) • Assess for drug intolerance and side effects/toxicities • Adherence assessment, counseling, and support • TB Screening • ART and CTX refill ***(in children adjust dose based on weight)*** • FP refill • Refer where clinically indicated **If patient is clinically well, give three months refill and appointment**	Do other lab tests if clinically indicated (Table 49)
6 monthly	• Comprehensive clinical assessment (Table 48) • Assess for drug intolerance and side effects/toxicities • Adherence assessment, counseling, and support • TB Screening • ART and CTX refill ***(in children adjust dose based on weight)*** • FP refills **If patient is clinically well, give XX months refill (According to the DSDM model that the patient subscribes to) and appointment**	Do other lab tests if clinically indicated (Table 49)

Time	Clinical assessment	Laboratory tests
Annually	• Comprehensive clinical assessment (Table 48) • Assess for drug intolerance and side effects/toxicities • Adherence assessment, counseling, and support • TB screening • ART and CTX refill ***(in children adjust dose based on weight)*** • FP refills **If clinically stable, give the appropriate number of months refill (according to the DSDM model the patient subscribes to) and appointment**	VL Cervical cancer screening Do other lab tests if clinically indicated (Table 49)

8.5.4. 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.
- Poor adherence in this period is also associated with the risk of early treatment failure and rapid development of drug resistance.

8.5.5. 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/mm^3) at ART initiation, disseminated opportunistic infections or tumors and/or** a shorter duration of therapy for opportunistic infections before ART starts.

8.5.5.1. 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.

8.5.5.2. 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.

8.6. ARV DRUG TOXICITY

Antiretroviral drugs 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 52 for common ARV side effects and toxicities.

8.6.1. MANAGING ARV DRUG TOXICITY

Health care workers should assess patients on ART for ARV 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 drug or drugs, or to a non-ARV medication taken at the same time.
3. Consider other disease processes. Not all problems that arise during treatment are caused by ARV drugs.
4. Manage the side effects and toxicities according to severity (Table 51).
5. Report the event using the National Drug Authority (NDA) adverse drug reaction form.

Table 51: 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.
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.

8.6.2. 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 52 for side effects of commonly used ARVs and recommended substitutions.

Table 52: Toxicities/side effects of commonly used ARVs and recommended substitutions

Age category	Regimen	Major toxicity events	Responsible ARV	Suggested management
Adults, adolescents, pregnant and lactating women	**TDF+3TC+EFV**	Persistent central nervous system toxicity (such as dizziness, insomnia, abnormal dreams) or mental symptoms (anxiety, depression, mental confusion)	**EFV**	Reassure, lower the dose of EFV to 400 mg. If persists substitute EFV with DTG and use regimen TDF+3TC+DTG.
		Convulsions		Substitute with DTG Use regimen TDF+3TC+DTG
		Hepatotoxicity		
		Severe skin and hypersensitivity reactions		
		Gynecomastia		
		Chronic kidney disease Acute kidney injury and Fanconi syndrome	**TDF**	Substitute with ABC Use regimen ABC+3TC+EFV
		Decreased bone mineral density		
		Lactic acidosis or severe hepatomegaly with steatosis		
	TDF+3TC+DTG	Chronic kidney disease Acute kidney injury and Fanconi syndrome	**TDF**	Substitute with ABC Use regimen ABC+3TC+DTG
		Decreased bone mineral density		
		Lactic acidosis or severe hepatomegaly with steatosis		
		Hepatotoxicity	**DTG**	Substitute with EFV Give TDF+3TC+EFV **If EFV is contraindicated:** use TDF+3TC+ATV/r
		Hypersensitivity reactions		
	ABC+3TC+DTG	Hypersensitivity reaction	ABC	Stop and substitute with TDF Use regimen: TDF+3TC+DTG **If TDF is contraindicated**: use AZT+3TC+DTG
		Hepatotoxicity	**DTG**	Substitute with EFV Give TDF+3TC+EFV **If EFV is contraindicated:** use TDF+3TC+ATV/r
		Hypersensitivity reactions		

Age category	Regimen	Major toxicity events	Responsible ARV	Suggested management
Adults, adolescents, pregnant and lactating women	**AZT+3TC+NVP**	Severe anemia, neutropenia	**AZT**	Substitute with TDF **Use regimen:** TDF+3TC+NVP **If TDF is contraindicated: use** ABC+3TC+NVP
		Lactic acidosis or severe hepatomegaly with steatosis lipoatrophy, lipodystrophy, myopathy		
		Severe vomiting		
		Acute symptomatic hepatitis	**NVP**	Substitute with DTG **Use regimen:** AZT+3TC+DTG
		Severe skin rash		
		Hypersensitivity reaction, Stevens-Johnson Syndrome (severe or life-threatening rash, mucosal involvement)		
	ATV/r-based regimen	Electrocardiographic abnormalities (PR and QRS interval prolongation)	**ATV/r**	Use with caution in people with pre-existing conduction disease or who are on concomitant drugs that may prolong the PR or QRS intervals.
		Indirect hyperbilirubinemia (clinical jaundice)		This phenomenon is clinically benign but potentially stigmatizing. Substitute with LPV/r only if adherence is compromised.
		History of nephrolithiasis		Substitute with LPV/r or DRV/r. If boosted PIs are contraindicated, and NNRTIs have failed in first-line ART, consider salvage therapy.
	DRV/r-based regimen	Hepatotoxicity	**DRV/r**	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.
		Severe skin and hypersensitivity reactions		
	ETV-based regimen	Severe skin and hypersensitivity reactions	**ETV**	Substitute with another therapeutic class (integrase inhibitors or boosted PIs).

Age category	Regimen	Major toxicity events	Responsible ARV	Suggested management
Children 0-<10 years	**ABC+3TC+EFV**	Hypersensitivity reaction	**ABC**	Stop and substitute with AZT Use regimen AZT+3TC+EFV
		Persistent central nervous system toxicity (such as dizziness, insomnia, abnormal dreams) or mental symptoms (anxiety, depression, mental confusion)	**EFV**	Re-assure; If fails to tolerate substitute with NVP Use regimen ABC+3TC+NVP
		Convulsions		Substitute with NVP Use regimen ABC+3TC+NVP
		Gynecomastia		
		Hepatotoxicity		Substitute with LPV/r Use regimen ABC+3TC+LPV/r
		Severe skin and hypersensitivity reactions		
	ABC+3TC+NVP	Hypersensitivity reaction	**ABC**	Stop and substitute with AZT Use regimen AZT+3TC+EFV
		Acute symptomatic hepatitis	**NVP**	**Mild Hepatotoxicity** Substitute with EFV Use regimen: ABC+3TC+EFV **Severe Hepatotoxicity** Substitute with LPV/r Use regimen: ABC+3TC+LPV/r
		Severe skin rash		Substitute with LPV/r Use regimen: ABC+3TC+LPV/r
		Hypersensitivity reaction, Stevens-Johnson Syndrome (severe or life-threatening rash, mucosal involvement)		
	ABC+3TC+LPV/r	Hypersensitivity	**ABC**	Stop and substitute with AZT Use regimen AZT+3TC+LPV/r
		Electrocardiographic abnormalities (PR and QRS interval prolongation, torsades de pointes)	**LPV/r**	Stop and substitute with NVP Use regimen: ABC/3TC/NVP
		Hepatotoxicity		
		Pancreatitis		
		Dyslipidemia		
		Diarrhoea		
		Unable to tolerate taste		

Age category	Regimen	Major toxicity events	Responsible ARV	Suggested management
Children 0-<10 years	**AZT+3TC+NVP**	Severe anemia, neutropenia	**AZT**	Substitute with ABC Use regimen: ABC+3TC+NVP
		Lactic acidosis or severe hepatomegaly with steatosis lipoatrophy, lipodystrophy, myopathy		
		Severe vomiting		
		Acute symptomatic hepatitis	**NVP**	**Mild Hepatotoxicity** Substitute with EFV Use regimen: AZT+3TC+EFV **Severe Hepatotoxicity** Substitute with LPV/r Use regimen: AZT+3TC+LPV/r
		Severe skin rash		Substitute with LPV/r Use regimen: AZT+3TC+LPV/r
		Hypersensitivity reaction, Stevens-Johnson Syndrome (severe or life-threatening rash, mucosal involvement)		
	RAL-based regimen	Rhabdomyolysis, myopathy, myalgia	**RAL**	In those older than 3 years, use DRV/r If <3 years, use LPV/r
		Hepatitis and hepatic failure Severe skin rash and hypersensitivity reaction		

8.6.3. DRUG SUBSTITUTIONS IN VIROLOGICALLY SUPPRESSED CHILDREN WHEN THEY TURN 3 AND 10 YEARS OF AGE

8.6.3.1. Children on LPV/r-based first-line and turn 3 years of age

When children on LPV/r based first line regimen turn 3 years of age, a viral load should be done and if they are virologically suppressed, LPV/r should be substituted with EFV.
Benefits: This will harmonize their treatment with the recommended regimen for that age group and simplify forecasting and quantification. Also, EFV is cheaper than LPV/r and the NEVERESTIII study showed that when this switch is made, EFV provides similar virologic suppression, improved immunologic response and lipid profile outcomes as those who continue on LPV/r. (see Table 53).

