THE REPUBLIC OF UGANDA

Ministry of Health

CONSOLIDATED GUIDELINES FOR PREVENTION AND TREATMENT OF HIV IN UGANDA

November 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 Healthcare 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
Ag. Director General Health Services

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ACP please advise who should sign acknowledgement

ABBREVIATIONS AND ACRONYMS

3TC Lamivudine

ABC Abacavir

ACTs- Artemisinin based combination therapies

AFHS Adolescent friendly health services

AFP Alpha feto protein

AIDS Acquired Immune Deficiency Syndrome

ALT Alanine Amino-transferase

ANC Antenatal care

ARM Artificial rapture of membranes

ART Antiretroviral therapy

ARV Anti-retroviral

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 Exclusively breastfeed

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

H Isoniazid

HBeAg 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

IGA's Income generating activities.

IMNCI Integrated maternal, newborn and Childhood illnesses

IPD Inpatient Department

IPT Intermittent preventing treatment

IRIS Immune reconstitution inflammatory syndrome

IRS Indoor residual spraying

ITC In-patient therapeutic center

ITN's Insecticide-treated nets

IUD Intrauterine device

IYCF Infant and young child feeding

KP Key populations

LFT's Liver function test

LMIS Laboratory Management Information system

LP Lumbar puncture

LPV/r Lopinavir/ritonavir

MAM Moderate Acute Malnutrition

MCH Maternal child health

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 Nucleoside reverse transcriptase Inhibitor

NRTI Nucleoside reverse transcriptase inhibitors

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 Post-natal care

PrEP Pre-exposure prophylaxis

PTT Prothrombin time

PWD's Persons with disabilities

QI Quality improvement

R Rifampicin

RAL Raltegravir

RFT's Renal function tests

RH Reproductive health

RUTF Ready to Use Therapeutic Feeds

SAM Severe acute malnutrition

SBBC Socio- behavioral change communication

SFP Supplementary feeding programs

SMC Safe male circumcision

SP Sulfamethoxazole-Pyrimethamine

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

Uganda has implemented the test and treat policy for all children, pregnant and breastfeeding women, HIV and TB or Hepatitis B co-infected people and the HIV-infected partner in a serodiscordant relationship 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 or clinical staging. These guidelines also recommend pre-exposure prophylaxis to key population, and a newer class of ARV drugs as an option for a first-line treatment option 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;

- Guidance on 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 and 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

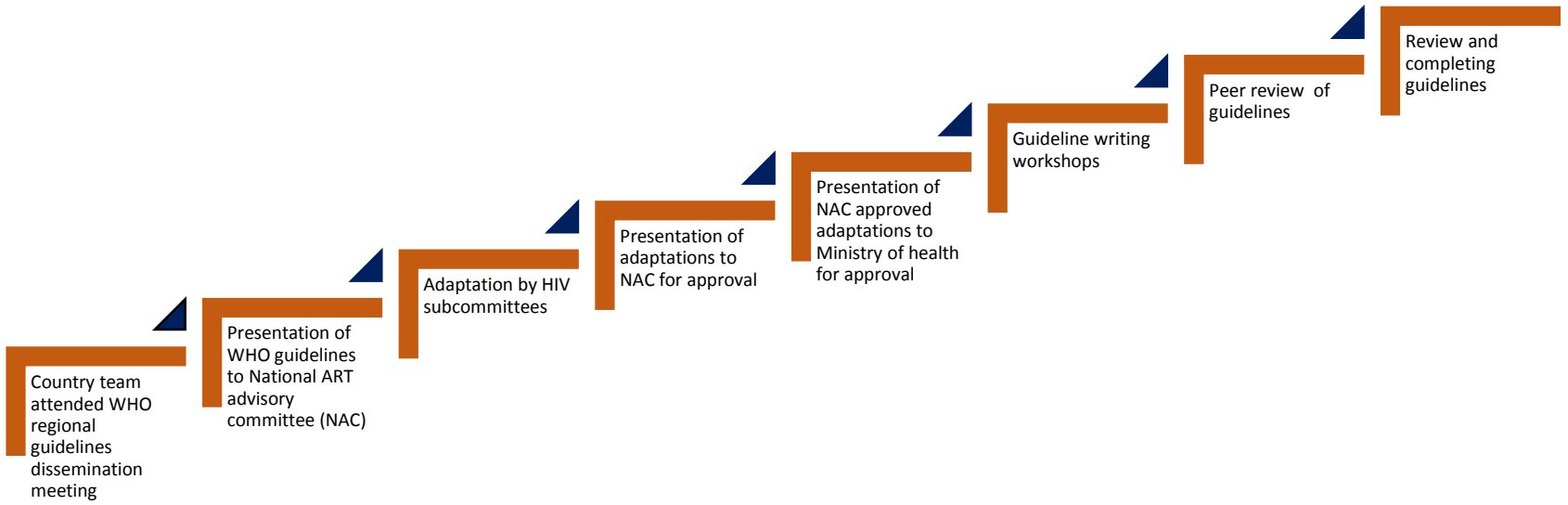
The primary audience for these guidelines are;

- Healthcare workers and district health teams
- Program managers of the HIV program, MCNH, reproductive health (RH), TB program, national medicines warehouses
- AIDS development, implementing partners, training institutions, and researchers, Civil society organization and community of PLHIV.

1.4. GUIDELINES DEVELOPMENT PROCESS

These guidelines were developed by a team of the technical experts within the country including those from the community of people living with HIV and external experts. The guidelines development process was a comprehensive process that involved attending the WHO regional guidelines dissemination meeting, adaptations of the guidelines, approval of the adaptation, 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 and 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. Figure 1 shows the guidelines development process.

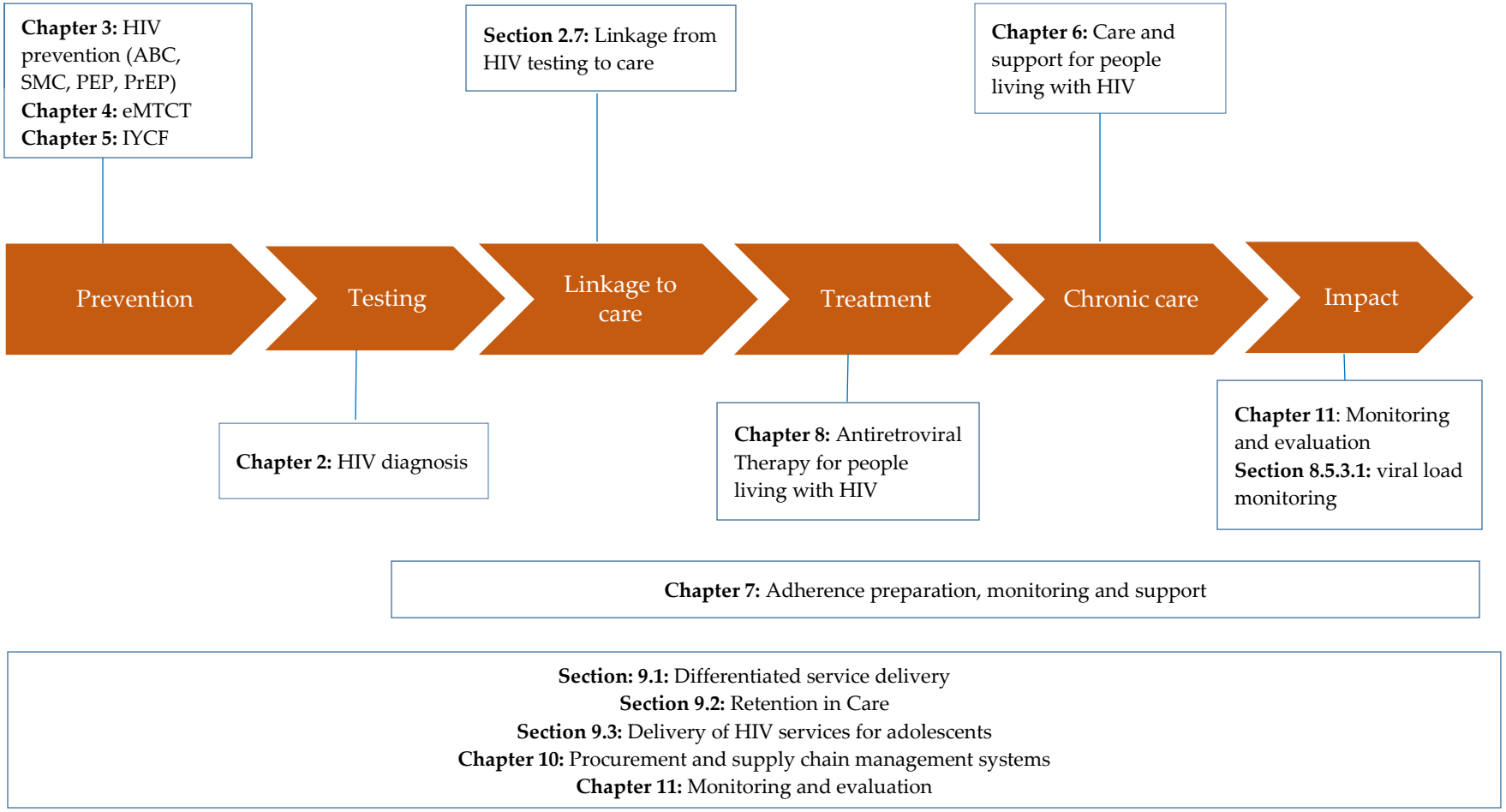
Figure 1: The Process of guidelines development



1.5. COMPONENTS OF THE GUIDELINES

The components of these guidelines are structured along the continuum of HIV testing, prevention, treatment, and care. Figure 2 shows the different components of the guidelines under each part of the continuum of care.

Figure 2: HIV continuum of care and the relevant sections of the guidelines

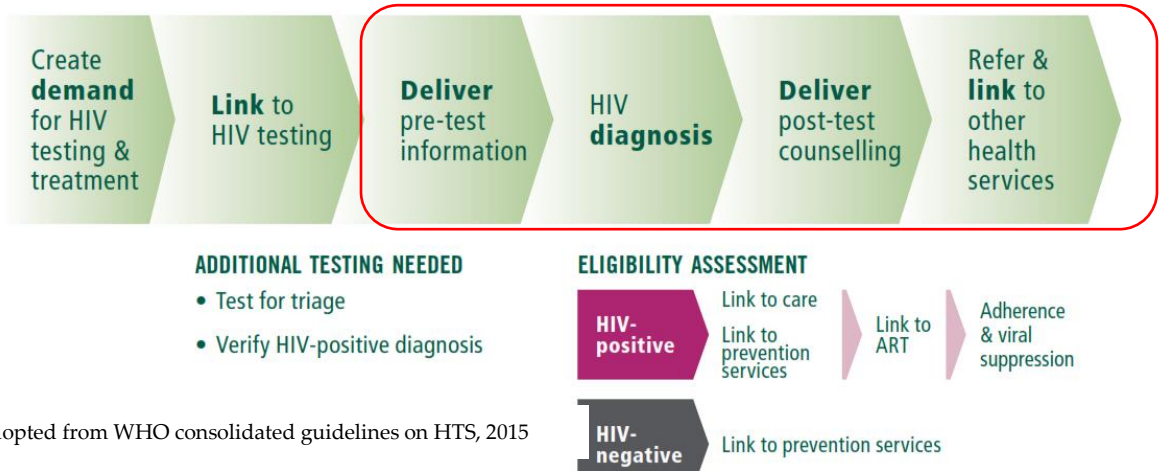


2. HIV DIAGNOSIS AND LINKAGE TO HIV CARE AND TREATMENT

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, 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 anti-retroviral 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 service delivery includes a range of activities and services that are described in the pathway in Figure 3 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). The HTS policy and implementation guidelines provide more details on HTS services.

Figure 3: 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- that is **C**onfidentiality, **C**onsent, **C**ounselling, **Correct** Test result and **C**onnection 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.
- **C**ounseling; 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 Counselling (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 clinic setting both inpatient and outpatient departments and all patients whether symptomatic or not. Health workers should prioritize PITC for patients at maternal and child health clinic, 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. 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 Counselling (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 approached are either Index client contact tracing, outreach or work-based HTS.

2.3.2.1. Index client contact tracing

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

- ***Home-Based HIV Testing and Counselling (HBHTC)*** Home-Based HIV Testing and Counseling (HBHTC) 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 Tuberculosis patients.
- ***Snowballing 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 be;

- ***Door-to-door HIV testing*** may be implemented ONLY in high HIV prevalence settings or communities for key populations such as the fisher folk, hotspots for Sex Workers. Or
- ***HTS integrated into health outreaches*** like immunization or VMMC
- ***Conducting 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. The HTS provider at the workplace should ensure that all clients diagnosed with HIV are effectively linked to HIV care, treatment and support services. Disclosure of HIV serostatus is at the discretion of the employee.

2.3.4. HIV SELF- TESTING (HIVST)

In Uganda, self-testing is still under pilot studies and has not yet been included among the service delivery approaches for HIV testing in Uganda.

2.4. TARGET POPULATIONS FOR HTS

HTS providers should target populations with high HIV risk, High HIV burden, and vulnerable/priority populations. These populations include, sex workers and their clients, long distance truck drivers, the fisher folks, men who have sex with men, boda-boda riders, and uniformed forces, couples and sexual partners especially discordant couples, infants and young children, sexually abused persons, adolescents and Youth especially girls, young women, emancipated minors, children and adolescents, 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, men. For guidance on the strategies and opportunities for reaching these different population groups, *refer* to the section on differentiated HTS models and the national HIV testing services policy and implementation guidelines, 2016.

2.5. HIV TESTING SERVICES PROTOCOLS

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

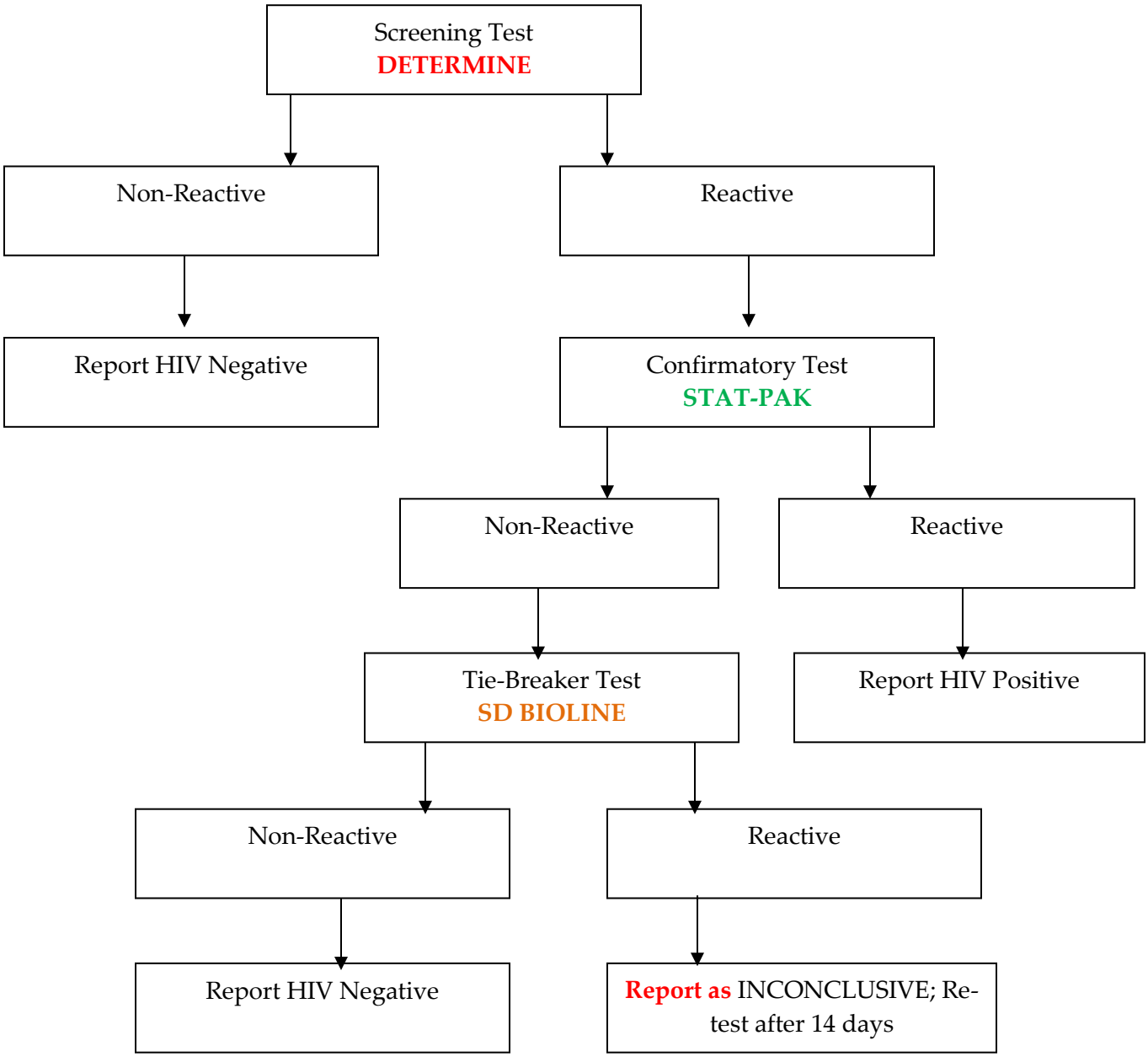
Table 1: HIV testing provision steps/protocol

Step	Activity	Description
1.	Pre-test information giving 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, we shall use the DNA PCR test and those above 18 months we shall use the antibody test. Refer to the HIV testing algorithms for the different age groups (*Section 2.5.1 and 2.5.2 below*).
3.	Post- test counseling (individual /couple)	Assess readiness to receive results, give results simply; address concerns, disclosure and partner testing, 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 referred for; fill the Triplicate referral form; when enrolled, enter the patient's pre-ART enrolment number into the HTS register.

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 4 below.
When using this algorithm in children 18 months and above who are still breastfeeding; if the HIV test done when they are breastfeeding is negative, a final test should be done six weeks after the child stops breastfeeding.

Figure 4: 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 the recommended test for determining the 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 5 below.

