THE REPUBLIC OF UGANDA

MINISTRY OF HEALTH

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

NOVEMBER 2022

THE REPUBLIC OF UGANDA

MINISTRY OF HEALTH

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

NOVEMBER 2022

Contents

List of Tables

List of Figures

FOREWORD

The Government of Uganda promotes a combination of interventions to manage a generalized HIV epidemic in the country. In the last two decades, the AIDS Control Program has integrated antiretroviral therapy (ART) into the comprehensive response to HIV prevention, care treatment, and support.

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

In the 2018 version of the "Consolidated Guidelines for the Prevention and Treatment of HIV and AIDS in Uganda, we recommended optimizing treatment by using Dolutegravir, in combination with Tenofovir and Lamivudine as the preferred first-line for eligible people living with HIV. We also provided guidance on HIV self-testing to increase access to testing and there was a renewed focus on the screening and treating for syphilis in pregnant women and their partners. In addition, we provided guidance on service delivery modalities for g different client categories to catalyze the pace towards achieving universal access to ART.

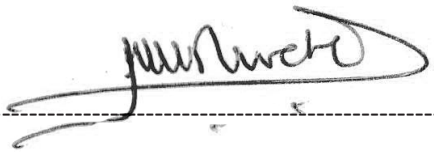
The 2020 version of the "Consolidated Guidelines for Prevention and Treatment of HIV in Uganda" reaffirmed optimizing ART by using Dolutegravir-containing regimens as preferred first-line for all eligible people living with HIV (including pregnant and breastfeeding adolescent girls and women, and children).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

The 2022 revision of the "Consolidated Guidelines for Prevention and Treatment of HIV in Uganda", provides clear guidance on HIV prevention

options that include PrEP, eMTCT, Circumcision and HIV services with a focus on case finding approaches. Furthermore, an updated, evidence-based and simplified guide to ART optimization with DTG in all age groups and sub populations and approaches to protect it from resistance through updated treatment monitoring is being provided. The guidelines also emphasize the management and integration of tertiary HIV in the general HIV care continuum with a focus on Advanced HIV Disease, HIV drug resistance and non-communicable diseases. Additionally, the guidelines also provide updated guidance on key operational and service delivery issues with the aim of increasing access to HIV services and strengthening the continuum of HIV care

These guidelines provide a simplified framework for healthcare workers, district health teams and Managers of different programs including HIV, Tuberculosis Reproductive Maternal, Newborn Child and Adolescent Health 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 call upon all Stakeholders in the fight against HIV in Uganda, to support the successful implementation of these Guidelines.



Dr. Henry Mwebesa

DIRECTOR GENERAL HEALTH SERVICES

ACKNOWLEDGMENTS

The Ministry of Health thanks all the stakeholders who participated in the Guidelines review and development. We thank the following chairpersons who led the guidelines adaptation meetings in the different technical committees; Prof. Moses Kamya (National HIV/AIDS Advisory Committee and Adult ART Subcommittee), and Prof. Philippa Musoke (PMTCT and Paediatric HIV Subcommittees). We also thank the organizations and individuals listed below who participated in the Guidelines development process during the adaptation meetings and the guidelines Writing Workshops.

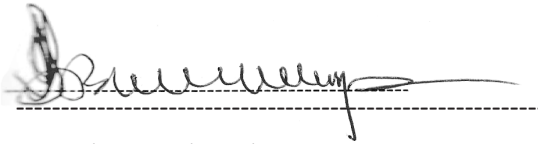
Contributors:

Ministry of Health: D Henry Mwebesa, Patrick Tusiime, Charles Oyo Akiya, Joshua Musinguzi, Susan Nabbada, Gerald Mutuungi, Annet Nabaggala, Annet Nakigozi, Arthur Ahimbisibwe, Alisen Ayitewala, Barbara Nanteza, Charles Kiyaga, Chris Okiira, Cordelia Katureebe, Christine Katusiime, Carol Achola, Daniel Idipo, Dan Mawerere, Diina Kwariisima, Doreen Ondo, Didas Tugumisirize, Ebony Quinto, Edward Katto, Eleanor Namusoke, Emmy Muramuzi, Florence Nampala, Frank Mugabe, Geoffrey Taasi, Gerald Pande, Ian Nyamitoro, Hakim Sendagire, Hasfa Lukwata, Herbert Kadama, Hudson Balidawa, Ivan Kato Arinaitwe, Ivan Arinaitwe, James Ochacacon, Jovah Praise, Juliet Cheptoris, Juliet Katushabe, Kenneth Kalani, Laura Ahumuza, Linda Nabitaka, Lordwin Kasambula, Mark Agara, Martin Nsereko, Maureen Mbabazi, Moorine Sekadde, Micheal Isabirye, Mina Nakawuka, Miriam Nakanwagi, Morris Seru, Pamela Achii, Patrick Twesigye, Peter Kyambadde, Peter Mudiope, Philip Kasibante, Promise Mbonye, Proscovia Namuwenge Raymond Byaruhanga, Robert Majwala, Ruth Nabbagala, Sam Balyejusa, Susan Wandera, Simon Kalyesubula, Simon Muchuro, Samalie Namukose, Samuel Mutyaba, Vasta Kibirige, Victor Bigira, Wilford Kirungi, Wilson Nyegenye, Viola Kasone and Zziwa Martin. **WHO**: Kaggwa Mugagga, Hasfa Kasule and Rita Nalwadda. **UNAIDS**: Jotham Mubabguzi **UNICEF**: Barbara Asire, Esther Nyamugisa Ochora, **CDC**, Bill Elur, Daniel Bogere, Esther Nazziwa, Emilio Dirlikov, Grace Namayanja, Jonathan Ntale, Jennifer Galbrach, Joseph Kabanda, Julius Kalamya, Madina Apolot, Margaret Achom, Mary Naluguza, Phoebe Namukanja, Rosemary Apondi, Samuel Wasike, Sophie Nantume, Stella Alamo, Steven Baveewo, Thomas Nsibambi, and Deus Lukoye **USAID**: Hilda Asiimwe, Jacqueline Calnan, Jennifer Namusobya, Miriam Mulungi, Patrick Komakech, Immaculate Ddumba, Seyoum Dejene, Esther Karamagi

Nkolo, Tamara Nsubuga-Nyombi, Fred Ntuuyo, Willy Kafeero, Sheila Kyobutungi, Dalsone Kwarisiima, Gladys Tugume, Ismail Mbabali and Daniel Kasozi. **Department of Defence(DOD):** Estella Birabwa and Juliet Akao **Clinton Health Access Initiative (CHAI):** Amanda Williams, Aston Nuwagira, Isaac Ikiring, Marvin Lubega, Robert Kirungi, Ronald Kizito, Vennie Nabitaka,. **Baylor Uganda:** Adeodata Kekitiinwa, Denise Birungi and Jackie Balungi. **Elizabeth Glazer Pediatric AIDS Foundation (EGPAF):** Ange Kiyonga, Edward Bitarakwate, Caroline Tiri, Dan Mugisha, Happy Betty, Mary Namubiru, Moses Luwunzu, Ronald Kamasi and Patrick Serunjogi. **Global fund FCO**: Damian Rutazaana. **ICWEA**: Moriko Lillian and Dorothy Namutamba **Joint Clinical Research Centre (JCRC):** Francis Ssali. **JCRC-PHAs:** Moses Nsubuga (Super Charger). **District Health Officers**, **Makerere University College of Health Sciences:** David Meya, Ethel Nakimuli, Fred Semitala, Moses Kamya, Philippa Musoke, Sabrina Kitaka, and Victor Musiime. **Makerere University College of Health Science Infectious Disease Institute (IDI):** Andrew Kambugu, Mary Mudiope, Joanita Kigozi, Martin Ssuna, Paul Kavuma, Peter Kalema and Timothy Muwonge. **Makerere University Joint AIDS Program (MJAP):** Isaac Kimera and Martin Muddu, **Makerere University John's Hopkins University Collaboration (MUJHU):** Emilly Lugolobi. **Makerere University School of Public Health:** Rhoda Wanyenze, Violet Gwokyalya, **Makerere University Walter Reed Project (MUWRP):** Anna Nakirijja, Fred Magala and Monica Etima. **MAMA'S Club:** Lydia Mungherera. **Mbarara Regional Referral Hospital:** Denis Nanseera, Alexa Namuli, Winnie Muhinike. **Medical Access:** Sowedi Muyingo, Gerald Sebulime. **Medical Research Council (MRC)/UVRI:** Christine Watera, Ivan Namukoola, Joseph Lutakome and Josephine Birungi, Pontiano Kaleebu, **Monitoring and Evaluation Technical Support (METS):** Alice Namale, Edgar Kansiime, Evelyn Akello, Simon Muhumuza and Godfrey Timbihurira **Mildmay:** Barbara Mukasa, Jane Nakaweesi, Stephen Watiti and Michael Sonko. **NAFOPHANU** Stella Kentutsi. **National Drug Authority:** Victoria Nabasa, Julius Mayengo, Paul Senoga. **National Medical Store:** Sande Izidoro. **TASO:** Muhirwwe Ninsiima, Baker Bakashaba, Molly Rwankore, Michael Etukoit and Obore Gilbert. **Uganda Network of AIDS Service Organizations (UNASO):** Martha Kawala. **UNYPA:** Nicholas Nuwagaba. **UGANDA CARES:** Agnes Bukirwa, Augustine Lubanga, Cecelia Natembo, Kawoya Sulaimani, Samson Okumu. **African Resource Center:** LeBeau Taljaard. **Uganda Cancer Institute:** Carol Nakisige. **Other resource persons:** Vincent Kawooya, Jane Nabalonzi, Janet Nerima, Simon Peter

Inyimai, Gabriel Kaddu, Peter Kiragga. **Mulago Specialised Women and Neonatal Hospital:** Jolly Beyeza-Kashesya, RAND Corp: **Glenn Wagner Children's Mercy Research Institute-University of Missouri-Kansas City:** Kathy Goggin, Emily Hurley, **University of California Global Health Institute:** Deborah Mindry University of Kansas Medical Center: Sarah Finocchario-Kessler, Augustina Delaney CDC Atlanta

Finally, we express our gratitude to the following organizations for the financial support towards the guidelines review and development process: World Health Organization-Uganda, Clinton Health Access Initiative-Uganda, Global Fund, PEPFAR through CDC, DOD and USAID and UNICEF.



Dr Joshua Musinguzi
PROGRAM MANAGER AIDS CONTROL PROGRAM

ABBREVIATIONS AND ACRONYMS

3TC	Lamivudine
ABC	Abacavir
ACTs	Artemisinin-based combination therapies
AFHS	Adolescent-friendly health services
AFP	Alpha-fetoprotein
AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine Amino-Transferase
ANC	Antenatal care
ARM	Artificial rupture of membranes
ART	Antiretroviral Therapy
ARV	Antiretroviral medicines
AST	Aspartate Aminotransferase
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
BCC	Behavioral change communication
BCG	Bacillus Calmette-Guerin
BP	Blood pressure
CASA	Community ART Support Agents
CBC	Complete bloodcount
CBO	Community-based organizations
CCLAD	Community client-led ART Delivery
CD4	Cluster of differentiation 4
CDC	Centers for Diseases Control and Prevention
CDDP	Community drug distribution points
CDO	Community Development Officer
CHEW	Community Health Extension Worker
CITC	Client-initiated Counseling and Testing
CM	Cryptococcal meningitis
CMV	Cytomegalovirus
COPD	Chronic obstructive pulmonary disease
CPT	Cotrimoxazole preventive therapy
CQI	Continuous quality improvement
CrAg	Cryptococcal Antigen
CSF	Cerebral spinal fluid
CTX	Cotrimoxazole

DBS	Dried blood spot
DM	Diabetes mellitus
DNA	Deoxyribonucleic Acid
DRV/r	Darunavir/Ritonavir
DSDM	Differentiated service Delivery Models
DTG	Dolutegravir
EBF	Exclusive breastfeeding
EFV	Efavirenz
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
eMTCT	Elimination of Mother-To-Child HIV Transmission
ETV	Etravirine
FBO	Faith-Based Organizations
FP	Family Planning
FPG	Fasting Plasma Glucose
FTC	Emtricitabine
GBV	Gender-based violence
GFR	Glomerular filtration rate
HBcAg	Hepatitis B core antigen
HBHTC	Home-based HIV testing and Counseling
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B Virus
HCC	Hepatocellular Carcinoma
HCIII	Health Centre III
HCIV	Health Centre IV
HCV	Hepatitis C virus
HEI	HIV-exposed infants
HIV	Human immunodeficiency virus
HIVST	HIV Self-Testing
HMIS	Health Management Information Systems
HPV	Human Papilloma Virus
HTS	HIV Testing Services
IAC	Intensive adherence counseling
ICF	Intensified Case Finding
IFN	Interferon
IGAs	Income Generating Activities
IMNCI	Integrated maternal, newborn and childhood illnesses
INH	Isoniazid
IPD	Inpatientdepartment

IPT	Isoniazid Preventive Therapy
IRIS	Immune reconstitution inflammatory syndrome
IRS	Indoor residual spraying
ITC	In-patient therapeutic center
LLINs	Long-lasting insecticide-treated nets
IUD	Intrauterine device
IYCF	Infant and young child feeding
KP	Key populations
LFTs	Liver function tests
LMIS	Laboratory management information system
LP	Lumbar puncture
LPV/r	Lopinavir/ritonavir
MAM	Moderate acute malnutrition
MCH	Maternal child health
MDR	Multi-drug resistant
MOH	Ministry of Health
MUAC	Mid-upperarm circumference
NAC	National ART Advisory Committee
NACS	Nutrition assessment, counseling and support
NCD	Non-Communicable Diseases
NDA	National Drug Authority
NGO	Non-government organization
NNRTI	Non-nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NVP	Nevirapine
OI	Opportunistic infection
OPD	Outpatient department
OTC	Outpatient therapeutic center
OVC	Orphans and vulnerable children
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PHDP	Positive health dignity and prevention
PHQ	Patient health questionnaire
PI	Protease inhibitor
PITC	Provider-initiated HIV testing and counseling
PJP	Pneumocystis jiroveci pneumonia
PLHIV	People living with HIV

PNC	Postnatal care
PrEP	Pre-exposure prophylaxis
PSS	Psychosocial Support
PTT	Prothrombin time
PWDs	Persons with disabilities
PV	Pharmacovigilance
QI	Quality improvement
R	Rifampicin
RAL	Raltegravir
RFTs	Renal function tests
RH	Reproductive health
RMNCAH	Reproductive Maternal Newborn, Child and Adolescent health
RUTF	Ready-to-use therapeutic feeds
SAM	Severe acute malnutrition
SBCC	Socio-behavioral change communication
SFP	Supplementary feeding programs
SMC	Safe male circumcision
SP	Sulfamethoxazole-pyrimethamine
SCC	Safes Conception Counselling
SCM	Safer Conception Method
STIs	Sexually transmitted infections
TAF	Tenofovir Alfenamide
TB	Tuberculosis
TDF	Tenofovir
TPHA	Treponema pallidum hemagglutination assay
TUI	Timed Unprotected Intercourse
USAID	United States Agency for International Development
UTI	Urinary tract infection
VCT	Voluntary counseling and testing
VHT	Village health team
VIA	Visual inspection with acetic acid
VL	Viral load
VMMC	Voluntary medical male circumcision
WAOS	Web-based ordering system
WFL/H	Weight for length/height
WHO	World Health Organization
YAPS	Young People and Adolescent Peer Support(ers)
YCC	Young child clinic

1.0 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 goal of the Test and Treat Guidelines is to further expand access to antiretroviral therapy (ART) and to optimize treatment for all eligible adults and children .

The 2018 version of the Guidelines recommended optimizing ART using a Dolutegravir-based regimen as the preferred first line for eligible PLHIV, with consideration for rising levels of pre-treatment drug resistance to non-nucleoside reverse transcriptase inhibitors (NNRTIs). These guidelines also provided operational and service delivery guidance to districts and health facilities to implement other new approaches including:

- HIV self-testing (HIVST) and assisted partner notification (APN),
- Effective integration of elimination of mother-to-child HIV transmission (eMTCT) services into Reproductive Maternal, Newborn, Child and Adolescent health services (RMNCAH),
- Differentiated service delivery, which reduces clinic visits and allows community ART distribution to PLHIV who are stable on ART,
- Working with community structures to optimize delivery of HIV services; and
- Retention, adherence to treatment, adolescent-friendly and responsive health services.

The 2020 version of the Guidelines recommended the optimization of ART using Dolutegravir-based regimens as preferred first line for all eligible PHLIV. The Guidelines also recommended procedures for ARV substitution in adults, adolescents, and children already on first-line ART and recommended options for subsequent second- and third-line regimens. These Guidelines also emphasized the importance of pharmacovigilance (PV) and described the procedures for identifying, investigating, reporting, and managing adverse effects of ART, anti-TB and other medications.

The objective of the 2022 Guidelines are:

1.2 OBJECTIVES

- To provide a standardized and simplified guide for offering HIV testing services with a focus on case finding approaches.
- To provide additional PrEP options such as the Dapivirine ring and injectable Cabotegravir, and for consolidating the existing prevention methods: Behavior Change Communication, eMTCT and Safe Male Circumcision.
- To provide an updated, evidence-based and simplified guide to ART optimization with DTG in all age groups and sub populations and approaches to protect it from resistance through updated treatment monitoring.
- To provide updated guidance on the management and integration of tertiary HIV in the general HIV care continuum with a focus on Advanced HIV Disease, HIV drug resistance and Non-Communicable Diseases.
- To provide updated guidance on key operational and service delivery issues with the aim of increasing access to HIV services and strengthening the continuum of HIV care.

1.3 TARGET AUDIENCE

The primary audiences for these guidelines are:

- Healthcare workers and district health teams
- Program managers of HIV, Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCAH) and TB programs as well as National Medicines Warehouses, and
- AIDS Development Partners, Implementing partners, Training institutions, Researchers, Civil Society Organizations and entire community of people living with HIV.

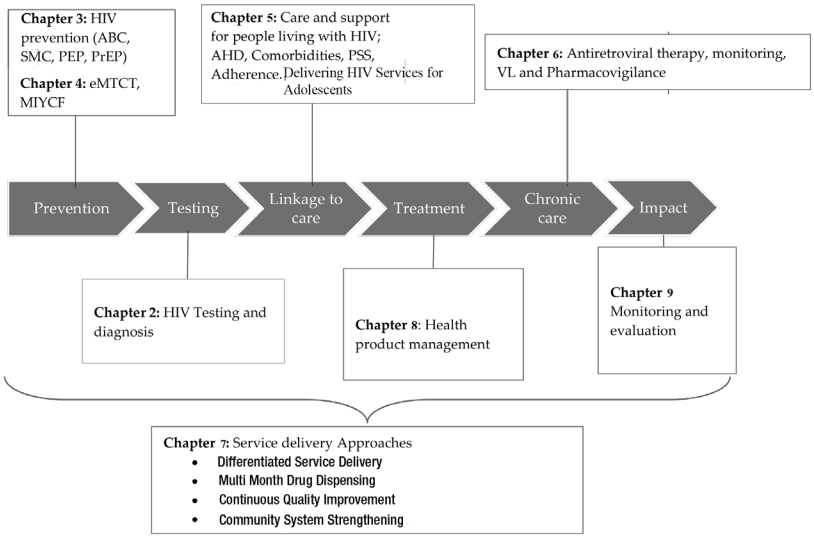
1.4 GUIDELINES DEVELOPMENT PROCESS

These Guidelines were developed by a team of internal and external technical experts, and with engagement of people living with HIV. The Guidelines development process was comprehensive and involved adaptation and approval of the Guidelines by the National ART Advisory Committee, and Top Management of Ministry of Health. There were a series of Writing Workshops and Peer Reviews with the guidance of a Consultant. The adaptation of the Guidelines by the different subcommittees involved reviews of evidence cited in the World Health organization Guidelines, presentation, and review of local evidence with concurrence at all stages. We also received technical support and peer review from external experts including those from

the World Health Organization, Centers for Disease Control and Prevention, United States Agency for International Development, Clinton Health Access Initiative and the Elizabeth Glaser Pediatric AIDS Foundation.

1.5 SUMMARY OF CHANGES IN 2022 HIV/AIDS GUIDELINES

Figure 1 : HIV continuum of Prevention and Care



Chapter 2- HIV TESTING SERVICES- Prioritize case finding approaches

HIVST

- Consent now 15 years and above.
- Target populations to include adolescent girls, Adolescent Girls, Youths and Women
- Blood based HIVST now in use

INDEX TESTING

- Biological Children recommended aged between 18 months to 19 years

Prioritize Case finding;

Optimized PITC,

Scale up, HIVST

Index Testing,

Recency,

Linkages

focused Community Testing

- If using Caregiver-assisted oral screening to conduct index testing for biological children, then recommended ages are 2 years to 14 years.
- HFs offering ICT assessed annually and accredited to ensure adherence to minimum standards around the 5Cs

LINKAGE
- Intra-facility linkage revised to 7 days or on the same day,
- Inter-facility and community linkages is at 14 days
- HIV tester and site certification
- Guidance provided on the verification and confirmation of the requirements needed for HIV testers and sites certification.

Chapter 3: PRE-EXPOSURE PROPHYLAXIS FOR HIV PREVENTION

Recommended Use of
- Dapivirine vaginal ring
- Injectable cabotegravir (LA-CAB

Dapivirine vaginal ring and Injectable Carbotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination prevention approaches

Chapter 5: CARE AND SUPPORT FOR PLHIV- TB SCREENING AND DIAGNOSIS

Systematic screening for TB among People living with HIV
- PLHIV should be systematically screened for TB disease at each visit to a health facility with a combination of;
- Intensified Case finding (ICF)- form
- C-Reactive Protein(CRP) and or CXR

Chapter 5: INITIATING ART AMONG PLHIV WITH TB

Treatment for drug sensitive TB ,

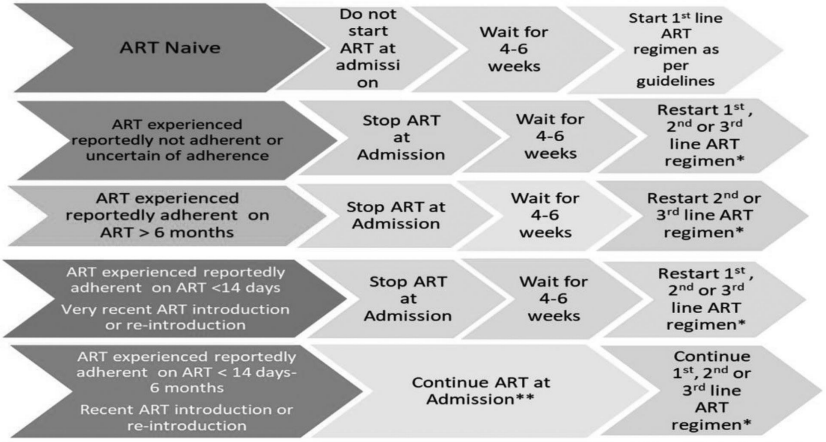
ART should be started at two weeks of initiating TB treatment, regardless of CD4 cell count, among people living with HIV (Except when signs and symptoms of meningitis are present)

Treatment of people with drug-resistant TB
- all people with HIV and drug-resistant TB, requiring second-line anti-TB drugs irrespective of CD4 cell count, should start ART as early as possible (within the first eight weeks) following initiation of anti-TB treatment

TB Preventive Treatment Options

- Use of 3HP (RPT + INH)
- 6H a**lso in practice**

Chapter- 5: ART timing with CCM



*Decision on which ART regimen to restart should be made according to patient's history, ART guidelines, HIV viral load and genotypic resistance testing if possible. If it is considered likely that the patient has developed resistance to 1st line ARVs, then restart with 2nd line containing boosted PI or DTG is possible. ** Unless documented to have a suppressed viral load at time of admission or within the month prior to admission, in which case continue ART

Chapter- 5: CARE AND SUPPORT FOR PLHIV- Mgt of CCM- Table 45 with details

Induction phase; (2 weeks) - Recommended:

- Amphotericin B liposomal single high dose (10mg/kg) + Flucytosine (100mg/kg/day in four divided doses) + Fluconazole 1200mg/ day for 14 days OR
- Amphotericin B deoxycholate (1mg/kg/day) + Flucytosine (100mg/kg/day in four divided doses) for 1 week, followed by 1 week of fluconazole (1200 mg/day for adults, 12 mg/kg/day for children and adolescents). OR
- Fluconazole (1200 mg daily for adults, 12 mg/kg/day for children and adolescents) + Flucytosine (100 mg/kg/day, divided into four doses per day. OR
- Amphotericin B deoxycholate (1mg/kg/day) + high-dose Fluconazole 1200mg/day.

Chapter 6: TERTIARY HIV MGT, AGING WITH HIV, INTERGRATION OF NCDs IN HIV MANAGEMENT

Consolidate and Scale Up Efforts On

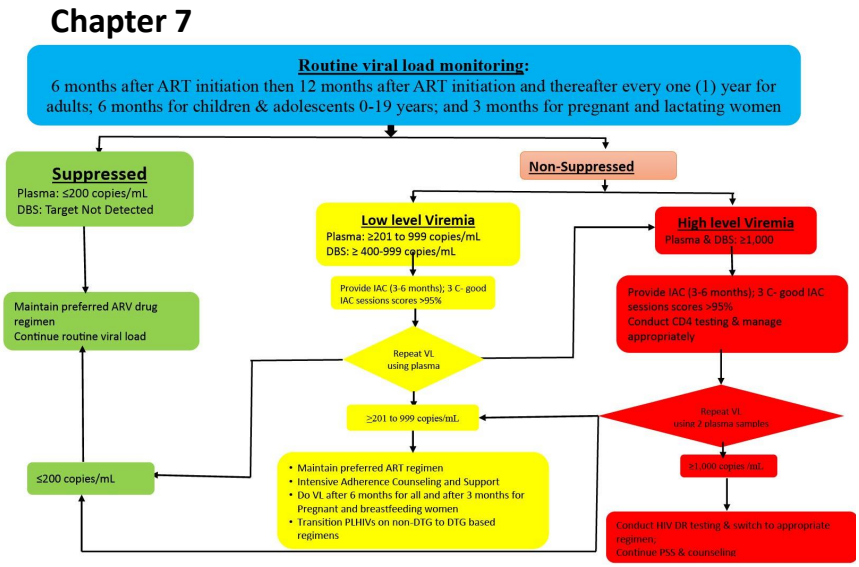
- HIV Drug Resistance
- AHD- (CCM, TB/HIV, Severe Bacterial Infection, Histoplasmosis)
- CaCx Mgt
- Hypertension and DM Mgt Intergration In HIV Mgt
- Mental Health Mgt Intergartion In HIV Care

Chapter 7: TB 74: Recommended first-line ARV regimens in Children, adolescents, adults and pregnant or breastfeeding women

Adults and adolescents ≥ 30Kg	TAF + FTC + DTG or TDF + 3TC + DTG	Pregnant and breastfeeding women: TDF + 3TC + EFV400 or TAF + FTC +EFV400 If DTG is contraindicated1: TDF + 3TC + EFV400 or TAF + FTC +EFV400 If TDF or TAF is contraindicated2: ABC + 3TC +DTG If both TDF or TAF and DTG are contraindicated: ABC +3TC +EFV400 If EFV and DTG are contraindicated: TDF +3TC + ATV/r or TAF + FTC +ATV/r or ABC + 3TC + ATV/r
Pregnant and breastfeeding women	TAF +FTC + DTG or TDF +3TC+ DTG	
Children ≥20Kg-<30Kg	ABC + 3TC + DTG or TAF +FTC + DTG	If DTG is contraindicated: ABC + 3TC + LPV/r (tablets) If ABC is contraindicated: AZT + 3TC + DTG or TAF + 3TC + DTG (TAF in children> 6 years and ≥25Kg)
Children <20Kg	ABC + 3TC + DTG	If intolerant or appropriate DTG formulations are not available: ABC +3TC + LPV/r (syrup, pellets, or tablets). If intolerant to LPV/r: ABC + 3TC + EFV (in children > 3 years and >10Kg) If ABC is contraindicated: AZT + 3TC + DTG or LPV/r

Chapter 7: ART FOR PLHIV: MONITORING RESPONSE TO ART- VL

- 6 months after ART initiation,
- then 12 months after ART initiation,
- and thereafter when established on ART
  - 1 year for adults;
  - 6 months for children & adolescents 0-19 years;
  - and 3 months for pregnant and lactating women
- POC- VL testing may be used to monitor treatment.
- HIV DR recommended for all PLHIV to guide the next course of treatment
- Incase more than one drugs are susceptible then refer to ART tables to choose the preferred or alternative drug



Chapter 6: Tb 81: Failing First line, Recommended Second- and third-line ART regimens for Pts

Population	Failing first line regimens	Recommended second line regimen; guided by HIV DR	Alternative second line regimen	Third line regimens
Adults and adolescents ≥ 30Kg, including pregnant and breastfeeding women	TAF + FTC + EFV or TDF + 3TC+EFV or TDF+3TC+NVP	AZT+3TC+DTG	AZT+3TC+ DRV/r or ATV/r	All third line regimens to be guided by HIV DR resistance testing. In case of susceptibility to all drugs, use the table to guide the preferred or alternative choices. NOTE: For details on the third-line ART, please see the third-line ART implementation guides.
	TAF + FTC + DTG or TDF+3TC+DTG	AZT+3TC+DRV/r	AZT+3TC+ATV/r	
	AZT+3TC+NVP , AZT+3TC+EFV , ABC/3TC/NVP ABC+ 3TC+ EFV	TAF + FTC + DTG or TDF+3TC+DTG	TAF + FTG + ATV/r or TDF+3TC+ATV/r	
	AZT+3TC+DTG , ABC+3TC+DTG	TAF+ FTC + DRV/r or TDF+3TC+ DRV/r	TAF+ FTC +ATV/r or TDF+3TC+ATV/r	
Children ≥ 20Kg - <30Kg	ABC+3TC+EFV , ABC+3TC+NVP	AZT+3TC+DTG	AZT+3TC+LPV/r	
	ABC+3TC+LPV/r	AZT+3TC+DTG	AZT+3TC+ DRV/r	
	ABC+3TC+DTG	AZT+3TC+DRV/r	AZT+3TC+LPV/r	
	AZT+3TC+EFV , AZT+3TC+NVP	TAF + FTC + DTG or ABC+3TC+DTG	TAF+ FTC +LPV/r or ABC+3TC+LPVr	
	AZT+3TC+LPV/r	TAF + FTC +DTG or ABC+3TC+DTG	TAF+ FTC + DRV/r or ABC+ 3TC+DRV/r	
	AZT+3TC+DTG	TAF+FTC + DRV/r or ABC+3TC+ DRV/r	TAF + FTC +LPV/r or ABC+3TC+ LPV/r	
Children <20Kg	ABC+3TC+EFV , ABC+3TC+NVP	AZT+3TC+DTG	AZT+3TC+LPV/r	
	ABC+3TC+LPV/r	AZT+3TC+DTG	AZT+3TC+DRV/r	
	ABC+3TC+DTG	AZT+3TC+ DRV/r	AZT+3TC+ LPV/r	
	AZT+3TC+EFV , AZT+3TC+NVP	ABC+3TC+DTG	ABC+3TC+LPV/r	
	AZT+3TC+LPV/r	ABC+3TC+DTG	ABC+3TC+DRV/r	
	AZT+3TC+DTG	ABC+3TC+ DRV/r	ABC+3TC+ LPV/r	

Chapter 7: DIFFERENTIATED SERVICES DELIVERY

- All PLHIV are eligible for differentiated Care and Treatment within or outside HFs
- People established on ART should be offered refills of ART lasting 3–6 months, preferably every six months if feasible.
- ART can be initiated out of the HFs with possible 6 MMD
- Regions supported by IPs should implement interventions to trace people who have disengaged from care and provide support for re-engagement

Chapter 7: Recommended Differentiated HIV Treatment and Care Models and Approaches

Category of Recipient of Care

- PLHIV newly identified and or re-engaging in care when clinically well
- PLHIV newly identified and *or re-engaging* in care with advanced HIV disease
- PLHIV established on ART and or with controlled chronic illnesses / NCDs.
- PLHIV with uncontrolled chronic illness / NCDs, and any Drug limiting toxicities
- PLHIV with treatment failure

Treatment at Facility or in Community

Group Model		Individual Model	
Group models Managed by HCW Examples FBG (e.g. FSG, Viraemia clinics, G-ANC) CDDP	Group models Managed by client Examples CCLAD CLDDP	Individual models based at facilities Examples FTDR FBIM (e.g. Adolescent centers)	Individual model based in community Examples CRPDDP Drop in centers Peer led models (e.g. YAPS, Home ART delivery)

Chapter 7: Definition of the Client Categories for Differentiating HIV Care and Treatment

❑ PLHIV newly identified and or re-engaging in care with Advanced HIV disease	❑ PLHIV newly identified and or re-engaging in care when clinically well	❑ PLHIV Established on ART and or with Controlled chronic illnesses / NCDs	❑ PLHIV with Treatment Failure	❑ PLHIV with uncontrolled chronic illness / NCDs and any Drug limiting toxicities
✓ CD4 <200 cells/mm^3 ✓ WHO stage 3 or 4 at presentation for care ✓ Children < 5 years	✓ CD4≥ 200 Cells/mm^3 ✓ WHO stage 1 and 2	✓ Receiving ART for at least 6 months ✓ No current illness ✓ Controlled chronic health conditions ✓ Good understanding of lifelong adherence ✓ Evidence of treatment success (at least one suppressed VL in the last 6 months) ✓ No ART limiting drug toxicity	✓ 2 consecutive Non suppressed VL ≥ 1000 copies ✓ Has current or history of WHO stages 3 or 4 event within the past one year.	✓ FBG ≥ 7mmol ✓ RBG ≥ 11mmol ✓ HTN ≥ 140/90mmhg ✓ SRQ≥ 6 ✓ Audit-C > 3 ✓ HPV/VIA positive clients

Chapter 7:..The 5 A's criteria to choosing a preferred DSD approach

Assess
- Explain the purpose of the session
- Assess the client's barriers to adherence to DSD approaches

Assist
- Evaluate the underlying causes of the identified barriers
- Identify client-specific strategies to overcome identified barriers
- Discuss the pros and cons of each strategy/option(s)

Advise
- Give necessary information about the different approaches
- Review benefits of good adherence in relation to DSD
- Discuss consequences of non-adherence

Agree on
- Agree on the client's action points to address the key barriers
- Evaluate each action point
- The document agreed upon action points

Arrange
- Summarize the session
- Arrange for ART refill in the agreed upon approach
- Schedule and Document the next appointment date on the visit session form
- Refer and link to other services as appropriate

Chapter 7: Moving towards an integrated service delivery approach to micro-plan for most vulnerable individuals, promote person-centered care, and efficiencies

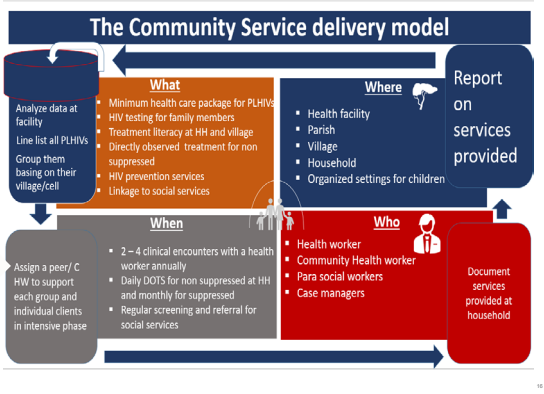
AIM: Prevent transmission, address mortality and provide holistic support.

Data-driven micro-planning
by multi-disciplinary teams to facilitate bi-directional facility-community linkage

AUDIT TOOL

Community attachment
10 households to one Community Health Worker
Address service delivery gaps at the household level

AUDIT TOOL

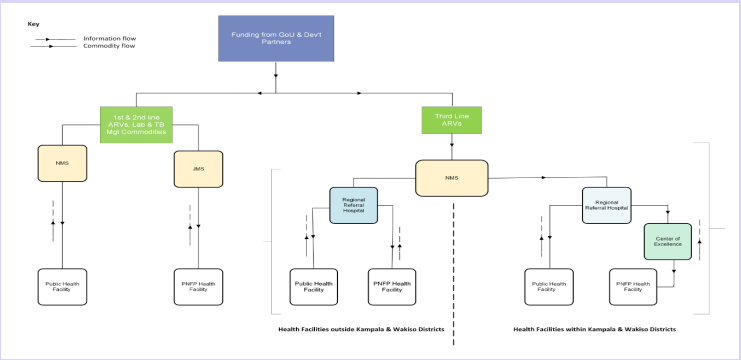


PEPFAR 20 YEARS OF IMPACT

Chapter 8: Integrating CQI into HIV services

- Establish health facility QI team
- Set up HIV work improvement teams (WIT)
- Identify gaps
- Gap analysis to get root causes
- Develop possible solutions
- Prioritizing solutions to address performance gaps
- Developing improvement projects using the documentation journal

Chapter 8: COMMODITY FLOW DIAGRAM



Chapter 8: NEW FORMULATIONS INTRODUCED

Dolutegravir/Emtricitabine/Tenofovir alafenamide 50/200/25mg (TAF/FTC/DTG 25/200/50mg)

Pack size

30 tablets

90 tablets

Darunavir/Ritonavir 400/50mg (DRV/r 400/50mg)

Pack size: 60 tablets

Lopinavir/Ritovir 40/10MG Granules-Pack of 120

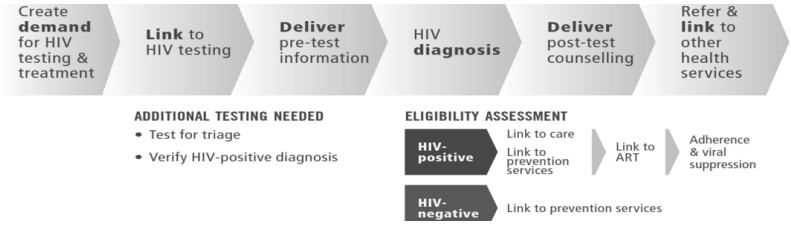
2.0 HIV TESTING SERVICES AND LINKAGE TO HIV CARE

2.1 INTRODUCTION

HIV testing is the entry point to HIV prevention, care, treatment, and support services. The aim of HIV testing services (HTS) is to promptly identify HIV status to ensure early linkage to prevention, treatment, and support services. Data from the UPHIA of 2020 indicate that, only 81% of the estimated 1.45 million HIV-positive persons aged 15 years and above knew their HIV serostatus, 96% of those were on ART, and 92% of those on ART were virally suppressed. 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. Because only 19% of PLHIV aged 15 years and above do not know their status, HTS should be differentiated to sub populations and geographical locations to identify those remaining cases.