8.6.3.2. Children on ABC-based first-line and turn 10 years of age and weigh 35 kg plus

When children on ABC based first line regimen turn 10 years of age and weigh 35kg, a viral load should be done and if they are virologically suppressed, ABC should be substituted with TDF
Benefits: TDF reduces pill burden, simplifies forecasting and quantification and is cheaper than ABC (see Table 53).

The children who are not viral suppressed should be investigated for treatment failure and managed accordingly.

Table 53: Regimen substitutions in virologically suppressed children by age band

Initial Regimen	Substitution Criteria	New Regimen
ABC/3TC+LPV/r	Virologic suppression and 3+ years of age	ABC/3TC+EFV
ABC/3TC+EFV	Virologic suppression , 10+ years of age and 35+ kg weight	TDF/3TC/EFV

8.7. 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 27 and Table 28 for TB/ARV co-management
	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)

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 54). Although immunological data were included in past guidelines, it is not recommended for monitoring response to ART in this guideline.

When treatment failure is confirmed, the patient should be switched to a new ARV regimen; 2nd line regimen for those failing on the 1st line regimen; and 3rd line regimen for those failing on 2nd line ARVs. Before switching therapy, it is essential to assess and address adherence issues.

Table 54: 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 3-6 months apart, with adherence support following the 1st VL test.	The patient should have been on ART for at least six months
Clinical failure	**Adults and adolescents** • New or recurrent WHO clinical stage 4 in a patient who has been on effective ART regimen for at least six months or some stage 3 condition (pulmonary TB or severe bacterial infection). **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. WHAT REGIMEN TO SWITCH TO (SECOND-LINE AND THIRD-LINE ART)

8.9.1. SECOND-LINE ARVS IN ADULTS, ADOLESCENTS, PREGNANT AND BREASTFEEDING WOMEN

RECOMMENDED 2nd line REGIMEN: 2 NRTIs +ATV/r

HIV-infected adults, adolescents, pregnant and breastfeeding women initiating 2nd line ART should be initiated on 2 NRTIs and ritonavir-boosted atazanavir (ATV/r). The choice of NRTI should be determined based on the regimen the patient was on (Table 55).

The recommended sequence is:

- After failing on TDF + 3TC or ABC+3TC based regimen, use AZT+3TC
- After failing on AZT+3TC based regimen, use TDF + 3TC

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).

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

LPV/r is should only be used to initiate adults, adolescents and pregnant women who weigh less than 40kg.

8.9.2. SECOND-LINE ARVS IN CHILDREN AGED 3 YEARS TO LESS THAN 10 YEARS

RECOMMENDED 2nd line REGIMEN: 2 NRTIs +LPV/r

HIV-infected children aged 3 to less than 10 years initiating 2nd line ART should be initiated on 2 NRTIs and ritonavir-boosted lopinavir (LPV/r). The recommended formulation is the LPV/r 100/25mg tablet.

The choice of NRTI should be determined based on the regimen the patient was on (see Table 55).

The recommended sequence of the NRTIs is below:

- After failing on ABC+3TC based regimen, use AZT+3TC.
- After failing on AZT+3TC based regimen, used ABC+3TC.

Rationale for using LPV/r:

Lopinavir boosted with ritonavir is the preferred protease inhibitor in children under 12 years. Whereas atazanavir can be used in children below 12 years, there is no optimal formulation.

WHEN TO USE ALTERNATIVE 2ND LINE REGIMEN: 2 NNRTIs + RAL

Raltegravir (RAL) is recommended in children who have used LPV/r in their first line regimen.

8.9.3. SECOND-LINE ARVS IN CHILDREN UNDER 3 YEARS

RECOMMENDED 2nd line REGIMEN: 2 NRTIs +RAL

HIV-infected children less than 3 years of age initiating 2nd line ART should be initiated on 2 NRTIs and RAL.

The choice of NRTI should be determined based on the regimen the patient was on (Table 55).

The recommended sequence of the NRTIs is:

- After failing on ABC+3TC based regimen, use AZT+3TC.
- After failing on AZT+3TC based regimen, used ABC+3TC.

The rationale for using raltegravir
Raltegravir is the recommended drug of choice for the second line ARVs in children with prior exposure to protease inhibitors because there is no data on safety and efficacy of dolutegravir in children under six years, while darunavir is contraindicated in this age group.

WHEN TO USE ALTERNATIVE 2ND LINE REGIMEN: 2 NRTIs + LPV/r
LPV/r is recommended in children who have used NNRTI (NVP) in their first line regimen.

8.9.4. THIRD-LINE ART REGIMENS

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

1. If they have two detectable viral load tests (VL >1000 copies/ml) 3 months apart.
2. The patient should have had three intensive adherence counseling sessions one month apart after the initial detectable viral load.
3. The patient has good adherence (>95%) as determined by adherence support team.
4. They have major resistance to PIs, as confirmed through resistance profiling.

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

- When a patient on second-line ART is confirmed to be failing ART, they should be referred to the nearest treatment center providing third line ART.
- Before anyone is switched onto third-line ART, they should have a resistance profiling test done to confirm PI resistance and to determine the most optimal treatment regimen.

Recommended third-line regimens for adults, adolescents, pregnant and breastfeeding women:

- The recommended third-line regimen will include boosted darunavir, an integrase inhibitor (INSTI) with an option of adding 2 NRTIs. The DRV/r would be 600mg twice daily, as compared to 800mg once daily in clients with no prior exposure to PIs.
- When patients have prior exposure to INSTIs, it is recommended that etravirine is included in the third-line regimen.
- The choice of NRTIs in the third-line regimen will be based on resistance profiling.

Recommended third-line regimens for children aged 3 years to under 10 years:

- The recommended third-line regimen for children below 6 years is ritonavir boosted darunavir, raltegravir and the option of adding 2 NRTIs. Etravirine is contraindicated in children below 6 years. In children above 6 years, etravirine or an integrase inhibitor (raltegravir) may be used.

Recommended third-line regimens for children under 3 years:

- For children under 3 years of age, regimen selection will be optimized based on resistance profiling.

Table 55: Second- and third-line ART regimens for patients failing on treatment

Population	Patients failing first-line regimens	Second-line regimens	Third-line regimens[1]
Adults, pregnant and breastfeeding women and adolescents	TDF + 3TC + EFV	AZT+3TC+ATV/r (recommended) or AZT+3TC+LPV/r (alternative)	All 3rd line regimens to be guided by resistance testing If patient is not exposed to INSTIs, DRV/r +DTG ± 1-2 NRTIs If patient is exposed to INSTIs, DRV/r + ETV±1-2 NRTIs
	TDF + 3TC + DTG		
	ABC+ 3TC+ DTG		
	ABC+ 3TC+ EFV		
	ABC/3TC/NVP		
	TDF/3TC/NVP		
	AZT/3TC/NVP	TDF+3TC+ATV/r (recommended) or TDF+3TC+LPV/r	
	AZT/3TC/EFV		
Children 3–<10 years	ABC + 3TC + EFV	AZT+3TC+LPV/r	For children above 6 years, and prior exposure to INSTIs, DRV/r±1-2 NRTIs
	ABC+ 3TC + NVP		
	AZT+3TC+NVP	ABC+3TC+LPV/r	For children below 6 years, DRV/r+ RAL+ 2 NRTIs
	AZT/3TC/EFV		
	AZT+3TC+LPV/r	ABC+3TC+RAL	Optimize regimen using genotype profile plus DRV/r + 2 NRTIs
	ABC/3TC/LPV/r	AZT+3TC+RAL	
Children under 3 years	ABC+3TC+LPV/r pellets	AZT+3TC+RAL	Optimize regimen using genotype profile
	AZT+3TC+LPV/r pellets	ABC+3TC+RAL	
	AZT+3TC+NVP	ABC+3TC+LPV/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 600/100mg taken twice a day.			