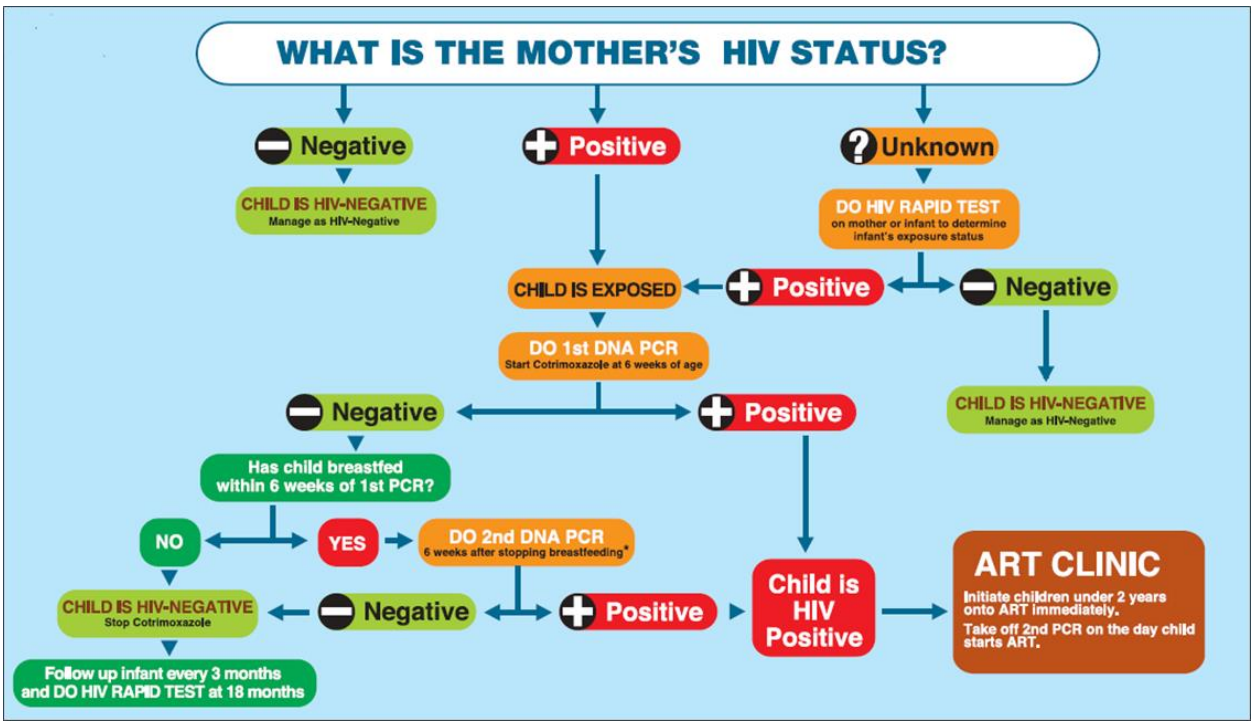
A **POSITIVE DNA PCR test** result indicates that the child is HIV-**infected.**

All infants with a positive DNA/PCR test results should be initiated on ART, and another blood sample is 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 5: HIV Testing Algorithm for children < 18months 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 for HIV-Positive Infants

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

2.6.3. Re-testing for HIV-Negative Individuals

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

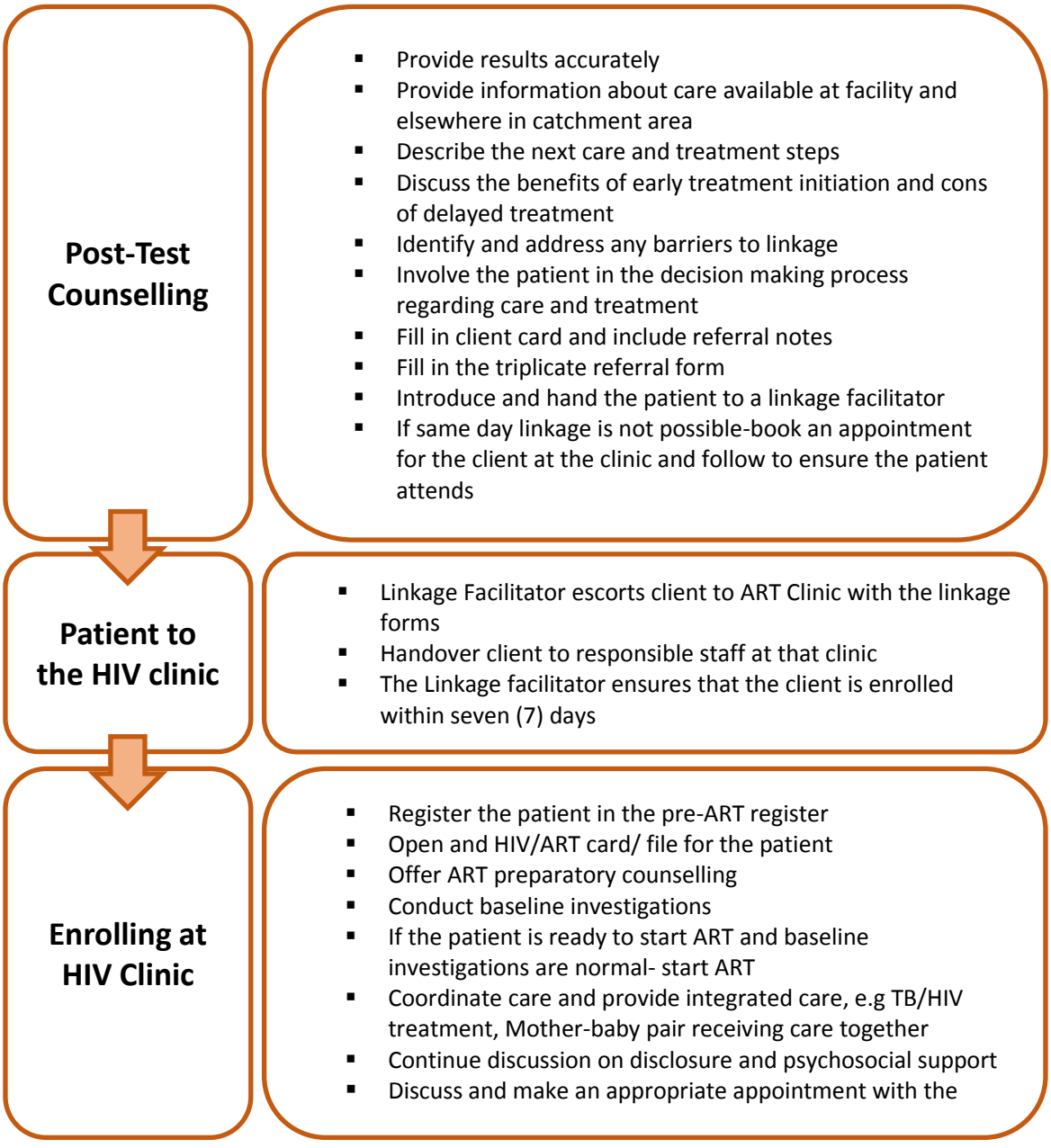
Table 2: Categories of HIV-Negative persons to re-test at specified time-points

s/no	Population category	When to re-test
1.	Individuals exposed to HIV within four weeks before HIV testing	Four weeks after the 1st test
2.	Key Populations	Every 3 Months
3.	HIV negative Partners in discordant couples	Every three months
4.	Pregnant women	1st trimester/1st ANC Visit, then in the 3rd Trimester/during labor and delivery
5.	Breastfeeding Women	Every three months until three months after cessation of breastfeeding
6.	Confirmed and presumptive TB Patients	Four weeks after the 1st test
7.	PEP clients	At one month, three month and six months after completing the PEP course.
8.	PrEP	As per the new guidelines
9.	STI patients	Four weeks after testing
10.	HIV-exposed infants(HEIs)	Six weeks upon cessation of breastfeeding and at 18 months of age
11.	children >18 months who are still breastfeeding	Six weeks upon cessation of breastfeeding
12.	INCONCLUSIVE Results	14 days after the last test

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

Linkage refers to the act/process of connecting individuals that have tested for HIV from one service point to another. Linkage to care is successful if the patient/client receives the services 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. We highly recommend the use of lay providers (community and facility-based) as linkage facilitators. The process of linkage within the same health facility is described in Figure 6 below:

Figure 6: Internal Linkage Facilitation Steps.



2.7.1. INTER-FACILITY LINKAGES

Inter-facility linkage refers to connecting a newly diagnosed patient at 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 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, document complete linkage.
Week 2	If the client didn't reach the 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 facility contact to confirm if the VHT visit to client's home made any impact. If client reached, document complete linkage. If the client didn't reach, 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 X to confirm if client reached. If yes, document linkage as complete. If no, document as Lost.

2.7.2. COMMUNITY- FACILITY LINKAGES

Community-facility linkage refers to connecting a client who tests HIV positive in the community to a health facility for HIV treatment, care, and support services. 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 test positive. Linkage from community to facility should be done within 30 days after diagnosis. The process of community-facility linkage is described in Table 3 below.

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

Timeline	Action
Day 1(referral day)	A client diagnosed HIV positive and referred to the 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 the client is 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, document complete linkage. Health facility Linkage facilitator ascertains referred clients who have come to the facility and documents those referrals as linked/complete. Then notify the CHW of all clients who have not yet been linked.
Week 2	CHW visits client's home to ascertain reasons for failure to reach the facility and makes a new appointment for facility visit. CHW documents the outcome of the visit. And notifies the health facility team.
Week 3	Health facility Linkage facilitator ascertains if the client was linked and notifies CHW of the pending clients
Week 4	CHW makes a final visit to client's home; discusses reasons for failure to reach facility; makes a final appointment if the client is willing or documents outcome (refused, not ready, relocated, etc.). Health facility Linkage facilitator If the client has not yet decided to enrol in care, the CHW will continue to make contact and encourage them to seek care.

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).
- Internal and external HIV test quality control processes performed including 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 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 the behavioral interventions is to delay sexual debut, eliminate unsafe sex, reduce multiple, especially concurrent sexual partnerships and discourage cross-generational and transactional sex. See Table 5 for services for behavioral 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 including training in GSD • Peer-led model for priority and key populations is recommended • Outreaches for key and priority populations is recommended • Job aides to support standardization for quality assurance • Linkage and follow-up between facility and community
Risk assessment for client	• Offer HTS to sexually active clients who have not tested in the last 12 months or 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 work). If client involved in transactional/sex work encourage correct and consistent condom use • Discuss knowledge of partner status about sexual behavior • Assess for STIs and link to treatment • Discuss sexually and reproductive health services and link to services as appropriate
Provide Socio-Behavioral Change Communication (SBCC) link to services as appropriate;	• Discuss delay onset of sexual debuts in children and adolescents (Abstinence); • Discuss correct and consistent condom use; 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, and wife replacement and childhood marriages. • Identify, refer and link clients to other available facility and community programs • Assess for violence, (physical, emotional, sexual-) if sexual, assess if the client was raped and act immediately (see section 3.4.1 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, ART, PEP, PrEP, blood transfusion safety, and STI screening and treatment, especially for Key populations. This section will discuss SMC, PEP, and PrEP. Other interventions will be discussed in other chapters: 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 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 • 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 STI's are present defer the circumcision and treat the STIs.See 6.6.1 • **Tetanus Immunization Status:** All persons undergoing circumcision should have at least two documented doses of TT vaccination given at least 28days apart and not more than 6-months. If there is no evidence of TT differ 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, differ SMC and refer. • **Existence of chronic disease conditions such as Diabetes, hypertension:** Differ SMC and refer
Consent/Assent	• Clients 18 years and above should consent before SMC. • For adolescents <18 years, assent and parental/legal guardian consent are required
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 • Follow-up of device circumcision: should follow device used and the manufacturer guidance.

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-occupation exposure.

Types of Exposure:

- **Occupational exposures** occur in the health care 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 & defilement, road traffic accidents and injuries at construction sites where exposure to body fluids occur.

Steps in assessing a potential PEP recipient

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

Table 7: Steps for providing pre-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. **Occupation 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 or has unknown HIV status or high risk **Do not provide PEP when:** • The exposed individual is already HIV positive; • When the source is established to be HIV negative; and exposure to bodily fluids that does not pose a significant risk: tears, non-blood-stained saliva, urine, and sweat. • Exposed people who decline 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. Table 52 • Provide enhanced adherence counseling if PEP if prescribed • Link for further support for sexual assault cases.
Step 4: Prescription:	• PEP should be started as early as possible not beyond 72 hrs. of exposure. • For recommended regimens **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	• To monitor adherence and manage side effects • Perform follow-up HIV testing after three months after exposure. • If HIV infected o Provide counseling and link to HIV clinic for care and treatment o If HIV-uninfected, provide HIV prevention education/risk reduction • Discontinue PEP after 28 days.

3.3.3. ORAL PRE-EXPOSURE PROPHYLAXIS (PREP)

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 be offered in sites with funded demonstration and special pilot projects. This guidance is, therefore, for those sites. PrEP is not to be rolled out in all public health facilities yet. Table 8 describes processes involved in offering PrEP.

Table 8: The Process of providing Pre-Exposure Prophylaxis (PrEP)

Process	Description
Eligibility of PrEP	PrEP provides an effective additional biomedical prevention option for HIV-negative people at substantial risk of HIV. These include people who: • Have multiple sexual partners • Engage in transactional sex including sex workers • Use or abuse of injectable drugs and alcohol • Have had more than one episode of an STI within the last twelve months • Discordant couples, especially if the HIV positive partner is not on ART or has been on ART for less than six months. • Recurrent users of PEP-(3 consecutive cycles of PEP) • Individuals who engage in anal sex. • Key populations who are unable and 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) and, uniformed forces and adolescents and young women engaged in transactional sex.
Screening for PrEP eligibility	After meeting the eligibility criteria, the following screening tests should be done before initiating PrEP. • Confirm HIV-negative status • Rule out acute HIV infection • Assess for hepatitis B infection • Assess for contra-indications 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, subsequent clinic visits should be every three months • 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 STI s at every visit and treat as needed
Guidance on discontinuing PrEP	• It's a personal Choice • 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 • Acquisition of HIV infection

3.4. STRUCTURAL INTERVENTION

3.4.1. PREVENTION AND MANAGEMENT OF GENDER BASED VIOLENCE

- Gender-based violence (GBV) has the potential to increase the risk to acquiring HIV. While among those on ART, 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, ANC/MCH, and IPD
- Every site providing GBV services and post-violence care, should have the following:
    - A written algorithm with steps of active case identification and follow-up
    - At least one staff trained to provide post-violence care
    - A focal point for GBV services at each facility
    - Provide PEP

Table 9 below 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-infected
- Post-exposure prophylaxis (PEP) for HIV *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 psycho-social 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. In Uganda, vertical HIV transmission for a long time, 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+ for the past three years, 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, we highlight guidance for delivering eMTCT services to achieve the elimination of Mother to Child transmission of HIV and syphilis and in-line with the national 90-90-90 goals/targets for HIV epidemic control. The section also provides technical guidance on, how eMTCT 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 4 approaches and are in Table 10 below. These interventions must be offered simultaneously within the platform of MNCAH services throughout the continuum of eMTCT services as will be described in Figure 7.

Table 10: The eMTCT approach

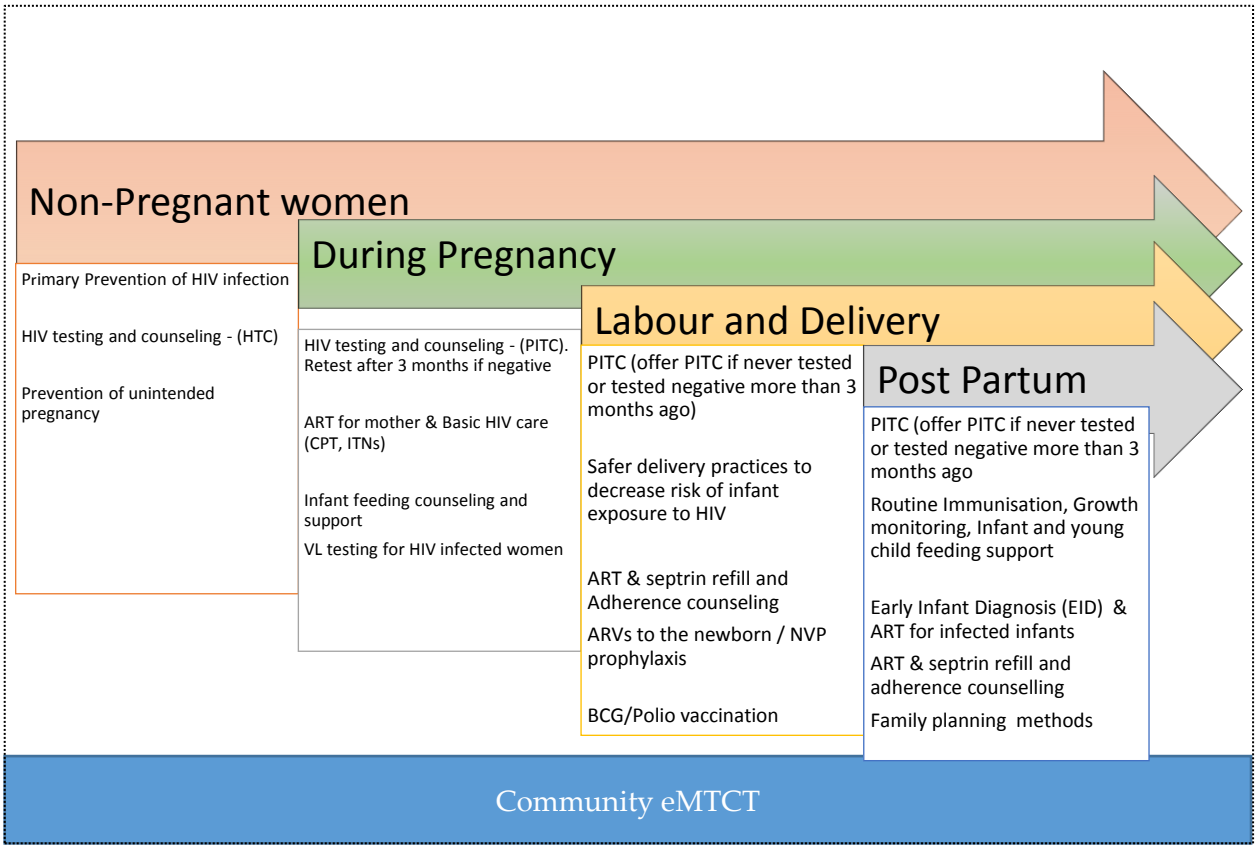
Element	Target group	Additional information
Prong 1: Primary prevention of HIV infection	Women and men of reproductive age including adolescents	This prong aims to prevent HIV in men, women of reproductive age and adolescents. Interventions include: • HIV testing services for pregnant and non-pregnant women of reproductive age – Couple counseling and partner testing & retesting for the HIV negative • 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), delay of onset of sexual activity – Health information and education about risky behavior and life skills and benefits of HTS • SMC, PrEP for discordant couples, 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	• FP counseling & voluntary services (informed decision) • HIV testing and counseling in RH/FP services • Safer sex practices, including dual protection (condom use promotion) • Pre-conception counseling and referral for infertility investigations 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 element focuses on: • Quality antenatal, labour and delivery and postnatal care • Access to HTS during ANC, Labour, delivery, and postpartum period • Early 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 screening and treatment
Prong 4: Provision of	Women living with HIV and	This element addresses the treatment, care and support needs of HIV-infected women, their children and families (family – centered approach)

Element	Target group	Additional information		
treatment, care, and support to women infected with HIV, their children, and their families	their families	**Package of services for mothers includes:** • Lifelong ART • Co-trimoxazole 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 screening and treatment • Cervical cancer screening and referral • Adherence 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 • STI, cervical and breast cancer screening	**Package of services for HIV-exposed and infected children:** ○ ARV prophylaxis ○ OI prophylaxis – CTX ○ INH prophylaxis – for TB exposed ○ Routine immunization & growth monitoring ○ HIV testing ○ IYCF assessment, counseling, and support ○ Prevention, screening & 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) ○ ART for HIV-infected children	**Package of services for partner and the family:** • HIV testing of partners, children and other family members and linkage to prevention & care services • ART for HIV-infected family members • Co-trimoxazole 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 screening • Adherence 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 & 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, Labor and Delivery, Post Natal 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 parts of the MNCAH services continuum; before pregnancy, antenatal, labour and delivery, postnatal & community. See Figure 7

Figure 7: The eMTCT continuum of services



4.4. SERVICES FOR NON-PREGNANT WOMEN

4.4.1. PRIMARY PREVENTION OF HIV INFECTION

When you prevent HIV in women of reproductive age, the risk of HIV infection to the infants is eliminated because over 90% of pediatric HIV infections are through MTCT. In Table 11 are some of the services to prevent HIV infection in women of reproductive age.