HTS delivery includes a range of activities and services that are described on the pathway in Figure 2 below. This section guides the provision of quality HTS for reaching populations most at risk of HIV. Health workers should use this guidance alongside the National HIV Testing Services Policy and Implementation Guidelines 2022.

Figure 2: Continuum of Linkage to Care and Prevention



Adopted from WHO consolidated guidelines on HTS, 2015.

2.2 PRINCIPLES OF HIV TESTING SERVICES (HTS)

HTS delivery shall be non-discriminatory and offered using a public health approach that observes the 5Cs (Confidentiality, Consent, Counselling,

Correct test result and Connection to appropriate services) irrespective of HTS approach. These principles are described below:

2.2.1 Guiding principles for HTS

Table 1: Guiding principles for HIV Testing Services

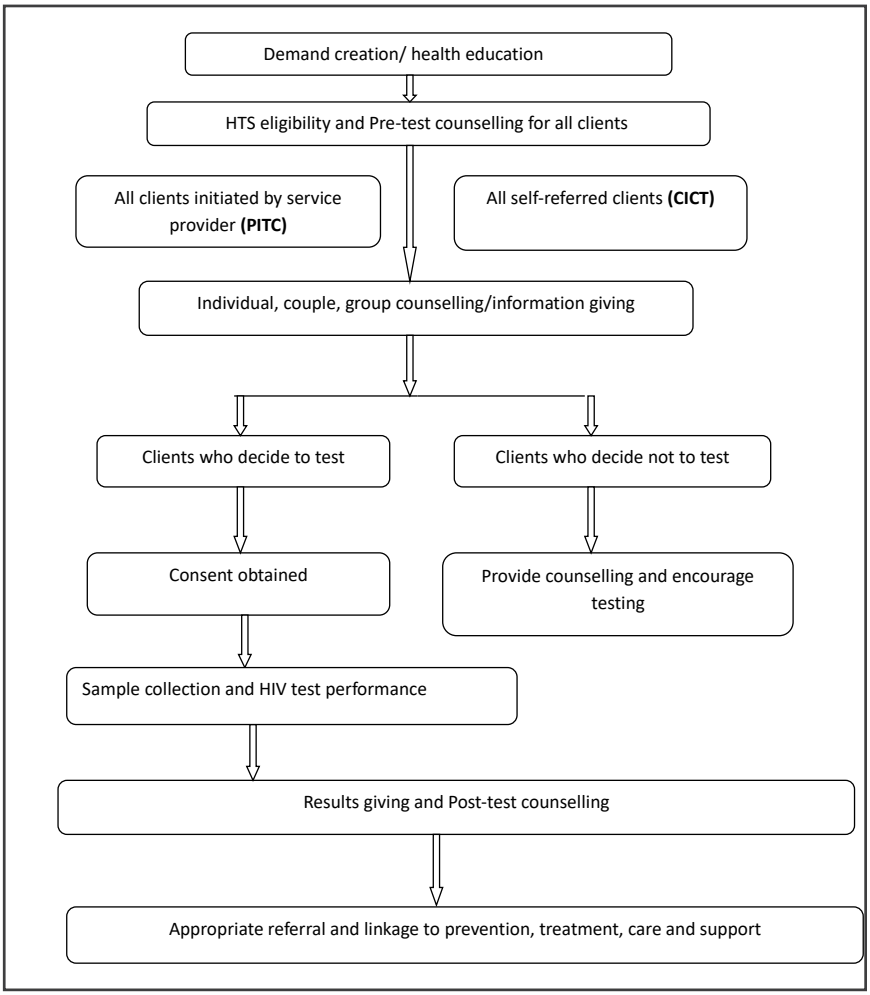
Consent	• All persons ≥12 years can consent to HTS on their own. For children under 12 years of age, HIV testing shall be done with the knowledge and consent of parents/ guardians. • Mandatory testing should not be implemented. • Written consent shall be obtained for HIV testing. • For HIV Self Testing, verbal consent shall be sufficient.
Confidentiality	• All providers should ensure privacy during HTS provision. • All information discussed with clients should not be disclosed to another person without the client's consent. • Confidentiality in the context of HIV Self Testing should be maintained around the distribution of HIV self-test kits, testing and shared HIV self-test result. • Shared confidentiality shall be acceptable if it's in the best interest of the client.
Counseling	• All persons accessing HTS should be provided with quality counseling before and after testing as per HTS protocol. • Quality counselling should be non-judgmental and client centered. • Provide adequate information before and after HIV Self Testing to individuals through health worker demonstrations, demonstration videos and print material, among others.
Correct results	• HTS providers should adhere to the National Testing Algorithm and must follow the Standard Operating Procedures for HIV testing to ensure that clients receive correct HIV test results.
Connection/ linkage to care	• Providers should link HTS clients to appropriate HIV prevention, treatment, care and support services. • Linkage should be done within 7 days (within the same facility) and within 14 days if referred to another facility or from the community.

2.3 HIV TESTING SERVICES PROTOCOL

The HTS protocol describes the minimum steps that shall be followed in order to provide quality and effective HTS. For HTS to be complete, the following key steps must be undertaken (see Figure 3):

- Demand creation/ health education
- HTS eligibility/Pre-test counseling/ information giving
- Testing for HIV
- Post-test Counseling
- Linkage into prevention, treatment, care and support services

Figure 3: The HTS Protocol



HTS service provision should follow the steps described in Table 2 below.

Table 2: HIV testing provision steps/protocol

	Activity	Description
1	Demand Creation	Demand creation refers to using communication approaches that influence attitude, perceptions, and social norms to generate demand and utilization of HTS. In order to address behavioral and structural barriers for HTS, a strategic mix of approaches that include mass media, social media, interpersonal communication, community dialogues, edutainment and use of champions/ peer mobilisers/ satisfied users should be utilized.
2.	Pre-test information and counseling/ Risk assessment	• Re-assurance about confidentiality • Benefits of testing for HIV • Information pertaining to the modes of HIV transmission • Assessment for client risks • Possible results and their implications • A brief procedure of the HIV testing process • The potential for incorrect results if a person already on ART is tested • An explanation of the informed consent form and possibility of opting out • Other relevant information as the counsellor may deem necessary
3.	HIV testing	This can be either an HIVST and/or following the national testing algorithm. Will be done using blood or oral fluid. For those below 18 months, a DNA PCR test will be done and those above 18 months an antibody test will be done. Refer to the HIV testing algorithms for the different age groups. For more details on HIV testing, refer to the HIV Testing Services Policy and implementation guidelines 2022

4.	Post-test counseling (individual/ couple)	Assess readiness to receive results. Give results simply and clearly. Address concerns, conduct risk reduction, encourage disclosure, and partner testing. Provide information on HIV prevention, care, treatment and support services; complete the HTS card and HTS register.
5.	Linkage to HIV Prevention, Treatment, Care, and support Services	Link to appropriate HIV prevention, treatment, care and support services. Complete/fill the HIV comprehensive referral form, Linkage and Pre-ART Register and other appropriate tools.

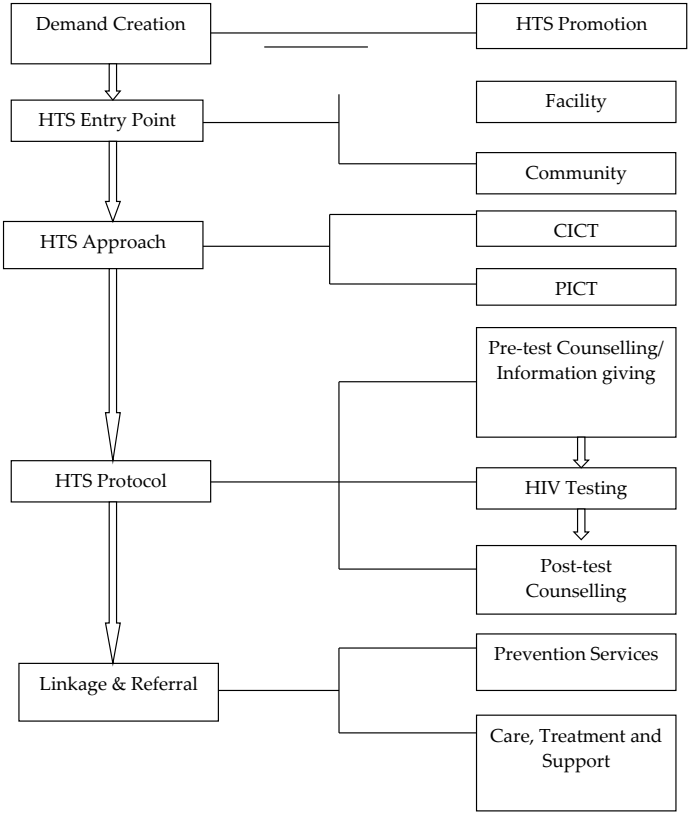
Note: Counselling for children should be age appropriate.

- **For children aged below 12 years:** Counselling should be offered to the parent/guardian. The child should only attend the counselling session if the parent/guardian finds it appropriate for him/her to participate.
- **For children aged 12 years and above:** Individual counselling should be offered to the child unless the child prefers to have the parent/guardian to participate in the counselling session.

2.3.1 HTS Cascade

In Uganda, the HTS cascade shall follow the steps depicted in **Figure 4** below.

Figure 4: The HTS Process



2.4 HTS ELIGIBILITY SCREENING

The following clients shall be screened for eligibility before HIV testing:

1. Adults and children in OPD Community
2. Clients seeking Voluntary Medical Male Circumcision
3. In-patients due to trauma and partners of pregnant and breast-feeding women

The following clients may not require screening before testing and these include:

1. Presumed/diagnosed TB clients
2. Malnourished individuals
3. In-patients
4. Clients with current STIs

5. Pregnant and breastfeeding women
6. Sexual offenders and survivors
7. Blood donors
8. Body tissue and organ donors

To optimize HTS, eligibility screening tools shall be utilized at both facility and community settings. This should be conducted using either paediatric & adolescent or adult screening tools that have been developed and validated.

2.5 THE CONCEPT OF TARGETED HIV TESTING

2.5.1 Definition

Targeted HIV testing is the process by which HTS is focused on an individual or group of individuals who are at high risk of HIV acquisition. It requires HTS providers to follow a set criterion (risk factors) to determine eligibility of an individual or groups of individuals prior to HIV testing.

2.5.2 Why Targeted HIV testing?

To optimize HIV case identification and linkage to care and prevention services, it is critical that the HTS program adopts a mix of effective and cost-effective innovations and approaches as recommended in the National Plan for Optimizing HIV Testing Services in Uganda, 2020/21-2022/23.

Based on the dynamics of the HIV epidemic in Uganda, specific risk factors that drive the epidemic have been identified. HTS delivery shall be focused on populations that are particularly at high risk of HIV acquisition.

These include:

1. Being in a sexual relationship with multiple concurrent partners
2. Belonging to a key, vulnerable or priority population (e.g., children, adolescent girls and young women, pregnant or breastfeeding women)
3. Being a sexual contact to an index client
4. Being a biological child to an HIV positive client
5. Not knowing your partner's HIV status
6. Being in a serodiscordant relationship

2.5.3 Benefits of Targeted HIV testing

- Prompt identification for population groups with high incidence
- Maximizes use of testing resources
- Permits health facilities to focus their activities on high-risk populations
- Yields a higher positivity rate than routine or conventional testing

- Reduces workload and improves outcomes from constrained health workforce

2.5.4 Targeted HIV Testing approaches in Uganda

In Uganda, targeted HIV testing is also referred to as "risk-based testing" where HTS delivery focuses on people who are at increased risk of acquiring HIV. The following approaches are utilized in risk-based testing to optimize HIV case identification and linkage:

- Screening for HIV testing eligibility for children, adolescents and adults
- Index client testing (ICT), including Assisted Partner notification (APN) and testing for biological children/ Know Your Child Status (KYCS).
- Social Network Strategy (SNS)
- HIV Self-Testing (HIVST)

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

Guide for health workers

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

Applicability: This guide is applicable to all personnel involved in screening children and adolescents aged 18 months to 14 years for eligibility to test for HIV.

Procedure and instruction: The eligibility screening tool will be administered either directly to adolescents aged 12 years and above or to the caregivers of children aged below 12 years. Follow the instructions below:

i) Create rapport with the child/adolescent and caregiver.
ii) Assure confidentiality of all information being shared during the process of eligibility screening.
iii) Be alert in observing both verbal and non-verbal communication from the child/adolescent and/or caregiver during screening. Provide a conducive environment for the child/adolescent and/or caregiver to speak freely.
iv) Clarify any questions/issues/concerns to the child/adolescent and/or the parent/caregiver.
v) Be empathetic.

Table 3: Screening questions for all children and adolescents <15 years

No	Screening Question	Guidance
1	Is the child's mother HIV positive?	Ask the mother whether she knows her current HIV status. If the mother is not present, ask if the child or caregiver knows the HIV status of the child's mother. The response may be 'Yes' or 'No.' If the mother's HIV status is known, ask if positive or negative. If the mother's HIV status is positive, test the child for HIV. If the mother's HIV status is negative or not known, continue to ask questions 2-6 as shown below.
2	Has the child/have you been sick in the last three months?	The answer to this question is 'Yes' if there has been any change in the health condition, even if it is relatively minor. Ask if the child received medication or made a clinic visit in the last 3 months, or if they were bedridden or not playing.
3	Has the child/have you had recurring skin problems?	You may need to ask this question in two parts: 1) If there was any skin problem (e.g., rash, itching and/or sores) and 2) If these were recurrent. Observe the child for any skin rash and/or scars suggestive of a previously treated skin rash. If child/ caregiver reports 1 or 2 isolated incidents of a skin problem that disappeared on its own or with treatment, select 'No' to this question.
4	Has the child/have you lost weight in the last few months?	Weight loss may not be easy to determine. Use different examples to describe weight loss, such as a decrease in body size, muscles, and/or loose or sagging clothes. Choose either 'Yes' or 'No' depending on whether the child has lost weight in the last 3 months. If the respondent is 'Not sure', the answer is likely to be 'No'.
5	Has the child/have you ever had TB?	Establish if the child has ever had or been treated for TB. Select 'Yes' if child has ever been diagnosed or treated for TB. Select 'No' if TB was suspected but not confirmed, or a persistent cough is reported, or if child reports that 'I think I was treated for TB, but not sure', or if the caregiver reports this on behalf of the child.

No	Screening Question	Guidance
6	Is the child/ are you growing well?	A child or caregiver may not easily be able to tell what growing well means. To assess if a child is growing well, ask if the child's height, weight or milestones compare with those of other children in the same class or of the same age or not.

Determine if the child/adolescent is eligible for an HIV test using the tool below:

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

- If the answer to the question, "Is the child's mother HIV-positive?" is 'Yes', test the child for HIV.
- If the answer to the question, "Is the child's mother HIV-positive?" is 'No' or 'I don't know', ask the set of 5 questions to the right.
- If 2 or more responses to the 5 questions on the right shaded in gray are selected, test the child for HIV.

Figure 5: Pediatric and Adolescent Eligibility Screening Tool for HIV Testing (18 months to 14 years)

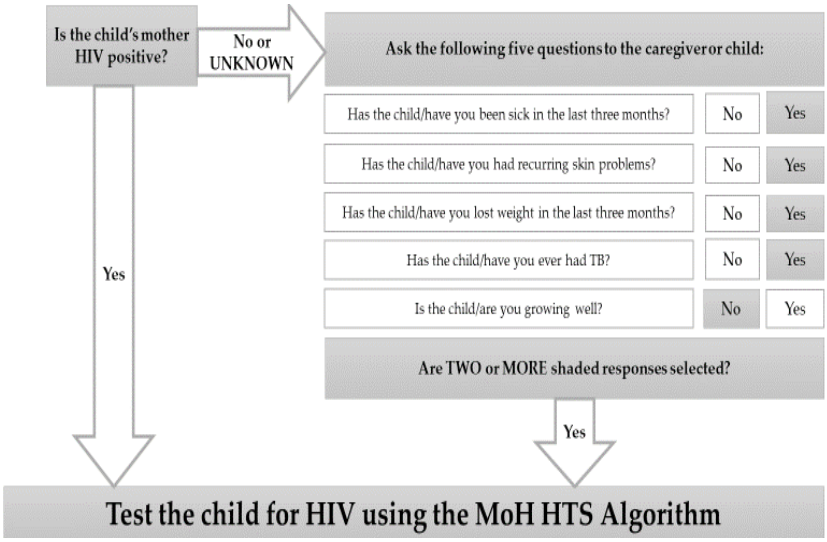


Figure 6: Eligibility Screening Tool for HIV Testing among adolescents and adults (15 years and above)

1	**Does the client belong to ANY of these categories?**		
1a	• **Not tested for HIV in the last 12 months.**	**YES**	**NO**
1b	• **Has TB Disease or presumptive TB (2 weeks' history of Cough, night sweats, weight loss, fever)**	**YES**	**NO**
1c	• **Has symptoms of Sexually Transmitted Infection (blisters, sores, unusual urethral or vaginal discharge)**	**YES**	**NO**
1d	• **Newly diagnosed with Hepatitis B or C**	**YES**	**NO**
1e	• **Has experienced or caused Sexual violence (SGBV)**	**YES**	**NO**
1f	• **Has a reactive HIV self-test result**	**YES**	**NO**
1g	• **Has been identified through an Index client**	**YES**	**NO**
1h	• **Has been exposed to blood or body fluids from a Known HIV positive or unknown HIV status source**	**YES**	**NO**
1i	• **Has signs and symptoms of HIV disease and has not had an HIV test in the last 1 month.**	**YES**	**NO**
	For clients who have not tested for HIV in the last 3 months		
2	**Have you had unprotected sex with partner(s) of unknown HIV status?**	**YES**	**NO**
3	**Have you had unprotected sex with an HIV positive partner? (includes discordance)**	**YES**	**NO**
4	**Have you shared injecting needles or piercing objects with anyone else?**	**YES**	**NO**

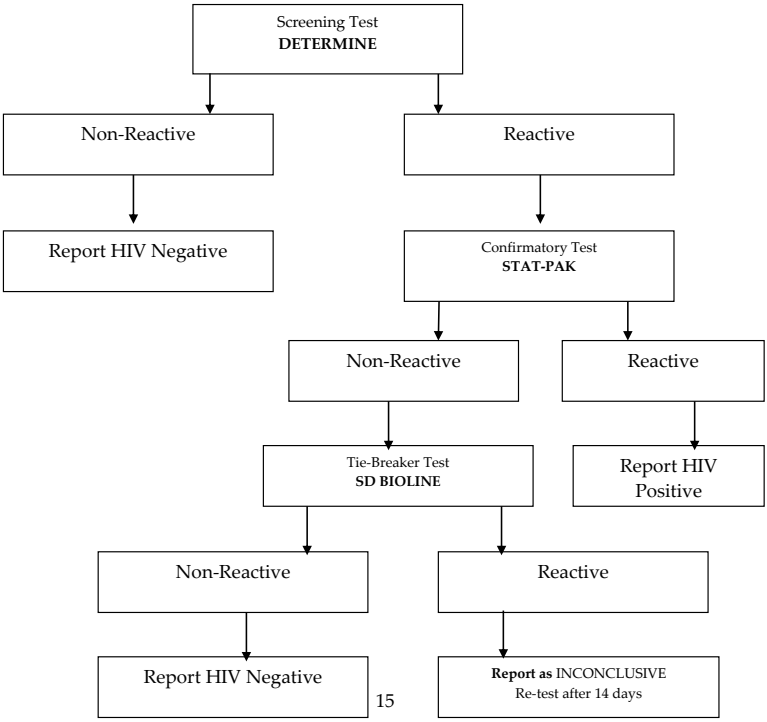
If YES to any of the above, Client is ELIGIBLE for HIV testing

If "NO" to all the above, client NOT ELIGIBLE for HIV testing

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 7 below. Note: if the child is still breastfeeding at 18 months or above and the HIV test is negative, a final test should be done 3 months after the child stops breastfeeding. See Figure 15 for the testing algorithm for infants <18 months.

Figure 7: Serial HIV Testing Algorithm for testing persons above 18 months of age in Uganda, 2022



The HIV testing algorithm for persons aged 18 months of age and above recommends: Determine as the screening test, Stat-Pak as the confirmatory test and SD Bioline as the third test (tie-breaker). A reactive test on SD Bioline is reported as inconclusive.

Note: An inconclusive result on the national HIV testing algorithm does not deem SD Bioline an inferior test assay.

2.6 RESOLVING INCONCLUSIVE HIV TEST RESULTS

2.6.1 Resolving a second HIV inconclusive Test Result

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

2.6.2 Retesting for Verification

A retest for verification is not performed to assess the competency of the first tester but it is a quality measure to ensure that a client who is enrolling in HIV Care is TRULY HIV positive.

The re-test for verification shall be performed by a health worker (tester), other than the one who performed the first test and using a different blood sample drawn from the same individual (client). Retesting for verification shall be performed at the point of ART Initiation. This may be performed at the Mother Baby Care Point (MBCP), HIV/ART clinic or laboratory. The respective national HIV testing algorithm must be followed during retesting for verification (same algorithm in test event 1 and 2).

2.6.3 Resolving Discrepant results on retesting for Verification

For clients whose results are NEGATIVE on retest for verification, samples should be collected, labelled "Discrepant" and sent to the national HIV reference laboratory (UVRI) for testing. A result will be sent back as either POSITIVE or NEGATIVE. Sample and result transportation will utilize the existing hub system.

Note: Before discrepant results are sent to national HIV reference laboratory (UVRI), rule out errors at facility level such improper handling of samples or testing kits and personnel incompetence. To ensure accuracy and reliability of HIV test results, the World Health Organization recommends this for all HIV antibody tie breaker tests. Therefore, the final HIV test result in the HTS client card, HTS Register, and the Daily Activity Register should be recorded as: NEGATIVE, POSITIVE, or INCONCLUSIVE.

2.7 MODELS & APPROACHES FOR HIV TESTING SERVICES

To improve access and efficiency of HTS, a mix of health facility and community-based models should be utilized. Under each of these models, the two main approaches for HTS will include: provider-initiated HIV testing and counseling (PITC) and client-initiated testing and counseling (CITC). The figure below provides a diagrammatic flow of HTS models and approaches in Uganda. HIV Self Testing shall be provided as an additional testing option across both testing models. Reporting for HTS shall be synchronized and aligned to these models to track efficiency of each.

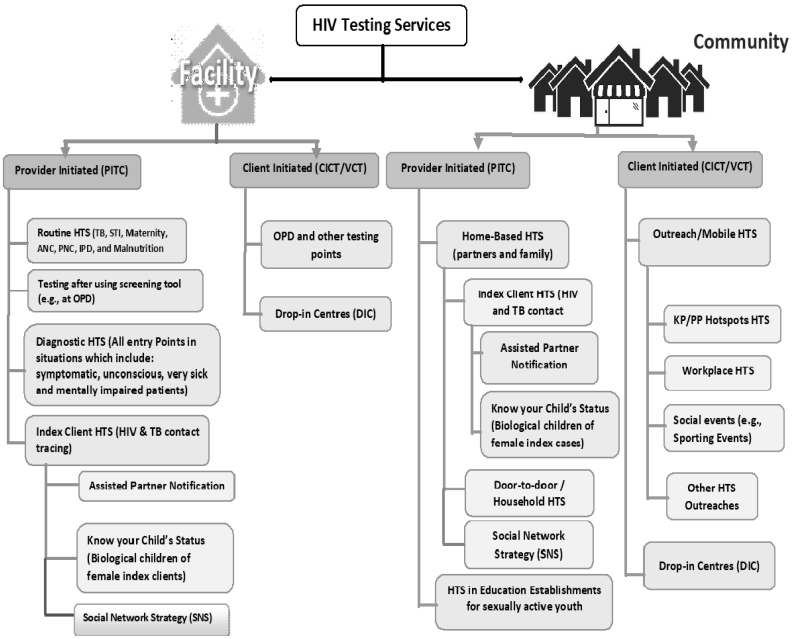
2.8 HTS AT HEALTH FACILITIES

Within the decentralized health system, HTS shall be offered up to HC II level. At HC IIs, HTS should be offered under supervision of higher-level health facilities. Both PITC and CICT shall be provided in health facilities by either the conventional HIV testing using the national algorithm or HIVST.

Provider-initiated HIV testing and counseling (PITC)

PITC should be conducted in either a health facility or community setting and is initiated by a health worker.

Figure 8: Differentiated HIV Testing Services Models and Approaches for Uganda



In this approach, health workers should screen for eligibility as a standard of care to clients. Adequate information should be provided to clients about the benefits of testing to enable them to make an informed decision. Service delivery points for PITC include Maternal and Child Health, adult and paediatric in-patient wards, TB clinics, nutrition units, family planning clinics, Sexually Transmitted Infections clinics, Out Patient Department and clinics managing survivors of sexual abuse. See section 6.5 in the national HTS policy and implementation guidelines 2022 for details on integration of HTS. PITC shall include diagnostic testing as well as routine testing.

2.8.2 Diagnostic testing

This shall be carried out on individuals as deemed necessary by the attending health care team with the purpose of better patient management. Such situations may include symptomatic, unconscious, very sick and mentally impaired patients. Through PITC, the patient or attendant should be given an opportunity to know his/her status to promote adherence; prevent further transmission and enhance psychosocial support for the patient.

2.8.3 Routine HIV testing

This shall be carried out for individuals likely to cause a risk of HIV infection to others. The following individuals shall be offered routine testing in reference to the Uganda HIV prevention and Control Act 2014:

- Pregnant and breastfeeding women
- Partners of pregnant and breastfeeding women
- Donors of blood, body tissue and organs.
- Sexual offenders and survivors

2.8.4 Client-initiated testing and counseling (CITC)

In this approach, individuals and couples willingly seek HTS either from the health facility or a preferred community setting and follow the approved HTS protocol. CICT should be offered to individuals or couples after risk screening.

2.9 HTS At Community Settings

HTS in communities will aim to serve populations that would otherwise not attend facility-based HTS. Services should be offered in homes, social gatherings, education establishments, DICs, safe spaces and at workplaces by either using the conventional HIV testing or HIV Self Testing national algorithm.

Programs offering HTS at community level shall ensure that follow-up and linkage to prevention, care, treatment and other support services follow respective protocols.

HTS in community settings shall aim to offer an integrated package of primary health care services, including STI screening and management, child health services and other health promotion interventions. Recording and reporting community HTS will utilise Ministry of Health reporting tools.

HTS at community level should be offered in the ways as listed below:

2.9.1 Outreach HIV testing services

Outreach HTS can be offered by higher to lower-level health facilities or to communities through planned and regular visits to the outreach sites or through community camping where outreach sites are inaccessible.

Note: HTS outreaches for general populations as well as during public campaigns are discouraged.

2.9.2 Home Based HIV Counselling and Testing (HBHCT)

HBHCT shall follow two main models:

- Door-to-door testing for all consenting individuals, couples or families in a specified geographic area.
- Index client contact tracing and testing that is offered to households with a consenting PLHIV or person with active or presumptive TB (index client).

Door-to-door testing may be implemented ONLY in high HIV prevalence settings or communities for key populations such as, hotspots for sex workers, men who have sex with men, or through the snow-ball approach.

HBHCT should be arranged in collaboration with existing health facilities and community support groups to ensure on-going care for persons who are offered HTS. HBHCT should offer the benefits of supported disclosure and adherence to ART and other medications.

2.9.3 HTS at the workplace

Workplace HTS conveniently provides HIV testing to individuals at their place of work. These are usually individuals whose work schedules do not permit them to leave their workplaces in search of health care. Workplace testing should be implemented with high levels of uptake and linkage to care and prevention services, particularly in high burden settings. Providers should ensure confidentiality, non-coercion and effective linkage to prevention, care, treatment and support services.

Employers in Uganda should mainstream the provision of HTS to employees and their families in the workplace as an integral component of staff welfare. HIV testing services at workplaces should be offered within the workplace in collaboration with health facilities that provide care treatment and prevention services.

2.9.4 HTS in Educational Institutions

HIV testing services in educational establishments should address sexually active youth in the context of sexual health education and behaviour change interventions. Provision of HTS in education institutions in Uganda should be done according to the National School Health Policy. HTS at the educational institutions should be implemented with high levels of uptake and linkage to care and prevention services

2.9.5 Mobile HTS

HTS is offered by mobile teams at hotspots for key and priority populations.

2.9.6 Drop-In Centres (DICs)

Drop-in Centres (DICs) are service delivery points targeting special sub-populations (Key Populations, Priority Populations and Vulnerable Populations), who would otherwise fail to access health services including HTS. These can be established by Community Based Organisations or Ministry Of Health together with its partners. Members of the general population should not be denied services at these sites.

The objectives of Drop In Centres are to promote and improve the quality of life through building capacity and skills empowerment, creating an enabling environment, establishing linkages with existing health services, Non-Government Organizations, Community Based Organizations and other welfare and development programs, and protecting and promoting the rights of the Key Populations, Priority Populations and Vulnerable Populations. For Key Populations, Priority Populations and Vulnerable Populations, a growing number of Community Based Organizations are utilising Drop In Centres to provide HTS.

2.10 INDEX TESTING

2.10.1 Index testing

Index testing involves tracing contacts of index HIV- positive clients and offering them testing services. Examples of these approaches include:

i) Assisted partner notification (APN)
ii) Index client testing for biological children/ Know Your Child Status (KYCS)

2.10.2 Assisted Partner Notification (APN)

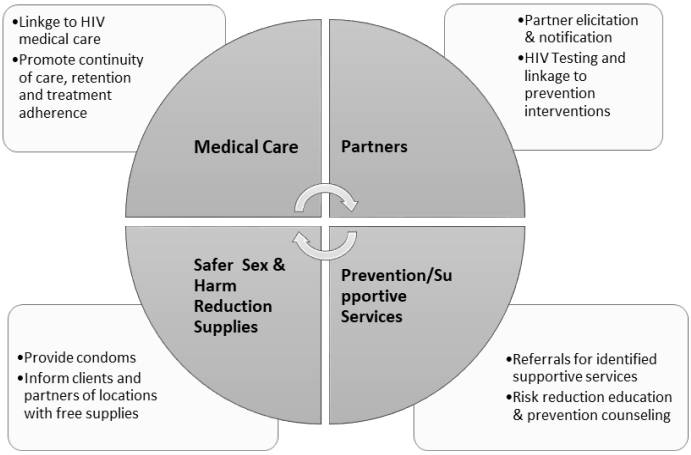
APN is part of a comprehensive array of services offered to persons infected with HIV or Sexually Transmitted Diseases and their partners. APN is a process through which HIV-positive index clients are interviewed to elicit information about their sexual partners, who can then be confidentially notified of their possible exposure or potential risk and offered HTS. Index clients should be encouraged to notify past partners, in addition to current partners, and engage them in testing services. APN is voluntary, confidential, client-centred, and free, for both the index client and his/her partner(s).

For additional information refer to the HTS Policy and Implementation Guidelines 2022.

2.10.3 Components of Assisted Partner Notification Services

APN includes, partner elicitation and notification, counselling and testing for HIV linkage to HIV care, treatment, prevention and other services as shown in the figure below.

Figure 9: Components of Assisted Partner Notification Services



2.10.4 Target Populations for APN

The target populations for APN are individuals aged 15 years and above with high likelihood to transmit HIV to their partner(s).

These include:

- All persons newly diagnosed with HIV including those on ART for less than 6 months
- PLHIV on ART with an identified risk (e.g., new sexual partner(s), People Who Use and Inject Drugs sharing contact(s), or STI diagnosis.)
- On ART but non- virally suppressed (including individuals with VL>200 copies/ml and 400 copies/ml for plasma and DBS respectively)
- Adolescents living with HIV below 15 years of age who are sexually active and meet any of the above criteria

2.10.5 Principles of APN

The principles of APN as stipulated in table 3 below include: voluntary and non-coercive; free; non-judgemental; confidential; client centred and focused; comprehensive and integrative; culturally and linguistically appropriate; and available and accessible to all clients.

Table 4: Principles of APN

Voluntary and non- coercive	APN is never coercive or mandatory and always relies on the willing participation of HIV-infected persons and their partners. Providers should encourage patient participation in APN by fostering rapport and an atmosphere of trust and mutual respect. All service recipients should be informed of benefits and risks from participating in APN.
Confidential	All information (both print and electronic) regarding index clients and their partners should be kept strictly confidential and not accessible or disclosed to anyone other than those who are authorized to have access (APN providers and their supervisors). Strict adherence to confidentiality should be followed during attempts to contact the patient, initial interview, notification of partners and subsequent contacts and re-interviews. During attempts to locate and schedule an interview with a patient, the APN provider should not disclose to anyone other than the patient the reason for locating the patient. The HIV status or any other potential HIV-identifying information is discussed with only the patient and authorized public health staff.

Client-centered and focused	All communication with patients should be centered on the needs of the patient. The APN process should be tailored to the behaviors, circumstances, and specific needs of each patient.
Comprehensive and Integrative	APN staff should be part and parcel of health services that are integrated to the greatest extent possible for persons with HIV infection or other STDs and their partners.
Available and accessible to all clients	APN staff should be available for persons who test HIV positive. All individuals who test positive should be informed of the option of obtaining APN without disclosing their identity or having their HIV test result disclosed. If the patient decides to participate in APN, the HIV counseling and testing provider trained on APN can provide APN at a place and time convenient to the patient. Partners of a person with HIV are notified of their HIV risk and are informed of anonymous and confidential testing options.

2.10.6 Partner Notification Methods

There are four notable partner notification methods as described below:

1. **Provider Referral** = The HTS provider will contact the partner(s) of an index client, and offer them HTS.
2. **Client Referral** = The index client informs their partner(s) about the need for them to test for HIV.
3. **Contact Referral** = The index client and HTS provider shall work together to notify the index client's partner(s). The index client shall be given 14 days to inform their partner(s) of the need to test for HIV. If after 14 days the index client has not yet informed his/her partner(s) the HTS provider shall contact the partner(s) and offer HTS.
4. **Dual Referral** = The HTS provider will sit with the index client and their partner(s) and discuss the need for HIV testing.

2.10.7 APN Implementation Process

The following steps shall be involved in the delivery of APN services:

Step 1: Index client Identification

Step 2: Index Client Interview and Elicitation

Step 3: Partner Notification

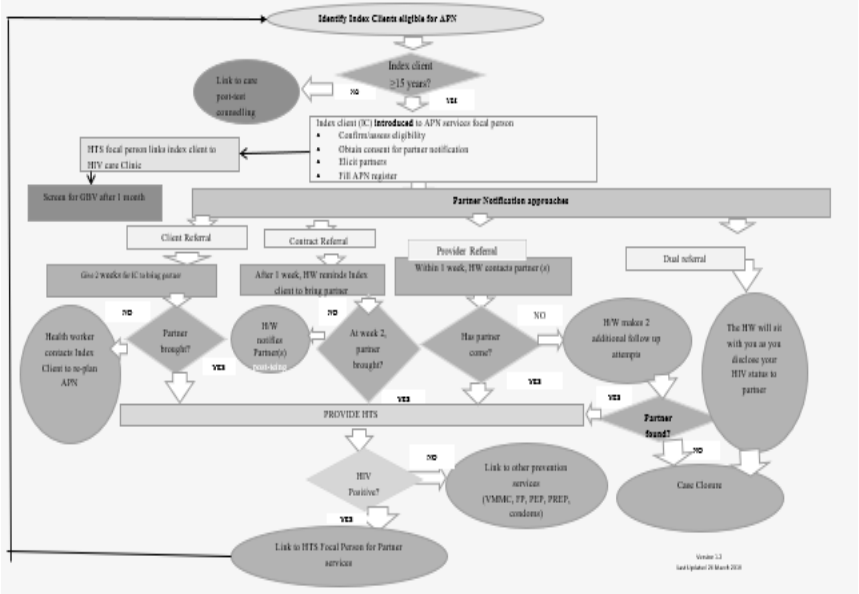
a) Index client Notification

b) Assisted/Provider Notification

Step 4: Partner Counselled and Referred to or Linked to Care Services:

Step 5: Case Closure

Figure 10: APN Flow Chart



2.10.8 Adverse Events / Challenges in APN

During APN implementation, adverse events may arise and therefore APN staff should follow appropriate national implementation Guidelines and Protocols to mitigate them. The common adverse events include index clients' acceptability of APN services, the potential for patient abuse or harm resulting from partner notification, and the potential negative effects on relationships between patients and their partners including physical, social, economic, and emotional harm.