9. SERVICE DELIVERY

This chapter will discuss differentiated service delivery, retention on ART, HIV service delivery to adolescents, and continuous quality improvement.

9.1. DIFFERENTIATED SERVICE DELIVERY (DSD)

9.1.1. INTRODUCTION

To achieve the UNAIDS 90–90–90 targets, Uganda has adopted innovative and efficient strategies to delivering HIV and TB prevention, care, and treatment services and address the needs of different sub-populations of clients under HIV care. These programmatic adaptations are called "differentiated HIV and TB service delivery models." This section presents the recommended differentiated care models for HIV testing services and care and treatment for PLHIV and TB for adoption by the facilities and communities managing PLHIV. The details on how the differentiated care models will be implemented in Uganda are described in the DSD operation guidelines.

9.1.2. CORE PRINCIPLES OF DIFFERENTIATED SERVICE DELIVERY

The core principles of differentiated care are client-centered and improved health system efficiency. These acknowledge specific barriers identified by clients and empower them to manage their disease with the support of the health system. Under the differentiated service delivery model, health systems will shift away from a "one-size-fits-all" model to focus on clients who are most in need.

9.1.3. 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.

9.1.4. THE TARGET GROUPS FOR DIFFERENTIATED SERVICE DELIVERY

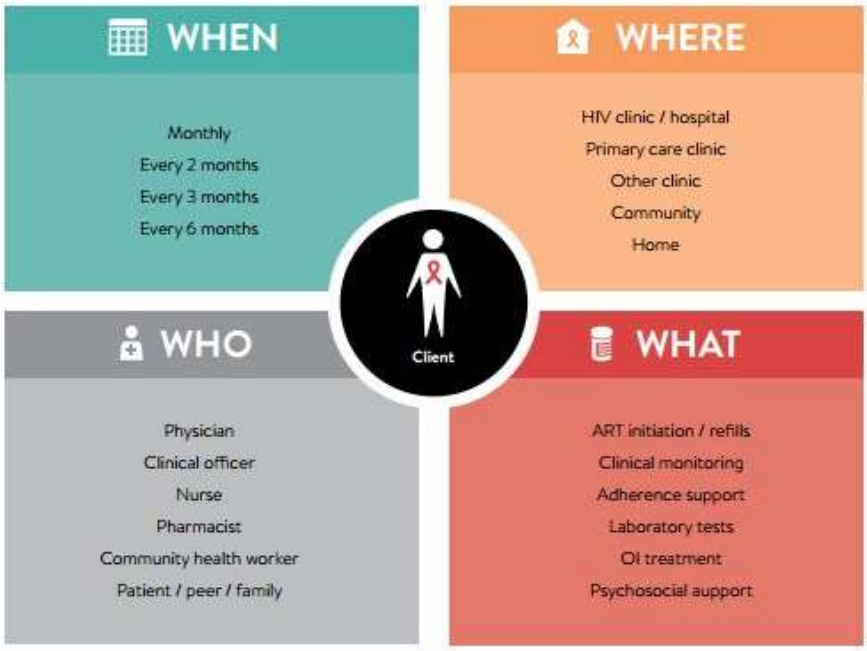
The DSDM will meet the different care and treatment needs of different groups of clients including stable clients, clients newly initiating ART, children, adolescents, pregnant and breastfeeding women, patients suspected of failing ART, and those with concurrent illness/ co-morbidities such as TB.

9.1.5. 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 16 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 16: The building blocks for differentiated service delivery



9.1.6. RECOMMENDED DIFFERENTIATED SERVICES

The two services for adopting differentiated models are:

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

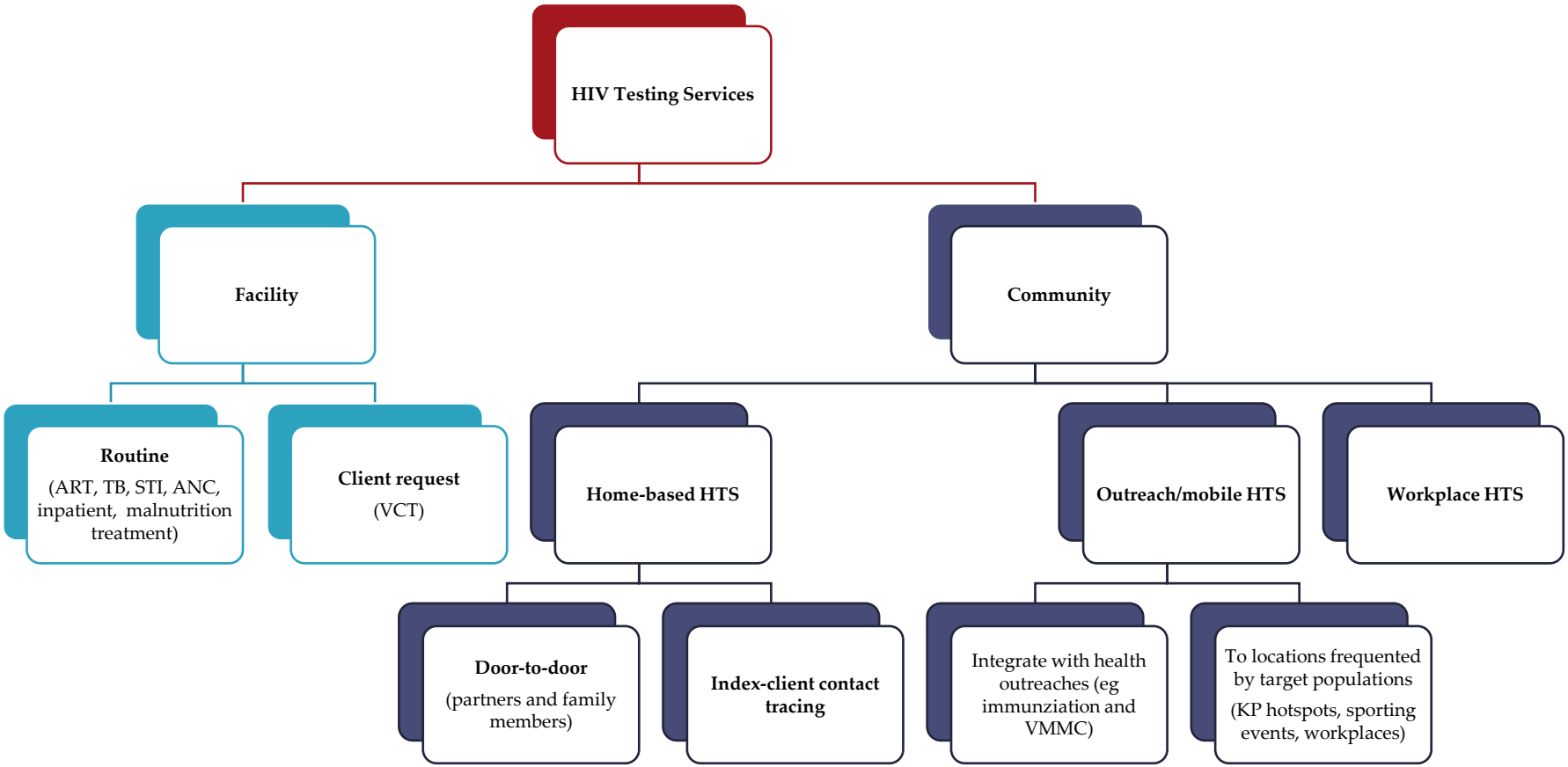
9.1.6.1. Differentiated HIV testing services

HIV testing services (HTS) serve as the entry point to HIV prevention, care, treatment and support services and are critical to the achievement of the 90-90-90 goals. It is estimated that only 65% of PLHIV in Uganda are aware of their HIV status against the goal of 90% of PLHIV identified and linked to care and treatment. Differentiated HTS will facilitate early diagnosis of as many people as possible aiming to maximize yield, efficiency, cost-effectiveness and equity.

HTS services will be offered in the facility (facility-based HTS model) or in the community (community-based HTS model) (Figure 17).

- Facility-based HTS shall include provider-initiated and client-initiated testing and counseling.
- Community-based HTS shall include home based HTS, outreach/mobile HTS, and workplace HTS.

Figure 17: Recommended differentiated HIV testing services delivery models and the respective target populations.