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. See Table 2
BCC	Safer sex practices, including dual protection (condom promotion) 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 a**ll women of reproductive age, including adolescent 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 screening and treatment	Counsel and screen women for STI including syphilis and manage the STI. See 6.6.1

4.4.2. PREVENTION OF UNINTENDED PREGNANCIES AMONG WOMEN LIVING WITH HIV

Family planning (FP) among 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. Do not coerce women to receive FP services. Respect and safeguard women's reproductive choices.
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, ART services.** Encourage HIV-infected women to discuss their RH 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 for 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 couple, 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 support to adhere to the chosen method. • Assess for possible side effects and manage accordingly. • Clients on Nevirapine-based ART and Injectable (Depo-Provera) should be counseled to return for injection on appointment date or before if they can't make it on that date.

Table 13: Interactions between ART and contraceptives

HIV Drug	NRTI (AZT/3TC/ FTC/TDF/ABC)	Nevirapine	Efavirenz	LPV/r	ATV/r
Injectable (Depo-Provera)	Nil	Nil	Limited information, additional barrier method advised	Nil	Limited information, alternative method advised
Implants (Implanon, Jadelle)	Nil	Levels of Levonorgestrel reduced, additional barrier method advised			Limited information, alternative method advised
Combined oral (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 (COCP with higher dose Ethinyl estradiol should be used)
Emergency contraception (Postinor-2)	Nil	Levels of Levonorgestrel reduced – increase dose of Postinor to 4 tablets			
IUD (TCu 380A)	Nil				
Condoms	Nil				

4.5. DURING PREGNANCY

This section outlines ANC services for all pregnant women, specific services for the HIV-infected pregnant woman and HIV-negative pregnant woman. 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 their Partner with same day results. – Offer HTS through PITC, VCT and couple testing should be encouraged with support for mutual disclosure • Link all HIV-positive seroconcordant and serodiscordant couples to ART. Offer PrEP to the negative partner in the discordant couple. • For HIV-negative pregnant women, retest in the third trimester, or during labor, or shortly after delivery, because of the high risk of acquiring HIV infection during pregnancy. • Re-test the following HIV negative pregnant women within four weeks of the first test – STI's or TB- infected pregnant women – Those with a specific incident of HIV-exposure within the past three months • Re-test HIV-negative pregnant women in a discordant relationship every 3months. • Provide risk reduction counseling to HIV-negative women.

Service	Description
Antenatal care package for all pregnant women (regardless of HIV status)	**General care:** • All pregnant women should have at least 4 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 appropriate feeding counseling. See Chapter 5 • Counsel and encourage to deliver at the health facility. • Screen for TB • Exam: Take Weight and BP at every visit **Laboratory services:** • Screen and treat for syphilis, HIV, Hep B, other STI's and anemia. Use syndromic approach to treating STI's. • 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.
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 during 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 after initiating ART and then follow the National VL testing algorithm (VL testing chart). To interpret *viral load results use algorithm in* Figure 16
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 for intermittent preventive treatment for malaria (IPT) • Screen for TB • INH for eligible women. See 6.5.2.10 • Screening and Management of Opportunistic infection
ART	• All women living with HIV identified during pregnancy, labour 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 8.4.2 • All women should receive Pre-ART adherence before initiating ART and ongoing adherence support after that. See 7 • 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.

Service	Description	
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 1000copies/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 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. See** Annex 1

4.6. DURING LABOUR AND DELIVERY

Labour and delivery are the period 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 below

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 • Retest HIV negative women who did not retest 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 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 **8.4.2** Continue to provide HIV care services to the mother.

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 5.
At discharge	• Counsel the mother and provide an appointment to return for postnatal services and exposed infant testing and care at six weeks. • If the mother is not going to receive services at this facility, link the mother to HIV care services in facility of their choice using linkage guidelines in section 2.7

4.7. DURING POST-PARTUM

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 month of age. This section will describe postnatal services for the mother. See Table 16. Services for infant including Care for the HIV-exposed infant (HEI) and Infant and young child feeding counseling are described in section 4.8 and chapter 5

Table 16: eMTCT services during the post-partum 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 schedules. At the post-natal visit; • Check for sepsis, anemia, high blood pressure, etc. and provide of vitamin A • Offer family planning counseling and services. See Table 12 • Review of ART regimen and provide adherence support • Re-enforce 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 delivered. • Provide ART for all women newly diagnosed at PNC according to guideline in section RECOMMENDED FIRST-LINE REGIMEN FOR INITIATING ART IN PREGNANT OR BREASTFEEDING WOMEN8.4.2 • Continue to provide risk reduction counseling and support to HIV-negative women • Do repeat testing every three months during breastfeeding.
HIV care and management for the HIV infected mother and family	• Antiretroviral therapy (ART) • Co-trimoxazole prophylaxis • Regular TB screening and provide INH prophylaxis if eligible. • Continued infant feeding counseling and support • Nutritional 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 is 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 HIV infected through MTCT
- Among those who get infected, to diagnose HIV infection early and treat.
- 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 to 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 below 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 infant	• Identify all HIV-exposed infants; document the HIV status of the mother in the child card and mothers' passport. For infants whose HIV status is not documented or is unknown should be offered rapid HIV test; including those whose mothers did not receive eMTCT services or have become newly infected after pregnancy. The entry points for identification of HIV-exposed babies 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 5 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. - And conduct rapid HIV test at 18 months for all infants who test negative at 1st or 2nd PCR.

Service	Description
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 • Review their immunization status at every visit • Some special considerations/ modifications – 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 6 and nine months even when the child has symptoms of HIV. The measles illness from the vaccine is milder while that from the wild measles virus 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 10Annex 10: Child Health Card. • 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 develop some milestones and after never progress to develop others. - Child may develop milestones and lose them after some time - Child may fail to develop milestones at all • Test children with developmental delay for HIV and if infected initiated on ART. • Measure the infant's head circumference

Service	Description
NVP prophylaxis	• Provide NVP syrup to HEI from birth until six weeks of age. • For high-risk babies; give NVP syrup from birth until 12 weeks of age. High-risk babies are breastfeeding infants whose mothers; - Have received ART for four weeks or less before delivery; or - Have VL >1000 copies in 4 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 6 weeks of age until they are proven to be uninfected. Dose is in Table 24 • Infants who become HIV infected should continue to receive Cotrimoxazole prophylaxis for life. • If Cotrimoxazole is contraindicated, offer Dapsone at dose of 2mg/kg once daily (up to 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:** In all HEI and HIV-infected children should receive ITNs and Cotrimoxazole. 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 IMNCI guidelines and provide treatment.
Counseling and feeding advice	Provide infant feeding counseling advice according to guidance in **Chapter 5**

Service	Description
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 and provide key aspects of home-based care for the child, including: – Dispensing prophylaxis and treatment – Maintaining adherence – Complying with the follow-up schedule – Good personal and food hygiene to prevent common infections – Seeking prompt treatment for any infections or other health-related problem • The most important thing for the child is to have a healthy mother. Ensure the mother/ infected caregiver is receiving their care. If the mother is sick, the infant will not receive care. • When members of the same family such as mother and 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, the 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 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 reproductive health and eMTCT services
- Identification, counseling, and referral of pregnant/ lactating mothers for a comprehensive ANC services including screening for Tb symptoms, skilled delivery, eMTCT services for mother and baby including EID, Post Natal Care, IYCFC, 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 HCT or through referral.

- Addressing social and behavioral factors that affect uptake of eMTCT services including stigma, disclosure, discrimination, GBV, etc
- Providing adherence support.
- Support for Follow-up, linkage, and tracking of mother-infant pairs through at least 18m post-partum and the infant's final survival and HIV-status is known.
- Community ART and cotrimoxazole refills.
- Provision of psycho- social support through Family Support Groups or other community-based PLHIV support groups, OVC programs, household economic strengthening/income generating activities, CBOs
- Assessing all eMTCT families for eligibility for OVC programs
- Promote family care, treatment & support including from treatment support 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 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 partnership and Networks with a community-based organization, NGOS and 'networks of PLHIV for community service delivery**. The networks and partnerships should be established by;
   - Conducting or updating community mapping of resources, identify referral trigger factors, develop referral directories and support documentation of referral processes.
   - Connecting with the Community Development Officers, CBO, FBO, NGO's 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 of comprehensive referral network systems and coordination of two-way referrals between community and health facilities. Also, establish mechanisms for assessing performance of these systems
   - Promoting integration of eMTCT and HIV into reproductive health, MCH, and other programs
   - Identification of and collaboration 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**
   - Community health workers including peer educators in the catchment area should be identified, trained and facilitated 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 can 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 and 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
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

See Table 18 below for nutrition counseling messages and services for HIV-infected pregnant women

Table 18: Nutrition counseling messages and services for pregnant women

Service	Description
Diet:	Add extra meals during pregnancy and breastfeeding; drink adequate fluids; eat plenty of fruits and vegetables; eat foods rich in vitamin C to enhance iron absorption; avoid tea or coffee close to (less than 1 hour) or with meals as this may interfere with absorption of iron; and use iodized salt to prevent pregnancy complications (abortions, miscarriages and stillbirths), fetal growth retardation, and maternal goiter. Maintain high levels of personal and food hygiene and food safety to prevent infections. Adolescent mothers may require more care, food and rest than other mothers since they are still growing. Avoid alcohol, narcotics or tobacco products and medicines not prescribed by a trained health care provider.
Medications during pregnancy	Supplemental iron to prevent anemia to reduce the risk of low birth weight; folic acid to prevent fetal brain and spinal cord congenital disabilities; de-worming tablets to treat 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 supplement with food to overcome side effects

Service	Description
	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 your 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 and management, 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 the 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, 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 cases of caesarean section.
- Newborn infants should be fed on 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, ways of holding and putting the baby to the breast (positioning and attachment) to enhance breastfeeding
- Mothers should continue supplementation with Iron 1 tablet/day and Folic acid 400ug 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, introducing appropriate complementary foods after that, and continue breastfeeding for the first 12 months of life while being fully supported for ART adherence. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk 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, introducing appropriate complementary foods after that, and continue breastfeeding until 24 months of life while being fully supported for ART adherence.

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. Use of clean open cups. Discourage use of feeding bottles, teats or spouted cups as they are very difficult to clean

5.5.1.1. 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. Alternative forms of milk (cow's milk, goat's milk, soya) should be given; of at least 500ml a day. (1 Nice cup) Encourage mothers to feed their children five times a day - 3 main meals and two extra foods between meals (snacks).

HIV-infected Encourage mothers to continue breastfeeding on demand, day and night up to 24 months and beyond to maintain the baby's health and nutrition. Give one extra snack to well children and 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

5.5.2. FEEDING A CHILD 2– 6YEARS

- Encourage mothers to give a variety of foods prepared from the family meal (each meal should consist of a carbohydrate, protein, vegetables) at least three main meals a day.
- Encourage caregivers to give nutritious snacks between meals e.g. a fruit (banana, pawpaw, orange, mangoes) 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/oil/cooked, skinned, 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.
- Mechanism of transition includes:
  - Expressing breast milk and feeding infant/child by cup
  - 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 such as mother absent, dead or mentally challenged, following 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. This section describes these services. Some of the services will be described in detail in this section, and for others, we will refer you to other sections within this very document. The details of this minimum healthcare services package can also be found in the *"Integrated Health Care Services Package for HIV Prevention, Treatment and Care Services for Uganda" document.*

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, and we make reference to the sections where they are explained in detail.

Table 19: A Summary of minimum care package for PLHIV

Service Area	Service Description
Clinical evaluation and monitoring of HIV disease	All HIV-infected people should receive a clinical evaluation and monitoring to ascertain WHO clinical stage of disease and exclude comorbidities.
Antiretroviral Therapy	ART should be initiated 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, counselling and support (NACS) section 6.4
Opportunistic infection screening, prevention, and management	• Provide Cotrimoxazole prophylaxis to every infected HIV patient for life. • Screen and manage other OIs like TB and Cryptococcal infection (refer to the co-morbidity section) • Provide INH prophylaxis if eligible.
Screening and treatment of Co-morbidities	Screen and manage the following NCD's • Hypertension • Diabetes • Dyslipidemias • Mental health - Assess for and manage depression
Sexual & reproductive health services	• Screen and manage sexually transmitted infections. • Family Planning and pre-conception services- see Table 12 • Maternal Health; Early Identification of pregnant mothers and link them to ANC, promote facility delivery and postnatal care- see chapter 4 • Cervical and breast cancer screening. See 6.6.2
Adherence Counseling	• Do adherence preparation, monitoring, and support section 7
Psychosocial Support & palliative care	• Assess family and community support to the client • Assess for stigma & discrimination • Link client to a psychosocial support group • Assess for any social challenges the client might have

Service Area	Service Description
	• Refer for palliative care where need be
Orphans & Vulnerable Children support	• Conduct basic assessment for vulnerability (should have at least three meals/day, school attendance, the existence of HIV infected or affected person in the household, child abuse, widowed, elderly or child-headed household). • HIV testing for family members either at facility or community level as appropriate • Refer & link to a Community Based Organization (CBO)/ Community Development Officer (CDO) • Conduct a nutrition assessment counseling and support • For HIV-positive children and their caretakers, initiate ART *For details of OVC care refer to the NSPPI, Ministry of Labor, Gender, and Social Development)*
Positive Health, Dignity, and Prevention	• Support client to disclose HIV status to family and significant others • 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 • Gender-based violence screening and support
Other prevention services	• Provide Immunizations according to the National immunizations schedule • Educate and promote use of Insecticide Treated Mosquito Nets (ITNs) • 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, ART initiation and at every visit thereafter to help guide patient care and monitor disease progress.

- HIV-related diseases are grouped into four (4) 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 infection increases energy requirements, reduces in dietary intake, can cause nutrient malabsorption and nutrient loss, and complex metabolic alterations that culminate in the weight loss and wasting. NACS, therefore, should be conducted to PLHIV from enrolment throughout the care continuum.

6.4.2. STEPS IN IMPLEMENTING NACS

NACS should be implementing in HIV care settings using the "The Seven Steps" approach in

Table 20; education, assessment, categorization, counseling, nutrition therapy, follow-up and community linkage

Table 20: Seven-step approach for implementing NACS

Step	Activities
Step 1: Nutrition and health education	**Purpose:** Create awareness on benefits of proper nutrition Sensitize clients on the benefits of proper nutrition and monitoring of nutrition status
Step 2: Nutrition Assessment	**Anthropometry*** - Take Weight, Length/height, Mid Upper Arm Circumference (MUAC), age. - Routinely monitor and promote growth for children <5 years
	Biochemical Analysis Monitor micronutrient deficiencies such as haemoglobin level
	Clinical assessment Check for signs undernutrition bilateral pitting oedema, wasting, hair changes, anaemia (pale conjunctiva, gums, nails, skin) breathlessness, 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- Figure 8
Step 4: Nutrition Counselling	Focus on consuming a variety of locally available high energy and nutrient dense foods, feeding frequency, increased intake per meal, high protein (especially animal) intake, 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). See dose in 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 Micronutrient guidelines, 2013)*
	Food and drug interactions Manage complications that affect food intake/utilization, drug adherence, and efficacy (*see NACS, 2016)*
Step6: Follow-up for nutrition care	**Follow-up all clients with acute malnutrition** Routine and scheduled follow-up clients on nutrition treatment

and support	Where appropriate, synchronize with other services
Step 7: Community linkage	Link malnourished patients to livelihood and/or Supplementary Feeding Programs (SFP) where possible

Figure 8: Algorithm for nutrition assessment, classification, and care plan of Acute Malnutrition