All APN providers shall be trained on the how to access and mitigate adverse events that impact implementation of APN services. Such training shall cover, among others:

- Maximizing acceptability of APN among patients and minimizing the negative effects resulting from notifying partners of their risk.

- Risks associated with home/field visits and how to assess the safety of each situation.
- Following appropriate safety Policies and Guidelines regarding field or home visits which should emphasize safety as a priority.
- Keeping supervisors and/or colleagues aware of their field visit appointments and locations.
- Counseling and communication skills.

2.10.9 Index client testing for biological children/Know Your Child's HIV Status

HIV positive clients and /or TB patients in care should be mobilized to bring their biological children and other household members whose HIV status is unknown for HIV testing. This also applies to HIV exposed infants whose mother accesses postnatal care (PNC), young child clinics (YCCs), family planning (FP) and/or gynecological services e.g., STI or cervical cancer screening.

When conducting partner services, it is also important to offer HIV testing services to the biological children (2 -19 years) of the HIV-positive client, when their HIV status is unknown. Index testing shall also be offered to nonbiological children (2 -19 years) not born to the index client but living in the same household. In all settings biological children of a parent with HIV should be routinely offered HTS and if found to have HIV or to be at high risk for infection through breastfeeding, should be linked to services for treatment or prevention.

2.10.10 Social Network Testing Strategy (SNS)

Social network strategy (SNS) is a case-finding strategy that uses social network connections to locate individuals at high risk for HIV. SNS can be particularly useful in finding Key Populations and others who are at risk for HIV.

Social network strategy addresses some of the challenges in scaling up HIV partner services among Key Populations and other high-risk individuals, particularly issues of confidentiality. By addressing confidentiality concerns, Social network strategy broadens the reach of partner services to include both HIV-positive and HIV-negative members of Key Populations and other high-risk individuals, their partners, social contacts and networks and other persons who are at risk of HIV but do not have easy access to HTS.

Underlying assumption – people in the same social network share similar risk behaviours for HIV

The overall SNS strategy is aimed at enlisting HIV-positive and high-risk HIV negative persons (recruiters) who identify individuals from their social networks for HTS.

SNS shall be implemented using the following appropriate tools:
- Standard Operating Procedures (SOPs)
- Facility registers
- Periodic reporting templates

Social network strategy processes shall involve training of health workers, identification of facility-based focal persons, identification of eligible high-risk clients including Key Populations and other high-risk individuals, conducting risk assessment for each social contact, developing appropriate notification plan(s) for the social contact (time, method, means of contact) to ensure he/she receives an HIV test.

Note:
i) Social contacts being tested should be linked to appropriate care, treatment, prevention and support services
ii) All named social contacts will be subjected to the HTS screening tools

SNS shall be implemented following four phases as illustrated in figure 8 below.

Figure 11: SNS Implementation – Four Phases

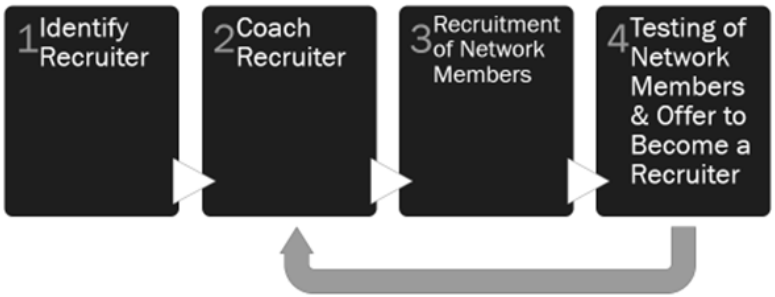
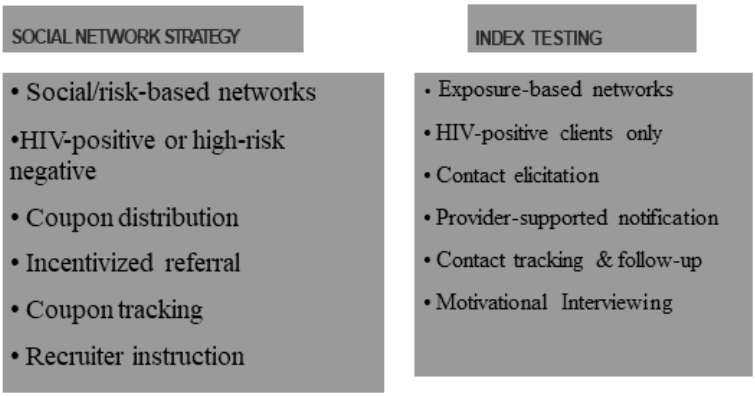


Figure 12: Differences in SNS and Index Testing



2.10.11 Accreditation of Health facilities to offer index client testing services

Index client testing (ICT) services should meet the HTS ethical principles of the 5Cs which include consent, confidentiality, counselling, correct test results and connection to HIV prevention, care, treatment and support services. Health facilities (sites) offering Index client testing services should ensure that appropriate systems are in place for testing, identification and responding to clients who disclose and fear or experience IPV from (a) partner(s). Mechanisms must be in place to monitor and address adverse events arising from the provision of Index client testing services.

The assessment for Index client testing shall be conducted using the minimum standards checklist provided by OGAC as it meets all the essential elements for quality Index client testing. The tool consists of 5 sections; however, section one (1) which consists of 33 checklist scores shall be the minimum for accreditation.

For details on accreditation on Index client testing services, refer to the HTS policy and implementation guidelines 2022

2.11 HIV SELF-TESTING

HIV self-testing (HIVST) is a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts. Prior to offering HIV self-testing, clients shall be screened for

eligibility according to the HTS screening protocol. HIV self-testing is a screening test (test for triage) and is not sufficient to make an HIV-positive diagnosis. Therefore, a reactive (positive) self-test result should be confirmed using the validated national testing algorithm by a trained HTS provider. HIVST results shall be reported and documented accordingly.

2.11.1 Guiding Principles for Implementation of HIVST

The 5C's guiding principles should be followed while delivering HIVST services: (Refer to Table 4 principles of APN testing)

2.11.2 Approaches to HIV self-testing

HIV self-testing will be provided through two main approaches:

Directly Assisted self-testing

A trained provider (a health worker, distributor or peer) supervises/assists an individual in performing the HIV self-testing. This involves an in-person demonstration before or during HIV self-testing, on how to perform the self-test and interpret results. This is in addition to the manufacturer-supplied instructions for use and other materials. Caregivers can directly assist children 18 Months -14 years to administer a self-test, if oriented by a trained provider.

Unassisted Self-Testing

Individuals are given HIV self-testing kits and they conduct the test and interpret results without any supervision or assistance from a trained provider (health provider, distributor or peer). However, general information on how to conduct the test should be made available to the user with additional manufacturer's instructions, telephone hot line, instructional videos, leaflets, social media and other internet-based links.

2.11.3 Target Populations for HIVST

The following population groups will be prioritized for HIV self-testing in Uganda:

- Children 2 -14 years (caregiver assisted oral screening)
- Adolescent Girls & Young Women & Boys (AGYWB)
- Individuals above 50 years and above
- Men including partners of pregnant women and lactating mothers
- Key populations and priority populations
- General population (through the private sector)

2.11.4 HIVST for PrEP and VMMC

Blood-based HIVST is an alternative for PrEP refill in case of absence of the national HTS standard recommended in patients on PrEP.

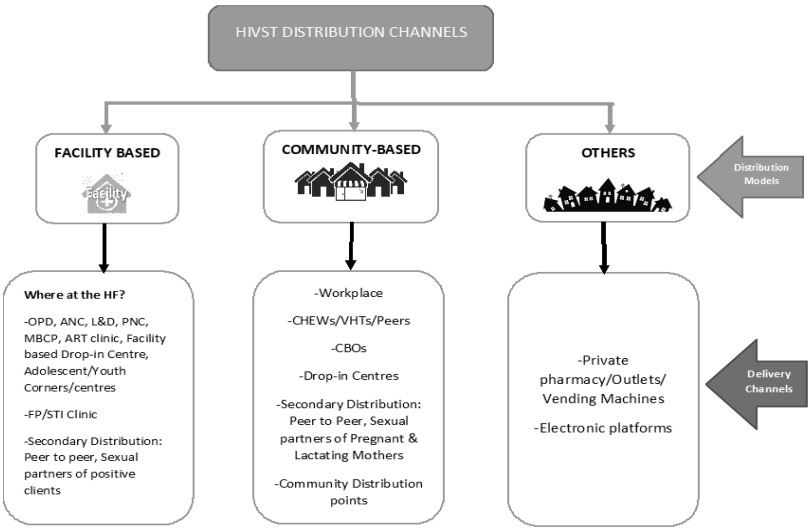
All individuals presenting for VMMC will now be tested for HIV regardless of age and risk.

2.11.5 HIV self-testing /Distribution Channels

HIV self-testing will be implemented through different distribution channels targeting different populations in the public and private sectors. Figure 8 shows the distribution channels that will be used to implement HIV self-testing. Additional evidence based channels may be adopted.

HIV self-testing kits may be distributed through primary or secondary modes both at the facility or community. For primary distribution, HIV self-testing kits will be distributed to primary recipients for self-use. With secondary distribution a primary client will take the HIV self-testing kit to their partner(s) or social contacts along with instructional materials on how to use them. Additional informational for linkage and treatment should also be provided.

Figure 13: HIVST Distribution Channels



2.11.6 Misuse and Adverse events associated with HIV self-testing

Misuse and adverse events associated with HIVST should be assessed pre- and post-distribution:

Individuals who disclose any form of violence by an intimate partner or social contact should be offered immediate support. Health care providers should offer first line support when clients disclose violence.

Do not provide HIV self-testing kits for secondary distribution to clients experiencing intimate partner violence. Partners of individuals experiencing intimate partner violence should be offered alternative HIV testing services.

A person testing negative is advised to re-test as per the national retesting guidelines.

The HIV Self Testing is NOT suitable for users who are taking antiretroviral treatment (ART)

There should be a system (framework) in place to report and document adverse events experienced during the provision of HIVST services. Providers experiencing adverse events should equally be offered first line support.

These events should be appropriately reported and documented using the standardised HMIS tools.

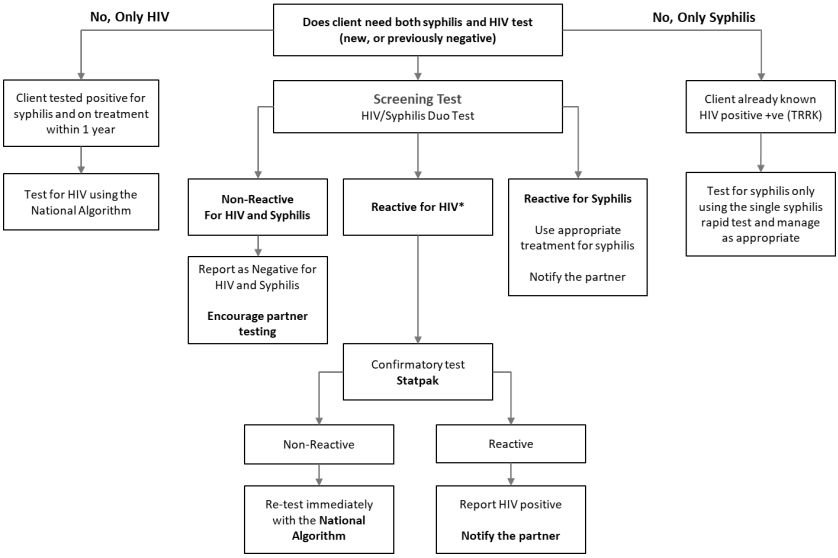
2.12 MATERNAL AND INFANT TESTING

2.12.1 Maternal and Child Health- HIV and Syphilis Testing Algorithm

Within Maternal and Child Health settings, the HIV/syphilis duo test kit will be used as a screening test for both women and their partners. Stat-Pak shall be used for HIV test confirmation. Women who are already known HIV positive will still need to test for syphilis using the single rapid syphilis test as depicted in Figure 14 below.

For samples that react on HIV syphilis duo but do not react on Stat-Pak the tester shall utilize the national HIV testing algorithm.. Index testing should be provided for those testing positive for HIV and/or syphilis.

Figure 14: HIV Testing Algorithm using the HIV-Syphilis Duo Kit in MCH Settings



2.12.2 HIV Testing Algorithm For Infants And Children Below 18 Months Of Age/ Early Infant Diagnosis (EID) Cascade

In sub-Saharan Africa approximately half of perinatally infected and a quarter of infants infected through breastfeeding will die before their second birthday, compared to <5% infant mortality in HIV-exposed uninfected infant[1]. The cascade of care required for optimally effective EID programs, essentially has two primary goals:

1. Correctly inform caregivers of infant infection status, and
2. Link all HIV-infected infants to care and ART.

Diagnosing HIV among infants is prudent and should be done at 4-6 weeks or at the earliest opportunity thereafter. All infants diagnosed with HIV should be initiated on ART immediately to reduce morbidity and mortality.

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

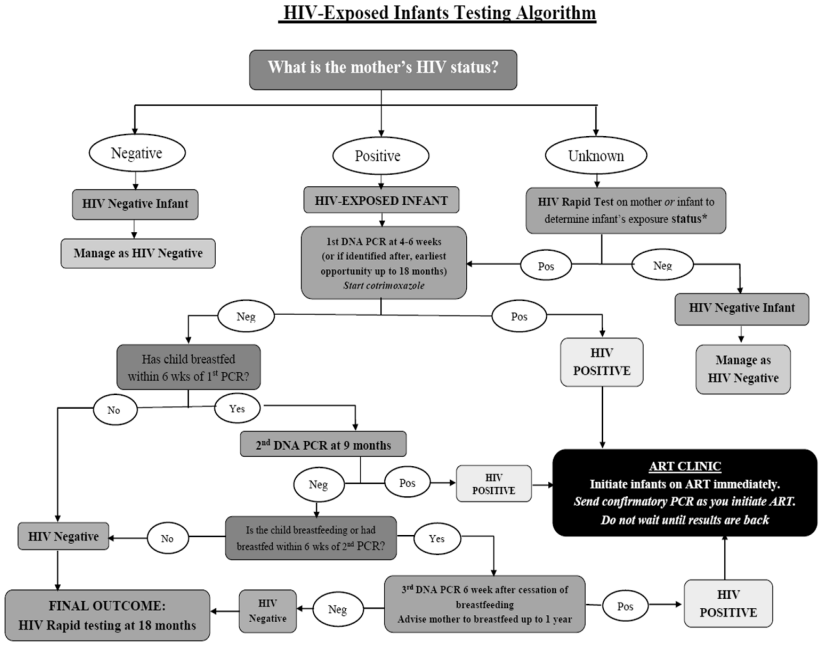
2.12.3 HIV testing schedule for infants

1 Davies M-A et al. Survival of HIV-1 vertically infected children. Curr Opin HIV AIDS 2016; 11(5): 455-464.

The 1st DNA/PCR test should be done at four to six weeks of age or the earliest opportunity thereafter. A 2nd DNA/PCR test has been introduced at 9 months of age for all infants irrespective of breastfeeding status. The 3rd PCR should be done 6 weeks after cessation of breastfeeding. Interpretation of the results and further testing are guided by the testing algorithm in Figure 15 below.

A positive DNA/PCR test result indicates that the child is HIV-positive. All infants with a positive DNA/PCR test result should be initiated on ART immediately and another blood sample should be collected on the day of ART initiation to confirm the positive DNA/PCR HIV test result. A negative 1st DNA/PCR test result means that the child is HIV-negative but could become infected if they are still breastfeeding. Infants testing HIV-negative on the first DNA/PCR should be retested using DNA/PCR at 9 months of age irrespective of breastfeeding status and retested again at six weeks after cessation of breastfeeding. Infants with negative third DNA/PCR test should have a final rapid antibody test performed at 18 months using the national HIV testing algorithm.

Figure 15: HIV testing algorithm for children <18 months of age



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

2.13 RE-TESTING OF NEWLY IDENTIFIED HIV POSITIVE PEOPLE

All newly identified HIV positive people, should be retested before initiating ART. This should be performed by a different tester using the approved national HIV testing algorithm at the ART initiation site/ care point. Table 6 below shows the categories of people to retest at specified time-points.

2.13.1 Retesting clients on ART

Retesting clients on ART is not recommended because most of these clients turn out with false HIV negative results.

2.13.2 Repeat Testing

Repeat testing should be conducted in specified circumstances to rule out laboratory or transcription errors and either to rule in or rule out sero-conversion. This could be followed by supplemental testing where additional assay(s) not used in the first testing algorithm may be used on the same specimens to obtain more information about the HIV test result.

Repeat testing for individuals thought to be in the window period is needed ONLY for those who report specific recent risk.

Table 6: Categories of HIV-negative persons to retest at specified time points

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

Pregnant women	1st trimester/1st ANC visit, again in the 3rd trimester for negative or unknown status women, with catch-up during labor or delivery for any women who missed HIV tests during ANC.
Breastfeeding women	Every three months until three months after cessation of breastfeeding. Align retesting to child immunization schedule as possible.
Confirmed and presumptive TB Patients	Four weeks after the 1st test
TB, Hepatitis and STI patients	Four weeks after testing
PEP clients	At one month, three months and six months after completing the PEP course
PrEP	Depends on risk of exposure in the past 3 months
HIV-exposed infants (HEIs)	4-6 weeks, 9 months of age, six weeks after cessation of breastfeeding and at 18 months of age
Children who are still breastfeeding beyond 18 months of age	3 months after cessation of breastfeeding
INCONCLUSIVE results	14 days after the last test
Children and adolescents (2-14years)	Risk based with exceptions explained earlier in these guidelines
Family planning clients	Risk based
Sexual offenders and survivors of SGBV	Four weeks after the 1st test
Index testing-Sexual partners	Four weeks after the 1st test
Blood, Tissue donors	Four weeks after the 1st test
General Population	Once a year depending on risk of exposure for the duration in which they have not had an HIV test > 3 months

2.13.3 Recent HIV Infection Surveillance

All newly-diagnosed HIV cases by the national HIV testing algorithm aged 15 years or older will be tested for HIV recent infection and routinely monitored by demographic and risk characteristics, Justification: As Uganda moves closer towards reaching 95-95-95 goals and sustained epidemic control, it is important to have individual-level data to monitor trends in the actual number of newly-diagnosed individuals with HIV. Also, information on the timing of HIV infection using tests for recent infection among newly-diagnosed persons provide important information on where and among whom recent transmission is occurring to guide rapid public health response efforts. These data will allow Uganda to better target HIV prevention programs to subpopulations and locations with a high burden of HIV and ongoing transmission.

Implementation guidance: HIV recent infection testing will be conducted at the health facility as well as the community level. At the facility, recent infection testing will be done at the HTS and Key Populations friendly service delivery points. At the community level, HIV recent infection testing will be integrated in the HTS outreach services and conducted at the outreach HTS service delivery points targeting key populations.

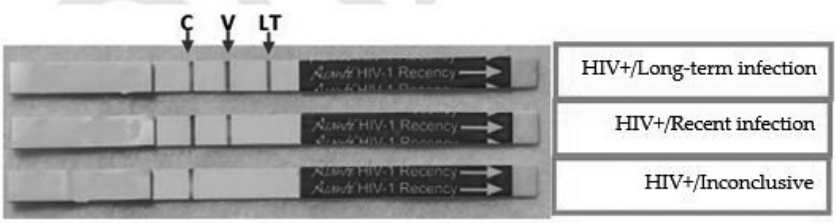
Eligible clients will be consented before testing for HIV recent infections. During the consenting process, clients will be provided with information on the purpose, risks, benefits, confidentiality and voluntary nature of participation. They will also be informed that their results will not be returned.

In testing for HIV recent infections, a point- of-care rapid test for recent infection (RTRI) or any other approved assay will be used to test HIV recent infection. Whole blood, plasma or serum may be used in conducting recent infection testing.

Interpretation of HIV Rapid Test for recent infection will follow the guidance depicted in Figure 14 below.

Recency testing data collection and use: Data on recent infection testing will be collected using approved HTS card, HTS addendum and HTS register. Collected data will be entered in Electronic Medical Record system and uploaded to the central server hosted by Central Public Health Laboratory (CPHL). This data will used for surveillance and public response only and not used for diagnostic purposes

Figure 16: HIV Rapid Test for Recent Infection Interpretation



V-Control line; V-Positive verification line; VL-Long term line

Recent infection testing algorithm (RITA): As part of laboratory quality control, clients who consent for point of care testing for recency are also consent to provide extra blood sample for shipment to Uganda Virus Research Institute (UVRI) for Viral Load testing and re-testing. RITA combines results of recent infection assay and viral load for final interpretation of recency status. Specimens that test recent on RTRI with a viral load result ≥1,000 copies/mL, will be classified as a RITA recent infection while specimens that test recent on RTRI with a viral load result <1,000 copies/mL will be classified as a RITA Long term infection. Including the additional VL reduces misclassification of an infection as a recent infection when the infection is actually long term.

2.15 LINKAGE TO HIV SERVICES

Linkage refers to an act of connecting an individual from one point of care to another. The second 95 in the UNAIDS fast-track targets of 95-95-95 by the year 2030 is "linkage of 95% of HIV positive individuals to treatment". Without effective strategies that ensure linkage and enrolment in care, the effect of HTS in reducing HIV transmission, morbidity and mortality cannot be fully realized. It is therefore the mandate of the HTS program to ensure identification and linkage of HIV positive individuals to care, treatment, support and prevention services.

HTS providers should address barriers to linkage to ease the process for PLHIV. Barriers may include:

- Client factors such as feeling healthy, depression, lack of social or family support and fear of disclosure
- Social or cultural factors such as stigma and discrimination
- Structural or economic factors; including legal issues and lack of transportation, health system barriers, such as poor referrals, stigmatizing or unfriendly services and long waiting times in facilities

2.15.1 Community-Facility, Intra and Inter-facility linkages

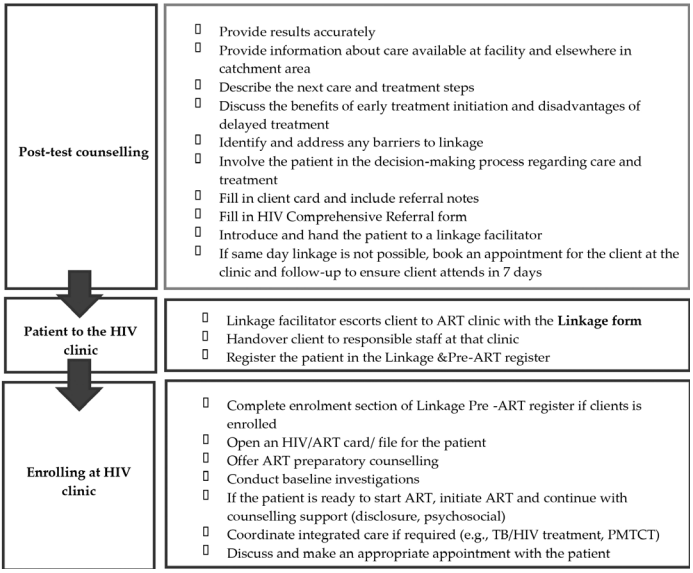
Linkage of HTS clients can be inter-facility, intra-facility or community-facility.

2.15.2 Intra-facility linkage

Intra-facility linkage refers to connecting a client from one point of care to another within the same facility. Intra-facility linkage should be encouraged for facilities that are accredited to offer HIV treatment. However, clients should be given an opportunity to choose the most appropriate facility to receive care, treatment or prevention services from. All intra-facility linkages shall be on the same day and where not possible, should be effected within 7 days.

The process of linkage within the same health facility is described in Figure 19 below.

Figure 19: Intra Health Facility Linkages for HIV Positive individuals



2.15.3 Inter-facility linkage

Inter-facility linkage refers to connecting clients from one facility to another facility for HIV treatment, care, and support services. The referring facility should track all HIV-positive clients referred to other facilities and ensure

they are enrolled in HIV care and treatment within 14 days, using the tracking schedule described in Table 7 below.

Table 7: Schedule for the tracking of inter-facility linkages for HIV positive individuals

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

2.15.4 Community-Facility Linkage

Community-facility linkage refers to connecting a client in the community to a health facility for HIV, treatment, care, prevention, and support services. HTS programs shall work with peer leaders, expert clients, YAPS, VHTs and CHEWs to create demand for community HIV testing approaches, referral and follow up of all individuals for appropriate services. Linkage from community to facility shall be done within 14 days. The process of community-facility linkage is described in Table 8.

Table 8: Schedule for follow-up/tracking community-facility-community linkages for HIV positive individuals

Timeline	Action
Day 1 (referral day)	- A client is diagnosed HIV positive and referred to the preferred facility using the HIV Comprehensive Referral form. - A copy of the referral form is given to the CHEW 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. - The HIV Comprehensive Referral form copy should be delivered to the facility where the client has been referred.
Week 1	-The organization doing community testing should call the client or the contact in the health facility where the client was referred. If client reached the facility, document complete linkage. -The health facility linkage facilitator identifies referred clients who have come to the facility and documents those referrals as linked/complete. - The facilitator notifies the CHEW of all clients who have not yet been linked. -The CHEW visits client's home to ascertain reasons for failure to reach the facility and makes a new appointment for facility visit. -The CHEW documents the outcome of the visit and notifies the health facility team.
Week 2	-The health facility linkage facilitator ascertains if the client was linked and notifies CHEW of the pending clients -The CHEW makes a final visit to client's home; discusses reasons for failure to reach the facility; makes a final appointment if the client is willing or documents outcome (refused, not ready, relocated, etc.). If the client has not yet decided to enrol in care, the CHEW will continue to contact and encourage them to seek care. A client is lost to linkage if he/she is not in care within 14 days of HIV diagnosis.

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

2.16 HIV TESTER AND SITE CERTIFICATION

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

2.16.1 Specific Objectives of Certification include:

Ensuring adherence to national standards of delivering HIV rapid testing

Ensure availability of competent personnel for HIV rapid testing

Ensure conformity of sites to national standards for quality results

2.16.2 Rationale of HIV Testing Certification

HIV rapid tester (Figure 20) and site certification (Figure 21) shall be key strategies to enhance the quality of HTS.

Despite many interventions to strengthen quality of HIV testing, gaps in quality assurance still exist including capacity of trained staff, unavailability of testing supplies, lack of post-market surveillance practices, deviation from testing procedures, low participation and performance rates in proficiency testing programs and under-utilization of testing data for timely corrective actions. A national certification program for HIV rapid testing may prove to be not only a healthcare cost saving approach, but also an expansion of quality of care.

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

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

Figure 20: Tester Certification Process

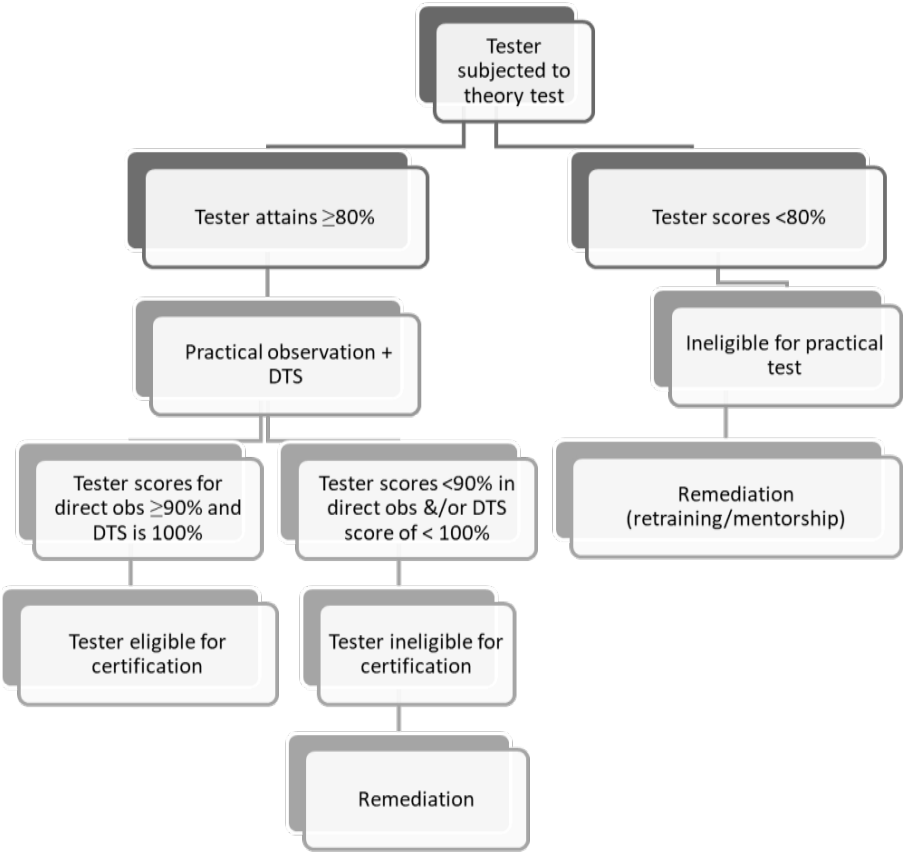
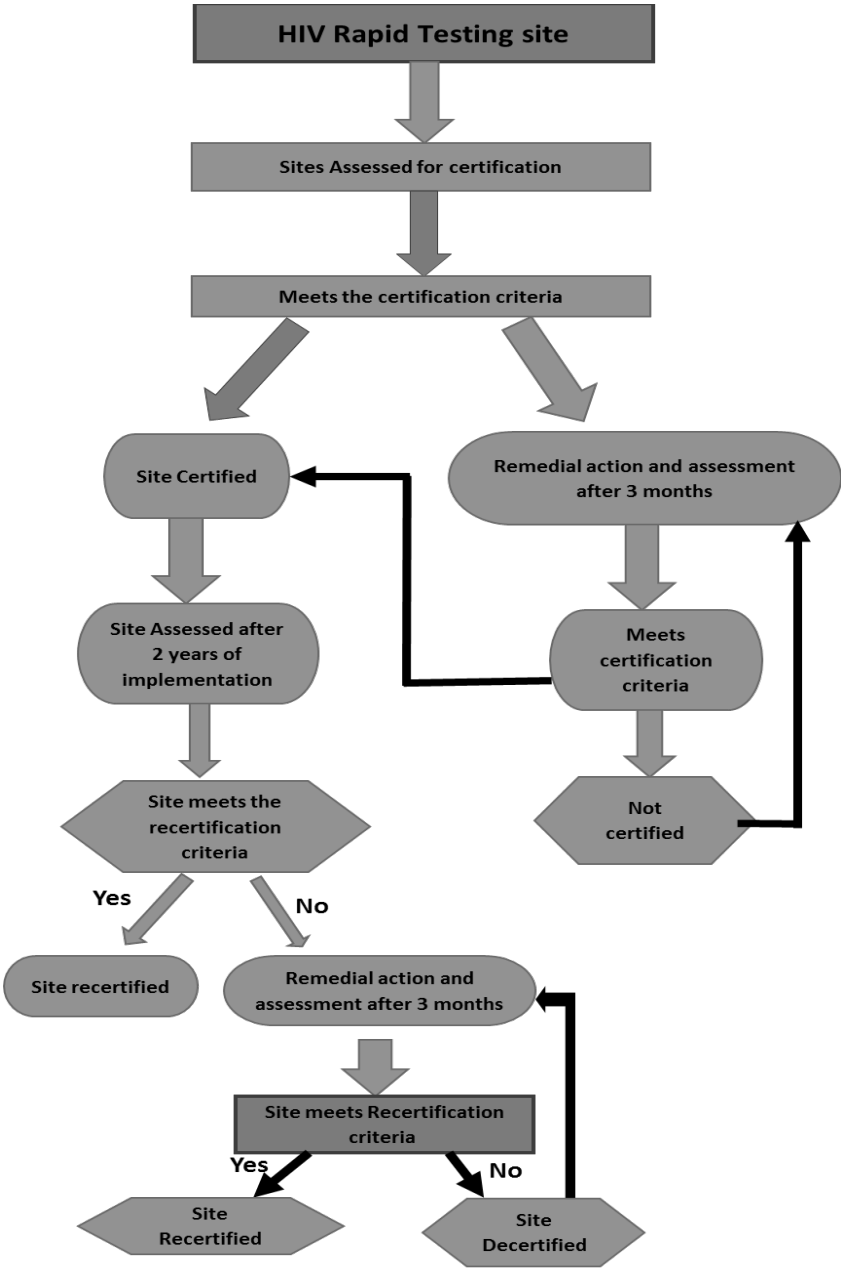


Figure 21: Site Certification Process



2.16.3 National Certification Committee (NCC)

This shall be a multi-sectorial committee that is independent of the assessors with diverse membership to increase objectivity, minimize bias and address conflict of interest. It shall be comprised of technical personnel from the following institutions: UVRI, Allied Health Professional council (AHPC), CPHL, Uganda Medical Laboratory Technologist Association (UMLTA), ACP, Quality Assurance Department (QAD), Civil Society Organizations (CSOs), Ministry of Trade - National Bureau of standards (UNBS), Ministry of Education, testers, Academia, NDA, Private practitioners, Uganda Healthcare Federation, Uganda National Health Consumer Association (UNHCO) and PLHIV Networks. Members serving on this committee shall be assigned by the Director-General, Health Services (DGHS), MOH and will serve for a three-year term before new members are nominated. The recommending authority upon satisfactory performance may renew the three-year term for each member of the independent certification committee.

2.16.4 HIV Testing Certifying Body

The National HIV Reference Laboratory (NHRL)/UVRI shall have the mandate from MOH to conduct quality assurance for HIV rapid testing in Uganda. UVRI shall be the Certifying Body for HIV rapid testing sites and testers. It shall work closely with the MOH/ACP and the QAD of MOH in fulfilling its role.

2.16.5 Implementation of HIV Testing Certification

Implementation of the HIV Testing Certification shall include a process of assessments/audits of the testers and testing sites, certification, decertification, recertification, monitoring and evaluation.

Certification shall ensure maintenance of standards and reliability of results generated to support clinical and public health activities by the HIV testing point (site) and HIV rapid tester (HIVRT). Both HIVRT and site certification shall be valid for a period of not more than two years.

Refer to HTS Policy and Implementation Guidelines 2022 on details for HIV Rapid Testing Certification.

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

- Utilize a strategic mix of facility-based and community-based HIV testing models to increase access.
- Optimize HTS to appropriately and efficiently target undiagnosed people living with HIV- especially men, adolescents and children.
- High HIV burden and risk populations for HTS include priority populations (PPs), vulnerable populations (VPs), key populations (KPs).
- HTS Optimization strategies include: screening for HIV testing eligibility (risk-based testing), Index Client Testing [APN/ testing for biological children/Know Your Child's HIV Status (KYCS)], SNS and HIVST.
- Index Client Testing services shall be provided with adherence to minimum standards to meet expectations of the consumers and community. All health facilities offering Index Client Testing (and APN) will be assessed annually and accredited to ensure adherence to minimum index testing standards.
- HIV self-testing with oral-fluid and blood-based kits shall be offered as an additional approach to HIV testing services in Uganda. Persons aged 2 years and above shall be considered for HIVST depending on eligibility. HIV self-testing is a screening test and is not sufficient to make an HIV-positive diagnosis. Therefore, a reactive (positive) self-test result should be confirmed using the national testing algorithm.
- HIV rapid testing shall be conducted in accredited sites by certified testers. Sites and testers that do not meet the minimum standards for accreditation shall be supported to attain accreditation status before being permitted to provide HTS
- Amid public health emergencies such as the COVID-19 pandemic, HTS implementation shall follow national guidance on Infection, Prevention and Control measures and ensure continuity of services.
- All intra-facility linkages shall be on the same day and where not possible, should be within 7 days; inter-facility and community linkages should be completed within 14 days. Community and inter-/intra-facility networking and collaborations should be promoted for effective linkages of clients. All HTS points should have a regularly updated referral directory of community and institutional prevention, care and support services. HTS providers should refer HIV Negative persons to appropriate HIV prevention services. All referrals and linkages should be documented using appropriate national data collection tools (HIV Comprehensive Referral and Linkage Form, Linkage and pre-ART register).

- HTS being the entry point for all HIV & AIDS related support, care and prevention services, will contribute to the HIV&AIDS surveillance function for public health action. HTS will also contribute to: HIV Recency Infection Surveillance, HIV case-Based surveillance, ANC Sentinel surveillance and Periodic Surveys.
- All individuals diagnosed as HIV-positive in communities or facilities should be linked into care and treatment. Linkage is considered successful when an HIV positive individual is enrolled into care and treatment.

Guidance on specific policy changes:

- **Re-testing for verification:** All newly diagnosed individuals should be retested before ART initiation (with the exception of infants <18 months).
- All babies testing HIV-positive at DNA/PCR HIV testing should be re-tested, but ART should initiated immediately. A confirmatory sample DBS should be collected on the same day the child is initiated on ART.
- Perform risk screening, apply appropriate HTS screening tool to various age groups for clients seeking VMMC.
- Test all pregnant women at first ANC. Retest all pregnant women who are negative or unknown at third trimester. If a previous test is missed, test at labor and delivery.
- Social network testing (SNS) should be implemented as a form of index testing.
- Testing every 3 months for KPs & PPs should be based on risk. Assess for risk every 3 months and test for HIV if there is exposure risk in the last 3 months.

HIV Self Testing (HIVST):

- HIVST kits are available off the counter for the public in pharmacies countrywide.
- Testing for lactating mothers: Retest all HIV negative breastfeeding mothers every 3 months until cessation of breastfeeding (no risk screening). Align re-testing to immunization schedule where possible.
- Age for APN: All individuals ≥ 18 years are eligible for APN. Individuals <18 years should be considered for APN if sexually active.
- Risk-based HIVST will target HIV negative KPs, PPs, men, adolescents, and index clients through APN.