9.1.6.2. Differentiated care and treatment services

The current care and treatment models require PLHIV to have multiple clinic visits leading to high travel costs, overcrowding and long waiting times at health facilities; yet over 60% of patients in Uganda are considered stable on treatment. Furthermore, health workers and the entire health system are overwhelmed with the huge number of clients with increasingly diverse needs. Differentiated care and treatment will involve modifications of client flow, schedules, and location of services thus resulting in improved access, coverage, and quality of care. While stable clients will be reviewed and have the ARVs refills every three months, complex/unstable (newly initiated/new naïve clients) shall be seen at the facilities monthly for the first three months, then at six months, nine months and 12 months. Preparations of these clients for DSD shall commence at the ninth month visit.

The DSD approach better reaches the needs of PLHIV and often results in increased levels of adherence, client satisfaction, and client empowerment.

The recommended differentiated HIV care and treatment models for PLHIV include facility-based models and community-based models (Figure 18).

- Three delivery approaches are recommended for the facility based model:
    - Fast-track drug pickup approach for stable* clients picking their drugs quarterly.
    - Comprehensive clinical evaluation for all stable adult clients, complex/unstable** clients, children, adolescents, eMTCT ANC, eMTCT mother-baby pairs, and key populations due for their clinical evaluation and any other related services.
    - Facility-based treatment clubs/health care managed groups for drug refills within their groups/clubs, adherence support, peer support and psychosocial support. The target group for this approach includes stable clients, adolescents, and eMTCT mothers in ANC and eMTCT mother-baby pairs as well as key populations.

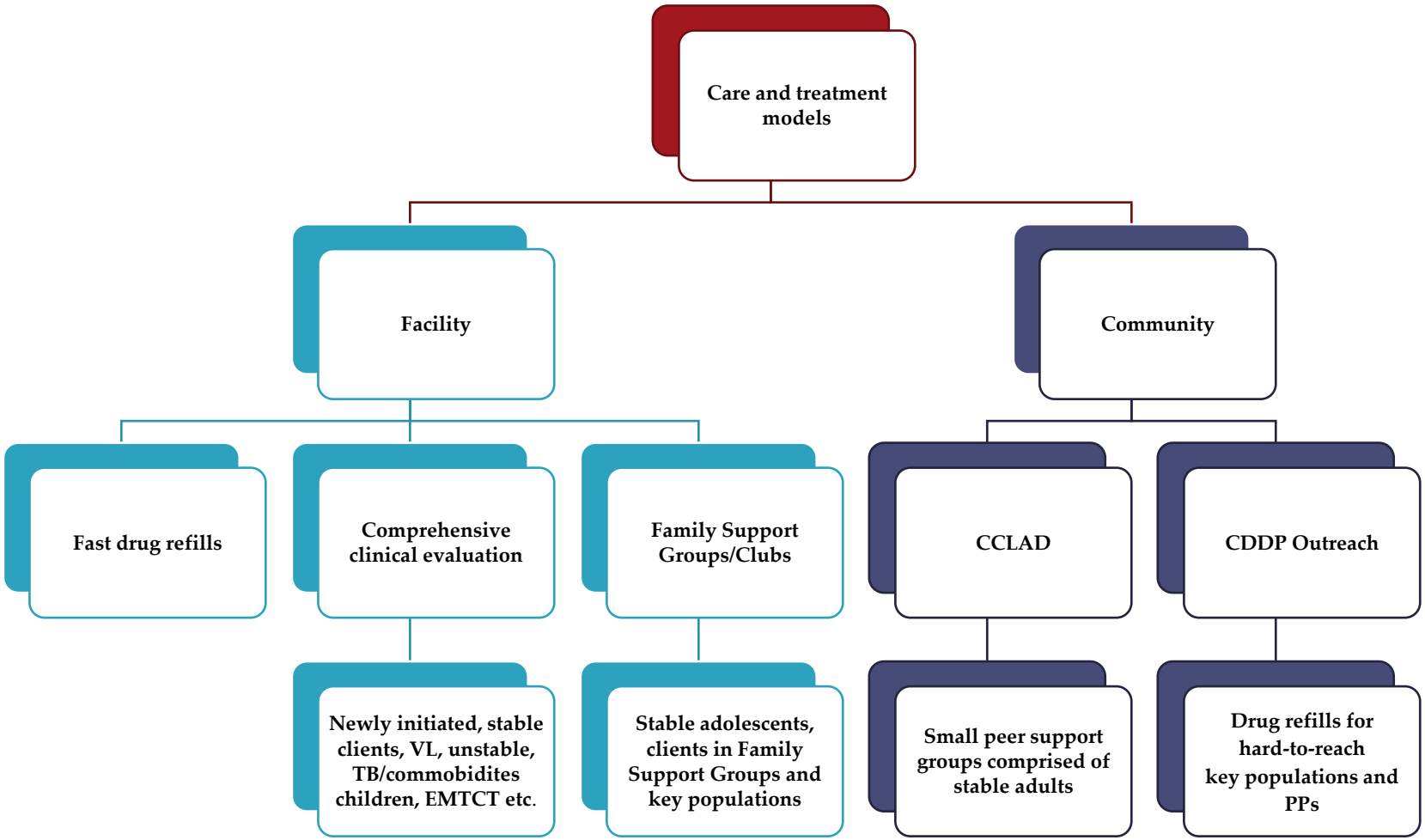
- Two delivery approaches are recommended for the community-based model:
    - Community drug distribution points (CDDPs), community outreaches by HCW targeting clients in remote areas with poor accessibility to health facilities for ART (islands, landing sites, pastoral areas, districts with many HCIIs that are not accredited to offer ART and are far from ART sites, etc.).
    - Community client-led ART delivery (CCLAD) that targets patients who are stable on ART, who shall be guided by the health care workers in the facilities where they are receiving their ARVs to form peer support groups comprising six members each.

9.1.7. CATEGORIZATION OF THE CLIENT CHARACTERISTICS FOR DIFFERENTIATED SERVICE DELIVERY

*__Stable client:__ *Adults and adolescents on ART for more than 12 months, virally suppressed with no concurrent illness or co-morbidity and demonstrated good adherence.*

**__Complex/unstable clients__ *include children, pregnant women, non-virally suppressed adults, clients with co-morbidities.*

Figure 18: Recommended differentiated care and treatment service delivery models and their respective target populations



9.1.8. MONITORING AND EVALUATION

All stakeholders (policy makers, program managers, RPMTs, DHTs, health facility in-charges, caregivers, health workers, community leaders and CBOs) working with PLHIV shall monitor key indicators to measure the progress of DSD implementation (rollout and functionality) and PLHIV outcomes both in the health facilities and in the community. Various levels of health care should analyze and compare the baseline value (before implementation of differentiated approaches) with the actual value when the approach has been used for a defined amount of time. Health facilities and communities should also track the outcomes and costs of delivering differentiated services. Refer to the DSD operational guidelines and the monitoring and evaluation (M&E) framework for details for DSD M&E aspects.

9.1.9. CONTINUOUS QUALITY IMPROVEMENT (CQI) DURING IMPLEMENTATION OF DSD

It is critical to maintain the quality of services as sites implement the differentiated service delivery models of care. The standard of care for differentiated HIV service delivery will be in line with recommendations for different sub-populations, i.e. HIV-positive pregnant and lactating women, their HEIs and male partners, children, adolescents and adults LHIV as per national HTS, care and treatment guidelines and policies. A continuous quality improvement approach shall be used to integrate DSD into routine client management both at health facilities and communities. Health facilities should do the following:

- Ensure functional QI committees and teams
- Implement QI projects and innovations to improve service delivery
- Document innovative outcomes through documentation journals
- Hold peer learning meetings to share and spread innovations

The detailed list of CQI indicators that will be tracked to monitor successful implementation can be accessed in the DSD operational guidelines and the M&E framework.

9.1.10. COMMUNICATING DSD

Effective communication is key for successful implementation of DSD. All stakeholders (policy makers, program managers, caregivers, health workers, PLHIV, and community leaders) should be empowered to communicate DSD effectively. This shall encourage PLHIV to access, utilize and adhere to care, treatment and support services. The DSD communication guidelines highlight target audience, key messages, methods of delivery and required resources. Refer to the DSD operational guidelines for details.

9.1.11. HUMAN RESOURCE REQUIREMENTS

Provision of HIV prevention, care and treatment services requires a multi-disciplinary team of health care providers at the different levels of service delivery. Task-shifting or task-sharing, including strengthening the community systems (role clarification, assignment, and supervision) shall be supplemented by mentorship and continuous quality improvement. Guidelines, job aides, and SOPs shall be provided to support consistent quality of service. The major roles of each team member are described in Annex 8.