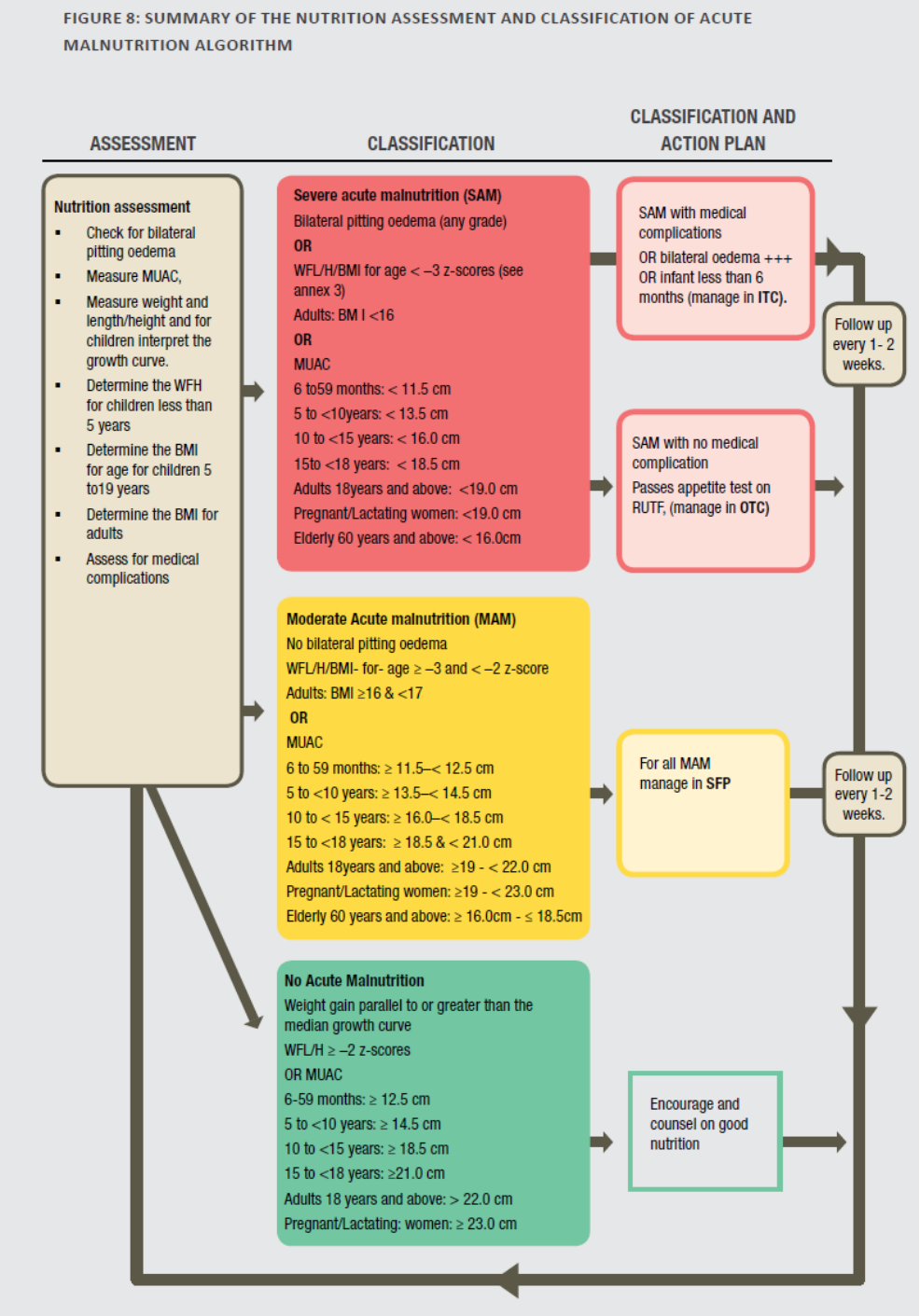


Table 21: Dosing of RUTF

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: IMAM, 2016 guidelines

Table 22: Rations of RUTF by age category

Age	Normal Daily Ration Size [gms]	Daily Ration + 50% ration Increase [gms]	Monthly Ration Size [KGs]
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 WFL/H or ≥ -2 z-scores (6-59 months) BMI-for-age ≥ -2 z-scores (5-19years) BMI >18kg/m2 (adults >18years) OR MUAC: ≥12.5 cm (6 months to <5years) ≥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 INR as "Cured". Link caregivers/ patients to other primary health care services or initiatives at facility/or community: • YCC or Growth Monitoring & 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)	*R*efer 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 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 as "transferred to

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, Hepatitis B and C virus infection and STI's. Management

of other co-infections like oral candidiasis, esophageal candidiasis, toxoplasmosis and chronic diarrhea can be found in Uganda clinical guidelines.

6.5.1. COTRIMOXAZOLE PREVENTIVE THERAPY (CPT)

- Cotrimoxazole preventive therapy (CPT) can reduce the risk of mortality, malaria, diarrhea and pneumonia caused by bacterial infections, and hospitalization. It is also the mainstay of prevention of *Pneumocystis jiroveci* pneumonia (PJP/PCP).
- **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

Contraindications to CPT

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

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

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

6.5.1.2. ALTERNATE DRUGS TO USE IN CASE OF HYPERSENSITIVITY TO COTRIMOXAZOLE

In patients with co-trimoxazole hypersensitivity, dapsone should be used. Dapsone provides protection against PJP/PCP. It does not have the other preventive benefits the CPT provides. Therefore, pregnant women receiving Dapsone should also receive IPT with SP.

Dose of Dapsone

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 to 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 45% of all TB cases in clinical settings are co-infected with HIV. Therefore, all PLHIV should be routinely screened for TB and all patients with presumptive or diagnosed TB should be routinely screened for HIV. 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 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 including cough of any duration, persistent fevers, weight loss, excessive night sweats should be assessed for TB. Where possible, screening by chest radiography 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), 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 transport Hub 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 or equal 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 and are shown in Table 26 below.

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 Medicine immediately and adjust the ART regimen as recommended below. (See Table 28)
2. If the patient is not on ART, initiate anti-TB Medicine immediately and start ART at two weeks of TB Treatment.
   Adults with CD4 count less than 50 cell/mm^3, ART should be initiated **BEFORE** completing two weeks on anti-TB Medicines.

6.5.2.7. FIRST-LINE ART REGIMEN FOR TB/HIV CO-INFECTED PATIENT 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 - <12 years	ABC+3TC+EFV
Children 0 - <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. See Table 28

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

Table 28: ARV regimen substitutions for patient's initiating TB treatment while on ART

Age Group	Regimen when diagnosed with TB	Recommended Action/ Substitution
Adults, Pregnant and Breastfeeding Women, and	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 50 mg twice daily

Adolescents		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 - <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 0 - <3 years	If on LPV/r or NVP based regimen	Give triple NRTI regimen ABC+3TC+AZT

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 Isoniazid Preventive Therapy for six months. See Table 29 for INH dose. IPT is not recommended for contacts of patients with MDR-TB

Eligibility for IPT

(i) HIV-positive infants and children < 5 years with a history of TB contact and have no signs and symptoms of active TB disease

(ii) HIV-positive children (≥ one year of age), adolescents and adults with no signs and symptoms of TB.

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
INH 100 mg (tablet)	**0.5**	**1**	**1.5**	**2**	**2.5**	**nr**
INH 300 mg (tablet)	**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) associated mortality is up to 39%. Patients with a CD4 cell count of <100 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 start guidelines 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 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 lateral flow assay 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 9
- After doing a serum CrAg test, the test results (negative or positive) determine the next steps.

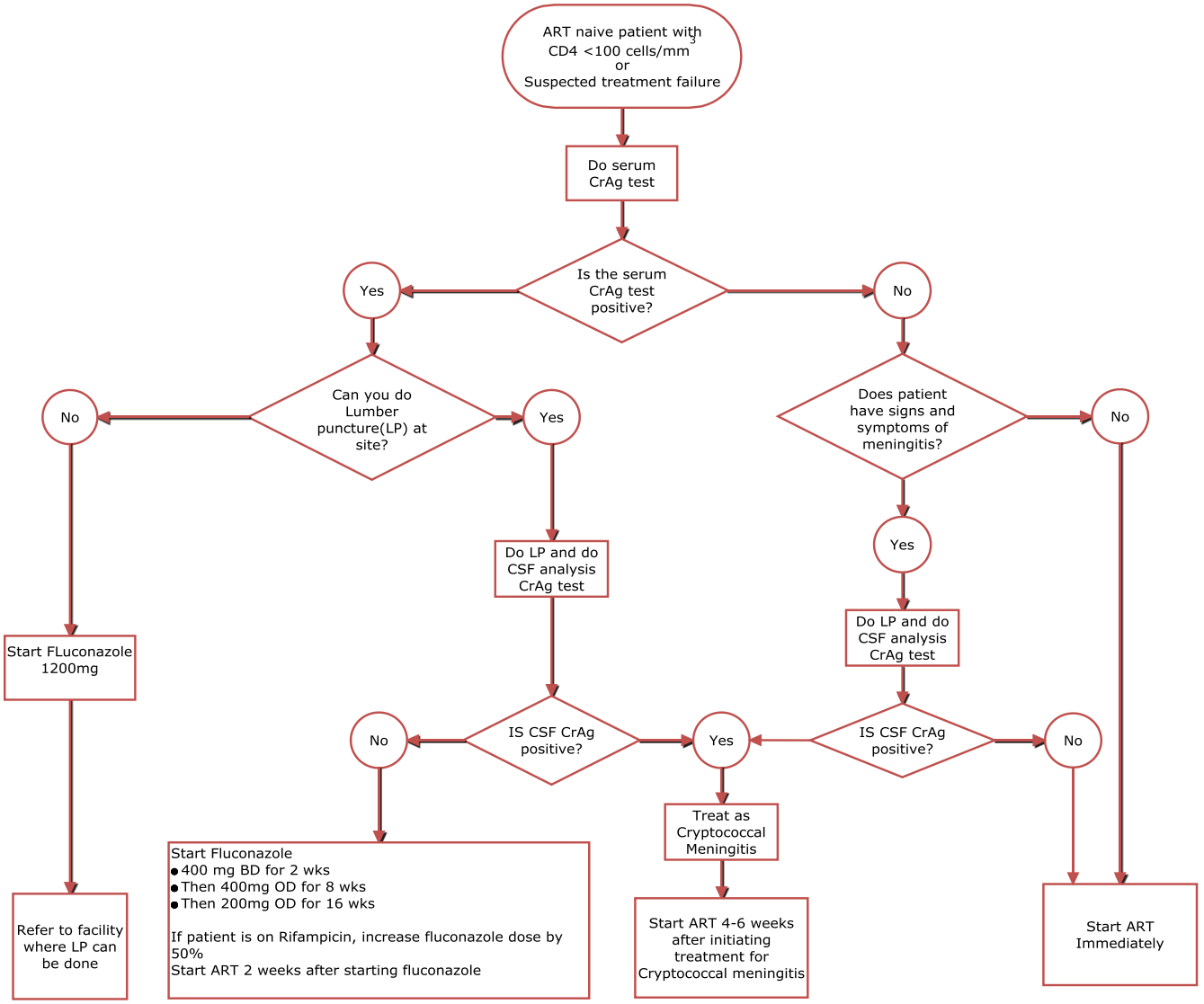
For serum CRAG positive patients and lumbar puncture can be performed at the facility

- Patients with a positive CrAg should be assessed for signs and symptoms of CM including a headache, presence of seizures, altered consciousness, photophobia, neck stiffness, and a positive Kernigs' 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 as per Table 31

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

Figure 9: Algorithm for screening and managing cryptococcal disease



For serum CrAg-positive patients and lumbar puncture cannot be performed at the facility

Health workers at HCIIIs and some HCIVs may not be trained to do LP's. Patients at such sites should also be assessed for signs of CM. The patient 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 Kernigs' 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 declines a lumbar puncture or the lumbar puncture cannot be performed, and the patient has signs and symptoms of cryptococcal meningitis 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 3 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 and how to prevent drug toxicity, how to manage increased intracranial pressure and relapse disease are summarized in Table 31 below.

Considerations for drug interactions during treatment of cryptococcal disease

- Antifungals and Aminoglycosides, e.g. Gentamicin: Increased risk of nephrotoxicity
- Antifungals and Cardiac Glycosides, e.g. Digoxin: Increased risk of cardiac toxicity, especially in clients with Hypokalemia
- Antifungals and Antiepileptic medicines: Antifungals may increase serum concentration of Carbamazepine, alprazolam, and other benzodiazepines
- Amphotericin B and non-potassium sparing diuretics: Increased risk of hypokalemia
- 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.
- Nevirapine use and Fluconazole: Fluconazole increases plasma concentration of Nevirapine and some Protease inhibitors
- 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. 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 High-dose fluconazole 800mg/day.
Or
Amphotericin B short course 5-7 days + high-dose fluconazole</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>In Amphotericin B is used in induction phase: Fluconazole 400-800mg/day (or 6-12 mg/kg/day in children and adolescent <19yr)

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 <19yr)</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 <19yr)</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 CD≥200 if viral load not available.
Children: If >25% or viral suppressed</td></tr>
<tr><td colspan="3">Relapse disease
Present with a recurrence of symptoms of meningitis and have a positive cerebrospinal fluid culture following a prior confirmed diagnosis of cryptococcal meningitis
Evaluate for drug resistance:
Send CSF to 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
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%.</td></tr>
<tr><td colspan="3">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.</td></tr>
</table>

• 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 below 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 radiograph 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 *P jiroveci* pneumonia (PJP) disease. Provide oxygen is in respiratory distress
Prevention	Initiate all HIV-infected people on cotrimoxazole preventive therapy.

6.5.5. HEPATITIS B VIRUS INFECTION

Hepatitis B virus (HBV) is the leading cause of chronic liver disease among HIV patients. In Uganda, the prevalence of Hepatitis B among HIV patients is estimated to be at 17%. Table 33 has 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 at six months** • A complete blood count • Liver function tests (ALT, AST, Albumin and bilirubin levels &PTT) • Abdominal ultrasound scan to assess for liver fibrosis • Do 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 SC once weekly for 48 weeks *or* Peg-IFN-alfa 2b 1.5 mcg/kg SC 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** • Liver function tests are abnormal, **or** If available do HBV DNA (hepatitis viral load) **Treatment Failure** Patients with HB VL >2000IU/ml at 24 weeks of therapy should be referred for further evaluation and management while continuing ART. Otherwise, continue ART.
Prevention	• Counsel on sexual transmission and the risks associated with sharing needles and syringes, tattooing or body-piercing. • Screen all household members and sexual partners/contacts of HBV/HIV con-infected clients for HBV. • Provide HBV vaccination for all sexual partners and contacts regardless of whether they are HIV-infected or not. • **Offer HBV vaccine to people in endemic areas. Available vaccines and their schedules are below.** • HBV vaccine IM (Engerix-B® 20 mcg/mL or Recombivax HB® 10 mcg/mL) at 0, 1, and 6 months • HBV vaccine IM (Engerix-B® 40 mcg/mL or Recombivax HB® 20 mcg/mL) at 0,1,2 and 6 months

6.5.6. HEPATITIS C AND HIV

Hepatitis C (HCV) affects 5-15% of PLHIV. The HCV-related liver disease progresses more rapidly in people co-infected with HIV. Assess for risk among intravenous drug injection users and individuals with tattoos. 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 as well as patients with jaundice, right upper quadrant. Refer for further evaluation and care if the HCV antibody test is positive. Persons with HBC/HIV co-infection should start ART with TDF-containing regimen.

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, use of insecticide-treated mosquito nets (ITNs), 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 insecticide-treated bed nets or have access to indoor residual spraying to reduce their risk of exposure to malaria.
- Intermittent preventive treatment with Sulfadoxine-Pyrimethamine should not be given to pregnant women with HIV receiving cotrimoxazole prophylaxis.
- PLHIV who develop malaria should receive prompt and effective anti-malaria treatment using artemisinin-based combination therapies (ACTs)
- PLHIV receiving AZT or EFV should, if possible, avoid amodiaquine-containing artemisinin-based combination regimens because of the increased risk of neutropenia in when used with AZT and hepatotoxicity when used with EFV.

6.6. SEXUAL AND REPRODUCTIVE HEALTH SERVICES

6.6.1. SCREENING AND MANAGEMENT OF SEXUALLY TRANSMITTED INFECTIONS (STI'S)

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 RPR (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 below.

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:** Any genital sore is any sore or lesion that appears on the ☐ Penis ☐ Scrotum ☐ Male urethra **For Women:** Genital Ulcer Sores in Females involving; ☐ the skin surrounding the vulva, ☐ labia ☐ vagina ☐ perineum ☐ perianal ☐ anal regions
ABNORMAL VAGINAL DISCHARGE	**Fungal cause:** ☐ Vaginal discharge with Thick, white, cheesy **Bacterial cause:** ☐ Vaginal discharge with White, gray, or yellow with 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 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 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 in 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 10-14 years are eligible for vaccination. Currently, HPV vaccination is not recommended for adolescent boys because it is not cost effective. Figure 10 describes the available HPV vaccine.

Figure 10: 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 and also the side effects of ARVs used for treatment. Therefore, at each clinic visit, the patient should be screened for diabetes, hypertension, and depression.

6.7.2. DIABETES MELLITUS (DM)

HIV-infected adults experience more chronic metabolic complications as a result of both the HIV infection itself and the 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 Diabetes Mellitus 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 e.g. Protease Inhibitors e.g. lopinavir, and ritonavir causes insulin resistance by causing Lipodystrophy, Impaired Glucose Transporter Type 4 translocation, Reduced adipocyte differentiation, reduced insulin secretion, dyslipidemia with lipotoxicity.
- Other ARVs like NNRTIs and Integrase Inhibitors can be used safely.

6.7.2.2. Screening and diagnosis

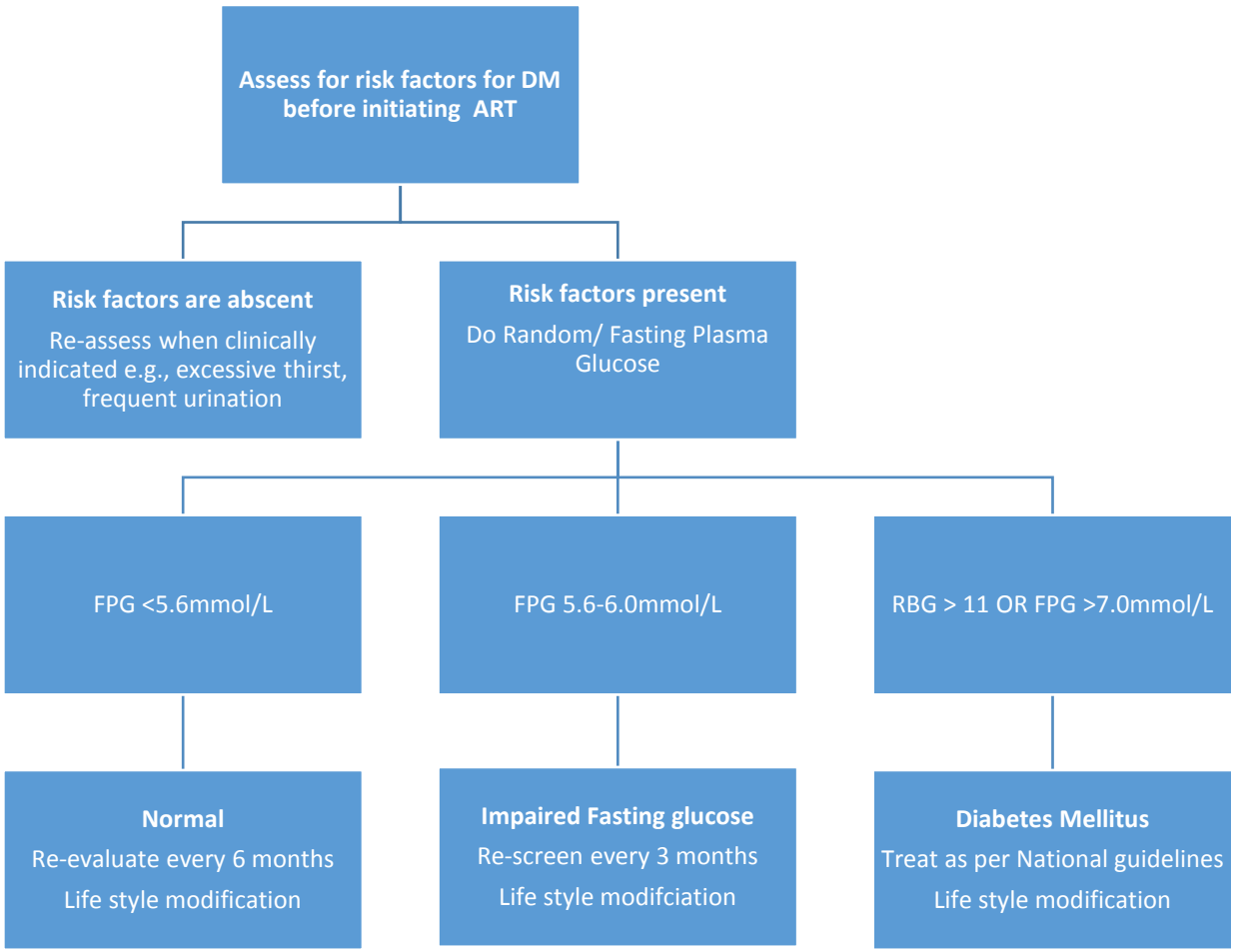
Patients should be assessed for risk factors for DM before initiation of ART and when clinically indicated. Those with risk factors should thereafter be re-evaluated every six months as detailed in the algorithm Figure **11**.