- HIVST in MCH should be non-discriminative: all mothers whose sexual partners are of unknown HIV status and have not come to the facility for testing should receive HIVST kits to deliver to their partners if they consent.
- Men in the general population should also be targeted for HIVST.
- Caregiver assisted oral screening for children aged 2-14 years and HIVST for adolescents aged 15-19 years shall be implemented upon guidance by MOH.
- HIV test kits made for professional use should only be sold on wholesale basis and not as single self-test devices. Selling these test kits to individuals for the purpose of self-testing is prohibited and should be discouraged. Only approved HIV self-testing kits should be sold over the counter to the public. Currently, Oraquick, Sure-check and INSTI have been evaluated and approved for use in Uganda.
- HIV syphilis DUO testing for key and priority populations, including pregnant and breastfeeding women, using the approved national algorithm shall be considered upon availability of HIV/syphilis DUO commodities.

3.0 HIV PREVENTION SERVICES

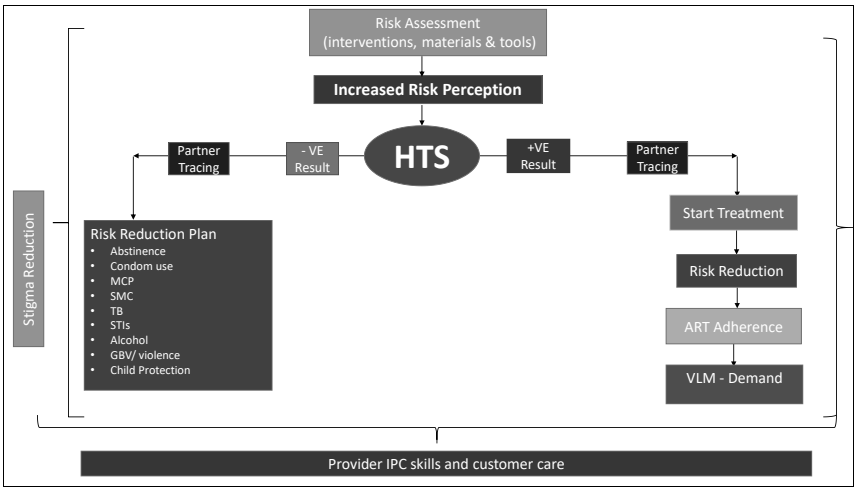
3.1 INTRODUCTION

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

3.2 BEHAVIORAL CHANGE AND RISK REDUCTION INTERVENTIONS

Behaviour change starts with a risk assessment.

Figure 22: Behavioral change risk assessment



3.2.1 Interventions

The priority of behavioral interventions is to delay sexual debut; reduce unsafe sex (including concurrent sexual partnerships), discourage cross-generational and transactional sex and promote consistent condom use. Table 9 below describes services for behavioral change and risk reduction.

Table 9: Services for Behavioral Change and Risk Reduction.

Area	Guidance
Service delivery	a. Each health facility/program should have a focal person for HIV prevention b. All staff offering HIV prevention services need to be trained, including training in Gender and Sexuality Diversity (GSD) c. Utilize peer-led models for priority key populations including young people d. Outreaches & Drop-in Centers for key and priority populations e. Job aides to support standardization for quality assurance f. Linkage and follow-up between facility and community is important g. Promote youth and key population friendly services
Risk assessment for client	a. Assess sexual behavior of the client (ask if condoms are used, frequency, the number of partners, transactional sex/sex work) and if the client is involved in transactional sex/sex work encourage correct and consistent condom use. b. Discuss knowledge of partner HIV status and sexual behavior. c. Assess for STIs and link to treatment. d. Asses for gender-based violence (GBV) e. Discuss sexual and reproductive health services and link to services as appropriate. f. Offer HTS to sexually active clients who have not tested in the last 12 months or have had unprotected sex in last three months. g. Conduct psychosocial assessment

Area	Guidance
Provide socio-behavioral change communication (SBCC) and link to services as appropriate	a. Build a lifestyle of prevention among young people b. Discuss delay of sexual debut in children and adolescents (abstinence) c. Discuss correct and consistent condom use and offer condoms as appropriate. d. Discourage multiple, concurrent sexual partnerships and promote faithfulness to a partner of known HIV status. e. Discourage cross-generational and transactional sex. f. Discourage risky cultural practices such as widow inheritance, wife replacement and child marriages. g. Identify, refer and link clients to other available services at facility and community level. h. Assess for violence, (physical, emotional, or sexual); if client discloses sexual violence, assess if the client was sexually assaulted and act immediately. i. (See Section 3.12 for GBV case management and Section 3.5 for PEP)
Condom promotion and provision	a. Discuss self risk assessment with the client b. Discuss correct and consistent condom use as an option for risk reduction c. Discuss the different types of condoms (rubber, nitrile, polyurethane, etc.) d. Discuss benefits of male and/or female condom use e. Clarify any questions and dispel myths around condoms f. Demonstrate how to use male and female condoms using appropriate tools (e.g. the O cube or cervical model for female condoms and the dildo for male condoms.) g. Demonstrate negotiation skills for safer sex h. Allow the client to role play negotiation skills for safer sex and how to introduce condoms in a relationship. i. Provide condoms to the client and information on where to access more

3.3 BIOMEDICAL PREVENTION INTERVENTIONS

The key biomedical interventions include STI screening and treatment, eMTCT, safe male circumcision (SMC), ART for prevention, PEP, PrEP, condom use and blood transfusion safety. Key and priority populations

in particular should receive STI screening and treatment. This section will discuss condom programming, SMC, PEP and PrEP, blood transfusion safety. Other biomedical interventions will be discussed in other chapters including: eMTCT (Chapter 4),ART (Chapter 8) and STI screening and treatment (Section6.14.1).

3.3.1 Comprehensive Condom Programming

Condom programming for HIV prevention is a means of ensuring that all sexually active persons at risk of HIV and/or unintended pregnancies are motivated to use condoms, have access to quality condoms, and can use them correctly and consistently. Condoms are the only prevention tools that offer triple protection from HIV, STIs and unintended pregnancies. The protection from condom use is over 85% when used correctly and consistently. The Ministry of Health has a condom program which addresses demand, supply, and support for male and female condom utilization, as a means of protection from STIs/HIV and unintended pregnancies.

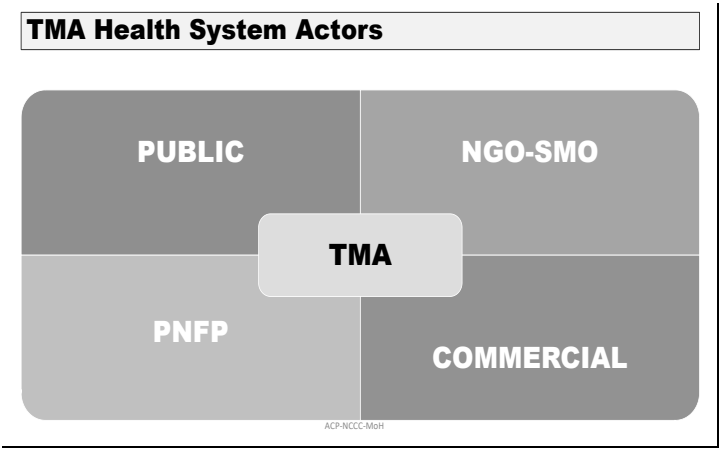
People Centered and Data Driven with active demand creation and sustenance interventions. More information can be accessed in the National Comprehensive Condom Programming Strategy and Implementation Plan (2020-2025).

3.3.2 Total Market Approach (TMA)

The Ministry of Health advocates for TMA to ensure availability of condoms to all sectors of the population. With the TMA, free condoms will target those who are unable to pay and disadvantaged/ vulnerable population segments, while the higher wealth quintile population segments of the community will either buy subsidized condoms from social marketing or high end Commercial Sector condoms.

The Total Market Approach seeks to maximize market Efficiency, Equity and Sustainability through the Coordination of the Public, Social Marketing, Private Cost Recovery and the Commercial Sectors. This Coordination is to be accompanied by Market Research and Segmentation, for equitable service delivery to the target populations.

Figure 23: Overview of TMA System

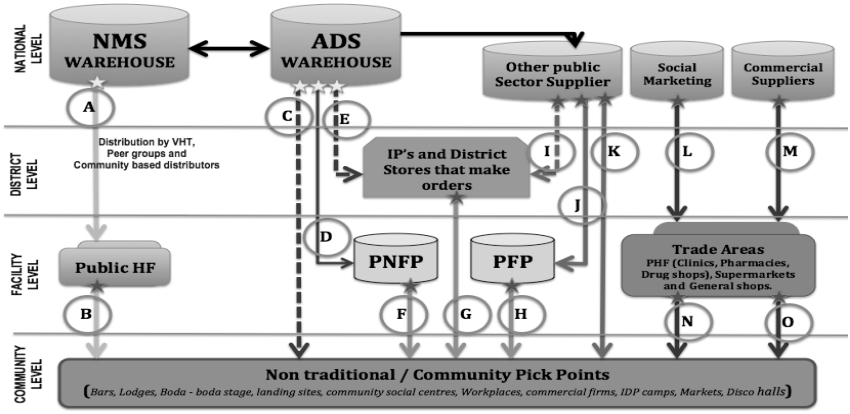


3.3.3 Condom Distribution Guidelines

The One Warehouse One Health facility (OWOH) policy for distribution of RH commodities including Condoms was introduced (2019) whereby National Medical Stores can only distribute commodities to public Health facilities and the Alternative Distribution System distributes to the PNFP Health Facilities. However Public Sector Condoms are to be made more available and accessible to the users through Health Facilities and geo-mapped Hot Spots and non-traditional pick points at Community level.

The guidelines specify the condom flow, reporting line as well as the roles of various stakeholders at National, District, Health facility and community level. The Guidelines also highlight the importance of forecasting, proper storage, records keeping, reporting and the use of effective distribution mechanisms. All data collection is to be reported through the MOH recommended system. More information can be accessed from the National Condom Distribution Guidelines – October 2021.

Figure 24: Condom distribution flow chart



3.3.4 Education, Promotion and Demand Creation

Government Policy states that Condom distribution should be accompanied with relevant information & education for the target populations.

Please take note of Table 6: on Condom Promotion and provision Services for Behavior Change and Risk Reduction for clients who opt to use Condoms.

In addition, Condom Programming requires vibrant Condom demand creation and sustenance interventions to improve uptake and use of Condoms, for triple protection.

3.3.5 Target Groups for condom use

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

1. Adults and youth engaged in multiple concurrent sexual partnerships.
2. Men and women who engage in transactional sex and their partners.
3. Adults working away from home such as transport and migrant workers, uniformed personnel, fisher folk, boda-boda riders.
4. People who inject drugs and men who have sex with men.
5. Adults and youth who access family planning/contraception clinics or service delivery points.
6. Discordant couples.
7. Individuals taking PEP or on PrEP, as well as women using the Dapivirine Ring

3.4 SAFE MALE CIRCUMCISION (SMC)

The Government of Uganda is promoting Safe Male Circumcision (SMC) as an important intervention for HIV prevention. Male circumcision is the surgical removal of the foreskin of the penis. SMC reduces the risk of HIV acquisition among circumcised men by approximately 60%. Table 10 describes the process involved in providing SMC.

Table 10: Process of providing safe male circumcision

Process	Description
Priority groups for SMC	• All healthy males including infants, although focus is on pivotal age of 15-45 years
Recommended methods for SMC	• Conventional surgery using the dorsal slit method and Shangring for adults; Mogen clamp for infants WHO pre-qualified devices

Eligibility Screening for SMC	• Screen for STIs: If STIs are present defer the circumcision and treat the STIs (See Section 9.1.1)
	• Tetanus immunization status:
	  • all clients adolescents and adults men seeking SMC servies should get one Tetanus dose before the procedure regurdless of the circumcision method
	  • Administer three dose TT vaccination schedule for both conventional and device methods: First TT shot on day 0, 2nd TT shot on day 28 and 3rd TT shot after 6 months.
	  • MoH recommends one TT dose for both conventional and device method but recommends the man to have the 2nd and 3rd dose for longer protection against tetanus infection
	• Penile abnormalities: If there are any penile abnormalities, refer for specialist care.
	• Bleeding disorders: If there is a history of bleeding disorders, defer SMC and refer for specialized care.
	• Existence of chronic disease conditions such as diabetes or hypertension: Defer SMC and refer to the nearest hospital.

Consent/assent	• All clients should receive information regarding SMC and understand the benefits and risks of SMC. • The client should provide consent/assent prior to SMC procedure.

HIV Testing	• All SMC clients should be offered HTS, though clients may opt out. • A positive HIV test is not a contraindication to circumcision. • Initiate ART in men and adolescents who test positive.
Follow up after SMC	• Following conventional surgery: at 48 hours, seven days, 14 days and at six weeks • Following device circumcision: follow the manufacturer guidance for device used

Refer to the SMC Guidelines for details

The following guidance has been added:

- **Age:** Ideally all males should be circumcised regardless of the age. SMC should be integrated in the main health services especially in health HCIVs and hospitals for sustainability.
- **Accreditation**: Unlike many other HIV prevention interventions that targets infected people, SMC targets health men. So the quality of the services should really be a priority. All sites that offer SMC should at least meet the minimum standards and this is ensured only when sites are accredited every 12 months.
- **Devices**: Over the years, a lot of innovations have been implemented to ensure scale-up of SMC services. Devices are on pf those innovations that have really helped in creating high demand among the laggards. Currently Shangring is highly acceptable among Ugandan males due to the fact that there is no injection, no sutures and the client returns once. On the other hand, the disposable kits have quality and waste disposal challenges and the re-usable kits main challenge is sterility.
- **Tetanus:** In the past tetanus infection caused fatal adverse events and this lead to a tetanus policy in the SMC program. MoH conducted a study about tetanus infection among circumcision clients and recommended one TT shot for every client before the procedure and there after recommended for all the clients to get 2nd and 3rd doses after 28 days and 6 months respectively.
- **Adverse Events:** MoH recommends for an adverse event rate to be less than 1% among circumcised men. All severe adverse events should be reported to MoH within 48 hours for audit but the notifiable should be immediately to the national SMC coordinator for proper management, audit and documentation.

3.5 POST-EXPOSURE PROPHYLAXIS FOR HIV

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

3.5.1 Types of HIV Exposure:

Occupational exposures occur in the health care settings and include SHARPS, e.g., needlestick injuries and splashes of body fluids to the skin and mucous membranes.

Non-occupational exposures include sexual assault (rape and defilement), road traffic accidents, unprotected sex with an HIV infected person, unprotected sex with a person of unknown HIV status.

3.5.2 Steps in Providing Post-Exposure Prophylaxis (PEP)

Health facilities providing PEP must have trained healthcare workers on infection prevention and control including management of PEP. The healthcare workers should use the steps in Table 11 to assess clients for PEP eligibility and provide PEP.

Table 11: Steps for Providing Post-Exposure Prophylaxis (PEP)

Step	Description
Step 1: Clinical Assessment and Providing First Aid	Conduct a rapid assessment of the client to assess exposure and risk and provide immediate care. a. Occupational exposure: b. After a needle stick or sharp injury c. Do not squeeze or rub the injury site d. Wash the site immediately with soap and water. e. Don't use strong, irritating antiseptics (like bleach or iodine) f. After a splash of blood or body fluids in contact with intact skin g. Wash the area immediately h. Don't use strong, irritating antiseptics (like bleach or iodine) For exposure-specific injuries, refer to the PEP Guidelines

Step	Description
Step 2: Eligibility assessment	Provide PEP when: a. Exposure occurred within the past 72 hours; and b. The exposed individual is not infected with HIV; and c. The 'source' is HIV-infected, has unknown HIV status or is high risk d. Do not provide PEP when: e. The exposed individual is already HIV-positive f. The source is established to be HIV-negative g. Individual was exposed to bodily fluids that do not pose a significant risk (e.g. tears, non-blood-stained saliva, urine, sweat) h. Exposed individual declines an HIV test
Step 3: Counseling and support	Counsel on: a. The risk of HIV from the exposure b. Risks and benefits of PEP c. Side effects of ARVs (see Table 60) d. Enhanced adherence if PEP is prescribed e. Importance of linkage for further support for sexual assault cases
Step 4: Prescription	a. PEP should be started as early as possible, ideally within first 2 hours but not beyond 72 hours after exposure b. Recommended regimens include: i) Adults and adolescents weighing>30Kg: ii) Preferred: TDF+3TC+DTG or TAF+FTC+DTG iii) First Alternative: TDF+3TC+ATV/r or TAF+FTC+ATV/r iv) Second Alternative: TDF+3TC+EFV or TAF+FTC+EFV v) Children weighing <30kg vi) Preferred: ABC+3TC+LPV/r Alternative: ABC+3TC+DTG b. A complete course of PEP should run for 28 days c. Do not delay the first doses because of lack of baseline HIV test or any reason d. Document the event and patient management in the PEP register (ensure confidentiality of patient data).

Step	Description
Step 5: Provide follow-up	Review client after one week for adherence support. Discontinue PEP after 28 days. Perform follow-up HIV testing at one month, three and 6 months after exposure. Counsel and link to HIV clinic for care and treatment if HIV-positive. Provide prevention education and risk reduction counseling if HIV-negative.

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

3.6 PRE-EXPOSURE PROPHYLAXIS (PrEP)

Definition: PrEP is the use of ARV drugs by HIV uninfected persons to prevent the acquisition of HIV before exposure to HIV. Table 12 describes processes involved in offering PrEP.

3.6.1 Oral PrEP

Table 12: The process of providing pre-exposure prophylaxis (PrEP)

Process	Description
Screening for risk of HIV	PrEP provides an effective additional biomedical prevention option for HIV-negative people at substantial risk of acquiring HIV infection. These include people who: • Live in discordant sexual relationships • Have had unprotected vaginal sexual intercourse with more than one partner of unknown HIV status in the past six months • Have had unprotected anal sexual intercourse in the past six months • Have had sex in exchange for money, goods or a service in the last six months • Use or abuse of drugs especially injectable drugs in the last six months • Have had more than one episode of a STI within the last twelve months • Are part of a discordant couple, especially if the HIV-positive partner is not on ART or has been on ART for less than six months or not virally suppressed. • Recurrent PEP users (PEP use >3 times a year). • Are members of key or priority populations who are unable or unwilling to achieve consistent use of condoms. NB: Eligibility is likely to be more prevalent in populations such as discordant couples, sex workers, fisher folk, long-distance truck drivers, men who have sex with men (MSM), uniformed forces, and adolescents and young women including pregnant and lactating AGYW.

Process	Description
Screening for PrEP eligibility	• After meeting the substantial risk for HIV criteria: • Confirm HIV-negative status using the national HTS algorithm • Rule out signs and symptoms of acute HIV infection • Assess for hepatitis B infection: if negative, patient is eligible for PrEP; if positive, refer patient for Hepatitis B management. • Note: HEP B positive test is not a contraindication for initiating PrEP, however, precaution needs to be taken when making a decision to stop PrEP to avoid HEP B viral load flare. • Creatinine test and creatinine clearance calculation using GFR formula is done. Do not offer PrEP if Creatinine clearance is less than 1.2mg/dl. • Note: Absence of this should not delay PrEP initiation in persons with no signs and symptoms of renal impairment. If available, creatinine test can be done at initiation and repeated every 6 months. • Assess for contraindications to TDF/FTC or TDF/3TC.
Steps to initiation of PrEP	• Provide risk-reduction and PrEP medication adherence counseling: • Provide condoms and education on their use • Initiate a medication adherence plan • Prescribe a once-daily pill of TDF (300mg) and FTC (200mg) or TDF (300mg)/ 3TC (300mg) • Initially, provide a 1-month TDF/FTC or TDF/3TC prescription (1 tablet orally, daily) together with a 1-month follow-up date • Counsel client on side effects of TDF/FTC or TDF/3TC

Process	Description
Follow-up/ monitoring clients on PrEP	• After the initial visit, the patient should be given a two-month follow-up appointment and thereafter quarterly appointments • Perform an HIV antibody test using the national HTS algorithm and every three months. • Note: Blood based HIVST is an alternative for PrEP refill in case of absence of the national HTS standard recommended in patients on PrEP. • For women, perform a pregnancy test if there is history of amenorrhea. • Review the patient's understanding of PrEP, any barriers to adherence, tolerance to the medication as well as any side effects. • Review the patient's risk exposure profile and perform risk-reduction counseling. Evaluate and support PrEP adherence at each clinic visit. Evaluate the patient for any symptoms of STIs at every visit and treat according to current STI treatment Guidelines.
Guidance on discontinuing PrEP	• Acquisition of HIV infection • Suspected signs and symptoms of acute HIV infection following a recent exposure within 4 weeks • Changed life situations resulting in no longer being at substantial risk of HIV acquisitio • Intolerable toxicities and side effects of ARVs • Chronic non-adherence to the prescribed regimen despite efforts to improve daily pill-taking. • Personal choice • HIV-negative in a sero-discordant relationship when the positive partner on ART for >6 months and has achieved sustained viral load suppression (condoms should still be used consistently). The HIV negative partner can be allowed to continue PrEP even if the positive partner is virally suppressed if they choose to.
For detailed guidance on the provision of PrEP, please refer to the Technical Guidance on Pre-Exposure Prophylaxis for Persons at High Risk of HIV in Uganda, 2022.	

3.6.2 Dapivirine Vaginal Ring (PrEP RING)

New Recommendation 2021: PrEP using the dapivirine vaginal ring

The dapivirine vaginal ring may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches.

Overview of the PrEP Ring

The PrEP ring is a long-acting HIV prevention method developed specifically for clients who are unable or do not want to take oral PrEP or when oral PrEP is not available. The ring has been studied for prevention of HIV only among women during receptive vaginal sex and does not prevent HIV acquisition through any other mode of transmission. The ring is made of a flexible silicone material containing 25 mg of an ARV drug called Dapivirine. It is inserted into the vagina and should remain in place for one month. Dapivirine belongs to a class of ARVs called non-nucleoside reverse transcriptase inhibitors (NNRTI) that reduce the ability of HIV to replicate itself inside a healthy cell. The ring delivers the drug directly to the site of potential infection over the course of one month, with low absorption elsewhere in the body, lowering the likelihood of systemic side effects. Clients can insert, remove, and replace the ring themselves each month, or with the assistance of a health care provider if desired. The PrEP ring does not prevent pregnancies. The number of pregnancies among active ring users during the clinical trials was small; studies are ongoing to further assess safety during pregnancy. An observational study suggests that small amounts of Dapivirine are present in breastmilk for those who use the ring while lactating. Results from a clinical trial of ring use while breastfeeding are pending. For more information on ring use during pregnancy and breastfeeding, see Management of Clients in Specific Situations below.

3.6.3 Formulation of the PrEP Ring

The PrEP ring is a flexible white silicone ring for vaginal insertion. The ring, which is available in only one size, contains approximately 25 mg of the NNRTI dapivirine.

3.6.4 PrEP Ring Effectiveness

The ring was clinically shown to reduce the likelihood of HIV-1 acquisition through vaginal sex in two randomized controlled trials: by 35% in IPM-027/The Ring Study and 27% in MTN-020/ASPIRE. The subgroup analysis by age of The Ring Study and ASPIRE data did not show efficacy among women 18–21 years old, who were also shown to have low adherence to the ring during the trials. These trials reported no notable differences in reproductive health outcomes, including STIs and adverse events related to pregnancy, fetal outcomes and/or infant outcomes, between the treatment and placebo arms. Results from two subsequent open-label extension studies — DREAM and HOPE — found increases in ring adherence and similar safety profiles; modeling data suggest even greater risk reduction across both studies. Results from one open-label extension study indicated a 62% reduction in HIV transmission, comparing study results to a simulated control. Further studies exploring the safety and acceptability of the ring among adolescents and young people AFAB ages 15–21 have demonstrated that the ring is acceptable to younger users, has a similar favorable safety profile among younger and older users, and can be used effectively by younger users with proper adherence support.

Possible Side Effects of the PrEP Ring

Possible side effects of the ring are typically mild and include urinary tract infections (UTIs – experienced by about 15% of users), vaginal discharge (experienced by about 7% of users), vulvar itching (experienced by about 6% of users), and pelvic and lower abdominal pain (experienced by about 6% of users). These side effects usually occur during the first month of use and resolve without the need to remove the ring. Ring users should be counseled on possible side effects and to contact their health care provider if they experience any urinary or reproductive tract changes, because these could be a sign of an STI or UTI needing treatment.

PrEP Ring and Other Drug Interactions

There are no known interactions between dapivirine and contraceptive hormones, hormones used for gender-affirming hormone therapy, alcohol, or recreational drugs. However, if a client or potential client thinks that their use of alcohol or other substances is interfering or may interfere with effective use of the ring, the provider should discuss and support behavior change and offer additional prevention options, including use of condoms and condom-compatible lubricant.

Contraindications for PrEP Ring Use

The ring should not be provided to people with:

An HIV-positive test result according to the national HIV testing algorithm

Known exposure to HIV in the past 72 hours (because such clients may derive more benefit from post-exposure prophylaxis (PEP) if the potential for HIV exposure was high)

Signs of AHI (Box 3) AND potential exposure within the past 14 days

Inability to commit to effectively using the ring and attend scheduled follow-up visits

Allergy or hypersensitivity to active substance or other substances listed in the product information sheet

3.6.5 PrEP Ring Use

The ring may be offered as an option for people AFAB who wish to prevent HIV acquisition through receptive vaginal sex and are unable or do not want to take oral PrEP, or when oral PrEP is not available. The ring must be inserted correctly into the vagina and worn for one month without removal. The ring must be in place for at least 24 hours before it is maximally effective. If a client wishes to discontinue use of the ring, they can remove it. It is not known how long the ring must remain in place after a potential exposure to be maximally effective. Ideally, clients who are discontinuing PrEP use will alert their providers and receive support to use other HIV prevention practices if they are still needed.

Inserting the PrEP Ring

Clients may need initial guidance and support to learn how to use the ring and, once confident, can continue to use the ring on their own. Some clients are comfortable using the ring on their own with minimal support from their first use. However, for clients who prefer support, a health care provider can help insert the ring or confirm placement. The ring is inserted by hand; there is no need to use a speculum or other tools to insert the ring. Clear visual instructions should be offered with the ring. Ring insertion steps for clients are listed in Box 3.

Box 3: Ring insertion steps for clients

1. Get into a position that is comfortable for inserting the ring, such as squatting, one leg lifted, or lying down. If a health care provider is assisting you, you should be in a reclining position.
2. With clean hands, squeeze the ring between the thumb and forefinger, pressing both sides of the ring together so that the ring forms a "figure 8" shape.
3. Use the other hand to open the folds of skin around the vagina.
4. Place the tip of the ring into the vaginal opening and use your fingers to push the folded ring gently up into the vagina.
5. Push the ring as far toward the lower back as possible. If the ring feels uncomfortable, it is probably not inserted far enough into the vagina. Use a finger to push it as far up into the vagina as is comfortable.

*Ring insertion should be painless. If you have any bleeding or discomfort upon insertion, contact your health care provider.

3.6.6 Removing the PrEP Ring

Clients can remove the ring without the help of a health care provider. However, for clients who prefer support, a health care provider can help remove the ring. The ring is removed by hand; there is no need to use a speculum or other tools to remove the ring. If a client is being assisted by a health care provider, they should be in a reclining position during removal. Ring removal steps for clients are listed in Box 4.

Box 4: Ring removal steps for clients

1. Get into a position that is comfortable for removing the ring, such as squatting, one leg lifted, or lying down.
2. With clean hands, insert one finger into the vagina and hook it around the edge of the ring.
3. Gently pull the ring out of the vagina.

*Ring removal should be painless. If you have any bleeding or discomfort upon removal, contact your health care provider.

3.7 SWITCHING BETWEEN PREP METHODS

Clients may switch between the ring and oral PrEP. Possible patterns of using different ARV-based prevention methods are many, and ideal use during a transition between methods is not currently known or understood and will require careful support and assessment.

Safety data on simultaneous use of oral PrEP and the ring are limited. Although use of both methods is not likely to be less well-tolerated than use of each individually, more data are needed to confirm the safety and efficacy of simultaneous use of oral PrEP and the ring.

Some clients may decide to use both the ring and oral daily PrEP at the same time. However, no evidence indicates that using them together will result in any advantage. Whatever the choice, using ring or oral PrEP in a way that is effectively prophylactic (as frequently as directed and for as long as is needed to cover periods of potential exposure) is important to optimize effectiveness of either method. Using either or both less frequently than directed or for a duration that is not long enough to cover periods of potential exposure would be ineffective for HIV prevention.

3.8 LONG-ACTING INJECTABLE CABOTEGRAVIR (CAB-LA)

3.8.1 New Recommendation 2021: Offering long acting injectable cabotegravir for HIV prevention

Cabotegravir extended-release suspension is a long-acting integrase inhibitor and is effective in preventing HIV. It is administered through an intramuscular injection (in the buttocks) by a health care worker once every 4 weeks for 2 months, pand then once every 2 months. It can be offered to adults and adolescents weighing at least 35 kilograms to reduce the risk of sexually acquired HIV. It is indicated for all HIV negative persons at high risk of HIV; however, it is contraindicated in people who are hypersensitive to any active substances in CAB-LA. t

3.8.2 Long acting injectable cabotegravir (CAB-LA) Initiation

Before initiation, individuals must be screened for HIV using the national HTS algorithm and rule out signs of Acute HIV infection as for oral PrEP.

- **Administration**: It's administrated in the buttock once every 8 weeks
- **Side effects:** The injectable cabotegravir is safe and well-tolerated.
- **Efficacy/Effectiveness:** The injectable cabotegravir was found to be over 95% effective
- **Safety:** No safety concerns have been associated

- **Acceptability and barriers:** In a study setting it was highly acceptable
- **Contraindications:** Hypersensitivity to active substance

3.8.3 Stopping CAB-LA

Assess reasons why the client is stopping CAB-LA and the HIV risk profile. If the client is no longer at risk of HIV, there is no need to tail off with oral PrEP. Patient should be counseled on HIV risk reduction. If the client is at risk of HIV, the patient should continue with oral PrEP as long as HIV risk exists.

3.8.4 Service Delivery for CAB-LA

CAB-LA will be rolled out in a phased manner starting with high volume PrEP implementing facilities with high catchment populations having high HIV prevalence and incidence.

Both the facility and community-based models will be used to roll out CAB-LA.

Note: For detailed guidance on the provision of CAB-LA, please refer to the Technical Guidance on Pre-Exposure Prophylaxis for Persons at High Risk of HIV in Uganda, 2022.

3.9 TRANSFUSION OF SAFE BLOOD

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

1. Donor selection: Blood should only be accepted from voluntary, non-remunerated, low risk, safe and healthy donors aged between 17 and 65 years. Efforts are directed towards maintaining adequate numbers of repeat donors.
2. *Pre-donation* counselling should be given to provide accurate information including modes of transmission of disease (HIV, Hepatitis B and C, Syphilis), risk behavior, prevention interventions and to allow for self-exclusion for patient safety.
3. *Clinical assessment* should be carried out to further screen for risk and determine overall health status and suitability of the donor.
4. Blood testing: All donated blood should be routinely screened for transfusion transmissible infections including HIV, Syphilis, Hepatitis B and Hepatitis C.
5. Post-donation counselling should be provided to donors whose test results are positive for HIV, Syphilis, Hepatitis B or C. Donors with positive results should be referred for care and treatment services.

6. *Safe and appropriate use of blood and blood products:* Hospitals should have the capacity to carry out assessments and tests to ensure that those in most need of a blood transfusion are identified and prioritized. They should have the capacity to carry out blood group and compatibility tests on recipients to ensure that donor and recipient blood are matched and that a safe transfusion can be executed. Hospitals should also have the capacity and SOPs in place to manage complications arising from a blood transfusion.

3.10 KEY AND PRIORITY POPULATION PROGRAMMING

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

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

3.11 STRUCTURAL INTERVENTIONS

Structural interventions are approaches that reduce HIV risk at the individual or group level. These are elements outside individual knowledge or awareness that have the potential to influence peoples' vulnerability to HIV infection.

The intervention focusses on addressing social (stigma, gender inequality), cultural (religious beliefs), economic (lack of livelihood opportunities) and legal- political (laws and regulation) factors. Structural interventions call for a multi-sectoral approach. The health sector will focus on interventions to address gender-based violence within health care settings.

3.12 PREVENTION AND MANAGEMENT OF GENDER-BASED VIOLENCE

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

- A written algorithm with steps for active case identification and follow-up
- At least one staff member trained to provide post-violence care
- A focal point for GBV services at each facility
- Provision of PEP
- Referral pathway available at each facility

Screening for GBV

All PLHIV should be routinely screened for GBV. Clients should therefore be assessed for GBV at least once every six months as part of the HIV program. For individuals outside HIV care settings, GBV screening should be provided at contact with the health care system. All individuals identified with signs of GBV should be linked to the GBV focal person at the facility for further assessment and help. **However, health care workers should screen clients with medical diagnosis suspected to be screened for GBV**:

- Injuries,
- Sexual Assault,
- UTIs,
- Recurrent STIs,
- Experiencing trauma,
- Children with malnutrition,
- Re-attendances with no clear diagnosis,
- Abortion,
- Unintended /teenage pregnancies,

Within the ART department:

- Adherence challenges,
- Disclosure challenges,
- Missed appointment for ART refills,
- Non-suppressed viral load
- HIVST and APN.

A simplified screening tool adapted from the GBV assessment tool should be used to screen for GBV as shown in Table 13.

Table 13: Gender-based violence (GBV) screening tool

Use this tool to identify GBV survivors for management and referrals

Names/ Initials		**Date …/.../…**	**Telephone No. ……**		
OPD /ART no.		**Village**			
Sex		**Subcounty**			
Age		**Highest Level of Education**			
Marital Status		**Screening point at Facility**	**Entry Points: ……**	**Community**	
Psychological /emotional Violence	Are you currently in a situation where someone threatens, frightens or insults you?			Yes	No
	Are you currently in a situation where you are subjected to practices that may result into trauma, anxiety, stress or shame?			Yes	No
	Are you currently in a situation where you are denied access to your children? Write N/A (not applicable, if person does not have children)			Yes	No
Physical Violence Code No; 100 Injuries due to GBV	Are you currently in a situation where someone physically hurts you? (Slapping, hitting, kicking, choking, hurting you with a weapon)			Yes	No

Sexual Violence	Do you have a sexually transmitted infection that you consider due to sexual violence? Code No STI due to GBV	Yes	No
	Have you ever experienced an abortion due to physical, psychological and/or sexual violence? Code No 113 Abortion due to GBV	Yes	No
	Are you currently in a situation where someone forces you into sex without your will or forces you to participate in sexual activities that make you feel uncomfortable?	Yes	No
	Are you currently in an intimate relationship in which you feel you were made to become pregnant against your will?	Yes	No
	Have you currently in an intimate relationship in which you feel you are denied of your sexual rights?	Yes	No
	Are you below 18 years and married/ cohabiting experiencing physical, psychological, economic and/or sexual violence in a relationship?	Yes	No

If yes to any of the above qns;

State the Potential risk to the client e.g pregnancy, death ……

Help given……

Referred (where) ……

Name of the provider …….. Cadre ……

Services to provide: Medical examinations and treatment, counseling support, STI/UTI screening for exposed clients, emergency contraception where legal and appropriate, referrals for legal support, Shelter, Child Protection Services, economic Empowerment

For sexual violence only: Rapid HIV testing and provision of PEP for eligible clients

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

All individuals identified with signs of GBV should be linked to the GBV focal person at the facility. The GBV focal person should provide first line support using LIVES approach. LIVES job aide below

Figure 26: Four-question Screening Tool for GBV

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

When managing rape victims, the minimum package of services is indicated in Table 14 below.

Table 14 : 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 a. Rapid HIV testing and referral to care and treatment if HIV-positive b. Post-exposure prophylaxis (PEP) for HIV if tested negative (see Section 3.3.3) c. STI screening/testing and treatment (see Section 6.14.1.2) d. Forensic interviews and examinations e. Emergency contraception, where legal and according to national guidelines, if person reached within the first 72 hours f. Counseling
The health facility should also identify, refer and link clients to non-clinical services:

Some of the services include the following: 1. Long-term psychosocial support 2. Legal counseling 3. Police (investigations, restraining orders) 4. Child protection services (e.g. emergency out-of-family care, reintegration into family care when possible, permanent options when reintegration into family impossible) 5. Economic empowerment 6. Emergency shelters 7. Long-term case management
Reporting:
Health facilities should use HMIS 105 to report GBV

Box 5: Key Highlights in HIV Prevention Services

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

4.0 ELIMINATION OF VERTICAL TRANSMISSION OF HIV AND IMPROVING MATERNAL, NEWBORN, CHILD AND ADOLESCENT HEALTH (MNCAH)

4.1 INTRODUCTION

Vertical transmission of HIV accounts for up to 18% of all new infections in Uganda and for up to 90% of infections among children. Current evidence shows that with effective interventions, including use of antiretroviral therapy, the rate of transmission could be reduced to less than 5% in a breastfeeding setting like in Uganda. Over the past decade, tremendous gains have been made in the prevention of mother-to-child transmission of HIV, primarily as a result of bold policies, including universal antiretroviral therapy (Option B+) for pregnant and breastfeeding women, which catalyzed important programmatic leaps. In 2021 estimates indicate high rates of infection in children, with over 5,955 children infected through vertical transmission. Major sources of infections are mothers who drop off ART either during pregnancy or breastfeeding and mothers who seroconvert during breastfeeding. The transmission rate is 7% at the end of breastfeeding, which implies that although the country is progressing towards elimination of mother-to-child transmission of HIV, virtual elimination has not yet been attained.