9.1.12. GUIDANCE ON HOW TO IMPLEMENT DSD

The success of DSD implementation is highly dependent on adequate training, mentorship and supervision of both the health workers and community service providers i.e. the community ART support agents (CASA). Site teams shall be trained on DSD in preparation for the phased introduction. High volume sites that are ready, based on the outcome of the site assessment, will be the first to be trained. The training for HCWs will detail the recommended DSD models and guide them on how to use their site data to categorize their patients on which models can be offered and where, as well as support clients to select the models that work best for them within the available options. The community service providers shall also undergo a simplified training on how to manage the community ART groups including basic information about ART, counseling and psychosocial support and monitoring and reporting

During and after the training, the HCWs are expected to define their plan, assess resource needs for introducing DSD, understand client group needs and barriers, and plan how to initiate and monitor DSD implementation within their facilities and the catchment communities. They will continue to utilize these data to switch clients from one model to the other depending on eligibility e.g. their viral suppression, adherence status, pregnancy, development of OIs, clients' choices, etc.

A mentorship tool based on the CQI approach shall be developed to support the national roll out. During mentorship, the team shall monitor the use of CQI approach in the routine implementation of differentiated care.

9.2. 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 56.

Table 56: Strategies for improving retention in care

Strategy	Rationale
1. **Decentralization of ART care and laboratory services** • 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.	Decentralization improves retention by: • Taking services closer to the target population, lowering transport costs for patients, and thereby increasing the likelihood to 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 see 9.1 and 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	Improving patient education and

Strategy	Rationale
strategy The country will use a communication strategy that will address individual, interpersonal, organization, community and society barriers to retention in care.	addressing barriers will improve health seeking behaviours.

9.3. DELIVERING HIV SERVICES FOR ADOLESCENTS

9.3.1. 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 and treatment services and improve the health outcomes of adolescents, health care providers need to provide adolescent-friendly health services (AFHS). AFHS services are visible, flexible, affordable, confidential, culturally appropriate and universally available. The following unique considerations apply to adolescents, and they do not stand alone. Health workers are encouraged to combine these with the general prevention, care and treatment services for adults.

Service	Guidance
Service Delivery The services offered should be **adolescent-friendly** so that they can meet the particular needs of this age group.	The HIV service delivery approach 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. To provide AFHS the health facility should: • Integrate adolescent health services into the already existing delivery systems making it 'a one-stop shopping center'. • Use a peer-led approach to delivering services. • Provide services for all adolescents regardless of their HIV status. • Dedicate time and a convenient place with privacy. <u>Service location</u> Identify a convenient, comfortable, private and accessible place/area with a separate waiting area to offer adolescent services. Have a separate adolescent clinic day or specially designated space. <u>Working hours</u> Have flexible clinic hours that take care of both in-school and out of school adolescents including clinic runs until late, after 5 pm and/ or over weekends. <u>Dedicated Staff</u> • Designate a health worker to be an adolescent focal person. • Health workers providing adolescent services need to be trained in adolescent health and HIV management. • Use job aides developed for adolescent service delivery during service

	provision. • Identify, train, and use peers to support the provision of services. • ***Ensure the clinic has the following cadre of staff; clinicians, counselors, nurses, and peers*** <u>Service provision</u> • Offer free or affordable services to adolescents. • Offer services in line with the standard minimum care package for adolescents. • Use the existing standard MOH referral system for services not provided. • Track and follow-up adolescents using the standard loss to follow-up protocol. • Health workers should work with adolescents to set up peer support groups for the different age categories. • Share available hotlines where the adolescents can access information or counseling off-site. • ***Pregnant adolescents should be encouraged to attend ANC with older mothers and come back to the adolescent clinic after birth till they get to age of transition*** • <u>Educational activities</u> • Provide educational/information materials in the form of posters and brochures in a language best understood by the adolescents.
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 Take into account 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 • 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)
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.
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. • Use feedback loop mechanism.
Psychosocial support for adolescents	All HIV tested 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 9). Key elements of psychosocial support include disclosure and ART support.
	Disclosure • Disclose to an adolescent their HIV status at the time of diagnosis or the earliest opportunity thereafter. • Encourage them to disclose their HIV status to their parent/guardian and significant others. • The readiness for disclosure to others should be determined by the

	adolescent in consultation with the caregiver and the health care provider. • Adolescents and young people need a lot of support from health providers, peers, and the community to disclose safely and confidently and to be able to cope with any negative reactions from family and friends. • Counsel about the potential benefits and risks of disclosure of their HIV status to others. Benefits of early disclosure include: • 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 Risks of disclosing: physical harm, discrimination, stigma, unwilling onward disclosure and isolation may be experienced as a result of disclosing HIV status to others. Reasons for delayed or non-disclosure: stigma, shame, and fear. • Discuss how to disclose using role play and support them to determine if, when, how and to whom to disclose their HIV status. • A health care provider or peer should be available to support with the disclosure. • Parents and guardians should also be encouraged and supported to disclose their status to their adolescents.
	Adherence to ART In addition to the general guidelines for adherence to ART, use the HEADSS assessment tool to assess factors influencing adherence among adolescents.
	Assess for GBV and refer as appropriate.
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.	• 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.
Transition Purposeful and planned transition to adult-oriented services is an	The transition should depend on the service delivery approach at each health facility. Transitioning should take into account the neurocognitive condition of the adolescent. In settings where there is an integrated clinic providing services for

important factor in the long-term well-being of an adolescent.	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.

9.4. INTEGRATING CONTINUOUS QUALITY IMPROVEMENT INTO HIV CARE SERVICES

9.4.1. 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 target. 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 5Ss (Sort, Set, Shine, Standardize, Sustain) and CQI methodologies while implementing quality improvement.

The health sector quality improvement framework clearly spells out quality improvement roles 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.

9.4.2. 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 57 below 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 57: 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. • The will use the CQI approach through applying the principles of an interactive 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 performance to set targets.

Step	Description
4. Prioritizing improvement gaps	• Use a prioritization matrix to list and score the gaps using set criteria. • Based on the ranking, WIT should select the gaps to address **in a specified time.**
5. 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. • Use QI tools such as brainstorming, flow charting, five whys, cause and effect analysis or driver diagrams, to identify the root causes of the performance gaps. • Brainstorm possible changes that the team will test to address the identified root causes using a PDSA cycle. • Document the data from the data review process 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.

9.4.3. MONITORING OF CQI IMPLEMENTATION

- Work improvement teams working on a particular improvement aim 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)

10. PROCUREMENT AND SUPPLY CHAIN MANAGEMENT SYSTEMS

10.1. 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.

10.2. 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 Section 8).
- 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, cotrimoxazole, dapsone, HIV test kits, fluconazole and other laboratory diagnostics.

10.3. PRODUCT QUANTIFICATION/ORDERING AND REPORTING

10.3.1. QUANTIFICATION AND FORECASTING

All facilities are required to estimate the amounts of HIV commodities required for all existing and anticipated new patients. Patient numbers and consumption information should be analyzed and used for decision making.

10.3.2. ORDERING OF ARVS

- Ordering and reporting of medicines 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 supplies of medicines in the facility.
- Facilities should order for medicines on a bi-monthly basis following schedules provided by their central warehouse.
- 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 has revised all logistics management information system (LMIS) tools to accommodate changes in the 2016 treatment guidelines. Health facilities should obtain copies of updated LMIS from the warehouses.

10.3.3. SOURCES OF ARV MEDICINES IN UGANDA

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, Joint Medical Stores, and Medical Access Uganda Limited. Newly accredited facilities should refer to the accreditation letter for information on warehouse allocation.

10.3.4. 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.
- 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

10.3.5. 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.

10.4. STOCK REDISTRIBUTION

When there is a risk of expiries or medicines stock out, health facilities should establish contacts with neighbouring facilities and/or implementing partners and regional central warehouse focal contact sites to facilitate the stock transfer. The stock should be redistributed in line with the *Ministry of Health Commodity Redistribution Strategy, 2012*. It is important to note that all HIV commodities are free of charge and that transfer to another facility does not lead to financial loss.

10.5. 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.

10.5.1. PRINCIPLES OF RATIONAL MEDICINES USE

10.5.1.1. Rational prescribing

Health care 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

10.5.1.2. Rational dispensing

Health care 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.