6.7.2.3. Treatment

HIV-positive patients with DM should be treated as per the National guidelines. (Uganda Clinical Guidelines). 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.
- Avoid Lopinavir/r can be used with close monitoring.

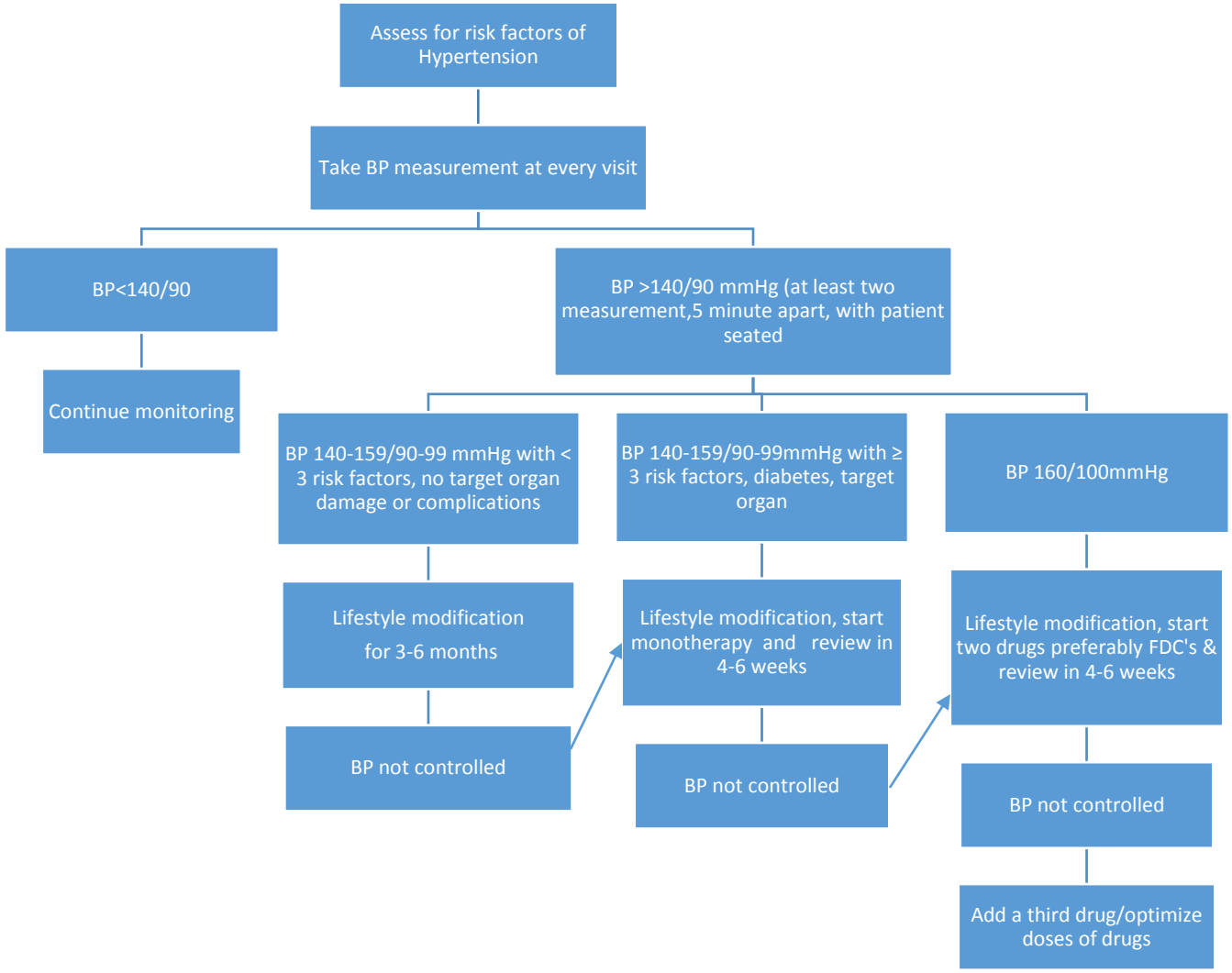
Figure 11: Algorithm for diagnosis and management of diabetes



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 >140/90mmHg at least two measurements five minutes apart with the patient seated should be managed as guided by the algorithm Figure 12. People with any risk factor identified should be advised to modify lifestyle as described in section 6.7.4 below

Figure 12: 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, esophagus, and breast.
- Hypertension, diabetes, heart disease, and stroke

2. Exercise

Clients should be advised to have aerobic exercises for at least 30 minutes 5 days a week. Aerobic exercise has positive effects on blood pressure whether or not a person has hypertension, producing average reductions of 4 mm Hg in systolic blood pressure and 3 mm Hg 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;

- Eat a diet high in fruits and vegetables and low in fat. And limit 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 reducing 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 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 13 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 three should be further evaluated using the longer version, the PHQ-9 Figure 14 in facilities where staff have been trained to use this tool.

Figure 13: 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 "X" 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, and 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 14: 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 "X" 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 difficu ☐ very difficu ☐ Extremely difficu ☐

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 Anti-depressants

Interactions between ARVs and anti-depressants are in Table 37 below

Table 37: Interactions between ARVs and common anti-depressants and recommended management

ARV	Anti-depressant	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. HPV VACCINE

Adolescents aged 10 to 14 years will receive the HPV according to the national recommendation. **See** Figure 10

6.8.3. 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. And is recommended during yellow fever outbreaks and for those intending to travel. 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. Some of the interventions are in Table 38 below

Table 38: Positive health, dignity, and prevention intervention

Intervention	Description
Support and promote adherence	See Chapter 7
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 like poor treatment adherence leading to 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 to sustained HIV viral suppression, reduced risk of drug resistance, improved overall health, quality of life, and survival, as well as decreased the 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, monitor and support them to adherence 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, who are at high risk of death. The healthcare team should use the 5 A's principle for chronic care as a guide to offer pre-ART adherence counseling and psychosocial support. These are; **Assess, Advise, Agree, Assist** and **Arrange** and are in Table 39 below.

Table 39: 5 A's 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. • Identify myths and misconceptions about HIV and ARVs • Potential barriers to adherence Table 41 • Patient psychosocial concerns & needs that may hinder adherence to ART • Patient willingness and commitment to take medicines correctly. • Patient readiness to honor subsequent appointment for treatment support. • Patients 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 • HIV and ARVs • Provide information on adherence to ART. Include information on the 5 R's- (taking the right medicine, at the right time, right dose, right way, and right frequency) • Demonstrate how the ARVs are taken.

Guide	Components
	• Provide information side effects of ARVs, improved quality of life while on ART, changes that may occur in a person's life once on treatment • Benefits of disclosure and support systems to adherence • How they will be monitored once on treatment and frequency Other ways of assessing adherence and response to treatment including pill counts • Emphasize that the importance of attending all the clinic appointments for review and support. • Discuss the Positive Health Dignity and Prevention package • The implication of not adhering to ARVs treatment. • Explain what VL test is and the meaning of suppressed and unsuppressed viral load
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 • To 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.
Agree on	• An adherence plan-Table 42 • Family and community support systems (Expert client in the community) • Possible home Visit and consent • Possibility testing of other family members including sexual partner and children • Assess client's readiness to start ART Table 43

Arrange	• For the patient to see a clinician for ARV prescription if they are ready to start ART
	• Arrange for 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.
	• For client to join psychosocial support groups and use support systems
	• Follow up appointments system (Home visiting where appropriate, Phone call reminders and text messages where appropriate)
	• Monthly counseling sessions for drug adherence.
	• To review 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 about HIV and ARVs and answers

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 body CD4 cells 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.
How do ARVs work ?	Its stops the virus from multiplying in the body resulting in an increase in the clients CD4 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. • In children, they will grow and develop better. • Increases your life span since one will not be falling sick often ○ Because you are not sick often, you 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 the client has been prepared enough to start ARVs using the 5 As approach
How much ARVs should the patient take daily and how often?	Although these are all ARVs, they are of different types and therefore a patient should take their medicine according to the health workers prescription. Drug sharing should be prevented it affects adherence. Patients qualify for different ARV drug regimens depending on age, type of job, weight in children, prevailing clinical condition and so 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, Steven Johnson's syndrome e.t.c
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 the patient return for HIV care?	• The patient should always return for care and monitoring as scheduled by the health worker. • When they experience a side effect or a psychosocial challenge • When they 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 not seen on the outside. It destroys cells that help your body fight diseases. Soon you may start falling sick often.

Questions	Answers
	• 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 one's immunity is low **For children & adolescents:** • They 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 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 an HI-free baby.*
Benefits of adhering to ARVs	• Suppresses the multiplication of the virus in their bodies. • The CD4 count will increase, and they 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 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	• The patients may not be able to suppress viral multiplication in their bodies • The virus will continue to destroy their immune system and decrease their CD4 count. • When their CD4 count is low, they will be prone to opportunistic infections, and they will develop more severe disease. • The virus in their bodies may also become resistant to ARVs • They will have limited options for treatment and require more costly ARVs for their treatment which may not be readily available in the country. • Become less productivity 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

Population	Barriers
Infants and Children	• Lack of a committed, involved and responsible caregiver. • HIV infected caregiver/parent with ill-health/adherence/emotional challenges. • Care giver'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 • 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
	  ○ Assuming increased responsibility for their care
	  ○ Issues relating to disclosure to peers or partners
	  ○ 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 include poor-quality clinical practices, gaps in provider knowledge and training, poor access to services.
Adults	• Social barriers (e.g. long work schedules/job time/nature of Job) • Forgetfulness

Population	Barriers
	• Lack of trust in providers or medicines • Stigma &.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, • nature of Job/engagement, • High Mobility • GBV • lack of peer support • Lack of knowledge by health workers on KPs
People with mental health conditions and Substance Abuse	• Uncontrolled depressive symptoms • forgetfulness, • poor organization • Poor comprehension of treatment plans.

Table 42: Ten question 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/factor may affect your adherence (explore for non-disclosure, alcohol and substance abuse, sexual partner(s), and stigma	

Table 43: ART Readiness Assessment Form

7.3. MONITORING ADHERENCE TO ART

Adherence to lifelong ART requires ongoing assessment and monitoring and should be part of

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			
4. Is willing to disclose/has disclosed HIV status to a sexual partner and significant other?			
5. Has received demonstration of how to take/administer ART and other prescribed medication?			
6. Has received information on predictable side effects of ART and understands what steps to take in case of these side effects?			
7. For patients dependent on a caregiver: caregiver is committed to long-term support of the patient, daily administration of ART, and meets the criteria above?			
8. Other likely barriers to adherence have been identified, and there is a plan in place to address them (e.g. frequent travel for work, plan to deal with unexpected travel, distance from clinic, etc.)?			
9. Patient/caregiver has provided address and contact details?			
10. Patient/caregiver feels ready to start ART today?			
B. Support Systems Criteria (applies to patients and caregivers)			
11. Has identified convenient time/s of the day for taking ART?			
12. Treatment supporter has been identified and engaged in HIV education, or will attend next/ counseling session?			
13. Is aware of the support group meeting time/s?			
14. If the facility has SMS reminder system: Has enrolled into SMS reminder system?			
14. Other support systems are in place or planned (e.g. setting phone alarm, pill box)?			
C. Medical Criteria			
15. Patient newly diagnosed with TB Differ ART and start at two 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 Kernigs' sign).* Differ ART until 4-6 weeks after treatment for cryptococcal meningitis			
• *The only absolute criteria for differing 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.			

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

7.3.2 SELF-REPORTING

Self-reporting is a 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 way as possible. All patients and 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 guide questions Table 44 to determine adherence and reasons for not adhering to ART.

Table 44: Four question guide for reviewing an adherence plan

Question	Client Response
How many times do you take drugs in a day?	
What time do you take it?	
How many doses have you missed in the past month?	
What are the reasons for missing your drugs	

- Use the number of missed of missed ARV doses in the past month to determine adherence level and appropriate action. See 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

$$\% \text{ adherence} = \frac{\text{no of pills taken}}{\text{Total number pills expected to have been taken.}} \times 100\%$$

- 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		% 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	

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 and are already a part of national monitoring and evaluation frameworks in many settings.

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, diaries can be used by clients.
- **Behavioral skills training and medication adherence training**. These included 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-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 lead 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 DETECTABLE 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 and 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 A's 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: 5 A's for adherence support for people with non-suppressed viral load

Guide	Components
Assess	• Clients adherence history • Patient psychosocial concerns & needs • Patient willingness and commitment to take medicines correctly. • Patients' understanding of the implications of a non-suppressed viral load. • The barriers to ART adherence. • Patient readiness to receive comprehensive counseling on a monthly basis. • Psychological state in the past two weeks
Advise (information giving)	• Explain what VL test is and results (Suppressed and non-suppressed viral load) • Non -suppressed Viral load means; o Either the ARVs are not working well, or patient is not taking medicine well. o The amount of virus in the patient's blood is high and is going to destroy their CD4 cells quickly thus lacking 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 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, family members • Brainstorm on strategies to facilitate good adherence e.g. appointment keeping for

Guide	Components
	re-fills and reviews such as treatment buddies, social support groups, Joining VSLAs, Linkage to CBOs, • To disclose to a trusted person of their own and significant other. • Document the agreed upon options on the HIV/ ART card, and Routine/ intensified adherence counseling form
Agree on	• Action plan on how to achieve Viral Suppression including • Use Table 42 to develop an adherence plan • The support systems to help the client implement the agreed action plan. • ***Support 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 • Phone call reminders • Monthly counseling sessions targeting drug adherence. • Follow 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 TO START 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 15 for the process of evaluating patients for ART

Figure 15: 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.
- Allows for harmonization of regimen across age and population
- Lower cost
- Help the country to achieve a recommended regimen for the vast majority of People living with HIV (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+EFV600mg) as a once-daily fixed dose combination. Table 47

Rationale for preferring TDF+3TC+EFV 600mg

TDF+3TC+EFV600mg is the recommended first line regimen because;

- Despite TDF+3TC+EFV400mg being comparable to TDF+3TC+EFV600mg regarding viral suppression and CD4 cell recovery, there is limited data and experience of the safety and efficacy of TDF+3TC+EFV400mg in pregnancy and TB/HIV co-infection
- There is no experience on the use of TDF+3TC+EFV400mg in ART-experienced PLHIV already on TDF+3TC+EFV600mg.
- Using TDF+3TC+EFV600mg harmonizes the regimen for adults, adolescents, and pregnant women.

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 like;

- Severe clinical depression, psychosis or suicidal tendencies.

- Ongoing complications of neurological disease that block the prescriber's ability to assess side effects of EFV
- Those using Anxiolytics especially, Benzodiazepines or Carbamazepine.
- In severe hepatic impairment
- In HIV/TB Co-infected PLHIV using Bedaquiline
- In 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, the fixed dose combination (TDF+3TC+DTG) is not yet available, and 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 contra-indicated, for example:

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

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

PREFERRED FIRST-LINE REGIMEN: TDF+3TC+EFV600mg

All HIV-infected pregnant, and breastfeeding women should be initiated on Tenofovir, Lamivudine, and Efavirenz (TDF+3TC+EFV600mg) Table 47

The rationale for using TDF+3TC+EFV600mg in pregnant and breastfeeding women is the same as in adults and adolescents in section 8.4.1 above

WHEN TO USE ALTERNATIVE FIRST LINE REGIMENS

AZT+3TC+ATV/r

Pregnant and breastfeeding women should be initiated on AZT+3TC+ATV/r only when TDF or EFV are contraindicated section 8.4.1 above.

8.4.3. RECOMMENDED FIRST-LINE REGIMEN FOR INITIATING ART IN CHILDREN 3 to 9.9 YEARS OF AGE

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

All HIV-infected children aged 3 to 9.9 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 dosing which may improve adherence.

WHEN TO USE ALTERNATIVE FIRST LINE REGIMENS

ABC + 3TC+NVP
Children aged 3-9.9 years should only be initiated on ABC+3TC+NVP if EFV is contraindicated like in the following conditions;

1. A child diagnosed with severe clinical depression or psychosis
2. A child with ongoing complications of neurological disease that block ability to assess side effects
3. A child using Benzodiazepines or Carbamazepine's

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 LPV/r based regimen as recommended first line
Children younger than 36 months have a reduced risk of discontinuing treatment, viral failure or death if they start on 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. Furthermore, LPV/r is known to have a high barrier to resistance. The other potential advantage is the considerable reduction in the incidence of malaria among children receiving LPV/r based ART, as demonstrated by a study among children in Uganda.