The World Health Assembly in 2016 endorsed three inter-linked global health sector strategies on HIV, viral hepatitis and sexually transmitted infections for the 2016 – 2021 period, which set ambitious targets for elimination of mother-to-child transmission (EMTCT) of HIV, hepatitis B and syphilis. This was based upon the pretext that mother-to-child transmission of the three infections can be effectively prevented by simple interventions including antenatal screening and treatment for women and their partners, and vaccination for infants within the reproductive, maternal, newborn and child health platform. The similarity in interventions to prevent

mother-to-child transmission of HIV, syphilis and hepatitis B, means that an integrated approach to triple elimination is highly feasible. The move towards triple elimination shall result in greater collaboration between the related programmes and thus improve accessibility, effectiveness, efficiency and sustainability of maternal, newborn and child health services to the individual family and community at large.

4.1.1 Pregnant and breastfeeding adolescent girls and young women

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

4.1.2 eMTCT Strategy

The eMTCT strategy comprises a package of interventions summarized in four approaches (see Table 15). These interventions must be offered simultaneously within the platform of MNCAH services throughout the continuum of eMTCT services as will be described in Figure 27.

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

eMTCT interventions should be integrated into the MNCAH services which include but not limited to the ANC, labour and delivery, postnatal care, adolescent clinics, sick child clinic and YCC at health facilities and community sites. The section defines which services in each eMTCT prong are offered in each of the parts of the MNCAH services continuum: before pregnancy, antenatal, labour and delivery, postnatal and community (see Figure 27).

Figure 27: The eMTCT continuum of services

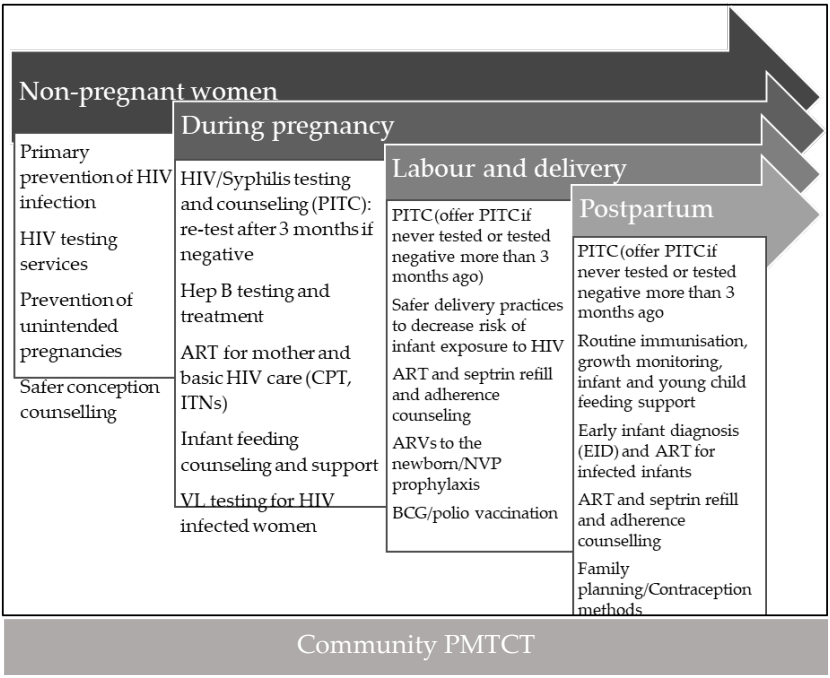


Table 15: The PMTCT Strategy

Intervention area	Target group	Additional information
Intervention area 1: Primary prevention of HIV infection	Adolescents, women, and men of reproductive age	• This prong aims to prevent HIV in women and girls of reproductive age, and male partners. Interventions include: • HIV testing services for pregnant and non-pregnant women of reproductive age • Couples counseling and partner testing and retesting for the HIV-negative individuals • Routine HIV testing services for pregnant and non-pregnant adolescents • Behavioral change communications and risk-reduction counseling to avoid high-risk sexual behavior including: • Safer sex practices, including dual protection (condom promotion) and delay of onset of sexual activity • Health information and education about risky behavior, life skills and benefits of HTS • SMC; PrEP for discordant couples, pregnant and lactating mothers and adolescent girls at substantial risk of HIV acquisition; and GBV screening and management • STI including syphilis and HBV screening and management • Regular discussion of childbearing needs (current and future) and safer conception methods (e.g., PrEP, timed unprotected intercourse) to reduce stigma and encourage testing, engagement in care and PrEP uptake.
Intervention area 2: Prevention of unintended pregnancies among women living with HIV	Adolescent girls and women living with HIV and their partners	• HIV testing and counseling in sexual and reproductive health (SRH) and FP settings • Regular discussions about childbearing needs (current and future) to reduce stigma and encourage engagement in care, partner testing and PrEP uptake by sero-discordant partner(s). • Education and provision of family planning (FP)/contraception counseling and/or safer conception counseling (SCC) consistent with PLHIV's childbearing desires: • FP: Safer sex practices, including dual protection (condom use promotion) • SCC: Pre-conception counseling (whenever possible with both partners), safer conception methods (e.g., PrEP, timed unprotected intercourse), and referral for infertility investigation and treatment

Intervention area	Target group	Additional information
Intervention area 3: Prevention of HIV transmission from women living with HIV to their infants	Pregnant and breastfeeding women living with HIV	• This prong focuses on: • Quality antenatal, labour and delivery, and postnatal care • Access to HTS during ANC, labour and delivery, and postpartum period • Initiation of ARVs for prevention of HIV transmission and mother's health • Adherence counseling and support • Retention monitoring • Viral load testing and monitoring • ARV prophylaxis for HIV-exposed infants • Safe delivery practices to decrease risk of infant exposure to HIV • Infant and young child feeding counseling • Community outreach and efforts to support partner involvement and testing • TB screening, diagnosis and treatment • INH prophylaxis • STI and HBV screening and treatment

Intervention area	Target group	Additional information		
Intervention area 4: Provision of treatment, care, and support to women infected with HIV, their children and their families	Women living with HIV and their families	This prong addresses the treatment, care and support needs of HIV-infected women, their children and families (family-centered approach):		
		• Package of services for mothers includes: • Lifelong ART • Cotrimoxazole prophylaxis • TB screening, diagnosis, and treatment • INH prophylaxis • Prevention, diagnosis and treatment of malaria • Continued infant feeding, assessment, counseling and support • Nutrition assessment, counseling, and support • Sexual and reproductive health services including FP and condom provision • STI and HBV screening and treatment • Breast and cervical cancer screening and referral • Adherence, disclosure and psychosocial support • Risk-reduction counseling • Routine laboratory monitoring (CD4 and viral load) • Routine follow-up, ARV refills and other routine MCH supplements and drugs (Fe/Folic, Mebendazole) • Effective referrals and linkages to other services (community and facility) • Symptom management and palliative care	• Package of services for HIV-exposed and infected children: • ARV prophylaxis for HEI • ART for HIV-infected children • OI prophylaxis and treatment (e.g., CTX) • INH prophylaxis for TB exposed • Routine immunization and growth monitoring • HIV testing • Infant and young child feeding (IYCF) assessment, counseling and support • Nutrition assessment, counseling and support • Prevention, screening and management of infections • Psychosocial care and support • Routine follow up and refills and provision of age-appropriate supplements • Effective referrals and linkages to other services (community and facility)	• Package of services for partner and the family: • HIV testing of partners, children and other family members and linkage to prevention and care services • ART for HIV-infected family members • Cotrimoxazole prophylaxis for HIV-positive family members • TB screening, diagnosis, and treatment and advice on TB infection control in the family • INH prophylaxis • Prevention, diagnosis, and treatment of malaria • Nutrition assessment counseling and support • Sexual and reproductive health services including FP and condom provision • STIand HBV screening and treatment • Adherence, disclosure and psychosocial support • Risk reduction counseling • Routine laboratory monitoring (CD4 and viral load) for the HIV-positive • Routine follow-up, ARV refills and other routine supplements and drugs (Mebendazole) • Effective referrals and linkages to other services (community and facility) • Symptom management and palliative care

4.3 SERVICES FOR NON-PREGNANT WOMEN

4.3.1 Primary Prevention of HIV Infection

Preventing HIV in women and girls of reproductive age reduces the risk of HIV infection to infants. Some of the services to prevent HIV infection in women and girls of reproductive age are presented in Table 16.

Table 16: Services for preventing HIV infection in women and girls of reproductive age

Service	Description
Routine HTS and syphilis testing in the MNCAH setting	• Provide HTS to all women and girls of reproductive age and their partners. Also test for syphilis and link to care as necessary. • Link all who test positive to HIV care and treatment services and offer risk reduction counseling to all who test HIV negative.
BCC	• Safer sex practices, including dual protection (condom promotion) and delay of onset of sexual activity • Discuss childbearing needs (current and future) to reduce stigma and encourage engagement in testing, future care and PrEP uptake. • Educate and provide FP/ contraception counseling and/or safer conception options (e.g., PrEP, timed unprotected intercourse) consistent with PLHIV's childbearing desires (current and future).
Other prevention services	• Offer and refer SMC services to male partners of girls and women • Screen all adolescent girls and women of reproductive age, for GBV and offer services within MCH including PEP • Offer PrEP to eligible adolescent girls and women of reproductive age in line with the guidelines for PrEP (see PrEP section); special consideration should be given to women and adolescents in discordant relations who desire to get pregnant (see Table 9 and Table 14).
STI and HBV screening and treatment	• Counsel and screen adolescent girls and women for STIs including syphilis and HBV and manage the STIs

4.4 PREVENTION OF UNINTENDED PREGNANCIES, CHILDBEARING NEEDS, AND SAFER CONCEPTION

Routine discussions with adolescent girls and women about their childbearing needs (current and future) can reduce stigma and encourage engagement in testing, care and PrEP uptake among sero-discordant partners. Non-judgmental education and provision of family planning (FP)/contraception counseling and/or safer conception options (e.g., PrEP, timed unprotected intercourse) consistent with PLHIV's childbearing desires (current and future) can reduce the number of unintended pregnancies, thereby reducing the number of infants exposed to HIV and the overall risk of MTCT. FP/contraception and safer conception methods also provides intrinsic benefits by saving lives and enhancing the health status of women and their families. However, FP and safer conception services should be provided based on respect and fulfillment of PLHIV's reproductive rights and choices as well as informed consent. Women and girls should not be coerced into contraception or childbearing; their sexual and reproductive choices should be respected and safeguarded. Table 17 describes the process of offering FP/contraception and safer conception counselling.

Table 17: Childbearing, family planning/contraception, and safer conception services for HIV-infected women of reproductive age.

Service	Explanation
Routinely discuss childbearing needs	• Encourage women and adolescent girls attending ANC, PNC, YCC and ART services to discuss their reproductive choices and support them as appropriate. • Facilitate routine discussions of childbearing needs (current and future) to reduce stigma and encourage engagement in care and PrEP uptake among sero-discordant partner(s). • Educate and provide FP/contraception counseling and/or safer conception options (e.g., PrEP, timed unprotected intercourse) consistent with patient's childbearing desires (current and future).

Service	Explanation

FP/contraception counseling	For HIV-positive women/couples who desire to NOT become pregnant.
	• Provide routine FP/contraception information and counseling to women and adolescent girls attending ANC, PNC, YCC and ART services. Family planning services can be included as part of DSD service delivery for all DSD models including community DSD models. Providers should ensure that schedules for ART refills and aligned with FP provision.
	• Information provided during counseling should cover:
	  • Family planning/contraceptive methods, advantages and side effects
	  • Common misconceptions about family planning/contraception
	• Advantages of dual protection and also how to negotiate condom use
	• What to do when pregnancy occurs:
	• Address misconceptions. Some are below:
	• "Using hormonal contraception increases the risk of HIV acquisition"
	  • Correct response: There is no increased risk of HIV acquisition in women using oral hormonal contraception. Since oral contraceptives are not a mode of barrier protection it is still important to use condoms to prevent all STIs including HIV.
	  • "Hormonal contraception causes a decrease in CD4 count, increased viral load and progression to AIDS event or death."
	  • Correct response: There is no evidence that hormonal contraception causes a decrease in CD4 count, an increase in viral load, or progression to AIDS event or death.

Service	Explanation
Safer conception counseling	• For HIV-positive women/couples who desire TO become pregnant. • Provide routine safer conception information and counseling to women and adolescent girls attending ANC, PNC, YCC and ART services. Whenever possible, facilitate a visit with both partners to discuss childbearing readiness, safer conception methods, fertility tracking and linkages to PMTCT. Childbearing readiness: • Determine couple's disclosure status (offer APN as needed), each partner's health status, each partner's childbearing desire, number and health status of current children, and strength of relationship to support childbearing and raising child (see Figure 10 APN flow Chart). • Safer conception methods (see Table 18): Serodiscordant couples: • Ensure HIV-positive partner is adherent to ARV and viral load is suppressed. Recommend delay in conception attempts until viral load suppression is obtained. Offer PrEP to the HIV-negative partner (See Table 10). Educate on Timed Unprotected Intercourse to enhance chances of conception and for couples who refuse PrEP (see Table 18). Seroconcordant couples: • Ensure partners are adherent to ARV and viral loads are suppressed. Educate on Timed Unprotected Intercourse to enhance chances of conception and for couples with ARV non-adherence, unsuppressed viral load, and/or recent STI history (see Table 18). • Ensure linkage to PMTCT and Early Infant Diagnosis for couples who are successful in conceiving.

Service	Explanation
After counseling, offer FP on a one-on-one basis	For HIV-positive women/couples who do not desire to become pregnant: • Offer effective contraception • Encourage dual contraception (use of both hormonal contraception and condoms) to prevent pregnancy, STIs, HIV transmission, and re-infection • The choice of contraceptive methods in HIV-infected women is much the same as in HIV-negative women • Consider some drug interactions between HIV medicines and contraceptives when offering FP methods to women and adoelscent girls on ART (see Table 18).
Ongoing support for adolescent girls and women when using FP	Counselling and adherence support for the chosen method: • Assess for possible side effects and manage accordingly • Clients on injectable FP (Depo-Provera) and ART should be counseled to return for injection on appointment date or before if they cannot make it on scheduled appointment date

Table 18: Safer Conception

HIV status of couple	Things to consider	Clinical Evaluation	Safer conception Methods	Pros	Cons
Sero-discordant	Disclosure Couples' communication Risk of HIV/STI transmission to partner and infant ART eligible partner(s) stabilized on optimal therapy before conception attempts, has undetectable VL (when testing is available) Identification and management of co-morbidities PrEP for HIV-negative partner Baseline fertility assessment	HIV status, CD4 count, VL STI screening and treatment (males) Fertility history, semen analysis, genital exam (females) Fertility history including miscarriages, ectopic pregnancies, age, pelvic exam, menstrual cycle / ovulation, hemoglobin measurement and viral load if HIV+	PrEP for HIV negative partner	Risk of HIV transmission is greatly decreased	Access to PrEP, PrEP side effects
			Timed Unprotected Intercourse (when HIV negative refuses PrEP)	Private, inexpensive, enhanced likelihood of successful conception	Risk of HIV/STI transmission reduced but still present; requires accurate timing of ovulation
Sero-concordant			Timed Unprotected Intercourse	Private, inexpensive, enhanced likelihood of successful conception	Some risk of STI transmission

4.4.1 Recommendations for hormonal contraceptive use among women at high risk of HIV infection- Medical Eligibility Criteria (MEC) for FP/contraceptive methods

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

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

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

4.4.2 Interactions between ART and Contraceptives

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

Table 19: Interactions between ART and Contraceptives

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

4.5 DURING PREGNANCY

This section outlines ANC services for all pregnant women including those who are HIV-negative, with specific services for women living with HIV. Table 20 describes services offered during pregnancy.

Table 20: ANC and PMTCT Services for Pregnant Women

Service	Description

Provide HTS, syphilis testing, and Hepatitis B testing in ANC	• Offer routine testing for HIV and syphilis at first ANC visit to all pregnant women and their partner(s), using a rights-based approach, with same-day results using the SD-Bioline duo HIV/syphilis test according to algorithm in Figure 14 (in chapter 2).
	• If found positive for syphilis, rapidly treat to reduce syphilis (and HIV, if positive for HIV) transmission from mother to child using the following:
	  • Pregnant women/girls with early syphilis (primary, secondary and early latent syphilis of not more than two years' duration): give Benzathine Penicillin G 2.4 million units intramuscularly once.
	  • In late syphilis or unknown stage of syphilis (infection of more than two years' duration without evidence of treponemal infection): give Benzathine Penicillin G 2.4 million units intramuscularly once weekly for three consecutive weeks.
	  • Note: Adequate maternal treatment for prevention of congenital syphilis is defined as at least one injection of 2.4 million units of intramuscular Benzathine Penicillin at least 30 days prior to delivery.
	  • Alternative treatment with Procaine Penicillin or Erythromycin, Azithromycin and Ceftriaxone if allergic to penicillin.
	Refer to Figure 28: Management of HIV and Syphilis in MCH.
	• For women already on ART:
	Offer syphilis screening using a syphilis rapid test.
	Offer HTS (including PITC, VCT and couple testing) and support mutual disclosure.
	• For Prevention:
	  • Link all HIV-positive seroconcordant couples as well as HIV-positive individuals in serodiscordant relationships to ART.
	  • Offer PrEP to all pregnant and breastfeeding mothers at substantial risk of HIV acquisition as well as negative partners in the discordant couples.
	  • For HIV-negative pregnant women, re-test in the third trimester, during labor, or shortly after delivery, because of the high risk of acquiring HIV infection during pregnancy
	  • Re-test HIV-negative pregnant women in a discordant relationship every three months.
	  • Re-test the following HIV negative pregnant women within four weeks of the first test:
	  • STI, HBV or TB-infected pregnant women.
	  • Those with a specific incidence of HIV-exposure within the past three months
	  • Provide risk reduction counseling to HIV-negative women.
	  • Test all pregnant women/girls and their partners for Hepatitis B during antenatal (See Figure 29)
	  • For patients who are HBsAg positive assess the HBeAg and HBV viral load. Patients who are HBeAG negative with a HBV VL of <200,000 IU/ml should be monitored with CBC, LFTs and VL at 6 and 12 months (see Figure 30).
	  • For patients who are HBsAg positive assess the HBeAg and HBV viral load. Patients who are HBeAg positive with HBV VL of >200,000 IU/ml should initiate prophylactic treatment at 24 weeks gestation or at the earliest contact. Discontinue medication 3 months after delivery and reassess and monitor as per Hep B guidelines. After starting treatment, LFTs should be monitored at 4, 8, 12 and 24 weeks and thereafter annually. Monitor HBV viral load at 6 and 12 months (see Figure 30).

Service	Description
ANC package for all pregnant women (regardless of HIV status)	General care: • All pregnant women/girls should have at least eight ANC visits; encourage and support mothers to start ANC in the first trimester • Routinely provide iron, folic acid, and multivitamin supplements • Deworm in the 2nd trimester using Mebendazole • Provide nutrition assessment, counseling and support (see Chapter 8) • Counsel and encourage women to deliver at the health facility • Screen for TB and take appropriate action • Take weight and BP at every visit Laboratory services: • Screen and treat for syphilis, HIV, hepatitis B, other STIs and anemia; use syndromic approach to treating STIs • Perform urinalysis to detect a urinary tract infection (UTI), protein in the urine (proteinuria), or blood in the urine (hematuria) indicating kidney damage, or sugar in urine suggesting diabetes. • Do a blood slide for malaria for all pregnant women. • Perform a blood group test in anticipation of blood transfusion and check for hereditary conditions if suspected (sickling test).
Laboratory investigations specific to HIV-positive pregnant women	• For HIV-positive women, perform a baseline CD4 count. The test result is not required for ART initiation. • For women and girls living with HIV who are already on ART, do VL test at first ANC visit, then follow the VL testing algorithm for pregnant and breast feeding women • For newly diagnosed HIV-positive pregnant women/girls, do VL test 3 months after initiating ART and then every 3 months until end of MTCT period • For women on DTG do lab investigation for monitoring blood sugar as per NCD guidelines

Service	Description
Comprehensive care for pregnant women living with HIV	At each visit provide: • Comprehensive clinical evaluation • Provide cotrimoxazole preventive therapy (CPT) • Pregnant women on CPT should not be given Sulphadoxine-Pyrimethamine (Fansidar) for intermittent preventive treatment for malaria (IPTp) • Screen for TB and take appropriate action • INH for eligible women/girls (see Section 7.5.1) • Screening and management of opportunistic infections (OIs) • Screening and management for NCDs including mental health assessment
Assess risk of unborn baby among pregnant women living with HIV at ANC 1	Conduct a risk assessment of the unborn baby at 1st ANC among all HIV positive pregnant women and at every visit and flag those at high-risk including: • Newly initiated on ART in the 3rd trimester or breastfeeding period • Most recent VL is non-suppressed • Mothers testing HIV positive later in pregnancy or during breastfeeding Closely monitor all high-risk pregnancies.
ART for pregnant or breastfeeding women and girls	• All women/girls living with HIV identified during pregnancy, labour and delivery or while breastfeeding should be started on lifelong ART. • ART should be initiated on the same day, • All women should receive Pre-ART adherence counseling before initiating ART and ongoing adherence support after that – intensively for first three months, than ongoing support (see Chapter 4) • Initiate mother on once-daily FDC of TDF+3TC+DTG with pharmacovigilance (See Chapter 14) • Mothers with hypertension, DM and those intolerant to DTG should be initiated on TDF+3TC+TLE400 • For 2nd line see ART guidelines section • Viral load is done 3 months after starting ART and every 3 months until end of breastfeeding. • ART should be initiated and maintained in mother-baby care point in MCH. What to do if mum refuses ART or if you know adherence is poor: Maternal VL suppression is key for preventing breastfeeding transmission, so if VL suppression is not certain infant prophylaxis may serve as a "back up" to prevent MTCT - similar to "Option A". Clinical providers should continue infant prophylaxis with NVP for these specific scenarios. Continuation of prophylaxis should be seen as an interim measure while maternal adherence is improved.

Service	Description	
Risk reduction counseling and support	• Encourage consistent and correct condom use. • Encourage women to deliver at the health facilities. • For negative pregnant women, offer other prevention services like SMC to partner and mitigate or manage GBV.	
Visit schedules for HIV-infected pregnant women	HIV-positive pregnant woman/ girl already on ART and stable: • Viral suppression achieved • 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/girl initiating ART in ANC (new clients)/unstable: • Recently initiated on ART (< 1 year on ART) or • Poor viral suppression, based on most recent VL as per VL algorithm • Adherence less than 95% • Stage T3,4 and active OIs • Comorbidities/ co-infections • CD4 <500 • Due for vital lab tests in the next two months,e.g., viral load • Has not disclosed to significant other/ household member/ family member
	• 8 ANC visits • Synchronize ART refills and adherence support with the ANC visits • Follow routine MCH schedule after delivery, together with the exposed infant visit schedule (see Annex 2)	• Follow-up visit 2 weeks after initiating ART, then monthly until delivery • Follow routine MCH schedule after delivery, together with the exposed infant visit schedule (see Annex 2)

Figure 28: Management of HIV and Syphilis in Maternal and Child Health care settings

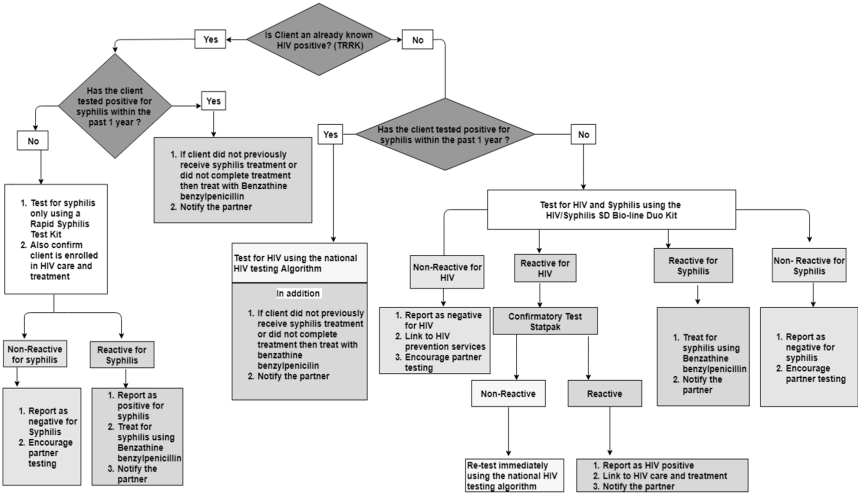


Figure 29: Algorithm for Hepatitis B screening and management in MCH

1	Does the client belong to ANY of these categories?		
1a	• Not tested for HIV in the last 12 months.	YES	NO
1b	• Has TB Disease or presumptive TB (2 weeks' history of Cough, night sweats, weight loss, fever)	YES	NO
1c	• Has symptoms of Sexually Transmitted Infection (blisters, sores, unusual urethral or vaginal discharge)	YES	NO
1d	• Newly diagnosed with Hepatitis B or C	YES	NO
1e	• Has experienced or caused Sexual violence (SGBV)	YES	NO
1f	• Has a reactive HIV self-test result	YES	NO
1g	• Has been identified through an Index client	YES	NO
1h	• Has been exposed to blood or body fluids from a Known HIV positive or unknown HIV status source	YES	NO
1i	• Has signs and symptoms of HIV disease and has not had an HIV test in the last 1 month.	YES	NO
	For clients who have not tested for HIV in the last 3 months		
2	Have you had unprotected sex with partner(s) of unknown HIV status?	YES	NO
3	Have you had unprotected sex with an HIV positive partner? (includes discordance)	YES	NO
4	Have you shared injecting needles or piercing objects with anyone else?	YES	NO

If YES to any of the above, Client is ELIGIBLE for HIV testing

If "NO" to all the above, client NOT ELIGIBLE for HIV testing

4.6 SERVICES TO BE PROVIDED DURING LABOUR AND DELIVERY

Labour and delivery are the periods of highest risk of transmission and should be handled with extra care to avoid transmission from mother to the child. This section outlines specific services to be offered during that period (see Table 21).

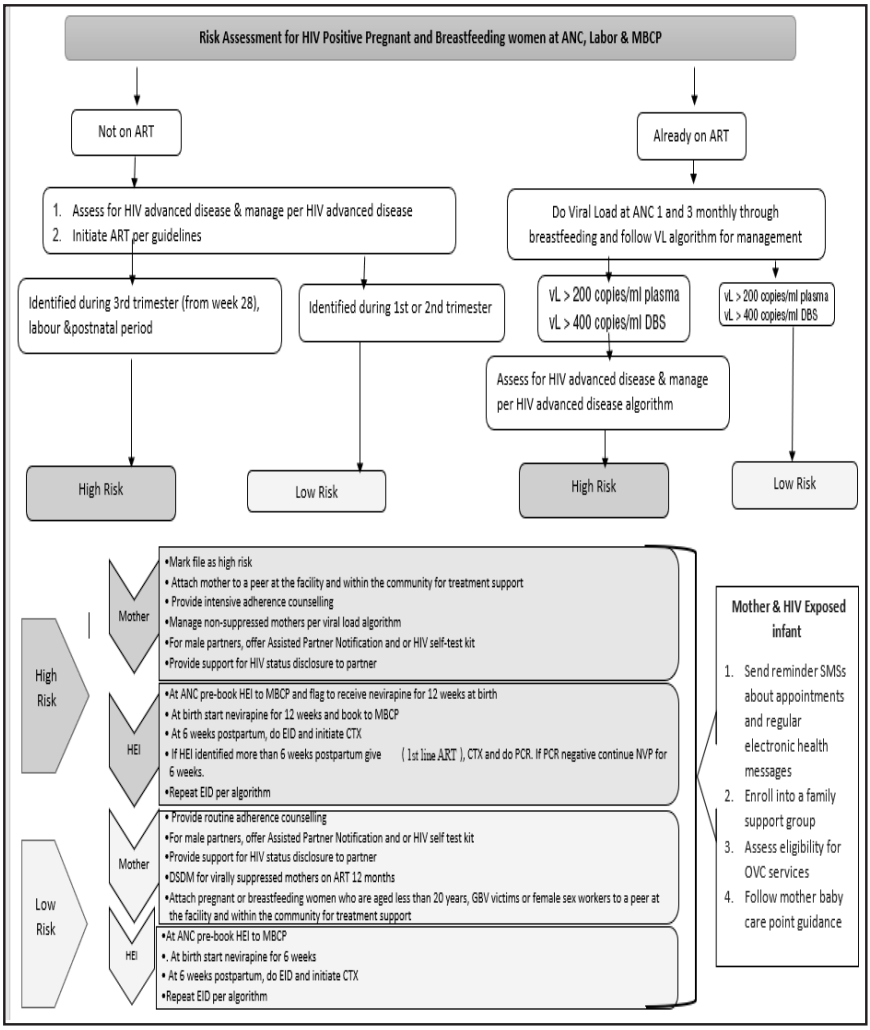
Table 21: eMTCT services during labour and delivery

Service	Description
Ascertain HIV status, offer PITC for the partner	• Offer HTS, syphilis and Hepatitis B testing to all women who have never tested and manage appropriately • Link all HIV-negative mothers to prevention services • Re-test HIV-negative women who did not re-test in 3rd trimester

Safe obstetric practices	• Safe obstetric practices help to reduce the risk of HIV transmission during labor and delivery and reduce maternal and infant death. The practices include:
	  • Use of a partogram to allow for early detection and management of prolonged labor
	  • Avoid routine (artificial) rupture of membranes (ARM); if prolonged labor 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 labor: this reduces the risk of postpartum hemorrhage, which increases the exposure of the newborn to maternal blood. Active management of the third stage of labor involves three important components: (i) giving oxytocin within 1 minute following the birth of the baby (ii) deliver the placenta using controlled cord traction (iii) massage the uterus after delivery of the placenta

Service	Description
Maternal ART and management for syphilis and Hepatitis B	• Give ART to mother (for mothers on treatment, continue the same ART regimen) • Initiate ART for mothers not yet on treatment (see Section 13.8) • Manage mothers positive for Hepatitis B • Give treatment for syphilis if mother is positive
ARV prophylaxis for the HIV-exposed infant	Initiate NVP prophylaxis for the infant at birth • Low risk: Counsel mother and provide NVP syrup for 6 weeks • High risk: Counsel mother and provide NVP syrup for up to 12 weeks High-risk infants are breastfeeding infants whose mothers): • Have received ART for four weeks or less before delivery. • Have unsuppressed viral load within four weeks before delivery, or were diagnosed with HIV during 3rd trimester or the breastfeeding period (postnatal).
	What to do if baby presents after 6 weeks: • Do first PCR • Give ART (1st line paed; give weight appropriate dose) for 6 weeks • If PCR results are negative, give NVP for 6 weeks (after completing the 6 weeks of ART) • If PCR results are positive, continue ART • Irrespective of timing, the mother should be started on ART as soon as possible for her own health and to decrease risk of transmission to breastfeeding baby.
Establishing breastfeeding	• Support the mother to initiate breastfeeding within 30 minutes of delivery • Offer infant feeding counseling to the mother according to the guidance and chosen method during pregnancy (see Chapter 5)
At discharge	• Counsel the mother and provide an appointment to return for postnatal services and exposed infant testing and care at 6 weeks • If the mother is not going to receive services at this facility, link the mother to HIV care services at the facility of their choice using linkage guidelines in Section 2.2

Figure 31: Assessment for High-Risk Mother-Infant Pairs



4.7 SERVICES TO BE PROVIDED DURING THE POSTPARTUM PERIOD

Following delivery, address the treatment, care and support needs of HIV-infected mothers, their children and families (Intervention area 4), provide family planning/contraception services (Intervention area 2) and continue to prevent HIV in mothers who were negative during pregnancy, labour, and

delivery. The HIV-infected mother should continue to receive her care in the mother-baby care point until the baby is 18 months of age. This section will describe postnatal services for the mother (see Table 22). Services for infants (including care for the HIV-exposed infant (HEI) and infant and young child feeding counseling) are described in Chapter 5.0.

Table 22: eMTCT services during the postpartum period

Service	Description

Postnatal services for all mothers regardless of HIV status	• Follow-up for the mother is usually scheduled at six weeks following delivery, which coincides with the baby's immunization schedule. At the postnatal visit:
	  • Check for sepsis, anemia, high blood pressure,etc. and provide vitamin A
	  • Offer FP/contraception counseling and services (see Table 14)
	  • Screen for TB and trat if infected
	  • Breast cancer screening
	  • Cervical cancer screening
	  • Screening for NCDs including mental health

HIV and syphilis testing services	• Provide HTS and syphilis testing for breastfeeding mothers who have never tested, and for their partner • Provide HIV retesting to mothers who were negative at ANC or labour and delivery • Provide ART for all mothers newly diagnosed at PNC according to the guidance in Section 13.8 • Continue to provide risk-reduction counseling and support to HIV-negative mothers • Do HIV retesting every three months during breastfeeding for all HIV negative mothers
HIV care and management for the HIV-infected mother and family	• ART • Cotrimoxazole prophylaxis • Regular TB screening and provide INH prophylaxis if eligible • Continued infant feeding counseling and support • Nutritional assessment, counseling and support • Sexual and reproductive health services including FP/contraception • Psychosocial support • Adherence counseling and support • Monitor retention in care • Assess all mothers who delivered outside the facility for OIs,provide appropriate care and initiate ART

Psycho-social support services	• Link the mother to support services like FSG if they exist, in addition to other services

4.8 CARE OF THE HIV-EXPOSED INFANT/CHILD

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

To prevent the infant from being infected with HIV through vertical transmission

To diagnose HIV infection early and treat

To offer child survival interventions to prevent early death from preventable childhood illnesses

4.8.1 Visit schedule for HIV-Exposed Infants

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

4.8.2 Healthcare Services for the HIV Exposed-Infants

Table 23 below summarizes the services for HEI during the 18 months of follow-up.

Table 23: HIV-exposed infant care services

Service	Description	
Identification of HIV-exposed infants	• Identify all HIV-exposed infants by determining their mother's HIV status and document the mother's status in the child card and mothers' passport. • If infant's HIV-exposure status is not documented or is unknown (i.e. the mother's status is unknown and she is not available for testing), then a rapid HIV testing can be offered. • Rapid diagnostic tests for HIV serology can be used to assess HIV exposure among infants younger than four months of age, or for infants 4–18 months of age whose mother's status cannot be ascertained (e.g. mother does not attend clinic with infant) • The mother should be retested for HIV every 3 months until end of breastfeeding. • The entry points for identification of HIV-exposed infants include YCC, OPD pediatric/Nutrition/TB 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 15 to test and interpret the test results: • Provide 1st PCR within 4-6 weeks, or the earliest opportunity thereafter. • Provide 2nd PCR at 9 months, or earliest opportunity thereafter • Provide 3rd PCR 6 weeks after cessation of breastfeeding • Do DBS for confirmatory DNA PCR for all infants who test positive on the same day they start ART • Do a DNA PCR test for all HEI who develop signs/symptoms suggestive of HIV during follow-up, irrespective of breastfeeding status. • Conduct rapid HIV test at 18 months for all infants who test negative at 1st, 2nd and 3rd PCR *** Where available point-of-care nucleic acid testing should be used to diagnose HIV among infants and children younger than 18 months of age. • ART for mothers and ePNP causes low viral particles which can be difficult to detect, sometimes below cycle threshold. An indeterminate range of viral copy equivalents should be used to improve the accuracy of all nucleic acid–based early infant diagnosis assays • Indeterminate range: a range of viral copy equivalents that would be too low to be accurately diagnosed as HIV infected. The indeterminate range suggested is currently estimated to be approximately equivalent to a cycle threshold of 33 on the Roche COBAS® Ampliprep/COBAS® TaqMan® HIV-1 Qualitative Test v2.0 assay	Provide 1st PCR within 4-6 weeks or the earliest opportunity Guidance for indeterminate test: Take off whole blood and test at CPHL and transport within 2 days Hold off ART until results of whole blood. Communicating results to caregiver Testing intervals for infants with repeated discordant results 4 weeks, 4 months, 8 months

Service	Description

Routine immunization	• HIV-infected children are more susceptible to vaccine-preventable diseases than their HIV-uninfected counterparts.
	• HIV-infected infants and children can safely receive most childhood vaccines if given at the right time. All HIV-infected and exposed children should be immunized as per EPI immunization schedule.
	• Health workers should review child immunization status at every visit.
	• Some special considerations/modifications for HIV-exposed children include:
	  • 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 even when the child has symptoms of HIV. The measles illness from the vaccine is milder than that from the wild measles virus, which is more severe and likely to cause death.
	  • Yellow Fever: Do not give yellow fever vaccine to symptomatic HIV-infected children; asymptomatic children in endemic areas should receive the vaccine at nine months of age.

Growth monitoring and nutritional assessment	• Growth and child nutrition should be monitored using weight, length/height, and MUAC at all encounters with a child, and recorded on the growth monitoring card (see Annex 11). • MUAC should only be measured starting at six months of age. • Failure to gain weight or height, slow weight or height gain, and loss of weight may be an indication of HIV infection in an infant/young child. Failure to thrive affects as many as 50% of HIV-infected infants and children. HIV-infected infants and children who are failing to thrive have a significantly increased risk of mortality. • Counsel the mother/caregiver on the child's growth trend and take appropriate action where necessary.