10.5.1.3. Distribution of medicines to patients

Health care workers should do the following while distributing ARV medicines:

- Ensure medicine shelf life is long enough.
- Issue 3 month of stock to stable patients.
- Supply medicine to new patients for a duration determined by the clinician.
- Appropriately record all medicines issued.

10.6. 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. 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 stock check and physical counts should be done.

10.7. PHARMACOVIGILANCE

It is important for patients to report any adverse drug effects to the health facility staff. The data needs to be captured and relayed to NDA and central warehouses for investigation and follow-up.

11. MONITORING AND EVALUATION

11.1. 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. The purpose of this chapter is to guide how to monitor implementation of the revised guidelines and program performance, and to provide a framework for assessing the impact of the guidelines. This chapter is aligned to the guidance contained in the *National HIV and AIDS Strategic Plan 2015/2016–2019/2020* and *National HIV and AIDS Monitoring and Evaluation Plan 2015/2016–2019/2020.*

11.2. OVERVIEW OF PATIENT MONITORING SYSTEM

The current patient monitoring system uses paper-based tools and an electronic medical records system. These systems should be used in tandem at the facility. However, the primary data collection method at facilities is the paper-based system. Several tools are used for paper based monitoring, which are detailed in the *Ministry of Health HMIS Manual, 2014*. Paper-based records are used to update electronic medical record systems where they exist. The recommended electronic medical records system is OpenMRS.

11.3. 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 58 below shows the different reports and frequency of submission.

Table 58: Routine reports and their frequency

Report	Description	Source documents	Frequency	Recipient
HMIS 106A: Health Unit Quarterly Report	Reports the quarterly attendance figures for HIV care/ART, ART outcomes, nutrition, and TB services	Pre-ART Register, ART Register, PEP Register, EID Register, TB Register	Quarterly	DHIS-2
HMIS 105: Health Unit Outpatient Monthly Report	Reports the monthly attendance figures for OPD, OPD diagnoses, MCH, HIV/AIDS service data, 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	DHIS-2
HMIS 102: Report Form for HIV-Exposed Infant at 24 months				DHIS-2
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	Health sub-district HQ and DHO
eMTCT SMS reports			Weekly	
eMTCT Early Retention Monitoring Report			Monthly	
HIV Drug Resistance Report			Annual	

Facility ARV stock and orders shall be monitored via the Web-Based ARV Ordering System (WAOS).

11.3.1. OTHER DATA SOURCES

The following sources complement the data generated from HMIS:

- Surveillance data from AIDS Indicator Survey, the 2016-17 UPHIA survey, ANC sentinel surveillance, HIV case-based surveillance
- Longitudinal and evaluation studies
- HIV estimates from mathematic modeling

11.4. INDICATORS FOR ROUTINE MONITORING

Indicators for routine monitoring have been updated and can be found in the *National HIV and AIDS Monitoring and Evaluation Plan 2015/2016–2019/2020.*

11.4.1. NEW CONSIDERATIONS FOR ROUTINE MONITORING

The indicators from the following programmatic areas identified in the revised guidelines will be incorporated into the M&E framework and monitoring and reporting tools:

- Differentiated service delivery models, especially the community models
- Viral load monitoring
- Pre-exposure prophylaxis

- Mental health

11.4.2. HIV DRUG RESISTANCE MONITORING

HIV drug resistance has been previously monitored using early warning indicators mainly through surveys. It is now recommended that these indicators should be integrated into the routine data collection and quarterly reports for program monitoring.

11.5. ROUTINE SUPERVISION AND DATA AUDITING

All program areas should institutionalize M&E support, supervision and routine data quality assessments. This is to ensure adherence standards and data quality.

11.6. DATA USE

The information generated from the M&E system shall be disseminated promptly and shall guide decision making.

11.7. RESEARCH AND EVALUATION

The program will continue to conduct the following research studies to inform the disease burden and evaluate the impact of programs:

- Uganda Population HIV Impact Assessment
- ANC sentinel surveillance
- HIV case-based surveillance
- Modes of transmission study

We also recommend programs and academia to conduct implementation science research especially in the area of differentiated service delivery and other relevant areas. The research should be conducted in line with the *National HIV and AIDS Monitoring and Evaluation Plan 2015/2016–2019/2020.*

Annex 1: HIV-exposed infants visit schedule and care package

Visit schedule	Birth	6 wks	10 wks	14 wks	5 mo	6 mo	9 mo	12 mo	15 mo	18 mo	24 mo
Immunization	X	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 6 weeks 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 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 OpenMRS/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 2: 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 one month 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 3: 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; (oro 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 4: 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

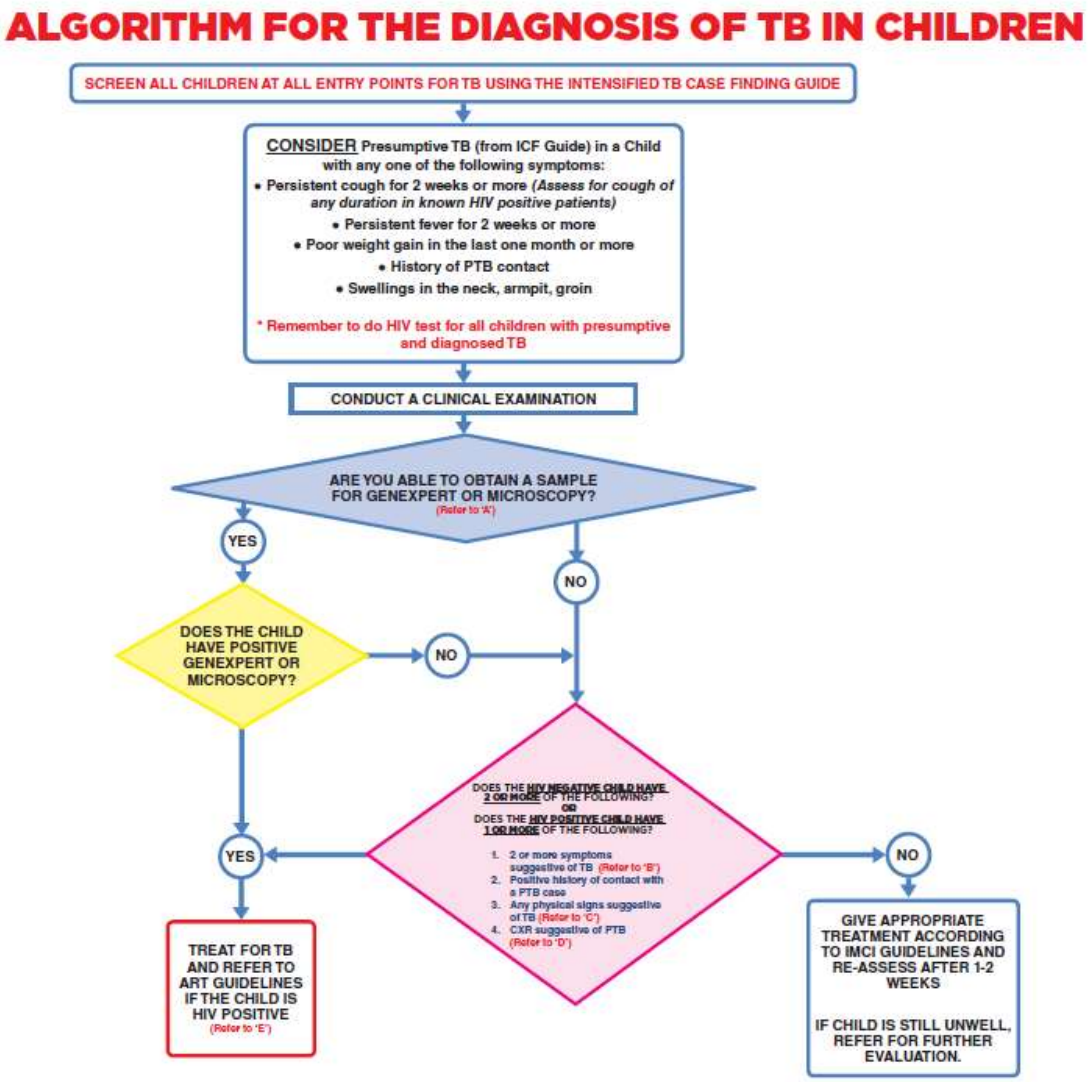
**For Children who are unable to produce sputum, refer to clinician for further investigations*

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.