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	**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+DTG
Pregnant and breastfeeding women	**RECOMMENDED 1ST LINE REGIMEN** • Pregnant OR breastfeeding women initiating ART	**TDF+3TC+EFV**
	If EFV[1] or TDF[2] are contraindicated	AZT+3TC+ATV/r
Children 3-9.9 years old	**RECOMMENDED 1st LINE REGIMEN** • Children 3-9.9 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
- Wt<35kg

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 and as 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

- Demographics (age, sex etc).
- Screen for signs and symptoms of OIs e.g. TB cryptococcal meningitis, Hep B & C infection and other illness, e.g., malaria
- Screen for pregnancy (women of reproductive age)
- Screen & manage OIs
- Screen & managed co-morbidities
- Screen and manage STI's
- Screen for symptoms of depression.
- Previous history of ART.
- Previous history of chronic illnesses (hypertension, DM, COPD, Kidney disease)
- Current medication
- Establish family planning methods currently in use.
- Assess development, sexual awareness and behavioral issues in adolescents.
- School attendance (children of school going age)
- Progress with disclosure if not done already
- Nutritional assessment-weight & height in all patients, plus Mid-upper arm circumference (MUAC) in children 6-59 months
- Growth & development assessment and monitoring in children under 5's
- Examination of vital signs, skin, eyes, oropharynx (presence of thrush), lymph nodes, lungs, heart, abdomen, genital tract (for STIs), extremities, nervous system
- 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 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.
- Measuring viral load 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).

Frequency of Viral load:

Adults: The First Viral load (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 16

Children and adolescents under 19 years of age: First VL test should be done at six months after initiating ART, and if it is suppressed, do VL every six months.

Pregnant women:

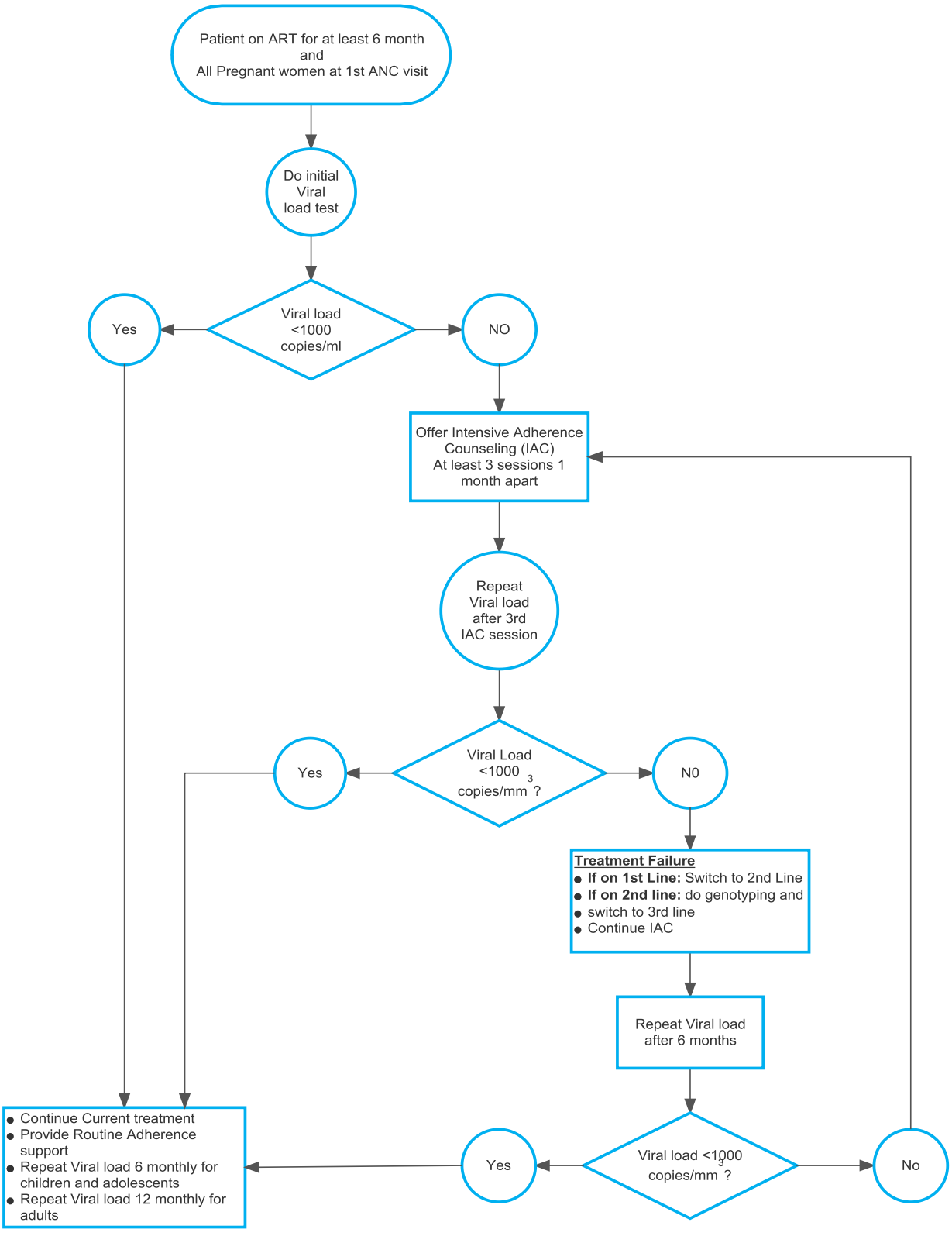
- If newly initiating ART, follow the standard algorithm like adults
- If already on ART, a VL test is done at ANC 1, irrespective of when the last VL Test was done, then follow the standard VL algorithm.

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

For non-suppressed PLHIV, repeat the VL test within six months after the last non-suppressed test. Within this period, the following should have been done:

- Contact the patient to return to facility within one week after facility receives results
- The facility ART Team should hold a case discussion 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.
- 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 on Table 53

Figure 16: 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 help to screen for risk for opportunistic infections, e.g. in patients with CD4 less than 100 cell/mm, screening for cryptococcal infection is recommended.
- ART patients with VL >1000 with 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. See Table 49 for the lab tests and their clinical indication.

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

Test	Indication
CRAG	(CD4<100cells/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	Comorbidities' e.g. DM, Hypertension
ALT, AST	Compromised liver function, e.g. Hepatitis B and C infection, ART hepatotoxicity
Lipid profile & Blood glucose	comorbidities, e.g., Diabetes Mellitus, hypertension and lifestyle risk factors, patients on ART for more than five years, PLHIV ≥ 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) Assess readiness for ART (refer to section) Provide CTX Provide FP if required	• HIV test, CD 4, HBsAg, CrAg if CD4 <100 **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 (HBVor HCV infection, • Lipid Profile and Blood Glucose

Time	Clinical assessment	Laboratory tests
During on ART		
1 month	• Comprehensive clinical assessment. seeTable 48 • Also, assess for; drug intolerance, side effects/toxicities, and IRIS • Adherence assessment, monitoring, and support • ART &CTX refill- ***In children adjust dose based on weight*** • FP refill **If the patient is clinically well, give one months' refill and appointment.**	Do other lab tests if clinically indicated see Table 49
2 month	• Comprehensive clinical assessment see Table 48 • Also, assess for; drug intolerance, side effects/toxicities, and IRIS • Adherence assessment, monitoring, and support • ART &CTX refill-***In children adjust dose based on weight*** • FP refill **If patient is clinically well, give one month refill**	Do other lab tests if clinically indicated see Table 49
3 month	• Comprehensive clinical assessment seeTable 48 • Also, assess for; drug intolerance, side effects/toxicities, and IRIS • Adherence assessment, monitoring, and support • ART &CTX refill-***In children adjust dose based on weight*** • FP refill **If patient is clinically well, give three months' refill**	Do other lab tests if clinically indicated see Table 49
During ART		
6 month	• Comprehensive clinical assessment seeTable 48 • Also, assess for; drug intolerance, side effects/toxicities, and IRIS • Adherence assessment, monitoring, and support • ART &CTX refill-***In children adjust dose based on weight*** • FP refill • **If patient is clinically well, give three months' refill**	Do VL test If VL is not suppressed, call the patient back for intensive adherence counseling. Do other lab tests if clinically indicated see Table 49
9 month	• Comprehensive clinical assessment See Table 48 • Also, assess for; side effects/toxicities. • Adherence assessment, monitoring, and support • ART &CTX refill-***In children adjust dose based on weight*** • FP refill • **Determine eligibility and prepare for DSDM**	For VL suppressed PLHIV, give VL results Do other lab tests if clinically indicated see Table 49

Time	Clinical assessment	Laboratory tests
12 month	• Comprehensive clinical assessment Table 48 • Also, assess for; side effects/toxicities • Adherence assessment, monitoring, and support • ART &CTX refill-***In children adjust dose based on weight*** • FP refill • **If patient is clinically well, give three months' refill**	2nd VL in children Do other lab tests if clinically indicated see Table 49
After 12 months on ART following DSDM		
3 monthly	• Adherence assessment, counseling, and support • TB Screening • ART and Cotrimoxazole refills • Family planning refills • Refer where clinically indicated	Do other lab tests if clinically indicated see Table 49
6 monthly	• Comprehensive clinical assessment as at month one above • Adherence assessment, counseling, and support • TB Screening • ART and Cotrimoxazole refills • Family planning refills	Do other lab tests if clinically indicated see Table 49
Annually	• Comprehensive clinical assessment as at month one above • Adherence assessment, counseling, and support • TB Screening • ART and Cotrimoxazole refills • Family planning refills	VL Cervical Cancer screening Do other lab tests if clinically indicated see 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, but
- 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 are for TB, cryptococcosis, 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.

8.5.5.1. Risk factors for IRIS include

- A low CD4+ cell count (<50 cells/mm3) at ART initiation.
- Disseminated opportunistic infections or tumors and
- A shorter duration of therapy for opportunistic infections before ART starts.

8.5.5.2. Managing IRIS

- Iris is generally self-limiting, and interruption of ART is rarely indicated.
- Treat the infection
- If the symptoms are protracted, reassure the patient to prevent discontinuation of or poor adherence to ART.

8.5.5.3. Steps to reduce development of IRIS

- Diagnose HIV early and initiate ART before CD4 declines to below 200 CD4 cells/mm3
- 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 e.g. 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 they 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

Healthcare 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 as shown in Table 51 below.
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 discontinuation ART. Continuation of 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 you are doing substitutions within six months of starting ART, you do not require to do a viral load test.

However, after six months on ART, you may require a viral load test to rule out treatment failure before you substitute only one drug 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, you need to switch to 2nd line.

See Table 52 below 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**	Re-assure, lower the dose of EFV to 400mg.If persists substitute with DTG 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	Gynecomastia	**TDF**	Substitute with ABC Use regimen ABC+3TC+DTG
		Chronic Kidney Disease Acute kidney injury and Fanconi syndrome		
		Decreased bone mineral density		
		Lactic acidosis or severe hepatomegaly with steatosis		
		Hepatotoxicity	**DTG**	Substitute with EFV Give TDF+3TC+EFV **If EFV is contraindicate** 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 contraindicate** 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** Substitute with ABC **Use regimen:** 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, Steven Johnson Syndrome (Severe or life-threatening rash)		
	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 substituting
	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 0-9.9 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, Steven Johnson Syndrome (Severe or life-threatening rash)		
	ABC+3TC+LPV/r	Hypersensitivity	ABC	Stop and substitute with AZT Use regimen AZT+3TC+LPV/r
		Electrocardiographic abnormalities (PR and QRS interval prolongation, torsade's de pointes)	LPV/r	Stop and substitute with NVP Use regimen: ABC/3TC/NVP
		Hepatotoxicity		
		Pancreatitis		
		Dyslipidemia		
		Diarrhoea		

Age category	Regimen	Major toxicity events	Responsible ARV	Suggested management
		Unable to tolerate taste		
Children 0-9.9 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: 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, Steven Johnson Syndrome (Severe or life-threatening rash)		
	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 VIROLOGICALLY SUPRESSED 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 viral 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 and improved immunologic response and lipid profile outcomes as those who continue on LPV/r.

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

When children on ABC based first line regimen turn 3 years of age and weight 35kg, a viral load should be done and if they are viral suppressed, ABC should be substituted with TDF
Benefits: TDF reduces pill burden, simplifies forecasting and quantification and is cheaper than ABC.

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

8.7. DRUG INTERACTIONS

Drug Family	ARV Drug	Interaction	Action
Anti-TB Medicines	NVP	Rifampicin decreases NVP concentrations in blood They 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 PI's	If given together with LPV/r- increase the dose of RTV to achieve 1:1 ratio.
Combined Oral Contraceptive Pills, 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.	ATV/r, LPV/r,	Risk of respiratory	Reduce dose of Midazolam

Drug Family	ARV Drug	Interaction	Action
Midazolam, Diazepam	DRV and RTV	depression (Midazolam) Increased sedation (Diazepam)	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 hrs before or 6 hrs after the product to avoid interaction.
Antimalarial 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 summarized in Table 53. Although in the previous guidelines, immunological criteria were included, in this guideline it is not recommended for monitoring response to ART.
- When treatment failure is confirmed, the patient should be switched to a new ARV regimen; 2nd line regimen for those failing on the first 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 53: 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 and 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 (2ND LINE AND 3RD LINE ART)

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

RECOMMENDED 2nd line REGIMEN: 2NRTI's +ATV/r

HIV-infected adults, adolescents, pregnant and breastfeeding women initiating 2nd line ART should be initiated on 2 NRTI's and ritonavir-boosted Atazanavir (ATV/r). The choice of NRTI should be determined based on the regimen the patient was on. Table **54**

The recommended sequence is below;

- 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

2NRTI's +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 9.9 YEARS

RECOMMENDED 2nd line REGIMEN: 2NRTI's +LPV/r

HIV-infected children aged 3-9.9 years initiating 2nd line ART should be initiated on 2 NRTI's 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. Table **54**

The recommended sequence of the NRTI's 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:
2NNRTI'S + RALs
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: 2NRTI's +RAL

HIV-infected children less than 3 years of age initiating 2nd line ART should be initiated on 2 NRTI's and Raltegravir (RAL).
The choice of NRTI should be determined based on the regimen the patient was on. Table **54**
The recommended sequence of the NRTI's is as for the children < 3 years of age is below;

- 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:
2NNRTI'S + LPV/r
LPV/r is recommended in children who have used NNRTI (NVP) in their first line regimen.

8.9.4. THIRD LINE ART REGIMEN

Eligibility for Third Line ART
Patients on 2nd line ART who meet the following criteria are eligible for 3rd 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 enhanced 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 the second line has suspected resistance to second-line ART

- When a patient on 2nd line ART is confirmed to be failing following criteria one above, they should be referred to the nearest treatment center providing third line ART.
- Before anyone is switched onto 3rd 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 Lactating Mothers

- The recommended 3rd line regimen will include boosted Darunavir, an integrase inhibitor 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 3rd line regimen.
- The choice of NRTIs in the 3rd line regimen will be based on resistance profiling.

Recommended Third Line Regimens for children aged 3 years to under 12 years

The recommended 3rd 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 54: Second and Third line ART regimens for patient failing on treatment

Population	Patients Failing First-Line Regimens	Second-Line Regimens	Third Line[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 INSTI's DRV/r +DTG ± 1-2 NRTIs If patient is exposed to INSTI's 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 – 9.9 Years	ABC + 3TC + EFV	AZT+3TC+LPV/r	For children above 6 years, and prior exposure to INSTI's 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 & 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 HTS and care and treatment for PLHIV & TB for adoption by the facilities and communities managing PHLIV. The details on how the differentiated care models will be implemented in Uganda are described in the DSD operation manual.

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 empowers them to manage their disease with the support of the health system. Under the differentiated service delivery models, the health systems will shift away from a "one-size-fits-all" to focus on clients who are most in need.

9.1.3. WHY WE NEED DIFFERENTIATED SERVICE DELIVERY

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 identify better 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

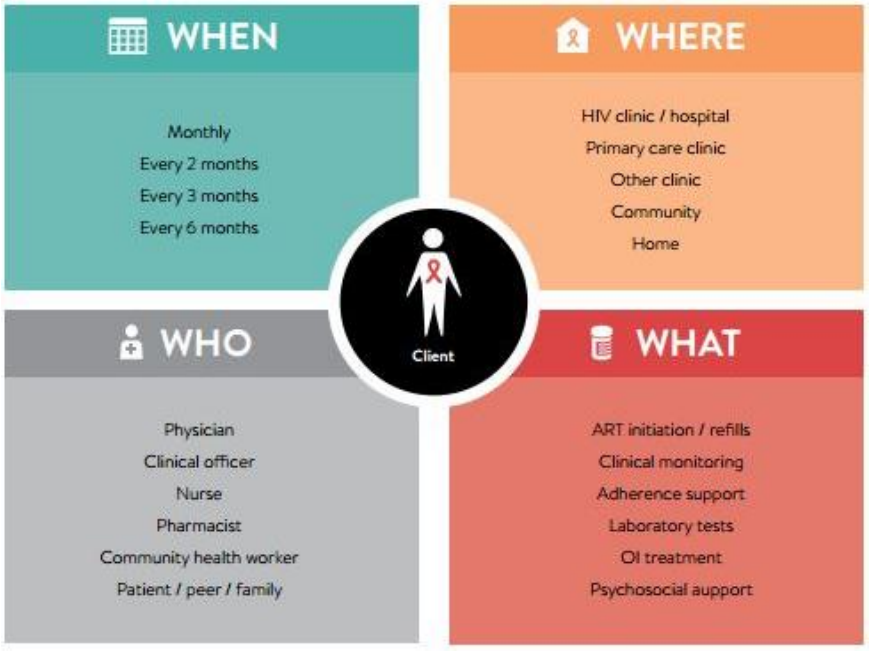
The DSD will meet the different care and treatment needs of different groups of clients including stable clients, clients newly initiating ART, children, adolescents, pregnant and lactating women, patients suspected of failing ART, and those with concurrent illness/ co-morbidities such as TB.