Service	Description
Development monitoring	• At each visit, assess the infant's age-specific developmental milestones. The age-specific milestones are summarized in Annex 2. • Infants are at high risk for HIV encephalopathy and severe neurologic disease • Early identification of developmental delay can facilitate intervention and these children can improve with treatment. • Some forms of development delay are: • The child may reach some developmental milestones but not others. • The child may reach some milestones but lose them after some time. • The child may fail to reach any developmental milestones at all. • Test children with developmental delay for HIV and, if infected, initiate on ART. • Measure the infant's head circumference.
Early Childhood Development	• The first two years of life are the most critical for brain development and influences during this period significantly contribute to longer-term developmental outcomes. • Years 0-8 are the most critical stage of life because the brain undergoes the most dramatic growth. • ECD therefore comprises all the essential care and support a young child needs to survive and thrive in life and spans from prenatal to eight years of age across multiple domains consisting of physical, cognitive, language and communication, social and emotional and spiritual development. • It is well established that infants and young children exposed or affected by HIV have poorer health and developmental outcomes compared to their non-HIV affected peers. Prevention of mother-to-child transmission (PMTCT) services, which focus on mothers and infants throughout the exposure period provide an ideal platform during a period of life that affects both longer-term health and developmental potential. The services along the PMTCT cascade are well aligned with intervention points for ECD. • ECD services and messages will be well integrated into PMTCT/HEI services to improve outcomes of HEI.

Service	Description
ARV prophylaxis	• Provide NVP syrup to HEI from birth until six weeks of age. • For high-risk infants, give NVP syrup from birth until 12 weeks of age. • If the baby presents after 6 weeks, conduct a 1st PCR test, provide 1st line ART (weight-based dose) for 6-weeks. • If PCR results are negative, give NVP for 6 weeks to complete after the 6 weeks of ART • If PCR results are positive, continue with 1st line ART • Regardless of timing, the mother should be started on ART
Opportunistic infection prophylaxis	**Cotrimoxazole prophylaxis:** • Cotrimoxazole (CTX) prophylaxis significantly reduces the incidence and severity of Pneumocystis Jiroveci pneumonia. It also offers protection against common bacterial infections, Toxoplasmosis and Malaria. • Provide CTX prophylaxis to all HIV-exposed infants from six weeks of age until they are confirmed uninfected (18 months or 6 weeks after cessation of breastfeeding). • Infants who become HIV-infected should continue to receive CTX prophylaxis for life. • If CTX is contraindicated, offer Dapsone at dose of 2mg/kg once daily (up to 100mg). **TB Preventive Treatment (TPT):** • Give INH for six months to HEI who are exposed to TB, after excluding TB disease. • For newborn infants, if the mother has TB disease and has been on anti-TB drugs for at least two weeks before delivery, INH prophylaxis should not be given.
	Malaria prevention: • All HEI and HIV-infected children should receive insecticide treated nets and CTX. Using both reduces risk of malaria by 97%.
Actively look for and treat infections early	• HEI are susceptible to common infections and OIs. • Counsel caregivers to seek care to receive timely treatment. • At every visit, assess HEI for signs and symptoms of common childhood illnesses using the Integrated Maternal, New-born and Childhood Illnesses Guidelines and provide treatment.

Service	Description
Counseling and feeding advice	• Provide infant feeding counseling and advice according to guidance in Chapter 5.

Educate the caregiver and family	• HEI depend on their caregivers to receive care.
	• Provide information to the caregivers and family about the care plan including what to expect and how to provide care for the infant.
	• Caregivers should participate in making decisions and planning care for the child, including decisions about therapy and where the child should receive care.
	• Empower caregivers to be partners with the health facility.
	• Provide key aspects of home-based care for the child, including:
	  • Dispensing prophylaxis and treatment
	  • Maintaining adherence
	  • Complying with the follow-up schedule
	  • Ensuring good personal and food hygiene to prevent common infections
	  • Seeking prompt treatment for any infections or other health-related problem
	• The most important thing for the child is to have a healthy mother. Ensure the mother/infected caregiver is receiving their care. If the mother is sick, the infant will not receive care.
	• When members of the same family as the mother-baby pair are in care, their appointments should be on the same day.

Referrals and Linkage	• Link the caregiver and HEI to appropriate services like OVC care, psychosocial support including FSG and other community support groups.
ART for infected infants	• Initiate ART in infants who become infected according to guidance in Section 13.10

4.9 HEALTHCARE SERVICES FOR INFANTS EXPOSED TO SYPHILIS AND MANAGEMENT OF CONGENTIAL SYPHILIS

Mother-to-child transmission (MTCT) of HIV and/or syphilis remains a significant cause of perinatal morbidity and mortality. Untreated maternal syphilis results in significant adverse pregnancy outcomes, such as spontaneous abortion, stillbirth, fetal death, preterm birth, low birth weight, neonatal death and congenital syphilis. Additionally, maternal syphilis has been shown to increase the risk of MTCT of HIV. Prenatal syphilis screening followed by treatment early in pregnancy can effectively treat the pregnant woman and prevent congenital syphilis.

Validation for the elimination of vertical transmission of syphilis calls for achieving case rate of congenital syphilis of ≤50 per 100 000 live births. Screening all pregnant women for HIV and syphilis at the first antenatal care visit is recommended by WHO and in nearly all countries of the world. Early diagnosis and treatment of both HIV and syphilis in pregnant women has been proven as an effective strategy.

Infants with confirmed congenital syphilis or infants who are clinically normal, but whose mothers either had untreated, inadequately treated (including treatment within 30 days of delivery) or syphilis that was treated with non penicillin regimens should be treated as per guidelines in Table 24 below. Infants whose mothers had syphilis that was adequately treated with no signs of reinfection should be closely monitored, as recommended by the WHO.

Table 24: Syphilis treatment for infants

Condition	Recommended	Alternative
Syphilis in infants (i.e., infants with confirmed congenital syphilis or infants who are clinically healthy but whose mothers had untreated syphilis, inadequately treated syphilis (including treatment within 30 days of delivery), or syphilis treated with non-penicillin regimen	Aqueous benzyl penicillin (Xpen) 100,000-150,000 U/kg/day is administered intravenously for 10-15 days.	Procaine penicillin 50,000 U/kg/day as a single dose is administered intramuscularly for 10-15 days.

In infants who are clinically healthy and whose mothers had syphilis that was adequately treated with no signs of reinfection.	Close monitoring of the infants.	Benzathine penicillin G 50,000 U/kg/day as a single dose intramuscularly.

4.10 HEALTH CARE SERVICES FOR THE INFANTS EXPOSED TO HEPATITIS B (PMTCT-HEPB)

In highly endemic areas, HBV is mostly spread from mother to child at birth (perinatal transmission) or through horizontal transmission (exposure to infected blood) from an infected close contact to an uninfected child during the first five years of life. In Africa, mother to child transmission is one of the most common routes through which new born babies are infected with hepatitis B infection. Infection may occur during delivery or after delivery, mainly in the first 6 weeks of life. About 90-95% of infants exposed perinatally will not be able to clear the infection and will lead to chronic infection. Exposure in early childhood will lead to chronic infection among 30-50% of those exposed, whereas only 3-5% of those exposed at age 5 or above will result in chronic infection. HBV infection often goes undetected in childhood, as those infected are typically asymptomatic until they present with liver complications later in life(>25-30years). Therefore, pregnant women will need to be screened for HBV during ANC as part of the triple elimination strategy for mother to child transmission.

Risk factors of mother to child transmission (MCT) of HBV include:

- HBsAg positive mother or mother known to have chronic HBV infection
- A positive test for hepatitis B e antigen in the mother.
- Mother with high HBV titres ≥ 200,000 IU Unvaccinated babies born to HBsAg positive mothers.
- Invasive procedures such as amniocentesis.

Care of neonate borne to a mother with chronic HBV infection:

The goal is to prevent vertical transmission and is focused on the baby.

Active immunization for birth dose (the neonate should receive the monovalent HBV vaccine preferably within the 24hours of life as it works best during this period. However, if missed, it should be considered at the first contact before 6 weeks).

The usual childhood vaccine schedule (routine national Expanded Program on Immunization, the pentavalent vaccine schedule at 6, 10, 14 weeks) should be followed and completed after the birth dose.

Where available, passive vaccination with the hepatitis B immunoglobulin should be also be offered within 24 hours of birth at a site different from where the HBV monovalent vaccine was administered.

Note:

- All HIV-HBV co-infected mothers should have PMTCT care done as is the case for HIV-mono-infected mothers.
- Neonates born to HIV-positive mothers should also be offered the HBV monovalent vaccine and the HBIG (if available) maybe administered at birth.
- Co-infected mothers should use combined ART regimen with at least 2 drugs active against both HBV and HIV. (Refer to the general guideline for treatment of HBV/HIV coinfection)

4.11 EPI/PMTCT/EID INTEGRATION

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

In contrast, the coverage of the Expanded Program on Immunizations (EPI) is over 97% of the target population for DPT 1 (Annual Health sector report 2014/15). Therefore, although many women deliver outside health facilities, most infants will routinely attend immunization or YCC clinics. According to the 2016 Uganda Demographic health survey, childhood immunization coverage was 94.9% at 6-weeks (DPT1-HepB-Hib); 89.9% at 10 weeks (DPT2-HepB-Hib) and 78.6% at 14 weeks (DPT3-HepB-Hib). Integrating EID with EPI services should be implemented to increase infant HIV testing, increase the number of infants identified early, improve enrollment in EID care and ultimately improve maternal retesting.

Table 25: Integration of EID into EPI services

At each immunization visit	• Proactively determine the need for re-testing at every immunization encounter.
	• Immunization card should have PMTCT section completed at discharge from delivery.
	• Screening for eligibility (for infant testing):
	  • Can take place at registration
	• Standardize the screening process for infant's HIV-exposed status at 6-week immunizations visit
	• If mother's status is unknown (or >3 months have elapsed since last test), re-test the mother (per algorithm for testing breast feeding mothers)
	• If mother is unavailable for testing, do a rapid test on the infant < 4 months of age. If >4 months of age, DBS should be sent for PCR testing.
	• If DBS cannot be collected at the same time as outreach, strong referral/linkage must be ensured with follow-up by the peer/mentor mother or community-based volunteer.
	• If an infant requires EID, or the mother needs re-testing, then mentor mother should escort mother-baby pair to designated testing area.
	Schedule:
	• Week 6 immunization (Polio, Penta, Pneumovax): First PCR
	• Month 9 immunization (Measles): Second PCR
	• Final outcome: 18 months if no longer breastfeeding, or 6 weeks after cession of breastfeeding
	  • If < 18 months, PCR
	  • If ≥ 18 months, RDT.
	• Date of last HIV test should be clearly noted on the immunization card.
	• If mother is newly positive during breastfeeding, immediately flag as high risk and link to treatment and facility or community psychosocial supportive services.
	• Data collection should include number of infants and mothers screened and number of newly identified mothers and HEIs

Box 6: Key highlights in Elimination of Mother-to-child transmission of HIV (eMTCT) and improving Maternal, Newborn, Child and Adolescent Health (MNCAH)

- The eMTCT strategy comprises a package of four approaches:
  - Primary prevention of HIV among females of reproductive age and their partners
  - prevention of unintended pregnancies among HIV infected women
  - prevention of HIV transmission from HIV infected women to their infants
  - provision of treatment, care, and support to women/ adolescent girls infected with HIV, their children and their families.
- eMTCT interventions should be integrated and offered simultaneously within the platform of MNCAH services.
- Provide Syphilis and Hepatitis B screening and treatment during ANC.
- Provide HIV prevention services to HIV-negative pregnant women in ANC and re-test in the third trimester, during labor, or shortly after delivery due to the high risk of acquiring HIV infection during pregnancy; and retest every 3 months during breastfeeding.
- Initiate HIV-positive pregnant or breastfeeding women in ANC/PNC onto ART on the same day as diagnosis and give adherence counseling for at least the first three months.
  - The preferred 1st line ART regimen is TDF + 3TC + DTG or TAF+FTC+DTG.
  - Viral load will be done 3 months after initiation of ART and every 3 months until end of eMTCT period
- Pregnant and breastfeeding women who are on TLE or other regimens and have suppressed VL at ANC 1, should remain on the same regimens until 6-9 months postpartum when they should be transitioned to TLD, if VL within past 6 months is suppressed.
- HIV-pregnant and breastfeeding women already on ART should have a viral load done at 1st ANC visit and every 3 months until end of eMTCT period
- The eMTCT strategy comprises a package of four approaches:
  - Primary prevention of HIV among females of reproductive age and their partners
  - prevention of unintended pregnancies among HIV infected women
  - prevention of HIV transmission from HIV infected women to their infants
  - provision of treatment, care, and support to women/ adolescent girls infected with HIV, their children and their families.

- eMTCT interventions should be integrated and offered simultaneously within the platform of MNCAH services.
- Provide Syphilis and Hepatitis B screening and treatment during ANC.
- Provide HIV prevention services to HIV-negative pregnant women in ANC and re-test in the third trimester, during labor, or shortly after delivery due to the high risk of acquiring HIV infection during pregnancy; and retest every 3 months during breastfeeding.
- Initiate HIV-positive pregnant or breastfeeding women in ANC/PNC onto ART on the same day as diagnosis and give adherence counseling for at least the first three months.
  - The preferred 1st line ART regimen is TDF + 3TC + DTG.
  - Viral load will be done 3 months after initiation of ART and every 3 months until end of eMTCT period
- Pregnant and breastfeeding women who are on TLE or other regimens and have suppressed VL at ANC 1, should remain on the same regimens until 6-9 months postpartum when they should be transitioned to TLD, if VL within past 6 months is suppressed.
- HIV-pregnant and breastfeeding women already on ART should have a viral load done at 1st ANC visit and every 3 months until end of eMTCT period

4.12 COMMUNITY PMTCT SERVICES

Community PMTCT 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 PMTCT implementing sites should establish a network of community-based structures and systems within their catchment area to support the health facility to deliver a minimum package of community-based MTCT services.

4.12.1 Minimum Package of Community PMTCT Services

The minimum package of community PMTCT services include:

- Community sensitization and mobilization for HIV prevention, reproductive health and PMTCT services
- Identification, counseling, registration and referral of pregnant/lactating mothers for comprehensive ANC services including screening for TB symptoms, skilled delivery, PMTCT services for mother and baby including EID, post-natal care, IYCF and FP.

- Identification of partners and children of pregnant and breastfeeding women in communities and ensuring that they know their HIV status, either through outreaches/home-based HTS or through referral
- Address social and behavioral factors that affect uptake of PMTCT services including stigma, disclosure, discrimination,GBV, etc.
- Adherence support.
- Follow-up, linkage, and tracking of mother-infant pairs through at least 18months postpartum and ensure infant's final survival and HIV status is known.
- Community ART and Cotrimoxazole refills.
- Provision of psychosocial support through Family Support Groups or other community based PLHIV support groups, OVC programs, and household economic strengthening/income generating activities.
- Assess infants with HIV positive mothers for eligibility for OVC programs.
- Promote family care, treatment, and support, including treatment support for those who are not part of the family.
- Health education and advocacy for PMTCT services.

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

4.12.2 Establishment of Community PMTCT Services

1. PMTCT sites should do the following in order to establish community PMTCT services:

- Establish partnerships and networks with community-based organizations (CBOs), NGOs and networks of PLHIV for community service delivery. The networks and partnerships should be established by:
- Conducting or updating community mapping of resources, identifying referral trigger factors, developing referral directories, and supporting documentation of referral processes.
- Connecting with the community development officers, CBOs, FBOs, NGOs and networks of PLHIV and other networks involved in community-based PMTCT and meeting to agree on a common objective and agenda.
- Establishing and strengthening comprehensive referral network systems and coordination of two-way referrals between community and health facilities and establishing mechanisms for assessing performance of these systems.
- Promoting integration of PMTCT and HIV into reproductive health, MCH, and other programs.

- Identifying and collaborating with relevant sectors for community empowerment and economic strengthening activities to reduce gender inequalities and increase women's access to assets.
- Promoting partner support by using different strategies to engage male partners.

2. Identify, train, and facilitate community health workers.

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

Establish coordination mechanism.

Each health facility should establish a mechanism for coordinating with the community structures. Communication channels between the partners should be clear and open.

4.13 ALDOSCENT GIRLS AND YOUNG WOMEN (AGYW)

Uganda has one of the youngest populations and adolescents and young people are exposed to numerous challenges including HIV infection. According to UPHIA 2020, the prevalence of HIV for AGYW was 2.9% which is three times higher than their male counterparts (0.8%). More so, the vulnerability and exposure to violence is very high according to UDHS 2016, the teenage pregnancy rate was 25%. In addition, the unmet need of the family is high at 30% with low condom use at 46%.

Because of this, the Ministry of Health developed the National Health Sector HIV Prevention Strategy for Adolescent Girls and Young Women, 2020-2025 to guide the implementation of AGYW focused interventions, strengthen the HIV prevention response among AGYW, accelerate progress towards 95:95:95 targets and end AIDS by 2030. Successful AGYW HIV strategy implementation requires a collaborative effort. This section will provide guidance on HIV prevention and sexual and reproductive health services to AGYW.

4.13.1 The Harmonised AGYW Service Package

Context-specific HIV services will be delivered to AGYW, families and communities to create a supportive and enabling environment and break the barriers to access to integrated HIV services for AGYW. The service package is guided by the National Heath Sector HIV Prevention AGYW Strategy (2020-2025).

The AGYW HIV Prevention Service Package is categorized along three thematic age categories of AGYW as shown in the figure below:

Figure 32: Tailored age-appropriate AGYW service package for impact

	10-14	15-19	20-24
Primary Interventions	• Screening for TB • Screening for HTS eligibility (if out of school) • HIV & Violence prevention & post violence care • Empowerment with parenting skills • Early warning systems • Role modeling • Age-appropriate life skills and sexuality education • Vocational Skills & tooling (if out of school) • Second Chance Education • Information and skills for menstrual hygiene management • Social Behavior Change Communication on risk avoidance	• Screening for TB • Screening for HTS eligibility • HIV & Violence Prevention and post violence care • Combination Socio-economic approaches (ifout of school) • Empowerment with parenting skills • Early Warning systems • Combined socio-economic approaches (if out of school) • Age-appropriate life skills and sexuality education • Health Facility or community SRHR services • Second Chance Education • Vocational skilling (if out of school) • Role Modeling • Information on menstrual hygiene management • Social Behavior change communication on risk reduction • SRH services	• Screening for TB • Screening for HTS eligibility • Community Based HIV & Violence Prevention • Combination socio-economic approaches (if out of school) • Information on menstrual hygiene management • Social Behavior change communication on risk reduction • Vocational skilling • Empowerment with parenting skills • SRH services

Secondary Interventions	• Risk based HTS • Violence prevention, post-violence and management care • Education subsidy • ART (for HIV-positive AGYW) •	• Risk Based HTS • Condoms (emancipated minors only) • Contraceptive mix (for only emancipated minors) • Violence prevention, post-violence care and management • Parenting (for those 15-17yrs) • Education Subsidy • PrEP (for emancipated minors at substantial risk) • ART (for HIV-positive AGYW) • Group-ANC model or longitudinal follow-up through 2y post-partum in PMTCT mother-baby care point (for pregnant and BF AGYW)	• Risk based HTS • Condoms • Contraceptive Mix • Violence prevention, post-violence care and management • PrEP • ART (for HIV-positive AGYW) • Education subsidies • Friendly PMTCT services for pregnant & breast feeding AGYW including Group ANC, follow up in the MBCP
CONTEXTUAL	• Reducing risk in sexual partners (HTS, VMMC, ART) • Community mobilization & Norms Change (SASA) • Male engagement (Male Action Groups, GREAT & Partner Tracking • Primary prevention for KPs (Adolescent and young KPs) • Condom promotion campaign/demand creation • Vocational training and skilling • Financial literacy and entrepreneurship; enterprise development assistance and VSLA for AGYW living with HIV • Socio economic approaches for caregivers (10-14) • PEP		

Table 26: HIV testing and prevention services for adolescent girls and young women 10-24 years

Service	Description
Routine HTS	• All AGYW attending facilities should be screened for HTS eligibility. • Provide HTS to all AGYW and their partners. Also test for syphilis and link to care as necessary. • Provide risk reduction counseling to all who test HIV negative. • Link all who test HIV-positive to care and treatment services • Services should be offered at the convenience of adolescents through flexible opening hours, walk ins or same day appointments • In facility setting, providers should physically escort adolescents to the next point of care to ensure their successful linkage to appropriate HIV prevention, treatment, and care and support services.
Self-testing	• Utilize a peer led approach. • Teach AGYW how to use a self-testing kit and provide the necessary HIV pretest counselling. • Follow up with the adolescents to ensure return of the self-testing results • If the HIVST result is positive, link the AGYW to laboratory for the confirmatory HIV test and ensure linkage to appropriate care and treatment. • For all HIV negative AGYW, provide the HIV prevention risk reduction messages. • Always screen AGYW for gender-based violence using standard tools • Provide first line support to AGYW who experience GBV. • Link to violence prevention and response services as necessary.
BCC	• Safer sex practices, including dual protection (condom promotion) and delay of onset of sexual activity (see Table 9.)
AGYW Male Partners	• Actively identify male partners of AGYW who are at risk of HIV infection using a standard tool • Screen for eligibility for HIV testing services. Also test for syphilis and link to care as necessary. • Avail HIVST kits to AGYW for their partners • Provide risk reduction counseling to all who test HIV negative. • If the HIVST result is positive, link to laboratory for the confirmatory HIV test and ensure linkage to appropriate care and treatment • Services should be offered at the convenience of AGYW's male partners through flexible opening hours, walk ins or same day appointments • Offer SMC services to male partners of the girls and women using standard SMC guidelines

PrEP	• Screen all the AGYW for eligibility for PrEP using the standard eligibility screen PrEP tool • Identify designated entry points (i.e. IPD, OPD, ANC, and SRH) and health workers or peers providing services for AGYW • Offer PrEP to eligible adolescent girls and young women 15-24 years in line with the guidelines for PrEP (see PrEP section); (if the Health facility is not providing PrEP, make appropriate referral to a nearby PrEP site.) • Use a peer led approach to PrEP service delivery. • Conduct APN and partner tracking • Monitor AGYW on PrEP at 1 month then every 3 months • Note: refer to the PrEP guideline (page XX) in this document
STI and HBV screening and treatment	Counsel and screen adolescent girls and women for STIs including syphilis and HBV and manage the STIs (see Section 9.1.1).
HPV Vaccination	Screen and refer eligible AGYW for HPV vaccination. The HPV vaccine protects against genital warts, one of the most common types of sexually transmitted infection. In the long term, the vaccine prevents development of cervical cancer in females and anal cancer in both women and men.

Table 27: Prevention of gender-based violence and post violence care

Service	Description
Violence prevention and post-violence care	• All AGYW attending the health facilities should be screened gender-based violence. **If the AGYW has experience sexual gender-based violence:** • Provide first line support using LIVES • Provide psychosocial support and counselling to SGBV survivors. • Screen all survivors for HIV, pregnancy, STI, trauma and manage accordingly. • Provider emergency contraceptives with in the 72 hours • Screen and provide Post Exposure Prophylaxis (PEP) to all eligible survivors. • If HIV positive link to appropriate HIV treatment and care services. • If HIV negative provide HIV prevention information and services • Link the survivor for legal services. • Ensure continue follow up for six months. • Services should be offered at the convenience of adolescents through flexible opening hours, walk ins or same day appointments and ensure confidentiality

4.13.2 Prevention of Unintended Pregnancies among

Family planning (FP)/contraception for adolescent girls and women reduces the number of unintended pregnancies, school dropout and improves their overall wellbeing. FP/contraception also provides intrinsic benefits by saving lives and enhancing the health status of girls and young women and their families. However, FP services should be provided based on respect and fulfillment of reproductive rights and choices. Adolescent girls and young women should not be coerced into contraception, but provided with information to make informed decisions and choices. Table 28 below describes the process of offering FP/contraception.

Table 28: Family planning/contraception services for AGYW and emancipated minors

Service	Explanation
Counselling	• Provide routine FP/contraception information and counseling to AGYW attending OPD,ANC/G-ANC/ PNC, YCC and safe spaces • Encourage AGYW to discuss their reproductive health choices and support them as appropriate. Information provided during counseling should cover: • All FP/contraceptive methods, advantages and side effects • Common misconceptions about FP/contraception • Advantages of dual protection and how to negotiate condom use • What to do if/when pregnancy occurs Address misconceptions
After counseling, offer FP on a one-on-one basis	For AGYW 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.
Promote Condom Use among Sexually active AGYW	• AGYW who are sexually active should be counselled on safe sex practices, correct and consistent condom use. • Avail condom dispensers in appropriate spaces that are youth friendly.

Service	Explanation
Ongoing support for AGYW	• Counselling and adherence suport for the chosen method (provide a health workers contact in case of any side effects) • Assess for possible side effects and manage accordingly • Clients on injectable FP (Depo-Provera) should be counseled to return for injection on appointment date or before if they cannot make it on scheduled appointment date
Integration of AGYW services	• All AGYW eligible for HIV related programs (GANC, YAPS, DREAMS, OVC, GBV among others) should be effectively linked • Screen AGYW for TB using standard tools and reffer those who need TB services using standard guidelines.

4.13.3 Multisectoral approach

Prevention of HIV among AGYW involves a range of services including Health, Justice, Education, and Social services. Health care providers should have a strong multi sectoral referral and linkage mechanism at all levels, which promotes service equity and reduces the vulnerability of AGYW to HIV infection.

4.14 MATERNAL, INFANT AND YOUNG CHILD FEEDING GUIDELINES

4.14.1 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 optimizes the maximum benefit of breastfeeding to improve the infant's chances of survival while reducing the risk of HIV transmission.

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

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

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

4.14.2 Services Offered During Pregnancy

Nutrition counseling messages and services for HIV-infected pregnant women are in Table 29.

Table 29: Nutrition Counseling Messages for Pregnant Women

Nutrition Information	
Diet	• During pregnancy and breastfeeding: add extra meals, drink adequate fluids, eat plenty of fruits and vegetable,; eat foods rich in vitamin C to enhance iron absorption, avoid tea or coffee within one hour or with meals as this may interfere with absorption of iron, and use iodized salt to prevent pregnancy complications (abortions, miscarriages, stillbirths, fetal growth retardation, and maternal goiter). • Maintain high levels of personal and food hygiene and food safety to prevent illness. • Advise adolescent mothers to take extra care to get adequate food and rest since they are still growing. • Avoid alcohol, narcotics or tobacco products, and medicines not prescribed by a trained health care provider.

Nutrition Information	
Medications during pregnancy	• Vitamins are important in pregnancy, including supplemental iron to prevent anemia and reduce the risk of low birth weight, folic acid to prevent fetal brain and spinal cord congenital disabilities, de-worming tablets to eliminate worms and prevent anemia. • Provide 60mg of elemental iron (200mg of ferrous sulphate) and 400ug folic acid OR combined iron (150mg with 0.5mg folic acid) after three months of gestation and continue to take them daily for six months. Take supplements with food to overcome side effects. • Give iron 120mg + 4000ug folic acid daily for three months to pregnant women with mild to moderate anemia. After completing this treatment, continue with routine supplementation for three months.

Initiatives to promote active Breastfeeding

The following activities should be done to promote breastfeeding:

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

4.14.3 Services Offered During Labour and Delivery

1. Help mothers initiate breastfeeding within half an hour after delivery including in cases of caesarean section.
2. Newborn infants should be fed only colostrum (the first milk) and SHOULD NOT be given pre-lacteal feeds such as glucose, dill/gripe water, mushroom soup, herbal extracts, etc.
3. Continue to counsel on demand feeding, exclusive breastfeeding, and ways of holding and putting the baby to the breast (positioning and attachment) to enhance breastfeeding.

4. Mothers should continue supplementation with iron one tablet/day and folic acid one tablet/day for three months after delivery in addition to intake of iron rich foods.

4.14.4 Services Offered During the Postnatal Period

Feeding a child 0-6 months

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

Heat-treated expressed breast milk

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

- When maternal VL is not suppressed.
- The infant has low birth weight or is otherwise ill in the neonatal period and unable to breastfeed.
- The mother is unwell and temporarily unable to breastfeed or has a temporary breast health problem such as mastitis

If ARV drugs are temporarily not available.

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

Feeding a child 6–12 months – Complementary Feeding

After six months of age, appropriate complementary foods should be introduced while continuing to breastfeed until 12 months.

Counseling messages on complementary feeding are summarized below:

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

Feeding a child 12–24 months

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

Feeding a child 2-6 years

Encourage mothers to give a variety of foods prepared from the family meal (each meal should consist of a carbohydrate, protein, vegetables & fruits) at least three times a day.

Encourage caregivers to give nutritious snacks between meals e.g. fruit (banana, pawpaw, orange, and mango), egg, bread, enriched thick porridge or a glass of milk.

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

Additional Support Messages

HIV-positive mothers who decide to stop breastfeeding at any time should stop gradually. This transition period should be between one to two weeks which is not too long to increase exposure and not too short to cause physical and psychological trauma to the mother and baby.

The mechanisms of transition include:

Expressing breast milk and feeding infant/child by cup; and

Substituting the expressed breast milk with suitable replacement feed gradually.

Replacement feeding (using alternative milk other than breast milk in the first six months of life) should be recommended only in extreme circumstances (e.g. mother is absent, dead or mentally challenged) in accordance with the regulations on the marketing of infant and young child foods.

Follow-up all HIV-exposed infants and continue to offer infant feeding counseling and support to mothers/caregivers.

If an HIV-exposed child falls sick, counsel the mother/caregiver to feed the child even more frequently than usual to meet that child's nutritional requirements.

Box 7: Key highlights in Maternal, Infant and Young Child Feeding guidelines

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

5.0 CARE AND SUPPORT FOR PEOPLE LIVING WITH HIV

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

5.1 MINIMUM SERVICE PACKAGE FOR PEOPLE LIVING WITH HIV AND WHO CLINICAL STAGING

The minimum care package should be offered to all people living with HIV upon enrollment and during their entire time in HIV care. The package should be tailored to their individual needs. The package is summarized in Table 30.

Table 30: Summary of Minimum Care Package for PLHIV

Service Area	Service Description
Clinical evaluation and monitoring of HIV disease	Provide clinical evaluation and monitoring to all PLHIV to ascertain the WHO clinical stage of disease and exclude comorbidities.
Antiretroviral therapy	Initiate at the earliest opportunity in all people with confirmed HIV infection; regardless of clinical stage or CD4 cell count (see Chapter 13).
Nutrition services	Conduct nutrition assessment, counseling and support (NACS) (see Section 8.1).
Opportunistic infection screening, prevention, and management	• Provide Cotrimoxazole prophylaxis if eligible. • Provide INH prophylaxis if eligible (see Section 7.5.3) • Screen and manage other OIs like TB and Cryptoccoccal infection (see Section 7.6)

Service Area	Service Description
Screening and treatment of co-morbidities	Screen and manage NCDs including: • Hypertension • Diabetes • Dyslipidemias • Mental health (especially depression) See Section 7 for detailed guidance on screening and managing NCDs.
Sexual and reproductive health services	• Screen and manage sexually transmitted infections • Provide family planning/contraceptive and pre-conception services (see Section 4.4.) • Ensure resources for early identification of pregnant mothers and linking them to ANC • Promote facility delivery and postnatal care (see Chapter 4) Provide cervical and breast cancer screening (see Section 9.2)
Adherence counseling	Do adherence preparation, monitoring and support (see Section 7.5)
Psychosocial support and palliative care	• Assess family and community support to the client • Assess for stigma and discrimination • Link client to a psychosocial support group • Assess for any social challenges the client might have • Refer for palliative care when required.
Orphans and vulnerable children (OVC)	• Conduct basic assessment for vulnerability • Provide HIV testing for family members either at facility or community level as appropriate • Refer and link to a CBO/CDO • Conduct nutrition assessment, counseling and support • Initiate ART for HIV-positive children and their caretakers • For details of OVC care, refer to the SPPI, Ministry of Labor, Gender, and Social Development

Service Area	Service Description
Positive health, dignity and prevention	• Support client to disclose HIV status to family and significant others • Provide active partner and family tracing for HIV testing • Educate, provide and promote correct and consistent use of condoms • Provide family planning counseling and services with consent of the patient • Provide STI screening, prevention and treatment services • Provide routine adherence counseling to patients on ART • Provide gender-based violence screening and support
Other prevention services	• Provide immunizations according to the national immunizations schedule • Educate and promote use of long-lasting insecticide-treated mosquito nets (LLINs) • Educate and promote use of safe water, sanitation and hygiene practices

WHO Clinical Staging

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

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

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

5.2 DELIVERING HIV SERVICES FOR ADOLESCENTS

An adolescent is a person aged 10–19 years. Adolescence is a period characterized by rapid physical, emotional, cognitive, and social changes. During this period, adolescents are at risk of poor health outcomes and

acquisition of new HIV infections. Therefore, to improve access to HIV prevention, care and treatment services and improve their health outcomes, health care providers need to provide adolescent-friendly health services (AFHS). The WHO minimum standards for adolescent health service delivery and Uganda's minimum health care package consider health services adolescent friendly/responsive if they meet the minimum service standards i.e. Provide aadolescent literacy (information and education); engage community support (e.g., care giver involvement, linkages to community services); offer an appropriate service package; ensure provider competencies; offer favorable facility characteristics (space, flexible hours, separate clinics, privacy, attractiveness, branding); ensure equity and non-discrimination; monitor and ensure adolescent participation (peer-led). Adolescent responsive services should also be accessible, acceptable, appropriate, equitable and effective. Health facilities providing HIV/ART services should therefore ensure that services are provided within this framework to target adolescents as indicated in Table 70 below.

Table 70: Adolescent Friendly HIV Services

Guidance
1. Service delivery: The services offered should be adolescent-friendly so that they can meet the needs of this age group.
Adolescent Literacy: Adolescents should be provided with accurate and comprehensive information about HIV to help them protect themselves from HIV infection. Such information should include the meaning of HIV and AIDS, how HIV is transmitted and how HIV is prevented. Adolescents living with HIV should be disclosed to about their HIV status and given information about their treatment. Key information should include: the basic care package, meaning of ART, TPT, benefits of ART, importance of ART, side-effects of ARVs and basic clinic routines. Provide educational/information materials in the form of posters and brochures in a language best understood by the adolescents. Share available hotlines where the adolescents can access information or counseling off-site. Community Engagement: The support of caregivers is important for positive outcomes for adolescents. Adolescents accessing HTS by themselves and testing HIV positive should be encouraged and supported to disclose to their parents or caregivers. Caregivers support adolescents to adhere to their medication, remind them about clinic appointments, provide life necessities and provide psychosocial support. In addition, vulnerable adolescents should be linked to other non-health community services to ensure comprehensive service provision and promote adherence as well as retention in care.

Guidance

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

Provider competencies:

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

Favorable facility characteristics:

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

Equity and non-discrimination:

a. HIV services should be made available to all adolescents irrespective of ethnicity, tribe, age, sex, or sexual orientation.

Guidance
b. Offer free or affordable services to adolescents. c. Offer services in line with the standard minimum care package for adolescents. d. Link adolescents to other services not provided by the facility to ensure comprehensive service delivery e. HIV services should be provided following a differentiated approach. Adolescents are a heterogenous group and therefore services should be tailored to the needs of various categories. For instance, health facilities should implement adolescent responsive MCH services for pregnant and breastfeeding adolescent girls e.g enrolment into Group ANC/ PNC. Monitoring and Evaluation of Adolescent HIV services: f. Adolescents' treatment outcomes across the clinical cascade should be monitored through routine data collection and reporting of the HIV indicators. These should be part of the facility report submitted routinely through the national reporting system. g. Track and follow-up adolescents using the standard loss to follow-up protocols and tools Adolescent participation (Peer-led): Participation of adolescents in their care is an effective approach in delivering adolescent health services. Facilities should identify, train, and use peers to support the provision of services across the clinical cascade using the standardized national peer support guidelines. Activities implemented by adolescent peer supporters should be monitoring to ascertain their contribution to the clinical cascade. h. Note: As much as possible, adolescent health/HIV services should be integrated into the already existing health service delivery systems making it 'a one-stop shopping center'.
2. HIV testing services (HTS): Access and uptake of HTS among adolescents is low partly due to their poor health seeking behavior as well as the absence of an enabling environment. HTS is an entry point to HIV prevention, care, and treatment services
HTS with linkage to prevention, treatment and care is recommended for all adolescents with a focus on those from key populations. Informed consent and HIV testing. Adolescents aged 12 years and above can consent on their own for HTS without the approval of their parent/guardian.

Guidance

Strategies for improving uptake of HTS among adolescents:

1. Use a peer-led approach where adolescent peers are trained to provide pre and post-test counseling as well as performing HIV tests.
2. Offer services at the convenience of adolescents through flexible working hours, walk-in services for those without an appointment, weekend or same-day appointments.
3. Offer services in a place that ensures privacy and confidentiality.
4. Provide age-appropriate information such as benefits of knowing one's HIV status.

Generating demand for HTS

Consider where the adolescents live (rural or urban).

A wide range of approaches can be used including:

1. Peer-to-peer engagement.
2. Multimedia campaigns including TV, radio, billboards and brochures.
3. Social media: Facebook, Twitter, WhatsApp, Instagram, etc.
4. Phone technology: SMS messages with a platform that allows self-assessment for risk and determining whether to test.
5. Performing artists and celebrities.
6. Sports gala.
7. Music and drama festivals.
8. School extracurricular activities/clubs.
9. Community events such as promotions, meetings, bazaars.
10. Health education.