JULY 2013 EDITION

Annex 5: 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

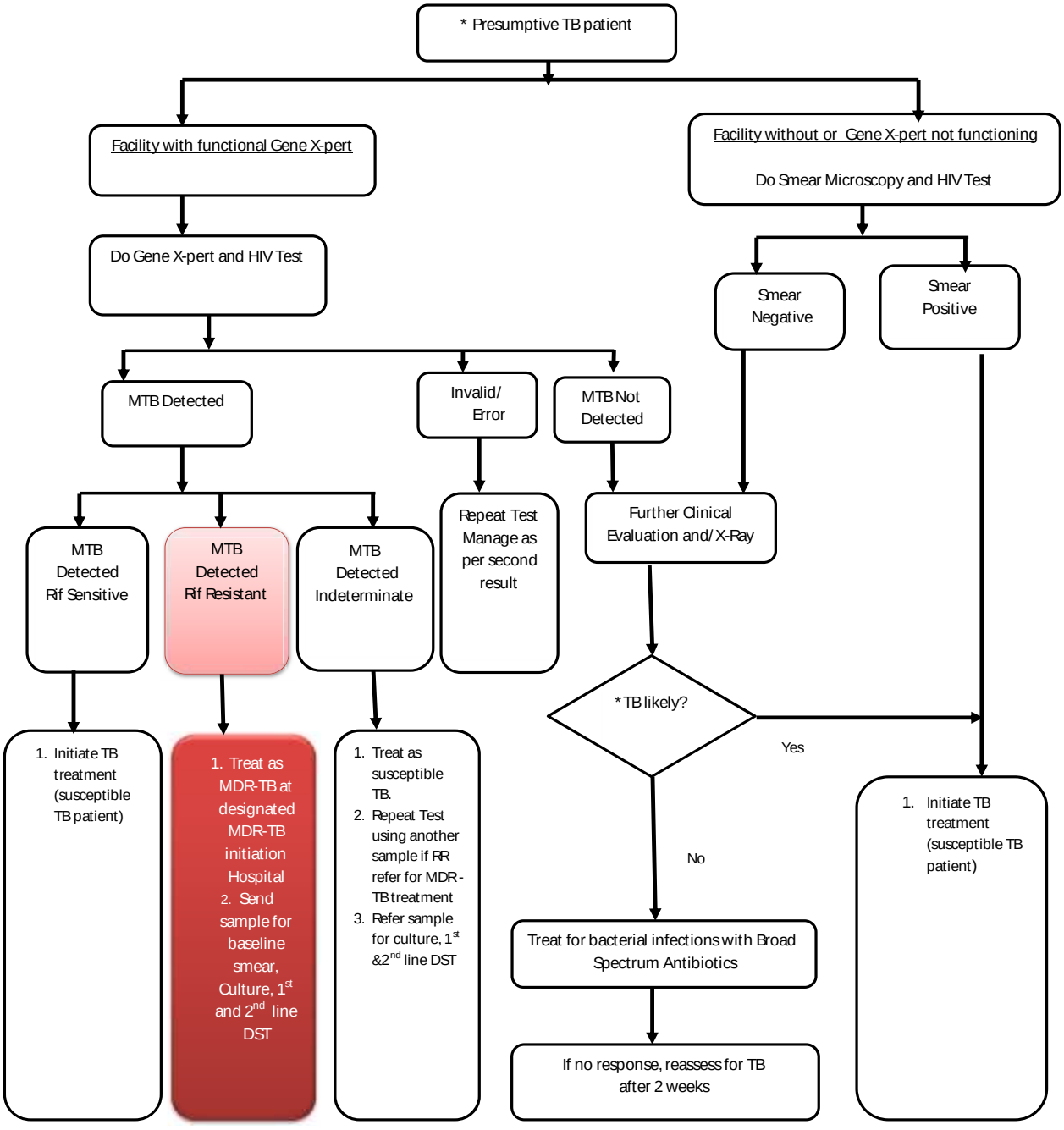
C PHYSICAL SIGNS SUGGESTIVE OF TB

- 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

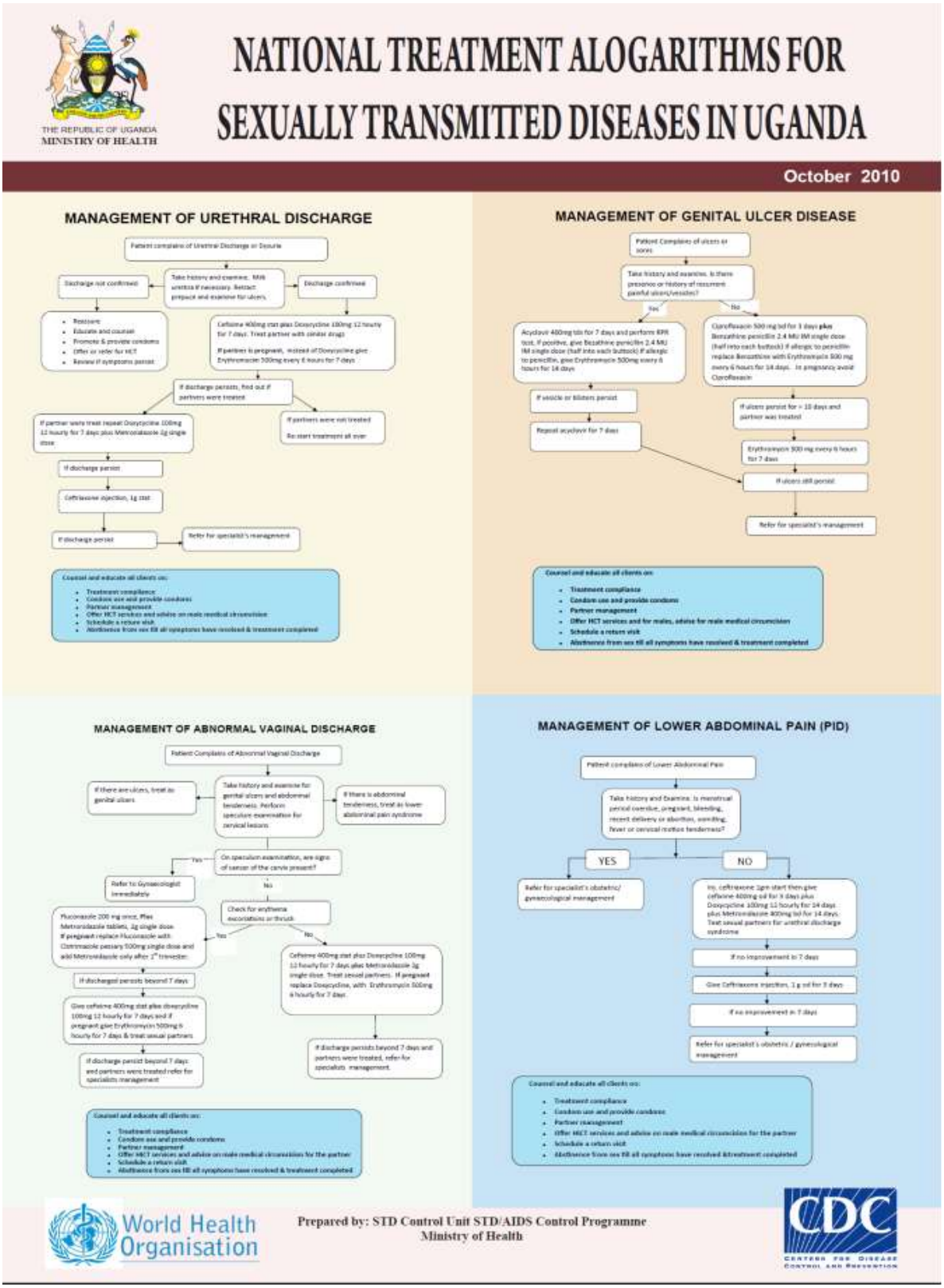
Annex 6: Algorithm for TB diagnosis in adults and adolescents

NATIONAL TB AND LEPROSY CONTROL PROGRAM
ALGORITHM FOR DIAGNOSIS AND MANAGEMENT OF TUBERCULOSIS



1. *Presumptive TB is presence of any or a combination of the following symptoms; cough≥ 2weeks or current cough if high risk patient (PLHIV, previously treated TB patients, prisoners, contacts of TB patients, diabetic patients, health workers, mining populations), Fever, Night sweats, history of contact with a TB case, Weight loss or poor weight gain for children.
2. Smear positive (AFB pos): is defined as at least one positive smear
3. Smear negative: defined as two negative smears. if patient is from high risk category in asterix one above, sample should be referred for GeneXpert test
4. HIV positive patients: Presumptive or diagnosed TB patients who are HIV positive should be offered comprehensive HIV care services. Those in whom TB has been excluded should be offered IPT as per IPT guidelines. HIV positive adults in whom TB is not picked by microscopy or GeneXpert and are very sick (CD4 less than 100) should be tested for TB using Urine TB LAM test
5. Treatment monitoring; Follow up sputum smear microscopy is done at the end of 2, 5 & 6 months for susceptible TB and monthly smear and culture for DR-TB.
6. Recording & Reporting: All diagnosed TB patients (resistant, sensitive, and indeterminate) record in the Unit TB register and included in facility quarterly(HMIS 106a) notification report and all rifampicin resistant(RR) TB patients should be notified in the weekly (HMIS 033b)report by the facility that refer the sample for Gene Xpert test. In addition record RR TB patients in the district line list and the Drug resistant TB register at the treatment initiation facility.