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 17 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 17: 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

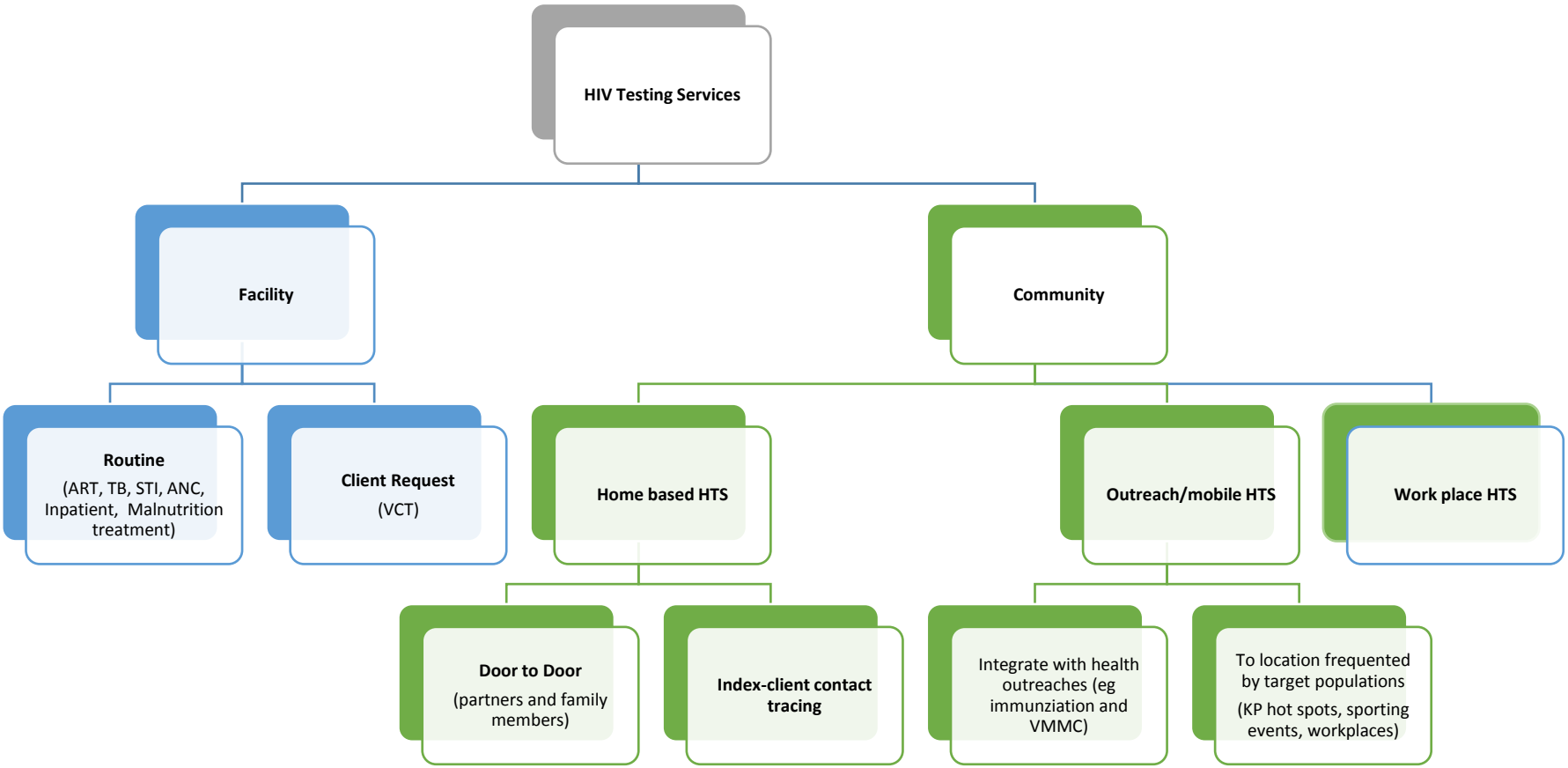
9.1.6.1. DIFFERENTIATED HIV TESTING SERVICES

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 18

- 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 18: 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 and 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 nine months' visit

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

The recommended differentiated HIV care and treatment models for PLHIV include; (i) Facility based models and (ii) Community-based models. Figure 19

- 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/healthcare 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.

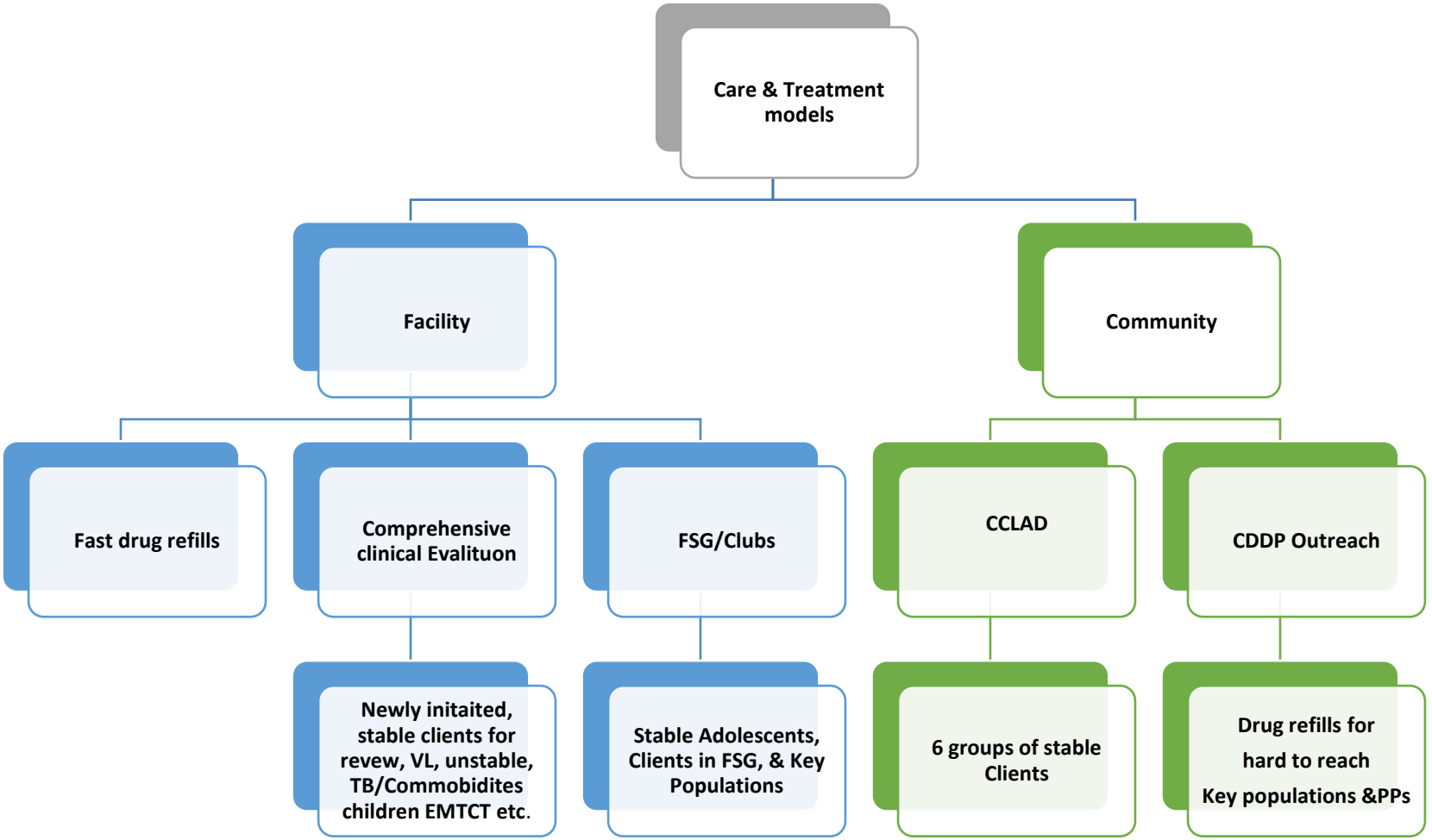
- Two delivery approaches are recommended for the Community-based model;
    - Community Drug Distribution Points (CDDP's), community outreaches by HCW targeting clients in remote areas with poor accessibility to health facilities for ART e.g. islands, landing sites, pastoral areas, districts with many HCIIs that are not accredited to offer ART and yet 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 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 19: 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 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 pregnant and lactating women, their HEIs and male partners, children, adolescents and Adults LHIV as per National HTS, Care & Treatment guidelines and policies. Continuous quality improvement approach shall be used to integrate DSD into routine client management both at the health facilities and community. 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, community leaders) should be empowered to communicate DSD effectively. This shall promote 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 below.

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 HCWs 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 starting with high volume sites that are ready, based on the outcome of the site assessment. The training for HCWs will detail the recommended differentiated service delivery 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 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 start 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 were 60% and 75% respectively. To mitigate such losses of patients from care during the test and start implementations the country will implement the strategies outlined in Table 55 below

Table 55: strategies for improving retention in Care.

Strategy	rationale
1. **Decentralization of ART care and Laboratory services** • MOH and district health teams will work to decentralized ART services to all HCIII's and eligible HCII's. • 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 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 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 • Partner 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	• Patients who miss appointments will be identified easily and will be followed and brought back into care if found.

Strategy	rationale
through CQI initiative	
4. Strengthening client counseling and education services at the health facilities • Health workers, counselors, VHT's, CHEWs, Expert clients, peer mothers and lay testers will be trained to provide standardized patient counseling services including adherence and psychosocial support. • Patients will be initiated on treatment when they have been prepared and are ready to start ART.	When patients are educated and counseled well, they are empowered to support their care and are more likely to stay in care.
5. Implement evidenced based communication strategy The country will use a communication strategy that will address individual, interpersonal, organization, community and society barriers to retention in care.	Improving patient education and addressing barriers will improve health seeking behaviours.

9.3. DELIVERING HIV SERVICES FOR ADOLESCENT.

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 adolescent's health care providers need to provide adolescent-friendly health services (AFHS). AFHS friendly 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 e.g. 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 adolescents job aides during service provision. Identify peers, train and use them to support the provision of services. ***Ensure the clinic has the following cadre of staff; clinician, counselor, nurse, peer***

	<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 inform of; posters brochures in a language best understood by the adolescent.
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 & care is recommended for all adolescents with a focus on those from key populations. **Informed consent and HIV testing** Adolescents 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, weekends 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, and they include; • Peer- to- peer engagement. • Multimedia campaigns including; TV, radio, and billboards, brochures. • Social media: Facebook, Twitter, WhatsApp, Instagram. • 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 e.g. clubs. • Community events; 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 in where adolescents routinely receive care including; • OPD/YCC, ANC, maternity, family planning and sexual and reproductive health service delivery points. • Youth/ adolescents information centers / corners. • Community-based / mobile outreach testing sites targeting key population e.g. Moonlight testing for out of school adolescents, bars, 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 (on-going risk is once every three months, and once a year if exposed after last HTS). Messages should focus on avoiding cross generation sex, multiple partners, transactional sex and promote abstinence ad delayed sexual activity. • Encourage condom use for 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. • Offer voluntary safe male medical circumcision. • 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, and paralegals. • 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. See 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. • The readiness for disclosure to others should be determined by 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.

	• Encourage them to disclose their HIV status to their parent/ guardian and significant others. • Counsel about the potential benefits and risks of disclosure of their HIV status to others. <u>Benefits of early disclosure include;</u> • Improved adherence to medicines and access 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. <u>Risks of disclosing</u>; physical harm, discrimination, stigma, unwilling onward disclosure and isolation may be experienced as a result of disclosing HIV status to others. <u>Risks for delayed or non-disclosure;</u> stigma, shame, and fear. • Discuss on how to disclose using role plays and support them to determine if, when, how and to whom to disclose their HIV status. • A health care provider or peer if needed 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 Gender-based Violence (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; life skills training. • Regularly update contact information especially physical address and telephone contacts, use appointments calendars and send messages (SMS reminders for appointments). • Conduct activities such as games and sports, music, drama, games 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 important factor in the long-term well-being of 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. Settings where there is an integrated clinic providing services for children, adolescents, and adults in the same facility the process should follow the steps below:

adolescent.	• 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 adolescents' 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, they express readiness to transition introduce the adult care team (who may be the same staff). However for health facilities with a separate adolescent clinic from the adult one in addition to the above schedule 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 clinic at the agreed appointment and hand them over.

9.4. INTEGRATING CONTINUOUS QUALITY IMPROVEMENT (CQI) 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 5s and continuous quality improvement (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 56** below describes the steps involved in using CQI to address HIV service delivery gaps. Step 1 and 2 describe the process of forming teams while step 4-5 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 56: 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 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 HIV QI indicators • Analyze the data and identify performance gaps by comparing performance Vs 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 the 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** • Listing 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 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. • Using QI tools such as brainstorming, flow charting, five whys, or cause and effect analysis or driver diagrams, the team should identify the root causes of the performance gaps • Brainstorming possible changes that the team will test to address the identified root causes using a PDSA cycle • Documenting the data from the data review process in the graph template of the DJ • Developing an action plan indicating the changes that the team as 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 through team meetings
- 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 C supervise and guide QI implementation at health facility
- 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
Health Sector Quality Improvement Framework and Strategic Plan (QIF & SP) 2015/16 - 2019/20

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 goal

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 (ART 2016).
- 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, Laboratory Officer, M&E officer, and store managers.
- Ordering process 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 Laboratory 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.
- M&E officers should analyze facility patient data and provide the following information
  - 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. New patients 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 / implementing partners and regional central warehouse focal

contact sites to facilitate the stock transfer. The stock should be redistributed in line with the MOH commodity redistribution strategy 2012.
It is important to note that all HIV commodities are free of charge and 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 the patients on how to take the medicines
- Counsel patient 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 how patients should take their medicines.
- Appropriately label the medicine packs to include the patient's name and dose.
- Medicines for distribution under the community drug delivery points should be packaged and labeled for each patient
- Offer further explanation/counseling to patients on multiple medicines because of other co-morbidities. Communicate possible drug interactions and adverse effects
- New formulations should be introduced to patients effectively 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 are 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, 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. Paper-based records are used to update electronic medical record systems where they exist.

11.2.1. UNIQUE IDENTIFIERS

A unique identifier will be assigned to each client to facilitate linking and tracking patients across different facilities, service areas, and databases.

11.2.2. PAPER-BASED MONITORING TOOLS

Several tools are used for paper based monitoring. Table 57 below shows the different tools and their description.

Table 57: Paper-based Monitoring Tools

Service	Paper-based Tool	Paper-based Tool Description
HIV Prevention		
VMMC	HMIS Form 035	Safe male circumcision procedures performed
PEP	HMIS Form 036	Post-exposure prophylaxis (PEP) provided
PrEP	TBD	Oral pre-exposure prophylaxis (PrEP) provided
___	TBD	Key population register of high-risk groups
Testing, Counseling, and Linkage		
HTS	HMIS Form 055	Record all clients accessing HIV counseling and testing services in facility
	HMIS Form 055B	Client card for HIV testing and counseling services
Linkage	HMIS Form 081A	Linkage to HIV services within the health facility
	HMIS Form 032	Record of referrals to higher-level health centers
Lab tests	HMIS Form 055A1	Daily activity laboratory log of tests consumed
Care and Treatment		

Service	Paper-based Tool	Paper-based Tool Description
Adults, adolescents, and children		
HIV care	HMIS Form 053	Appointment register of all HV-positive clients receiving HIV care services at facility
	TBD	Register of HIV-positive clients receiving HIV care services in community
Pre-ART	HMIS Form 080	Register of all HIV-positive persons enrolled in HIV care
ART care	HMIS Form 122A	Individual client card used to record HIV/ART care of an HIV-positive individual
	HMIS Form 081	Register of all clients accessing ART services
Adverse events	___	Pharmacovigilance form to submit to NDA to report adverse reactions or side effects to any drug
Pregnant women and infants		
HIV-exposed infants	HMIS Form 082	Register of all HIV-exposed infants
	HMIS Form 082A	Individual chart for used to monitor an HIV-exposed infant
Support	HMIS Form 052	Register clients linked to family support groups
Other ANC monitoring tools	*HMIS Form 071*	*Register of antenatal clients attending a facility*
	HMIS Form 072	*Register of admissions, deliveries, admissions of obstetrical complications*
	HMIS Form 078	*Register of postnatal clients attending a facility*
Monitoring ART Response		
VL/CD4	HMIS Form 095	Record of tests and results for viral load and CD4 counts
VL suppression	TBD	Register of all clients on ART whose viral load is not suppressed
Management of Coinfections and Comorbidities		
Nutrition	HMIS Form 077	Integrated nutrition register recording information on clients in feeding programs
STIs	HMIS Form 122A	Individual client card used to record HIV/ART care including STI information
Tuberculosis	HMIS Form 096A	Record of TB patients and progress and outcome of treatment
	HMIS Form 089	Records of person information, tests and results of TB/HIV laboratory tests
	TBD	Presumptive TB case register
Commodities		
ARV ordering	HMIS Form 084B	ARV and eMTCT medication order form
Stock monitoring	HMIS Form 083	Summarize facility stock
	HMIS Form 015	Track facility commodities

11.2.3. ELECTRONIC MONITORING TOOLS

All ART sites should be using an electronic medical records system. Priority should be given to high-volume ART sites (more than 500 patients in HIV care.) The recommended electronic medical records system is Open MRS.

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

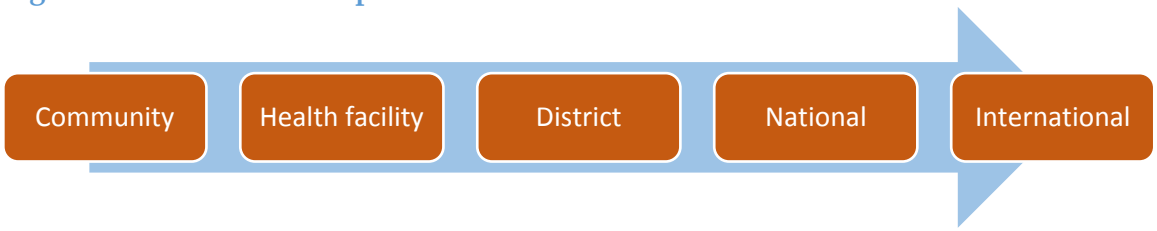
Report	Description	Source Documents	Frequency	Recipient
HMIS 106A: Health Unit Quarterly Report	Reports the quarterly attendance figures for HIV care/ART, nutrition, and TB services	Pre-ART Register, ART Register, PEP Register, EID Register, TB Register	Quarterly	DHIS-2
HMIS 105: Health Unit Outpatient 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	Report 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. DATA FLOW

Figure 20 below shows data flow from the points of data collection up to international level.

Figure 20: HIV data and report flow



11.3.2. OTHER DATA SOURCES

The following sources complement the data generated from HMIS:

- Surveillance data from AIDS Indicator Survey, HIV/AIDS Sero-behavioral Survey, ANC sentinel surveillance, HIV case-based surveillance
- Longitudinal and evaluation studies
- HIV estimates from 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 should incorporate into the M&E framework and monitoring and reporting tools.