Providing opportunities for HIV testing.

HTS services should be offered using facility or community service delivery approach as integrated or stand-alone services.

For the facility approach, create HIV testing opportunities within existing service points where adolescents routinely receive care including:

1. OPD/YCC, ANC, maternity, family planning and sexual and reproductive health service delivery points.
2. Youth/adolescent information centers/corners.
3. Community-based/mobile outreach testing sites targeting key populations
4. examples include moonlight testing for out of school adolescents, bars, and brothels).

Prevention services for adolescents: Provide adolescent friendly risk-reduction interventions to prevent HIV, teenage pregnancy, and other STIs.

Guidance
• Assess the sexual behavior of the adolescent. • Provide HTS to sexually active adolescents (test every three months for on-going risk, and once a year if exposed after last HTS). Messages should focus on avoiding cross generation sex, multiple partners, transactional sex and promote abstinence and delayed sexual activity. • Encourage condom use for those sexually active. • Screen for STIs and treat as appropriate. • Identify and link adolescents to other available services at the facility as appropriate (VMMC, ART). • Offer voluntary contraception options. • Assess for gender-based violence (GBV) and refer as appropriate. • Identify, refer and link adolescents to other available community programs.
Linkage to care and treatment.
A peer-led approach should be used to link adolescents living with HIV (ALHIV) into care and treatment services preferably on the same day. • Use community-based structures such as village health teams, and community health extension workers to complement peer leaders • Ensure complete linkage through establishing a feedback mechanism.
HIV care and treatment for adolescents
ART delivery for adolescents will mainly be facility-based using any of the three delivery approaches recommended for the facility-based model: • Fast-track drug pickup approach for stable clients picking their drugs quarterly. • Comprehensive clinical evaluation for all. • Facility-based treatment clubs/healthcare managed groups for drug refills within their groups/clubs, adherence support, peer support and psychosocial support.
Psychosocial support for adolescents.

Guidance
All HIV positive adolescents should receive psychosocial assessment and support as part of their routine care. The assessment should be done using the Home, Education/ Eating/ Employment, Activity, Drugs, Sex, and Sexuality, Suicidal ideation/mental health (HEADSS) tool at each clinical visit (Annex 10). In addition, they should be assessed for adherence, mental health problems; social vulnerabilities and violence using standard national tools. Adolescents should be supported to deal with common psychosocial problems including disclosure of HIV status; stigma and discrimination; adherence, loss and bereavement as well as socio-economic challenges. All these singly or in combination affect the quality of treatment outcomes.
Benefits of psychosocial wellbeing include: 1. Improved adherence to medicines and access to essential services. 2. Reduced psychological distress. 3. Increased likelihood of appropriate disclosure to others. 4. Better engagement in HIV-related care. 5. A better understanding of HIV and related conditions. 6. Improved uptake of Positive Health Dignity and Prevention (PHDP) services.
Retention: Adolescents living with HIV may need additional support to remain engaged in care. Retention in ART care is critical for continued adherence to ART, monitoring for drug toxicity/resistance and successful viral suppression.
• Offer adolescent-friendly services. • Form and use peer support groups. • Conduct special programs for adolescents including life skills training. • Regularly update contact information especially physical address and telephone contacts, use appointment calendars and send messages (SMS reminders for appointments). • Conduct activities such as games and sports, music, drama, etc. • Identify, refer and link adolescents to other available community programs. • Consider providing ART within community settings.
Transition: Purposeful and planned transition to adult-oriented services is an important factor in the long-term well-being of an adolescent.

Guidance
The transition should depend on the service delivery approach at each health facility. Transitioning should consider the neurocognitive condition of the adolescent. In settings where there is an integrated clinic providing services for children, adolescents, and adults at the same facility the process should follow the steps below: • Identify and develop a transition team at the adolescent clinic. The team should include: a clinician, counselor, peer supporter, caregiver and adolescent. • Develop a transition plan when the adolescent turns 18 years or at the first encounter if older than that. • Update the transition plan and assess the adolescent's readiness at each clinical encounter over at least a two-year period. • Once the young adult is 20 years and older and is ready to transition, give them an appointment for the adult clinic. • On the same day that they express readiness to transition introduce the adolescent to the adult care team (who may be the same staff). However, for health facilities with a separate adolescent clinic from the adult one they should also: Invite the adult transition team to meet at the adolescent clinic, the young person who is ready to transition and agree on an appointment date (if feasible). Introduce the adult treatment team to the adolescent at the agreed appointment and hand them over.

5.2.1 Supporting Continuity in Care and Treatment

All PLHIV should be supported to remain in care. For the test and treat guideline implementation to contribute to the achievement of the 95-95-95 targets, patients must be retained in HIV care and efforts should be made to avoid interruption in treatment (IIT).

5.2.2 Prevention of Interruption in Treatment

To mitigate such losses of patients from care during the test and start implementations the country will implement the strategies outlined in Table 71 below.

Table 71: Strategies for Preventing interruption in Treatment

Strategy	Rationale
Decentralization of ART care and laboratory services • MOH and district health teams will work to decentralize ART services to all HCIIIs and eligible HCIIs. • Laboratory services will be decentralized to the appropriate health services. • Where specific labs services are not available, health facilities will be supported to access the services through the current transport hub and sample referral system.	Decentralization improves retention by: • Taking services closer to the target population, lowering transport costs for patients, and thereby increasing the likelihood that they stay in care. • Improving access to all HIV services. • Reducing patient burden at higher level facilities and may reduce waiting time at those facilities.
Implementing differentiated service delivery models • Health care workers will be trained and supported to implement DSD models starting at high volume sites. • For more details of the models refer to the DSD implementation manual.	• DSD will reduce frequency of clinic visits by dispensing medication for longer periods • Community models will take services closer to the clients and reduce transport costs for patients • Health worker time will be freed, and they can give sufficient time to the patients who require more care and time
Institute/strengthen comprehensive patient appointment and tracking systems. Will include: • Use of appointment books • SMS reminders and phone calls • Home visits • Partnerships with community-based service providers to support community follow-up, and patient tracking • Early retention and birth cohort control monitoring • All these strategies should be implemented through CQI initiatives	• Patients who miss appointments will be identified easily and will be followed-up and brought back into care if found.

Strategy	Rationale
• Strengthening client counseling and education services at the health facilities • Health workers, counselors, VHTs, CHEWs, expert clients, peer mothers and lay testers will be trained to provide standardized patient counseling services including adherence and psychosocial support. • Patients will be initiated on treatment when they have been prepared and are ready to start ART.	• When patients are educated and counseled well, they are empowered to support their care and are more likely to stay in care.
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.

5.2.3 Tracing and re-engagement in care

HIV programs should implement interventions to trace people who have disengaged from care and provide support for re-engagement. Tracing and re-engagement action is more successful when people are traced soon after a missed visit compared with a longer period of disengagement. Approaches to tracing included remote communication (phone, text messages, mail and email), in-person tracing and a combination of both approaches.

5.2.4 Implementation considerations

Support for re-engagement in care can include interventions directed towards people living with HIV, such as peer or health-care provider outreach and navigation back to care. It can also be directed towards health-care providers and health facilities through systems to alert healthcare providers that people have disengaged and prompt action.

Interventions can include reminders (such as phone calls or text messages), economic interventions (such as financial incentives or conditional cash transfers), case management or policy interventions, with steps taken to ensure confidentiality.

Programme- or facility-level confidential contact details should be kept up to date to ensure successful tracing if and when required.

When considering tracing people who are not engaged in care, adequate assessment of the risks to vulnerable and key populations is critical. For example, women are subject to increased levels of both intimate partner and gender-based violence in the context of HIV, and appropriately training health care providers is essential.

The criteria for tracing and recall should consider those who are seven or more calendar days late for a scheduled appointment. Although efforts should be made to trace everyone who has missed appointments and/or has abnormal results, the following groups should be given priority:

- People initiating treatment in the past six months with advanced HIV disease
- People with abnormal results
- People not initiating treatment
- People overdue for clinical consultations or laboratory tests.

A non-judgmental approach is essential to supporting people in returning to care; this requires reducing system barriers and improving interpersonal communication by developing the capacity of health-care providers.

All patients interrupting their treatment more than 28 days are referred to as lost to follow up and should be traced and supported to re-engage in care. The following interventions will be implemented:

- Support patient tracking and follow up
- Line list all missed appointments
- Conduct phone call follow up
- Link to community follow up structures (Peer networks, OVCs, CBOs, PLHIV networks, KP CSOs etc.)
- Conduct home visits
- Document all patient tracking and follow-up outcomes in the HIV care card and electronic records
- Conduct appropriate investigations

5.2.5 People interrupting treatment (less than 90 days)

Conduct a comprehensive clinical evaluation to identify signs and symptoms of AHD and co-morbidities; conduct a PSS assessment to identify barriers to continuity.

Table 72: Re-engaging Adolescents after <90 days

Absence of signs and symptoms	Presence of signs and symptoms
provide adherence counselling and PSS	Screen, identify and manage and refer appropriately TB, CCM, HTN, DM, Mental health etc
restart most recent ART regimen	Conduct a CD4 count test, if <200cc/ul, follow AHD protocol,
viral load test as per original schedule of their follow-up	Provide adherence counselling and PSS
	Restart ART

5.2.6 People interrupting treatment (more than 90 days)

Conduct a comprehensive clinical evaluation to identify signs and symptoms of AHD and co-morbidities; conduct PSS assessment to identify barriers to continuity;

conduct a CD4 cell count.

Table 73: Re-engaging Adolescents after >90 days

CD4 count >200 cells/ul	CD4 count < 200 cells/ul
Provide intensive adherence counselling and PSS for continuity in care.	Conduct AHD screen as per AHD protocol
Restart most recent ART regimen	Restart most recent ART regimen
Repeat viral load test at 3 months after restarting ART.	Repeat viral load test at 3 months after restarting ART.
Manage comorbidities and OIs	Manage comorbidities and other OIs
	Provide intensive adherence counselling and PSS for continuity in care

Box 9: Key highlights in Psychosocial Care and Adherence Support for PLHIV

Psychosocial care and support are an essential component of HIV prevention, care and treatment as it addresses fear, stigma and impacts on behavior change, access to services, adherence to medication and retention in care.

Poor adherence is the major cause of ART treatment failure. Adherence to ART is therefore critical to viral load suppression, reduced risk of drug resistance development and improved treatment outcomes. Adherence should be routinely assessed and continuously reinforced. Intensive Adherence Counseling and support (IAC) is a targeted and structured counseling and support intervention and should be offered to patients on ART with a non-suppressed viral load (patients with viral load >200 copies/ml or 400 for plasma and DBS respectivly).

It is important to establish referral and linkage systems within facilities and in the communities for increased access and retention along the continuum of care.

Establishing adolescent friendly service delivery in order to create demand and increase access to services among this population. Implementation of innovative approaches including peer-led approaches, social media, mobile phones technology, flexible clinic hours, dedicated spaces and community/school activities in prevention, care and treatment services are recommended.

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

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

5.3.1 Management of Advanced HIV Disease

5.3.1.1 Definition of Advanced HIV Disease

For adults, adolescents, and children five years or older, Advanced HIV Disease (AHD) is defined as CD4 cell count <200cells/mm3 or with a current WHO stage 3 or 4 event. Children younger than five years of age with HIV regardless of CD4 cell count are considered as having advanced HIV disease due to high viremia and rapid disease progression with high mortality. However, children younger than 5 years who have been on ART for more than one year, are virally suppressed and are clinically stable, are not considered to have AHD.

5.3.1.2 Background

Approximately, 30% and 15% of newly identified PLHIV present to care with CD4 cell counts less than 200cells/mm3 and 100cells/mm3 respectively. Furthermore, a proportion of PLHIV in care experience treatment failure to ART regimens and approximately 25% of PLHIV are returning to care with advanced HIV disease after treatment interruption. PLHIV with advanced disease are particularly at high risk of death, even after initiating ART, with this risk increasing with decreasing CD4 cell count. The most common causes of death among adults with advanced disease include TB, Cryptococcal Meningitis (CM), Histoplasmosis, aspergillosis and severe bacterial infections. Similarly, the major causes of morbidity and mortality among children living with HIV are pneumonia (including pneumocystis pneumonia), TB, severe bacterial infections, diarrheal diseases and severe acute malnutrition. All efforts should be made to identify these conditions early to avert mortality. Despite the shift to 'test and treat' for ART, CD4 cell count remains an important parameter and should be done in all ART-naïve individuals, non-suppressed and those returning to care after treatment interruption for more than 90 days to guide identification of Advanced HIV Disease.

5.3.1.3 Identifying individuals with Advanced HIV Disease

- Identifying people with advanced HIV disease who are eligible for elements of the package of care requires performing a CD4 cell count for newly initiating patients, patients re-engaging in care after more than 90 days, patients who are not virologically suppressed and patients presenting with symptoms suggesting WHO Stage 3 or 4 disease.

- CD4 cell count testing can be performed using point of care technologies such as laboratory based CD4 analyzers and device -free semi-quantitative rapid tests.
- If a CD4 cell count is not readily available onsite, use a symptom screen that assesses for symptoms associated with opportunistic disease (refer to Figure 33 below), and send the CD4 sample to the hub for testing.
- Note that relying on WHO clinical staging alone risks missing substantial numbers of people living with HIV with severe immune suppression.

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

Table 31 below summarizes the recommended package of interventions for managing PLHIV with advanced disease. It includes interventions for screening, prophylaxis and treatment for opportunistic conditions, rapid ART initiation and enhanced adherence support. The package below should be offered to people with advanced HIV disease who are new, re-engaging with care after 90 days of ART interruption, or to those with viral non-suppression. People living with HIV should be systematically screened for TB disease at each visit to a health facility (refer to section 7.4 for details on TB screening and management).

5.3.1.5 Package Of Care For Children With AHD

Screen, Treat, Optimize and Prevent AIDS (STOP AIDS) Package

The STOP AIDS package of care is the WHO recommended set of interventions for children presenting with advanced HIV disease. The Table 31 below summarizes the recommended interventions for screening, treating, optimizing ART and preventing advanced HIV in children living with HIV

Table 31: Screening, diagnosis, treating and prevention components of the package of care for children and adolescents with advanced HIV disease

Intervention	Component	<5 years	5–9 years	10–19 years
Screening and diagnosis	• Screen for TB using the TB ICF guide or CXR. Use Point of care CRP for adolescents in addition to the ICF guide • Use the recommended clinical algorithm for diagnosis of TB (Figure 35) • Use the following diagnostic tests to confirm TB **Rapid molecular diagnostic tests e.g., GeneXpert, TRUENAT or TBLAMP assays as the preferred test using (expectorated or induced) sputum, gastric aspirate, stool or nasopharyngeal aspirate or other extrapulmonary specimens **Lateral flow urine lipoarabinomannan (LF-LAM) assay	Yes	Yes	Yes
	Use CXR to aid TB diagnosis if available.	Yes	Yes	Yes
	Cryptococcal antigen screening among adolescents (Specimen: Serum, plasma, or whole blood) If blood cryptococcal antigen positive or symptomatic, do a lumbar puncture	No	No	Yes
	Malnutrition; Assess weight for Height, Height for Age and Mid Upper Arm Circumference	Yes	Yes	Yes

Treat	**If/When diagnosed,** treat for TB, severe pneumonia, severe bacterial infections, cryptococcal meningitis and severe acute malnutrition according to national guidelines	Yes	Yes	Yes
Optimize ART	**Rapidly initiate** optimal antiretroviral regimen i.e. within seven days and antiretroviral therapy counselling	Yes	Yes	Yes
Prevention through prophylaxis, pre-emptive treatment and vaccination	Co-trimoxazole to prevent severe bacterial infections and pneumocystis pneumonia	Yes	Yes	Yes
	TB preventive treatment	Yes	Yes	Yes
	Fluconazole pre-emptive therapy for those with cryptococcal antigen–positive test without evidence of meningitis	Not applicable	Not applicable	Yes
	HPV vaccine	No	No	Yes
	BCG vaccination at birth	Yes	No	No
	Pneumococcal conjugate vaccine (catch-up)	Yes	No	No

Treating TB in Children

Treat drug-sensitive TB among children with a four-drug regimen that includes rifampicin (R), isoniazid (H), pyrazinamide (Z) and ethambutol (E). Drug–drug interactions between rifampicin and Lopinavir/ritonavir (LPV/r) need to be taken into account and antiretroviral therapy adjusted accordingly, using a super-boosting strategy or double-dose LPV/r depending on age and ability to swallow medication. Drug–drug interactions between rifampicin and dolutegravir (DTG) can also be adjusted for by double-dosing DTG (children >25 kg). Shorter TB treatment duration for children will be available in the future and updates will be communicated.

Treating severe pneumonia in children living with HIV

The most common cause of severe pneumonia in children living with HIV include *Streptococcus pneumoniae* and *Staphylococcus aureus,* therefore antibiotics that are effective against these organisms can be used. Treat all infants living with HIV with severe pneumonia empirically with co-trimoxazole and the antibiotics recommended in national guidelines because of the high prevalence of *Pneumocystis* pneumonia in this age group.

For children between one and five years old, the recommendation is to use antibiotics recommended in national guidelines and not cotrimoxazole due to the lower prevalence of PCP in this age group

Treating severe bacterial infections

The commonest causes of severe bacterial infections in children living with HIV in the community are Streptococcus or Staphylococcus whereas gram negative bacteria are the commonest cause for health facility associated bacterial infections. Salmonella is also a common cause of bacteraemia among children living with HIV. Treatment should be provided according to current national guidelines and tailored according to age, suspicion of meningitis and blood and cerebrospinal fluid culture if available

Treating Cryptococcal Meningitis in adolescents

Routine cryptococcal antigen screening and pre-emptive therapy are not recommended for children younger than 10 years because of the low prevalence of cryptococcal meningitis in this age group. However, if a child younger than 10 years presents with signs and symptoms of meningitis, cryptococcal meningitis should still be considered and the appropriate investigations and treatment for this should be implemented. A short-course (one- week) induction regimen with amphotericin B deoxycholate (1.0 mg/kg per day) and flucytosine (100 mg/kg per day, divided into four doses per day) is the preferred option for children living with HIV

Treating malnutrition in Children with HIV

Severe acute malnutrition is common at HIV diagnosis and carries a high risk of mortality. The availability of ready- to-use therapeutic food where appropriate, are considered essential components of HIV treatment for children

5.3.1.6 Package of Care for Adults with AHD

The package of care for adults with AHD has similar interventions with that of the children. However, there are some differences in the components of care provided to adults. Table 32 shows the recommended package of care for adults.

Table 32: Package of care for adults with advanced HIV disease

Intervention	Component	Eligibility criteria
Diagnosis	Urine TB LAM	CD4 ≤200 cells/mm3 or Danger signs or WHO Stage 3 or 4
	Sputum Xpert MTB/ RIF	All presumptive TB cases regardless of CD4 count
	Cryptococcal antigen screening (CrAg)	CD4 ≤200 cells/mm3 or Danger signs or WHO Stage 3 or 4
	Nutritional assessment and Support	All regardless of CD4 count
Prophylaxis and Pre-emptive treatment	Cotrimoxazole prophylaxis	Newly initiating PLHIV WHO stage 3 or 4 event or other symptoms of AHD Pregnant and breast-feeding women Children (aged ≤15) Patients suspected to have treatment failure
	TB preventive Therapy	Negative TB Symptom Screen Any CD4 count
	Fluconazole Pre-emptive treatment	PLHIV with a Positive serum CrAg test who have a negative CSF CrAg (on Lumbar Puncture)
Rapid ART initiation	Rapid ART initiation	Any CD4 and Negative TB and CM Symptom Screen
	Defer ART initiation in presence of:	Positive TB and CM Symptom Screen or TB diagnosis or Positive CrAg

Adherence support	Tailored counselling to ensure optimal adherence to the advanced disease package, including phone calls and home visits	Any person with advanced HIV disease

Using TBLAM for TB diagnosis in advanced HIV disease

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

- People living with HIV:
  - With advanced HIV disease or
  - Who are seriously ill irrespective of signs and symptoms of TB and CD4 cell count or
  - With unsuppressed viral load (i.e. VL > 1000 copies/ml of blood)

Note:

1. TB LAM MUST NOT be used for HIV NEGATIVE patients
2. The above national recommendations apply to both *in-patient and out-patient settings*
3. Whereas children less than 5 years who are new and have been on ART for less than one year are all considered to have AHD, they will only be eligible for a TBLAM test if they have AHD symptoms and signs (refer to the symptom and advanced disease management pathway)

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

5.3.1.7 Rapid ART Initiation

All patients should undergo the symptom screen for the Advanced Disease Pathway (see Figure 33 below). Patients presenting for the first time or those returning to care and not on ART should undergo the symptom screen for the Advanced Disease Pathway before rapid ART initiation is offered. Rapid ART initiation should be deferred when symptom screen is positive or when there is a TB diagnosis, or the patient is CrAg positive. Note that CD4 testing is not a pre-condition for ART initiation.

5.3.1.8 People interrupting treatment (more than 90 days)

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

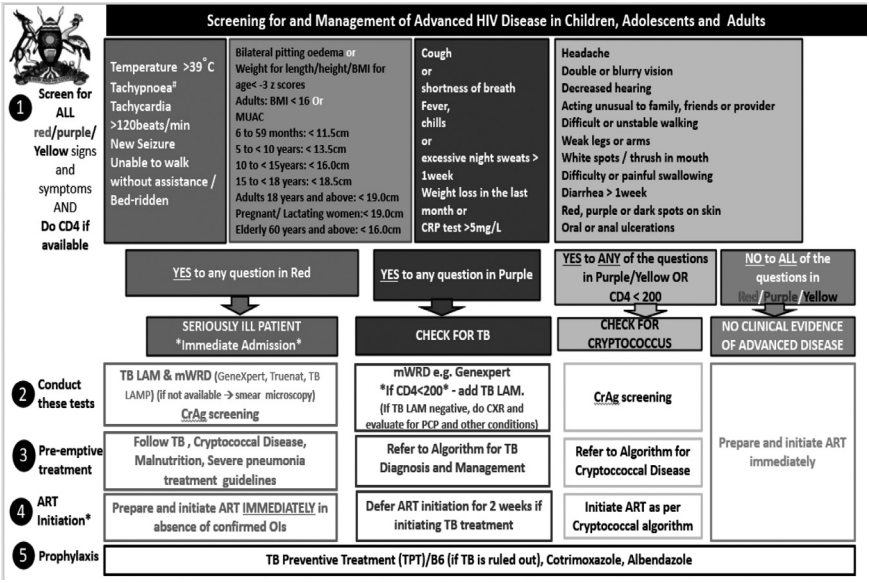
5.3.1.9 People interrupting treatment (less than 90 days)

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

5.3.1.10 Adherence support

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

Figure 33: Symptom Screen and Advanced Disease Management Pathway

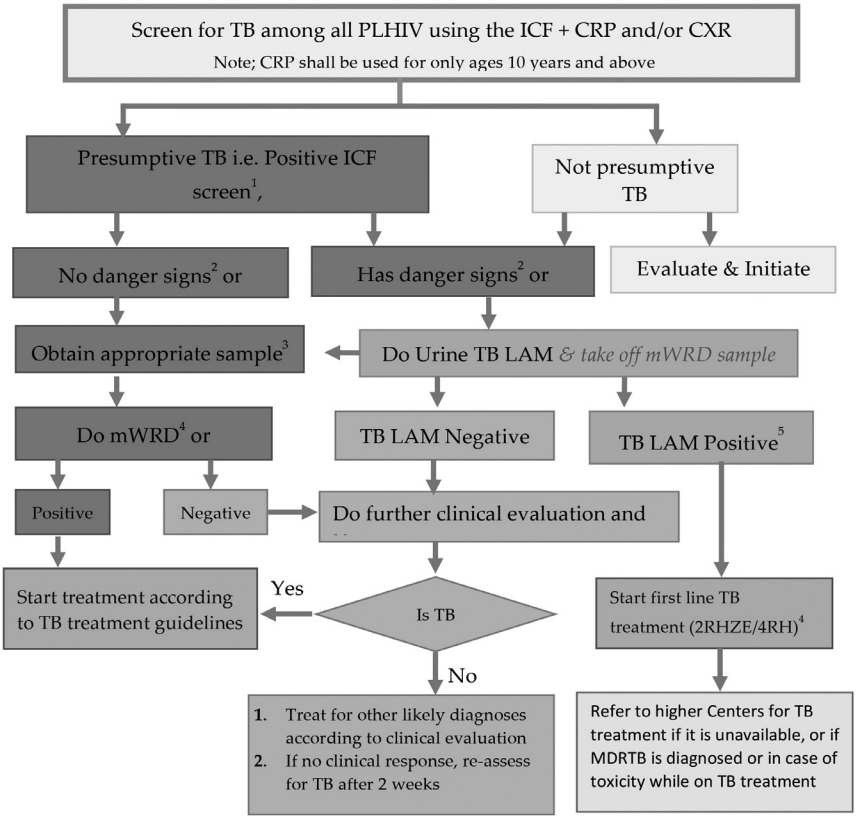


5.4 CO-INFECTION SCREENING, TREATMENT, AND PREVENTION

5.4.1 HIV and Tuberculosis

HIV is the strongest risk factor for developing TB disease. PLHIV are 20–37 times more likely to develop TB than HIV-uninfected individuals. TB is also the leading cause of HIV-related hospitalization and mortality. TB accounts for 27% and 30% of deaths among hospitalized HIV-infected adults and children, respectively. Also, patients with TB and HIV have poorer treatment outcomes (such as death) compared to patients with TB alone. In Uganda, about 40% of all TB cases in clinical settings are co-infected with HIV. Therefore, all patients with presumptive or diagnosed TB should be routinely screened for HIV and all PLHIV should be routinely screened for TB. The Ministry of Health further recommends that TB/HIV services should be provided at the same location and preferably by the same health worker (see **Figure 34**).

Figure 34: Algorithm for screening, diagnosis, and management of TB among PLHIV



1. Positive ICF screen is presence of current cough, fever >2-week, noticeable weight loss, excessive night sweats, **if child**-poor weight gain and history of contact with a PTB patient
2. **Danger signs for adults** refer to signs of a seriously sick person and they include respiratory rate > 30/min, temperature >39 °C, heart rate 120/min and unable to walk unaided. **Danger signs for children** include lethargy, convulsions, inability to feed, repeated vomiting, temperature above 390c and tachycardia/ tachypnoea
3. Appropriate sample types include; sputum, CSF, Gastric aspirate, urine, stool

4. Do a Molecular WHO Recommended Diagnostic (mWRD) test e.g., Genexpert, TRUENAT and TB-LAMP, if you are able to obtain a specimen, so as to rule out rifampicin resistance. Note TB LAMP does not detect rifampicin resistance.
5. For any TB LAM positive other co-morbidities such as cryptococcus, bacterial infections should be ruled out.
6. Children less than 5 years who are new and have been on ART for less than one year are eligible for a TB LAM test if they have AHD symptoms and signs (refer to the symptom screen and advanced disease management pathway).

Figure 35: Algorithm for the Diagnosis of TB in Children

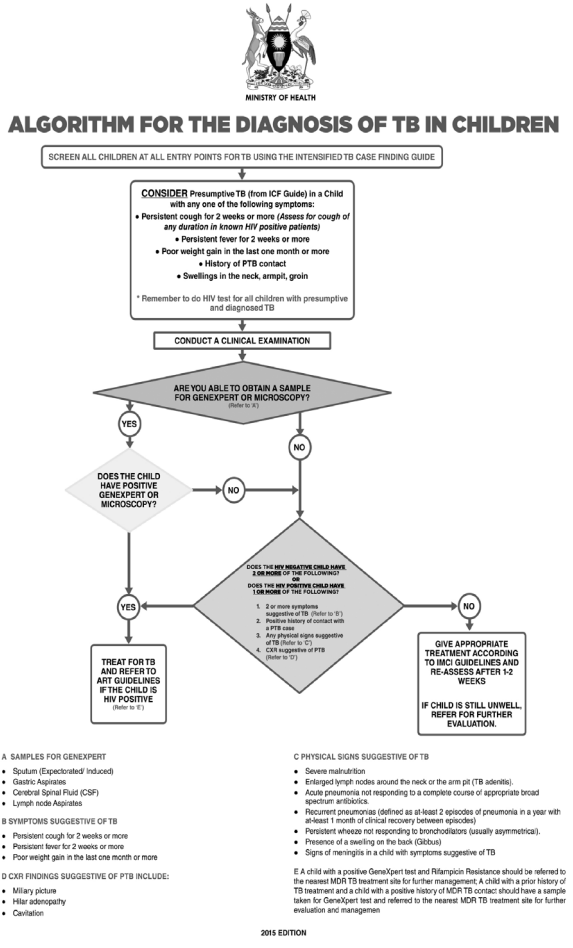
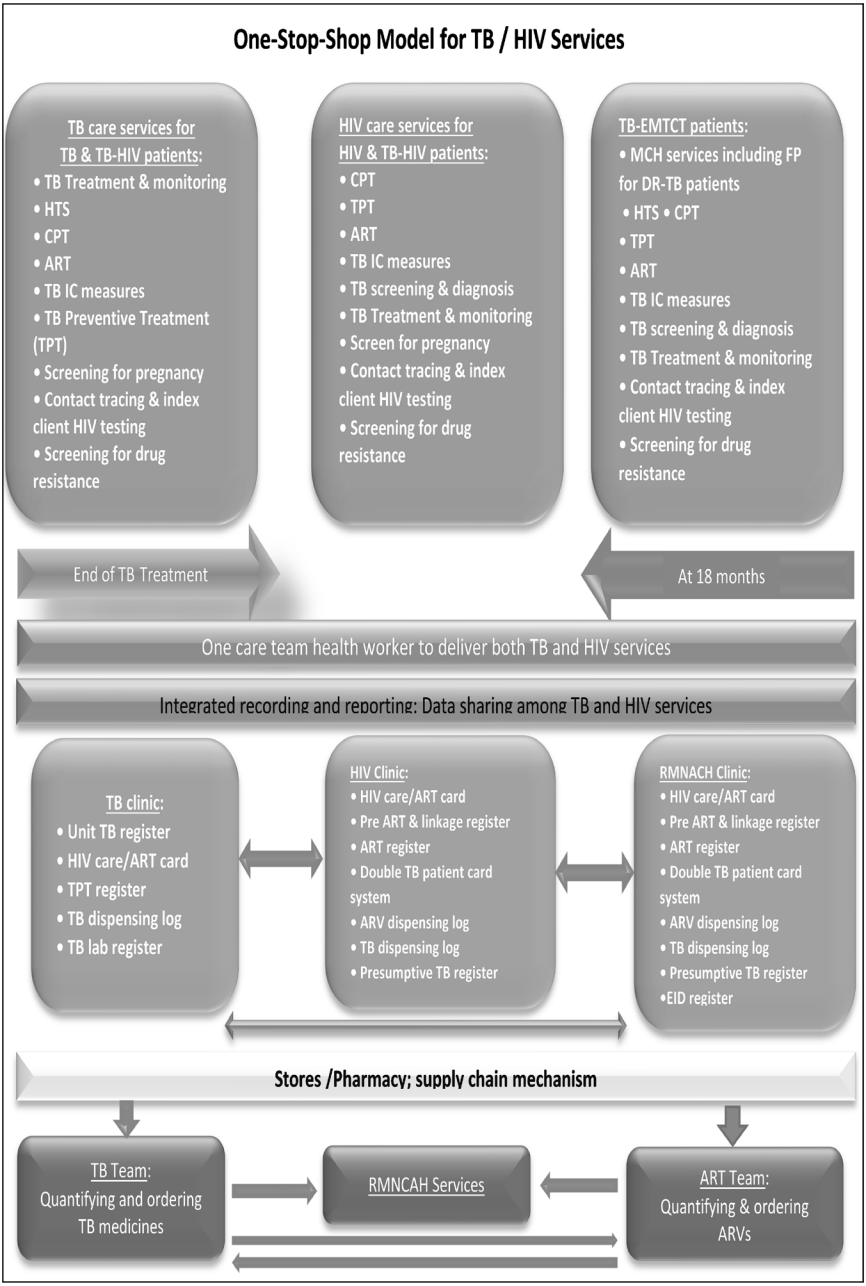


Figure 36: One stop shop model for TBHIV service delivery



TB SCREENING IN INFANTS, CHILDREN, ADOLESCENTS AND ADULTS

TB Screening

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

Tools for systematic TB screening and diagnosis among people living with HIV

All PLHIV should be screened for TB at each care visit using the ICF guide. If available, POC-CRP should be used for TB screening in addition to the symptom screen for adolescents and adults. If available, CXR should also be used for TB screening.

Note: Computer-aided detection (CAD) software programs are recommended for individuals aged 15 years and older

If the symptom screen is positive and/or CRP cutoff is more than 5mg/L, or CXR is abnormal, the client has presumptive TB and should be tested using a molecular WHO recommended rapid diagnostic test (mWRD) e.g., nucleic acid amplification test (NAAT) such as GeneXpert, TRUENAT and TB LAMP. If mWRD is not available on site, do smear microscopy and refer a sample for mWRD test. If the mWRD is negative, do further clinical evaluation and a chest X- ray to aid in clinical diagnosis of TB. (See section on diagnosis).

Note: CRP point of care test is not recommended for children younger than 10 years of age. For TB screening where CRP is not available, use a chest X-ray

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

The molecular WHO recommended rapid diagnostic (mWRD) test is the recommended TB diagnostic test for all PLHIV (Annex 6 and Annex 7) with

presumptive TB. Examples include; GeneXpert, TRUENAT, TB LAMP. For PLHIV with CD4<200 cells/ μL and seriously ill PLHIV (have danger signs), do a lateral flow urine lipoarabinomannan assay (Urine TB LAM) test because it has a shorter turnaround time followed by mWRD which is more sensitive and can detect rifampicin resistance (*note that among mWRDs, the Xpert MTB/RIF detects rifampicin resistance in a single step whereas the TRUNAT detects rifampicin resistance in two steps).* If either test is positive, classify patient as PBC (Pulmonary Bacteriologically Confirmed) and start anti-TB treatment. In health facilities without on-site access to mWRD, smear microscopy (Ziehl- Nielsen/Fluorescent microscopy) TB test should be performed and a second sample referred for mWRD testing using the hub transport system. If the mWRD is positive and indicates rifampicin resistance, refer the patient to an MDR-TB treatment site.

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

Note: The mWRD used should have the capacity to detect rifampicin resistance.

TB Treatment

The recommended TB treatment regimens for TB-HIV co-infected patients are similar to those used for HIV-negative individuals with TB (Table 35).

Table 35: Anti-TB treatment regimens for infants, children, adolescents, and adults

Population group	Site of TB disease	Regimen	
		Intensive phase	Continuation phase
Adults and Adolescents	All forms of TB (Excluding TB Meningitis and bone TB)	2RHZE	4RH
	TB Meningitis Bone (osteoarticular) TB	2RHZE	10RH
Children	All forms of TB (Excluding TB Meningitis and bone TB)	2RHZ+E*	4RH
	TB Meningitis Bone (osteoarticular) TB	2RHZ+E*	10RH

For all PLHIV patients:
1. Xpert MTB +ve/Rif sensitive: Treat as a new patient.
2. Xpert MTB +ve/Rif resistant: Refer to MDR-TB treatment site for further management.
3. Xpert MTB +ve/Rif indeterminate: Start First line TB treatment and send sample for culture and drug susceptibility testing.
4. Xpert MTB Trace/Rif indeterminate: Start First line TB treatment and send sample for culture and drug susceptibility testing.

*In children, Ethambutol should be given as separate tablet using the recommended dosages

Table 36: Dosage of Anti TB medicines by weight band for children

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

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

Table 37: Dosage of Anti TB medicines by weight band for adults

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

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

Table 38: Dosage of Anti TB medicines by weight for children and adults

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

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.

Timing of ART for adults, adolescents and children being treated for HIV-associated TB

ART should be started as soon as possible within two weeks of initiating TB treatment, regardless of CD4 cell count, among people living with HIV (Except when signs and symptoms of meningitis are present)

- If the patient is already on ART, start TB treatment immediately and adjust the ART regimen as recommended (Table 36 and Table 37).
- If the patient is not on ART, initiate anti-TB treatment immediately and start ART two weeks after initiation of TB treatment.
- If the patient is not on ART and is diagnosed with MDR-TB, ART should be initiated 4-6 weeks after second-line TB treatment initiation. However, if the patient is already on ART, continue ART and adjust ART regimen as per the MDR TB guidelines.

First-line ART regimen for TB/HIV co-infected patients who are not on ART

There are situations when a new patient is diagnosed with both HIV and TB. The recommended first line regimen for a TB patient initiating ART are as indicated in **Table 39**.