Annex 7: Treatment algorithms for sexually transmitted diseases in Uganda



Annex 8: Human resources for differentiated service delivery and their roles

	Doctor and clinical officers	Nurses	Midwives	Trained nursing assistants	Pharmacists/ pharmacy technicians/ dispensers/ nurses/ storekeepers	Laboratory technicians/ laboratory assistants	Lay providers, CDOs, CBOs and CSOs working with PLHIV VHT	Health information assistants/data clerks
Comprehensive clinical services including, including NACS, symptom screening for NCDs, TB, STIs and hepatitis	X	X	X					
Prescription of ART, initiation, and follow-up of adults and children	X	X	X					
Switching and substituting ART regimens	X							
Management of complicated case (e.g. cryptococcal meningitis second-line failure treatment failure, etc.)	X							
Initiation of TB medications for smear or X-pert positive adults and children	X	X						
TB- treatment initiation for adults requiring CXR interpretation and children where no sputum is available	X							
HIV testing services	X	X	X	X	X	X	X	X
Health education	X	X	X	X			X	
Registration and filling of appointment diaries		X	X	X	X	X		
Performing vital signs (triage)	X	X	X	X				
DBS and VL sample collecting, testing and results delivery	X	X	X	X		X	X	
Coordinating and supervising community groups	X	X	X	X				
Linkage facilitation	X	X	X	X			X	

	Doctor and clinical officers	Nurses	Midwives	Trained nursing assistants	Pharmacists/ pharmacy technicians/ dispensers/ nurses/ storekeepers	Laboratory technicians/ laboratory assistants	Lay providers, CDOs, CBOs and CSOs working with PLHIV VHT	Health information assistants/data clerks
Pre-packing medicines, picking drug refills, distributing refills, forecasting and ordering of commodities from the warehouses, dispensing medications, filling/updating the dispensing log and track tools		x	x	x*			x*	x*
ART preparation and adherence counseling for adults, children, and pregnant women including treatment failure	x	x	x	x		x	x	x
Defaulter tracing		x	x	x		x	x	x
Client records management/data entry and updating registers (for area of service)		x	x	x		x	x	x
Phlebotomy	x	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

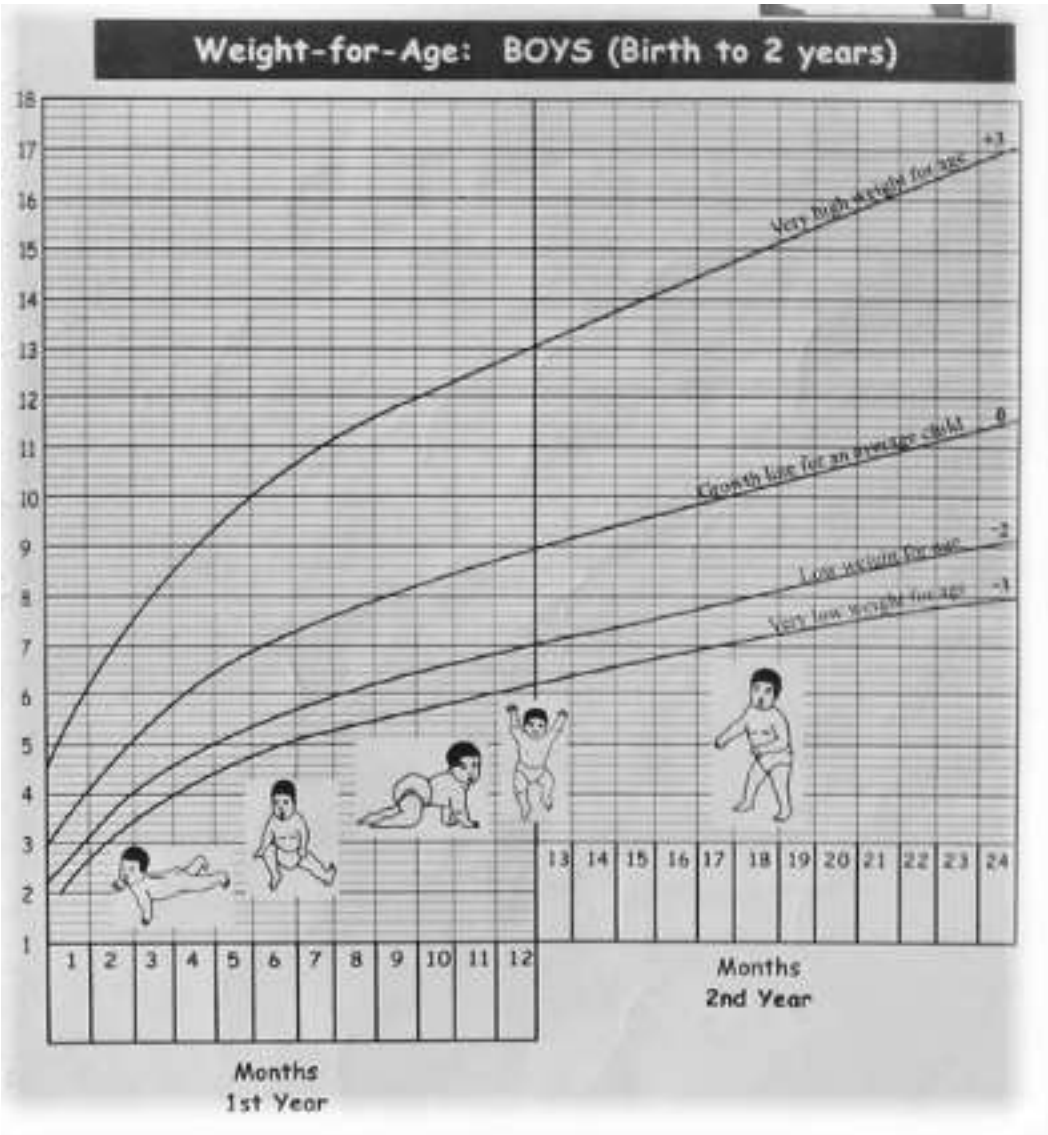
***Lay clients include; expert clients, VHTs, CHEWS, and mentor mothers*

Annex 9: 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 a home 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? • Does the young person have a car, 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 they paid 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 the interview, avoidance of eye contact--depression posturing • Preoccupation with death (clothing, media, music, art)	

Annex 10: Child health card



Annex 11: ARV dosing table

Formulation	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
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
DTG 50mg	-	-	-	-	-	-	-	-	-	-	-	-	–	1
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 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	-	-	-	-

[1] For children≥10kg that are able to swallow tablets, give LPV/r 100/25mg tablet

[2] 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

Formulation	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
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 And RTV 0.5ml	3 And RTV 0.5ml	5 And RTV 50mg	5 And RTV 50mg	5 And RTV 50mg	5 And RTV 50mg	-	-	-	-
DRV 600mg[4]	-	-	-	-	-	-	-	-	-	-	1 And RTV 100mg	1 And RTV 100mg	1 And RTV 100mg	1 And RTV 100mg
RTV 25mg	-	-	-	-	-	-	2	2	2	2	3	3	-	-
RTV 100mg	-	-	-	-	-	-	-	-	-	-	-	-	1	1
ETV 200mg	-	-	-	-	-	-	-	-	-	-	-	-	1	1
SQV 500mg[5]	-	-	-	-	-	-	-	-	-	-	-	-	2 And RTV 100mg	2 And RTV 100mg
DRV 600mg	-	-	-	-	-	-	-	-	-	-	1 And RTV 100mg	1 And RTV 100mg	1 And RTV 100mg	1 And RTV 100mg

[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.