- Differentiated service delivery models- especially the community models.
- Viral load monitoring
- Pre-Exposure Prophylaxis
- And Mental health

11.4.2. HIV DRUG RESISTANCE MONITORING

HIV drug resistance has been previous been monitored using early warning indicators mainly through surveys. We now recommend 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 (RDQAs). 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;

- AIDS Indicator Survey and HIV/AIDS Sero-behavioral Survey
- ANC sentinel surveillance
- HIV case-based surveillance
- Modes of transmission study

We also recommend programs and academia to conduct especially 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

EXPOSED INFANT 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		--		--
Clinical Assessment[a]	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
Cotrim and ARV Prophylaxis	Stable mother[c] - Give baby Nevirapine prophylaxis for 6weeks Unstable mother[d] – Give baby Nevirapine prophylaxis for 12 weeks Cotrimoxazole should be started at six weeks of age or thereafter and continued until infant is determined to be HIV negative										
InfantDiagnosis Testing[e]	None	Do 1st PCR at 6 weeks of age or as soon as infant is identified 2nd PCR should be done 6 weeks after cessation of breastfeeding								Do antibody test at 18 mo	
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 & 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 esophagus, 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 Clinical Staging of HIV for infants &children with HIV infection

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. Recurrent severe 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 sarcoma
7. Oesophageal candidiasis (or Candida of trachea, bronchi or lungs)
8. Central nervous system toxoplasmosis (after the neonatal period)
9. HIV encephalopathy
10. Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ, 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

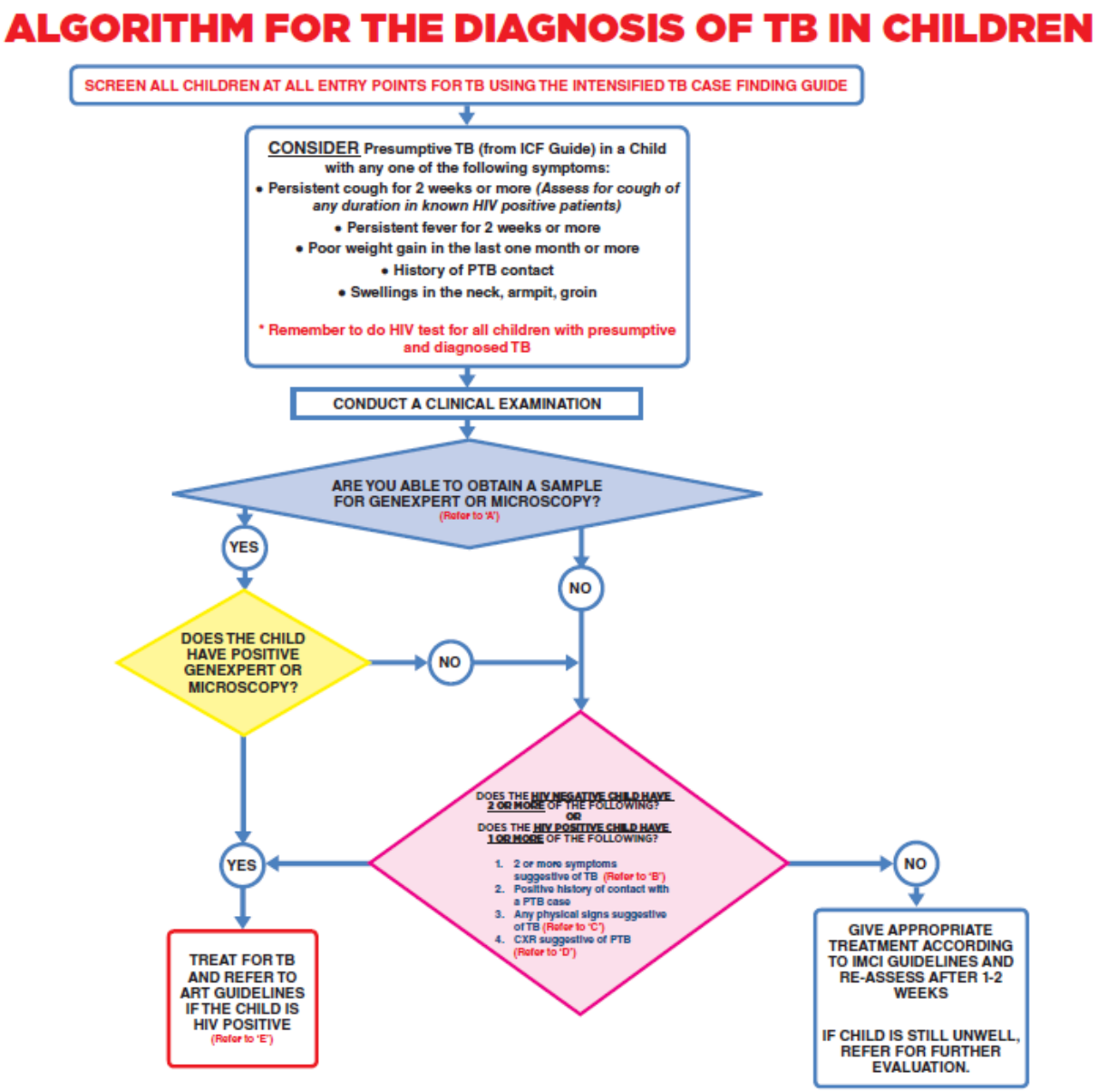
**For Children who are unable to produce sputum, refer to clinician for further investigations*

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:

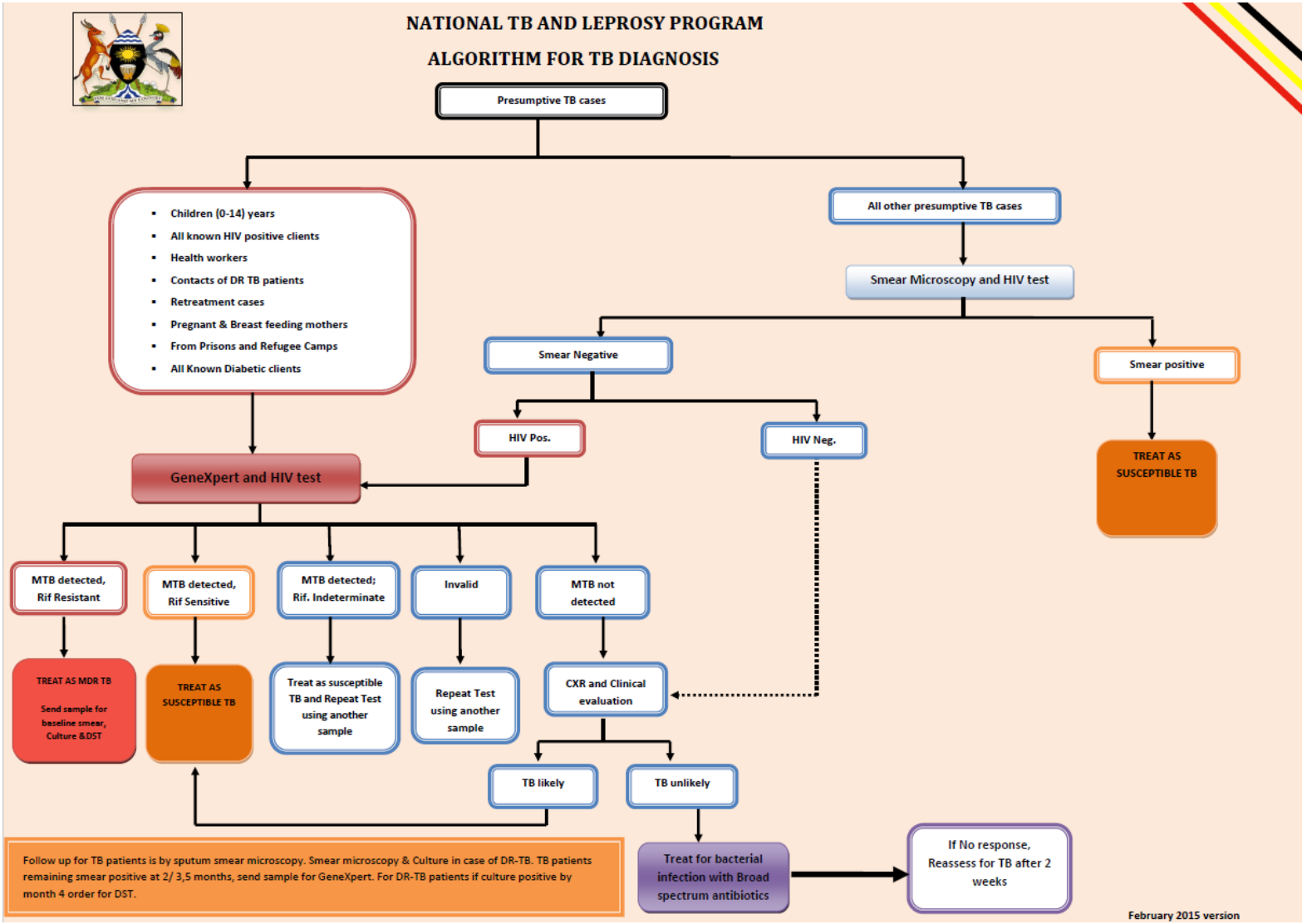
- Miliary picture
- Hilar adenopathy
- Cavitation

C PHYSICAL SIGNS SUGGESTIVE OF TB

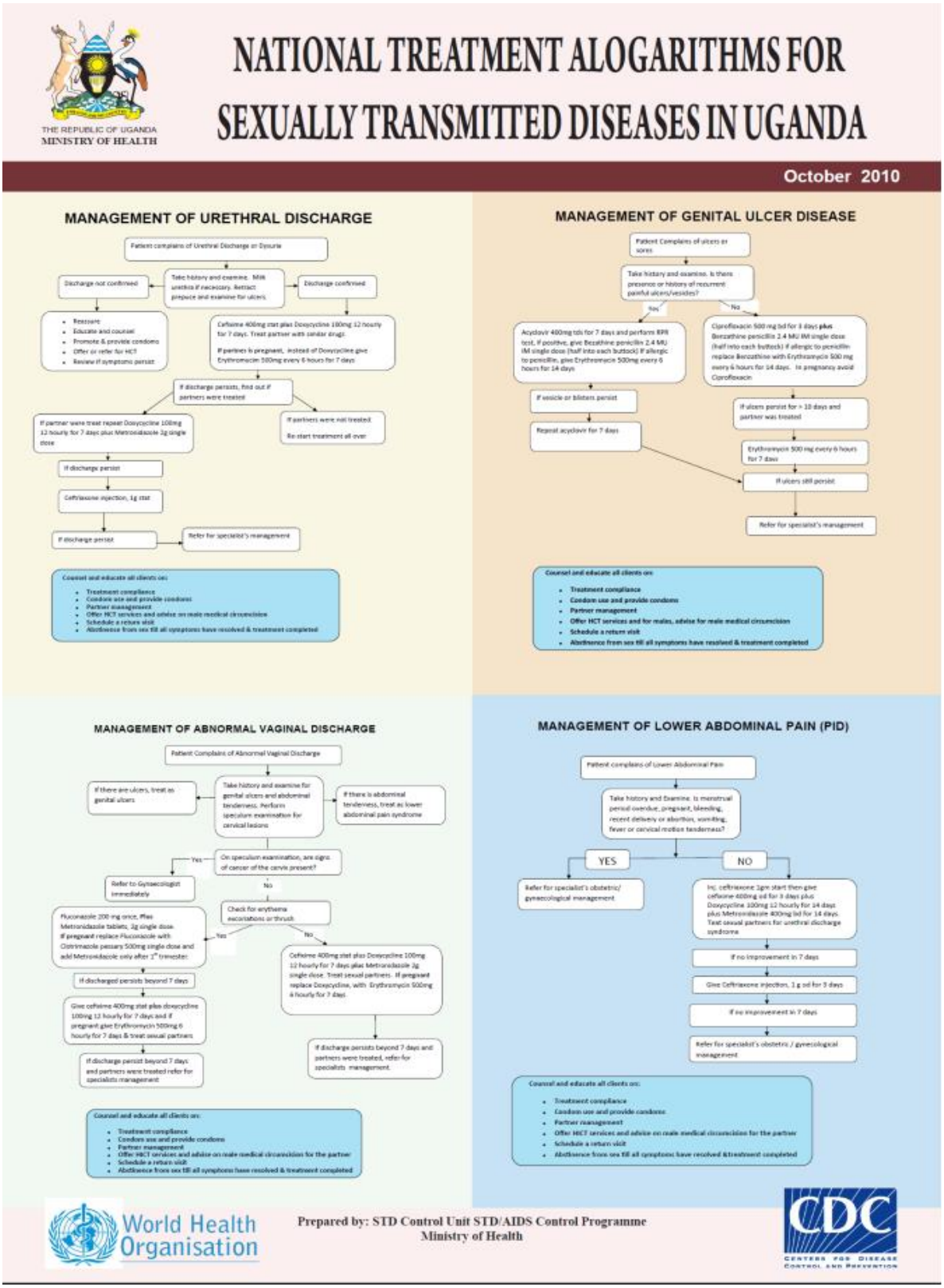
- Severe malnutrition
- Enlarged lymph nodes around the neck or the arm pit (TB adenitis).
- Acute pneumonia not responding to a complete course of appropriate broad spectrum antibiotics.
- Recurrent pneumonias (defined as at-least 2 episodes of pneumonia in a year with at-least 1 month of clinical recovery 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



Annex 7: Treatment algorithms for sexually transmitted diseases in Uganda.



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

	Doctor and clinical officer	Nurse	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 Clerk
Comprehensive clinical services including, including NACS, symptom screening for NCD's, TB, STI's and hepatitis	x	x	x					
Prescription of ART, initiation, and follow-up of adults and children	x	x	x					
Switching and substituting ART regimens The care team was suggesting involving a switch team(multidisciplinary)	x							
Management of complicated case (e.g. CCM; second line failure treatment failure etc.)	x							
TB initiation of smear or X-pert positive cases for adults and children	x	X						
TB 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, VL sample collecting, testing and results delivery	x	x	x	x		x	x	
Coordinating and supervising the community groups	x	x	x	x				
Linkage facilitation	x	x	x	x			x	
Pre-packing medicines, Pick drug refills, distribution of refill, Forecasting and ordering of commodities from the warehouses, Dispensing 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

	Doctor and clinical officer	Nurse	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 Clerk
Client records management/Data entry & 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*

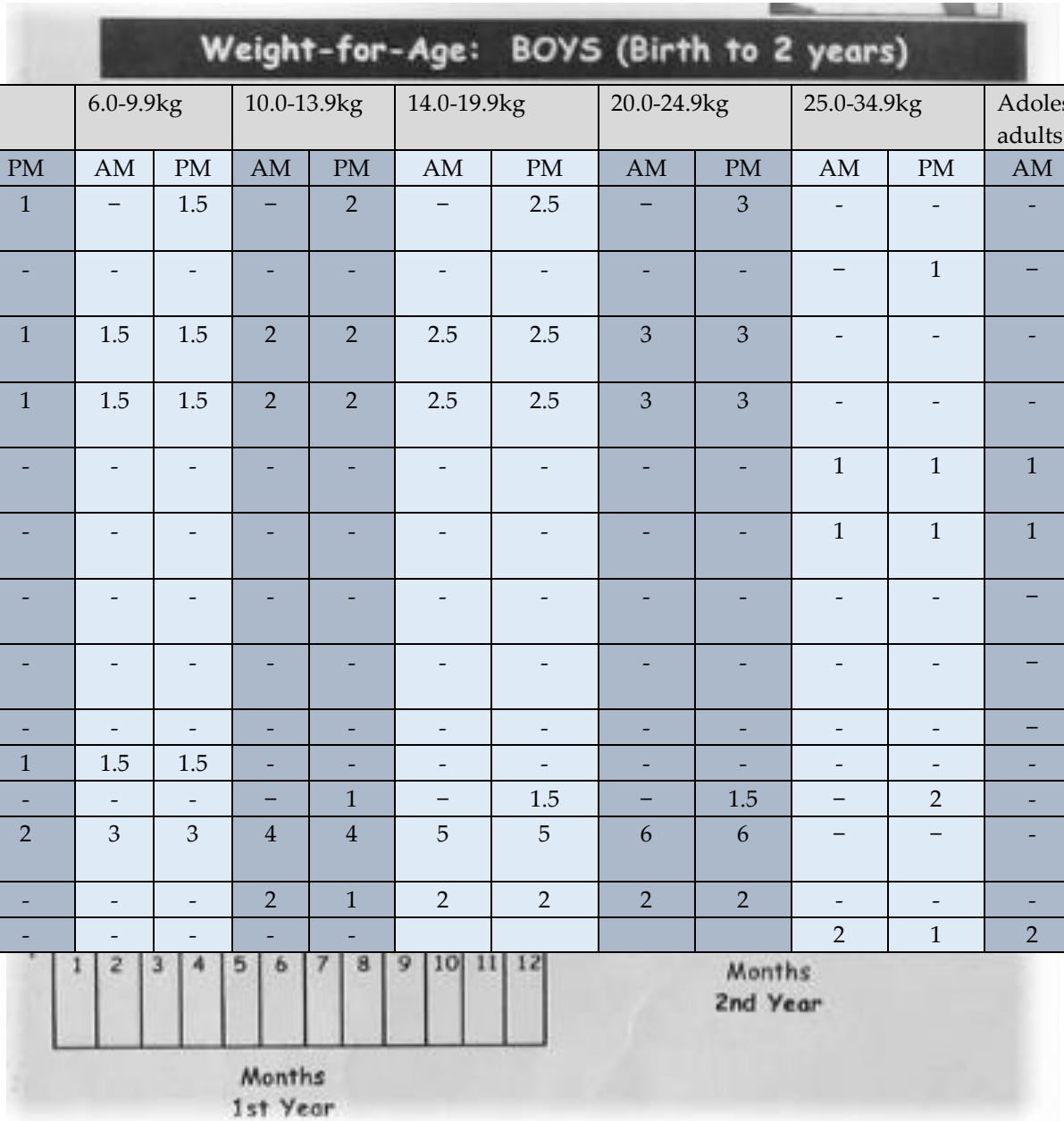
***Lay clients include; Expert Clients, VHTs, CHEWS, Mentor Mothers*

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 you disclosed your 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? • Church attendance, clubs, projects? • Hobbies--other activities? • Reading for fun--what? • TV--how much weekly--favourite shows? • Favourite music? • Does a young person have a car, use seat belts? • History of arrests--acting out--crime?	
Drugs	• 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).	

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	-	-
LPV/r pellets 40/10mg[1]	2	2	3	3	4	4	5	5	6	6	–	–	-	-
LPV/r 100/25mg[2]	-	-	-	-	2	1	2	2	2	2	-	-	-	-
LPV/r 200/50mg	-	-	-	-	-	-					2	1	2	2



Annex 10: Child Health Card

Annex 11: Adult and Pediatric ARV Dosing chart

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
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

[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

[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.