Table 39: ART regimens for TB/HIV co-infected patients initiating First- and Second -line ART

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

Children< 20Kg	ABC+3TC+ DTG Increase dose of DTG to twice a day	If ABC is contraindicated, use AZT:
		AZT+3TC+DTG Increase dose of DTG to twice a day
		If DTG is contraindicated use LPV/r or EFV or RAL or Triple NRTI:
		ABC or AZT→ +3TC+LPV/r Super-boosting LPV/r morning and evening doses with additional ritonavir (RTV) (to make LPV/r ratio of 1:1 instead of 4:1, i.e. equal doses of LPV and RTV). After TB treatment return to normal dose of LPV/r. OR Substitute Rifampicin with Rifabutin
		ABC or AZT→+3TC+EFV In children >3 years or weighing >10Kg- Substitute EFV with DTG or LPV/r after TB treatment
		ABC or AZT → +3TC + RAL Double the dose of RAL -substitute RAL with DTG or LPV/r after TB Treatment
		ABC+3TC+AZT In children <3 years or weighing <10Kg- Substitute AZT with DTG or LPV/r after TB treatment

Patient category	**Recommended ART regimen**	**Alternative ART regimens**
		Second Line
Adults and adolescents ≥30Kg, including pregnant and breastfeeding women	AZT or TDF+3TC+ DTG or TAF+FTC +DTG Increase dose of DTG to twice a day	AZT or TDF +3TC+LPV/r or TAF+FTC+LPV/r Double both the morning and evening doses of LPV/r. After TB treatment return to normal dose of LPV/r. OR Substitute Rifampicin with Rifabutin
	AZT or TDF +3TC+ATV/r TAF+FTC+ATV/r Substitute Rifampicin with Rifabutin	

Children ≥ 20Kg – <30Kg	TAF + FTC + DTG or AZT or ABC→ +3TC+DTG Increase dose of DTG to twice a day	TAF +FTC + LPV/r or AZT or ABC→ +3TC+LPV/r Double both the morning and evening doses of LPV/r. After TB treatment return to normal dose of LPV/r. Substitute Rifampicin with Rifabutin
	TAF+FTC +DTG or AZT or ABC→ +3TC+LPV/r Substitute Rifampicin with Rifabutin OR Double the am and pm dose of LPV/r	TAF + FTC + DRV/r or AZT or ABC→ +3TC+DRV/r Substitute Rifampicin with Rifabutin
Children <20Kg	AZT or ABC→ +3TC+DTG Increase dose of DTG to twice a day	AZT or ABC → +3TC+LPV/r Super-boosting LPV/r morning and evening doses with additional ritonavir (RTV) (to make LPV/r ratio of 1:1 instead of 4:1, i.e. equal doses of LPV and RTV). After TB treatment return to normal dose of LPV/r. OR Substitute Rifampicin with Rifabutin
		TAF or AZT or ABC → +3TC + RAL Double the dose of RAL (substitute RAL with DTG or LPV/r after TB Treatment)
	AZT or ABC → +3TC+LPV/r Substitute Rifampicin with Rifabutin OR Double the am and pm dose of LPV/r	AZT or ABC → +3TC+DRV/r Substitute Rifampicin with Rifabutin

Note: for patients on rifapentine based regimen, look out for potential drug-drug interactions

ART and TB treatment Drug interaction

Patients should be initiated on ART following the ART guidelines for initiating 1st and 2nd line ART (See **Table 39**), however, considerations must be taken to avoid drug-drug interactions that interfere with the effectiveness of ART (see Table 40 and Table 82).

Notes:

1. The use of Rifampicin with PIs is contraindicated. These guidelines recommend substitution of Rifampicin with Rifabutin when using PIs. However, in the absence of Rifabutin:
2. LPV/r can be given at double the usual dose (give double the dose in the morning and double the dose in the evening). In children <20kg who are on LPV/r regimens, super boost the morning and evening doses with ritonavir with additional ritonavir (RTV) (to make LPV/r ratio of 1:1 instead of 4:1, i.e. equal doses of LPV and RTV). After TB treatment return to normal dose of LPV/r.
3. Doubling the dose of ATV/r or DRV/r is NOT recommended. ATV/r and DRV/r should only be used with a TB regimen containing Rifabutin. In the scenario where Rifabutin is unavailable, an alternative ARV should be selected.
4. For patients initiating 2nd line ART, it is important to take into consideration the previous failing regimen to ensure selection of an effective regimen for use in 2nd line ART-TB co-treatment.
5. Raltegravir (given as a double dose) is recommended in TB-HIV co-treatment for children who cannot tolerate double dosing of LPV/r or for whom Rifabutin is unavailable for treatment with DRV/r.
6. Children <20Kg on TB treatment should only be initiated on a triple NRTI regimen (ABC+3TC+AZT) if all the other options provided in the table above are not feasible, as this is an inferior regimen.

   After completion of TB treatment, all ART regimens that are not optimal, should be optimized (in line with the ART guidelines).

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

Anti-TB treatment should be initiated immediately upon diagnosis while continuing ART. However, the ARV regimen should be reviewed and may need substitutions to ensure optimal treatment of both TB and HIV and to decrease the potential for toxicities and drug–drug interactions (**Table 40**).

Table 40: ARV regimen substitutions for patients initiating TB treatment while already on ART

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

Age Group	Regimen when diagnosed with TB	Recommended action/substitution
Children ≥ 20Kg-<30Kg	If on DTG-based regimen	Continue the same regimen but increase the dose of DTG to twice daily. After TB treatment, return to DTG once a day.
	If on EFV-based regimen*	Continue the same regimen. After TB treatment optimize the regimen if virally suppressed (substitute EFV with DTG). If not virally suppressed switch to 2nd line ART
	If on NVP -based regimen*	• Substitute NVP with EFV (if >3 years and >10Kg) OR • If EFV is contraindicated, give a triple NRTI regimen (ABC+3TC+AZT). After TB treatment optimize treatment with a DTG-based regimen if virally suppressed. If not virally suppressed switch to 2nd line ART
	If on LPV/r-based regimen	Double both the morning and evening doses of LPV/r. After TB treatment return to normal dose of LPV/r. OR Substitute Rifampicin with Rifabutin. If the child cannot tolerate double dose of LPV/r a. Substitute LPV/r with Raltegravir. Double the dose of Raltegravir. Return to LPV/r after completion of TB treatment.
	If on DRV//r-based regimen	Substitute Rifampicin with Rifabutin
Children <20Kg	If on DTG-based regimen	Continue the same regimen but **increase the dose of DTG to twice daily**. After TB treatment, return to DTG once a day.
	If on LPV/r-based regimen	Continue the same regimen but either Super-boosting LPV/r morning and evening doses with additional ritonavir (RTV) (to make LPV/r ratio of 1:1 instead of 4:1, i.e. equal doses of LPV and RTV) After TB treatment return to normal dose of LPV/r. OR Substitute Rifampicin with Rifabutin. If the child cannot tolerate double dose of LPV/r a. Substitute LPV/r with Raltegravir. Double the dose of Raltegravir. Return to LPV/r after completion of TB treatment.

Age Group	Regimen when diagnosed with TB	Recommended action/substitution
	If on NVP-based regimen*	• If >3 years and >10Kg substitute NVP with EFV. • If EFV is contraindicated, give a triple NRTI regimen (ABC+3TC+AZT). • If <3 years and <10Kg give triple NRTI regimen (ABC+3TC+AZT). After TB treatment optimize treatment with a DTG or LPV/r -based regimen if virally suppressed. If not virally suppressed switch to 2nd line ART.
	If on DRV/r-based regimen	Substitute Rifampicin with Rifabutin

Note:

1. In case ARVs are to be substituted in patients initiating TB treatment while on ART, careful consideration of previous ART regimens should be taken in order not to give an ARV to which the client may already have resistance.
2. Raltegravir (given as a double dose) is recommended in TB-HIV co-treatment for children who cannot tolerate double dosing of LPV/r or for whom Rifabutin is unavailable for treatment with DRV/r.
3. Children on NVP-based regimens should be switched to a triple NRTI regimen (ABC+3TC+AZT) only if EFV is contraindicated, as this is an inferior regimen.
4. *After completion of TB treatment, ensure that the ART regimen is optimized:
5. If virally suppressed, optimize the regimen.
6. For adults, when optimizing 2nd line PI-based regimens, ensure that the client was not previously exposed to DTG in the 1st line ART regimen. If the client was on a DTG-based 1st line ART Regimen and is currently on a PI-based 2nd line regimen and virally suppressed, maintain the PI-based regimen after TB treatment.
7. If viral load is not suppressed switch the client to 2nd or 3rd line following the recommendations in Chapter 13 (see recommended first and second line in Table 81).

Treatment of people with drug-resistant TB

WHO recommends ART for all people with HIV and drug-resistant TB, requiring second-line anti-TB drugs irrespective of CD4 cell count, as early

as possible (within the first eight weeks) following initiation of anti-TB treatment

Note: Multidrug-resistant TB is TB that is resistant to at least isoniazid and rifampicin. People with both HIV and multidrug-resistant TB face complicated clinical management, fewer treatment options and poorer treatment outcomes

TB PREVENTION

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

TB Preventive Treatment (TPT)

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

Algorithms to rule out active TB disease

Adults and adolescents living with HIV should be screened for TB according to a clinical algorithm. Those who do not report any of the symptoms of current cough, fever, weight loss or night sweats are unlikely to have active TB and should be offered preventive treatment, regardless of their ART status.

Adults and adolescents living with HIV who are screened for TB according to a clinical algorithm and who report any of the symptoms of current cough, fever, weight loss or night sweats may have active TB and should be evaluated for TB and other diseases and offered preventive treatment if active TB is excluded.

Chest radiography may be offered to people living with HIV receiving ART and TB preventive treatment given to those with no abnormal radiographic findings

Infants and children living with HIV who have poor weight gain, fever or current cough or who have a history of contact with a person with TB

should be evaluated for TB and other diseases that cause such symptoms. If TB disease is excluded after an appropriate clinical evaluation or according to national guidelines, these children should be offered TB preventive treatment, regardless of their age.

The following regimens could be used for TPT as guided in **Table 41** and **Table 42** below:

- 6H: Daily Isoniazid for 6 months.
- Note: Isoniazid may be available in combination with co-trimoxazole and pyridoxine as a fixed dose combination referred to as Q-TIB: In this case, Q-TIB is also administered daily for 6 months.
- 3HP: Weekly Isoniazid and Rifapentine for 3 months (Recommended for patients aged more than 2 years).
- 3RH: Daily Rifampicin and Isoniazid for 3 months (Recommended for children less than 15 years).

NOTE: Isoniazid containing TPT should be coupled with pyridoxine to prevent peripheral neuropathy

Eligibility for TPT

- Infants aged <one year living with HIV who are in contact with a person with TB and who are unlikely to have active TB on an appropriate clinical evaluation or according to national guidelines should receive TB preventive treatment
- HIV-positive children (≥one year of age), adolescents and adults with no signs and symptoms of TB irrespective of ART status
- HIV-positive infants and children <5 years with a history of TB contact who have no signs and symptoms of active TB disease, irrespective of previous TPT.
- HIV-positive pregnant mothers with a history of contact with a TB patient a after ruling out active TB.
- HIV-positive pregnant mothers with a WHO Stage 3 or 4 event and/or CD4<200 without active TB.
- TPT should also be given to those who have previously been treated for TB immediately after completing TB treatment.
- Note:
- TPT should be offered to eligible patients irrespective of the degree of immunosuppression and even when latent TB infection testing is unavailable.
- **For HIV-positive pregnant mothers without a history of TB exposure, TPT will be deferred until 3 months after delivery.**

- For HIV positive women and adolescent girls **on TPT who get pregnant**, continue and complete the TPT while closely monitoring for side effects.

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

Table 41: TPT regimen for adolescents ≥ 15 years and adults on ART

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

Table 42: TPT regimen for children < 15 years on ART

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

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

Timing of TPT in children

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

Co-administration of DTG and TPT

Although studies have found that the co-administration of DTG and INH is well tolerated, liver injury is a recognized adverse effect of each of

these drugs. Since there is potential for hepatotoxicity, the following are recommendations for co-administration.

a. New Patient: For newly identified patients, start on TLD with active symptomatic monitoring for adverse events (Chapter 14). Initiate TPT after 3 months to allow time for potential unmasking of TB and to monitor any toxicities that may arise from DTG, prior to initiation of TPT.

b. For stable patients already transitioned to DTG: If patient has been on TLD for 3 months or more, initiate TPT immediately.

c. If client is already on TPT and a non-DTG based regimen: Optimization to DTG will be deferred until completion of TPT.

d. Stable patients for DTG transition and have not received TPT before:
   a. In case TLE stock is available: First complete TPT and then transition to DTG.
   b. In case TLE stock is not available: Transition to DTG and initiate TPT after 3 months.

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

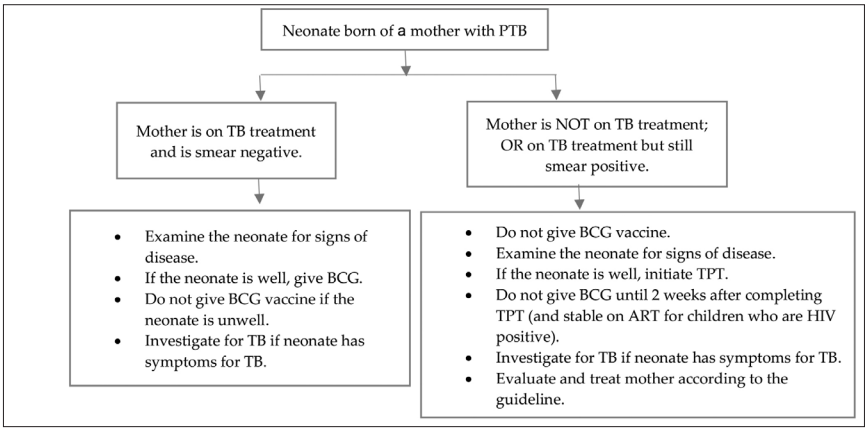
Table 43: TPT dosing table

Medicine frequency & duration	Formulation	Dose of TPT medicine (mgs)	Dose/ weight	Recommended number of tablets per body weight in kilograms								
3HP (once weekly rifapentine plus isoniazid for 3 months)	Fixed Doze Combination (FDC) Tablet			3–5.9 kgs	6–9.9 Kgs	10–15 kgs	16–23 kgs	24–30 kgs	31-34 kgs	35-45 kgs	>45 kgs	
		Rifapentine 300mg/ Isoniazid 300mg				1	1.5	2	2.5	3	3	
	Single medicine tablet	Pyridoxine 25mg/day				1	1	1	1	1	1	
6H (daily isoniazid for 6 months)				3–5.9 kgs	6–9.9 Kgs	10–13.9 kgs	14–19.9 kgs	20–24.9 kgs	25-34.5 kgs	35-44.5 kgs	45-49.9 kgs	≥50 kgs
	Single medicine tablet	Isoniazid 100 mg	<10 years 10mg/kg	0.5	1	1.5	2	2.5				
			> 10 years 5mg/kg						1.5	2	2.5	
		Isoniazid 300 mg	> 10 years 5mg/kg									1
	Single medicine tablet	Pyridoxine 25 mg		0.5	0.5	1	1	1	1	1	1	1
3RH (daily Rifampicin Isoniazid for 3 months)				< 4 kgs	4-7 Kgs	8-11 kgs	12-15 kgs	16–24 kgs	25-32 kgs	33-39 kgs	40-54 kgs	
	Fixed Doze Combination (FDC) Tablet	RH 75mg/50mg	< 10 years R - 15mg/kg H - 10mg/kg	0.5	1	2	3	4	4			
		RH 150mg/75mg	> 10 years R - 10mg/kg H - 5 mg/kg							2	3	
	Single medicine tablet	Pyridoxine 25 mg/day		0.5	1	1	1	1	1	1	1	

BCG vaccination

BCG is protective against severe forms of TB such as miliary TB and TB Meningitis and is administered at birth in Uganda. However, if an infant did not receive BCG at birth and is **confirmed to be HIV-positive**, s/he should not be given BCG unless they are stable on ART. The follow up of a neonate born to an HIV-positive mother with active TB is summarized in **Figure 38**.

Figure 37: Follow up of a Neonate born to an HIV-positive Mother with Active TB.



COTRIMOXAZOLE PREVENTIVE THERAPY

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

The following groups have been prioritized for cotrimoxazole preventive therapy:

- All PLHIV newly initiating on ART.
- Those having a current WHO stage 3 or 4 event or other symptoms of advanced disease.
- Pregnant and breast-feeding women.

Note: Additional intermittent preventive treatment for malaria using Sulfadoxine-Pyrimethamine (SP) is not required for pregnant women on CPT.

- Children and adolescents aged 0-15 years.
- Patients with treatment failure or having AHD.

Table 33: Cotrimoxazole dosing

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

Co-trimoxazole toxicity

Adverse effects of Co-trimoxazole are rare but include skin rash, Stevens-Johnson syndrome, anaemia, neutropenia, jaundice and renal failure. In the event of skin reaction to Cotrimoxazole, see guidance on management in Table 34.

Table 34: Management of Cotrimoxazole hypersensitivity

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

Guidance for when to stop CPT in stable PLHIV

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

- Patient should be older than 15 years of age.
- Patient should not be pregnant.

- Patient should have been on ART for at least one year.
- Patient should not have a current WHO stage 3 or 4 event or other symptoms of advanced HIV disease at the time of stopping CPT.

Restarting CPT in PLHIV

CPT can be restarted in the following scenarios:

- **New pregnancy**
  In case **CPT** was stopped earlier (in stable women), re-start CPT and maintain it throughout pregnancy and in the immediate postpartum period (up to 6 weeks after delivery).
- **Suspected treatment failure**
  If VL becomes unsuppressed in a patient whose CPT was previously discontinued, re-start CPT and continue until the VL is again suppressed.
- **New Treatment WHO stage 3 or 4 condition**
  In case CPT was discontinued earlier, it should be restarted when a patient develops an active WHO stage 3 or 4 infection and continued until the condition has been treated and resolved.

Contraindications to CPT

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

Alternate Drugs for Hypersensitivity or Contraindication to Cotrimoxazole

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

Dapsone dosing

- Weight of ≥25Kg: 100mg once a day or 1.4mg/kg in children

5.4.2 HIV and Cryptoccoccal Infection

In Uganda, Cryptococcal Meningitis (CM) is associated with mortality of up to 39%. Patients with a CD4 cell count of <200 cells/mm^3 are at the

highest risk of CM. This section describes screening and management of early Cryptococcal disease.

Screening and management of early Cryptococcal disease

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

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

How to screen for Cryptococcal disease

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

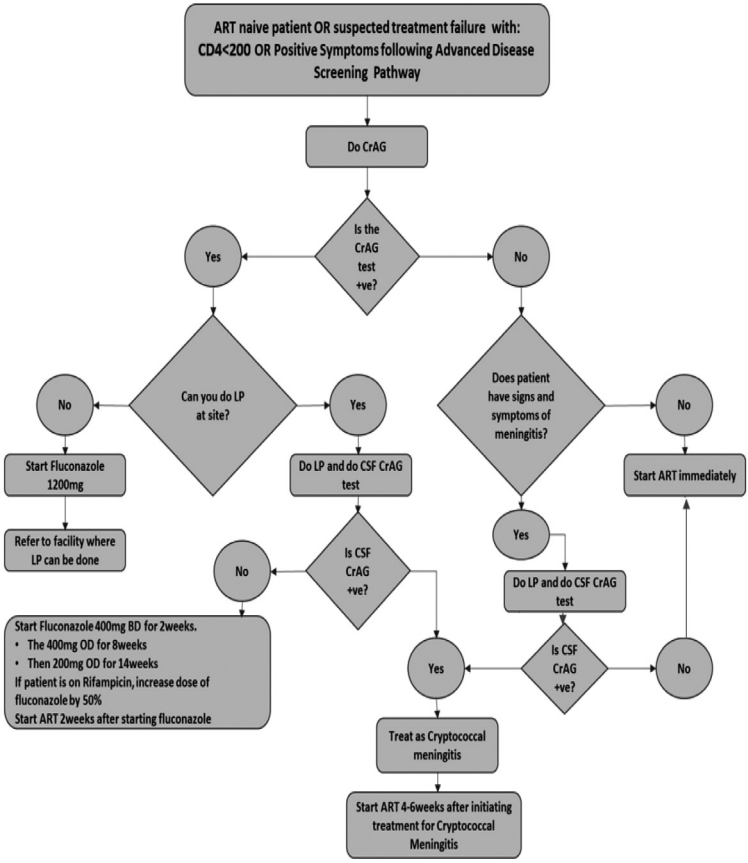
For serum CrAg positive patients at facilities where lumbar puncture can be performed

- Patients with a positive serum CrAg should be assessed for early and late signs and symptoms of CM including decreased hearing, dizziness or light-headedness, cognitive delay (acting unusual to friends, family or provider), difficulty walking, double or blurry vision, weak arms or legs, headache, presence of seizures, altered consciousness, photophobia, neck stiffness, or a positive Kernig's or Brudzinski sign.
- Patients with a positive serum CrAg are at high risk of having CM even in the absence of symptoms. Therefore, a lumbar puncture is recommended for all patients with a positive serum CrAg test to exclude CM. The CrAg test should be conducted on CSF.
  - If the CSF CrAg test is negative with or without signs of CNS disease: the patient has Cryptoccoccal disease but without CNS involvement and the patient should be started on pre-emptive therapy.
  - If the CSF CrAg test is positive, the patient has CM and should be treated for Cryptococcal Meningitis (see **Table 44**).

Table 44: Treatment regimen for non-meningeal Cryptococcal disease

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

Figure 38: Algorithm for screening and managing Cryptococcal disease



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

Health workers at some health facilities may not be trained to do LPs. Patients at such sites should also be assessed for signs of CM. Patients with early or late Cryptococcal disease findings 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 decreased hearing, dizziness or light-headedness, cognitive delay (acting unusual to friends, family or provider), difficulty walking, double or blurry vision, weak arms or legs, headache, presence of seizures, altered consciousness, photophobia, neck stiffness, and a positive Kernig's or Brudzinski's sign.

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

Diagnosis of Cryptococcal Meningitis

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

Treatment of Cryptococcal Meningitis

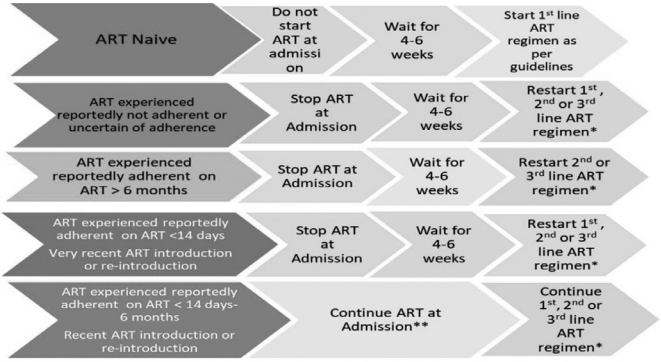
There are three phases in the treatment of Cryptococcal Meningitis: the induction phase, consolidation phase, and maintenance phase. The drugs for the different phases, duration of treatment, when to initiate ART, when to stop antifungals, how to prevent drug toxicity, how to manage increased intracranial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

Considerations for drug interactions during treatment of Cryptococcal disease

- Antifungals and aminoglycosides (e.g. Gentamicin): Increased risk of nephrotoxicity. Avoid combining the drug classes.

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

Figure 39: ART timing with CCM



*Decision on which ART regimen to restart should be made according to patient's history, ART guidelines, HIV viral load and genotypic resistance testing if possible. If it is considered likely that the patient has developed resistance to 1st line ARVs, then restart with 2nd line containing boosted PI or DTG is possible. ** Unless documented to have a suppressed viral load at time of admission or within the month prior to admission, in which case continue ART

Table 45: Management of Cryptococcal Meningitis

Phase	Drug	Comments
Newly Diagnosed Patient		
Induction Phase (2 weeks)	Recommended: Amphotericin B liposomal single high dose (10mg/kg) + Flucytosine (100mg/kg/day in four divided doses) + Fluconazole 1200mg/day for 14 days Or Amphotericin B deoxycholate (1mg/kg/day) + Flucytosine (100mg/kg/day in four divided doses) for 1 week, followed by 1 week of fluconazole (1200 mg/day for adults, 12 mg/kg/day for children and adolescents). Or Fluconazole (1200 mg daily for adults, 12 mg/kg/day for children and adolescents) + Flucytosine (100 mg/kg/day, divided into four doses per day. Or Amphotericin B deoxycholate (1mg/kg/day) + high-dose Fluconazole 1200mg/day. Or Alternative: Fluconazole 1200mg/day (or 6-12mg/kg/day in children)	Preventing Amphotericin toxicity: To prevent nephrotoxicity and hypokalemia, for patients on amphotericin deoxycholate do the following: • Pre-hydration with 1L normal saline before starting the daily Amphotericin B 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 (mixed in 500ml NS over 4 hours) of potassium chloride or 1 tablet of 600mg twice daily while on amphotericin B can decrease the incidence of Amphotericin B-related hypokalemia. • For electrolyte supplementation, two tablets daily of Magnesium Chloride 310 mg or slow Magnesium Chloride 535mg or Magnesium trisilicate 250mg while on amphotericin B • Consider alternate day Amphotericin B if creatinine is >3mg/dl. • To monitor for flucytosine (5FC) toxicity, CBC with differential counts at least twice weekly is recommended

Consolidation phase (8 weeks)	Fluconazole 800mg/day (or 6-12mg/kg/day in children and adolescents)	Initiate ART 4–6 weeks after starting CM treatment and there is clinical response to antifungal therapy.
Maintenance Phase (18 months)	Fluconazole 200mg/day (or 6 mg/kg/day up to 200mg in children and adolescents)	Criteria to stop after a minimum of 18 months of maintenance phase: Adults: VL<1,000 copies/mm^3 & CD4 ≥ 200 or CD4 ≥200 (if viral load not available) after 12 and 18 months Children: If CD4>25% or viral suppressed
Relapse disease		
Presents with a recurrence of symptoms of Meningitis and have a positive cerebrospinal fluid culture following a prior confirmed diagnosis of Cryptococcal Meningitis. Evaluate for drug resistance: Send CSF to Central Public Health Laboratory (CPHL) for culture and sensitivity testing, if there are no drug resistance results, re-initiate the induction therapy for two weeks and complete other phases of treatment.		
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 >250mm H_2O will need a therapeutic LP the following day to reduce the CSF pressure to <200 mm. In the absence of a manometer, one may use an IV giving set to create an improvised manometer measuring the height with a meter stick. Removing 20-30mL of CSF (even in the absence of a manometer) may be adequate to decrease CSF pressure. Most patients will need 2-3LPs during the induction phase.		

Table 46: Liposomal Amphotericin B dosing weight bands

Patient's weight (Kg)	Number if vials	Total dose of Liposomal Amphotericin B (mg)	Volume of reconstituted LiposomalAmphotericin in ml at 4mg/ml	Additional dextrose (ml) to create 500ml total infusion
36-40	8	400	100	400
41-45	9	450	112.5	387.5
46-50	10	500	125	375
51-55	11	550	137.5	362.5
56-60	12	600	150	350
61-65	13	650	162.5	337.5
66-70	14	700	175	325
71-75	15	750	187.5	312.5
76-80	16	800	200	300
81-85	17	850	212.5	287.5
86-90	18	900	225	275

Table 47: Flucytosine (5FC) dosing weight bands

Weight (kg)	Daily dose (mg) 100mg/kg	Number of tablets per day	A suggested schedule of dosing (Meds dosed 6 hourly)			
35-39	3500	7	2	2	2	1
40-44	4000	8	2	2	2	2
45-49	4500	9	3	2	2	2
50-54	5000	10	3	2	3	2
55-59	5500	11	3	3	3	2
60-64	6000	12	3	3	3	3
65-69	6500	13	4	3	3	3
70-74	7000	14	4	3	4	3
75-79	7500	15	4	4	4	3
80-84	8000	16	4	4	4	4

5.4.3 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 49 below describes the signs, symptoms and management of PJP.

Table 49: Signs/symptoms, management and prevention of *Pneumocystis Jiroveci Pneumonia*

Signs and symptoms	**Symptoms:** Progressive exertional dyspnea (95%), fever and chills (>80%), non-productive cough (95%), chest discomfort, difficult breathing, fast breathing and weight loss. **Signs:** Pulmonary symptoms: tachypnea, pulmonary examination may reveal mild crackles and rhonchi but may yield normal findings in up to half of the patients. Children may have cyanosis, nasal flaring, and intercostal retractions.

Diagnosis	Chest X-Ray is the main diagnostic tool • Diffuse interstitial infiltrates extending from the peri-hilar region • Pneumatoceles and pneumothorax are possible but not common. • Pleural effusions and intrathoracic adenopathy are rare. ***However, the chest X-Ray may also be normal***
Management and treatment	**Admit** **Give oxygen** **Preferred therapy:** Cotrimoxazole (10-20mg/kg/day IV) for 21 days **Adjunctive therapy:** Use corticosteroids only in patients with severe PJP
Prevention	Initiate all HIV-infected people on Cotrimoxazole preventive therapy

5.4.4 HIV and Hepatitis B

Signs and symptoms	**Acute Phase:** Non specific signs and symptoms : abdominal pain, fever, nausea, vomiting, +/-jaundice. **Chronic Phase:** Chronic fatigue, ascites, bleeding under the skin, jaundice, and mental derangement.
Screening for HBV	All PLHIV initiating or failing on ART should be routinely screened for HBV infection using Hep B surface Antigen (HBsAg).
Tests in persons diagnosed with HBV infection	These tests should be done at baseline and at six months • A complete blood count. • Liver function tests (ALT,AST, albumin and bilirubin levels, and PTT). • Abdominal ultrasound scan • AFP and HBeAg if available.
Treatment of HBV/HIV co-infected person	Initiate ART with TDF or TAF -containing regimen. If ART cannot be given or if the patient refuses ART use: Peg-IFN-alfa 2a 180 mcg subcutaneously once weekly for 48 weeks *or* Peg-IFN-alfa 2b 1.5 mcg/kg subcutaneously once weekly for 48 weeks.

Follow-up after six months	Evaluate the patient for HBV treatment failure: • If jaundice, malaise and abdominal right upper quadrant pain are present **or** if LFTs are abnormal **do a viral load test.** • If HB VL unavailable or HB VL >2000IU/ml at 24 weeks of Rx: refer for further evaluation and management while continuing ART.
HBV prevention	• Risk reduction: Safe sex practices, avoid needle sharing and minimize risk from household contacts. • Screen all household members and sexual partners/ contacts • HBV vaccination to all people regardless of HIV status in endemic areas.

5.4.5 HIV and Histoplasmosis

Histoplasmosis is a disease caused by the fungus *Histoplasma Capsulatum*. Histoplasmosis is one of the most frequent opportunistic infections caused by fungal pathogens among people living with HIV. The symptoms of disseminated histoplasmosis are non-specific and may be indistinguishable from those of other infectious diseases, especially disseminated tuberculosis (TB), thus complicating diagnosis and treatment.

Table 48: Classification and Treatment regimen for disseminated Histoplasmosis disease

Classification	Induction Phase	Maintenance phase
Treating severe or moderately severe histoplasmosis among PLHIV	**Preferred regimen** liposomal amphotericin B, 3.0 mg/kg, for two weeks for children and adolescents **Alternate regimen** deoxycholate amphotericin B, 0.7– 1.0 mg/kg for two weeks	Itraconazole 200 mg twice daily for 12 months
Mild to moderate histoplasmosis among PLHIV:	Itraconazole 200 mg three times daily for three days and then 200 mg twice daily for two weeks	Itraconazole 200 mg twice daily for 12 months

Antiretroviral therapy should be initiated as soon as possible among people with disseminated histoplasmosis for whom central nervous system involvement is not suspected or proven

5.4.6 HIV and Aspergillosis

Aspergillus species continue to be an important cause of life-threatening infection in immunocompromised patients. Recent evidence suggests that chronic pulmonary aspergillosis and aspergillus sensitisation might be responsible for significant mortality in patients treated for tuberculosis in Uganda. Aspergillus infection may complicate active pulmonary TB and efforts need to be made to rule out aspergillosis in PLHIV presenting with advanced HIV disease.

There are 3 major forms of aspergillosis: invasive aspergillosis (IA); chronic (and saprophytic) forms of aspergillosis; and allergic forms of aspergillosis. Given the clinical importance of IA, emphasis is placed upon the diagnosis, treatment, and prevention of the different forms of IA, including invasive pulmonary aspergillosis (IPA), Aspergillus sinusitis, disseminated aspergillosis, and several types of single-organ IA

Signs and symptoms	Signs and symptoms depend on which organs are affected, but in general, invasive aspergillosis can cause: Fever and chills. A cough that brings up blood (hemoptysis) Shortness of breath. Chest or joint pain. Headaches or eye symptoms. Skin lesions
Risk factors	Weakened immunity Low white blood cell count Lung cavities Asthma or cystic fibrosis Long term corticosteroid therapy

Diagnosis	Imaging tests. A chest X-ray or computerized tomography (CT) scan — a type of X-ray that produces more-detailed images than conventional X-rays do — can usually reveal a fungal mass (aspergilloma), as well as characteristic signs of invasive aspergillosis and allergic bronchopulmonary aspergillosis Sputum for staining; In this test, a sample of your sputum is stained with a dye and checked for the presence of aspergillus filaments. The specimen is then placed in a culture that encourages the mold to grow to help confirm the diagnosis. Tissue and blood test; Skin testing, as well as sputum and blood tests, may be helpful in confirming allergic bronchopulmonary aspergillosis. For the skin test, a small amount of aspergillus antigen is injected into the skin of your forearm. If your blood has antibodies to the mold, you'll develop a hard, red bump at the injection site. Blood tests look for high levels of certain antibodies, indicating an allergic response. Biopsy. In some cases, examining a sample of tissue from your lungs or sinuses under a microscope may be necessary to confirm a diagnosis of invasive aspergillosis.
Management and treatment	Voriconazole (preferred) or Amphotericin B (alternate) for 6-12 weeks Prophylaxis with itraconazole for 6 months
Prevention	Avoid places where you're likely to encounter mold, such as damp places, construction sites, compost piles and buildings that store grain

5.4.7 HIV and NON-COMMUNICABLE DISEASE

Uganda suffers a dual burden of NCDs and HIV/AIDS with an overall prevalence of pre-hypertension of 38.8% among its 42 million population. HIV-infected adults experience more chronic metabolic complications because of both the HIV infection itself and ART. They are more likely to develop Diabetes Mellitus (DM), hypertension and mental illness as compared to HIV-negative individuals. Studies report that up to 10% of HIV-positive patients on ART develop DM within four years and 24.3% of 15,000 persons living with HIV (PLHIV) screened at an urban clinic in Uganda were found to be hypertensive. Currently health care services for

these conditions are organised in separate(vertical) clinics making it difficult for a patient with multiple conditions to access care. Evidence from studies have shown that Integrating care for HIV and NCDs is feasible, acceptable, less costly and a possible solution to improving access to care among patients with multiple conditions.

At each clinic visit, the patient should be screened for the common NCDs particularly diabetes mellitus, hypertension and mental health (anxiety, depression, substance and alcohol use disorders).

5.4.7.1 Diabetes Mellitus (DM)

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

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

Screening and diagnosis for DM

Patients should be assessed for risk factors for DM before initiation of ART, while on ART, and when clinically indicated using the DM screening tool. All PLHIV should thereafter be re-screened every six months (see Figure 43).

Treatment For DM

HIV-positive patients with DM should be treated as per the treatment protocol (see Figure 44) adopted from the Uganda Clinical Guidelines. However, the following should be observed:

- Reinforce lifestyle interventions at every clinic visit (refer to section 1.1.4)
  - Healthy heart diet
  - Adequate exercise (at least 30 minutes per day or 150 minutes per week)

- Weight loss/management
- Cessation of smoking
- Elimination/reduction of alcohol consumption
- Advise on foot care for all diabetics to prevent wounds/ulcers from developing.

- Metabolically neutral ARVs should be prescribed for patients at risk of developing DM. These include ABC, TDF and 3TC.
- Exclude HIV-associated nephropathy and liver toxicity before initiating metformin because it may lead to Metformin Associated Lactic Acidosis (MALA).
- HIV patients on metformin should be educated about the symptoms of lactic acidosis, including fatigue, weight loss, nausea, abdominal pain, dyspnea, and arrhythmia. Liver-related symptoms such as tender hepatomegaly, edema, ascites, and encephalopathy may occur, but jaundice is uncommon.
- The gastrointestinal side effects of metformin are increased in patients with HIV enteropathy. Metformin should, therefore, be started at a low dose and increased gradually.
- Lopinavir/r, ATV/r, and DRV/r can be used with close monitoring.
- DTG should not be used.

Figure 42: Algorithm for Screening, Diagnosis and Management of Diabetes Mellitus

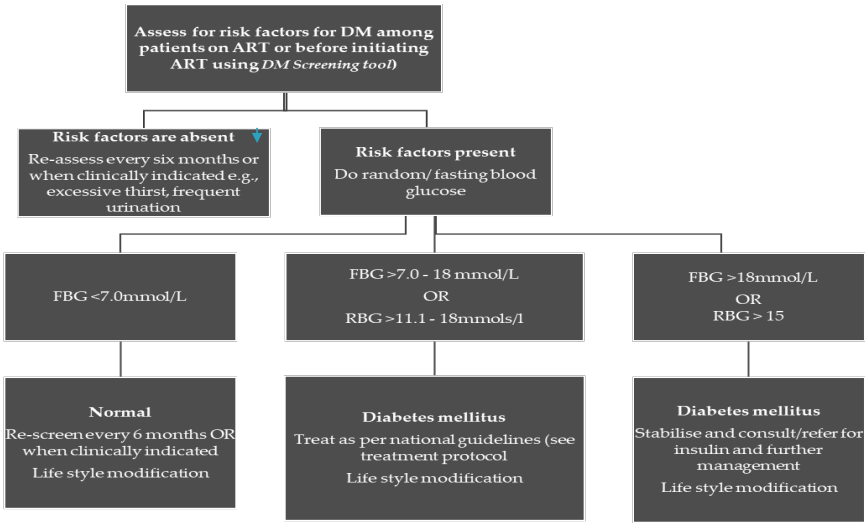


Figure 43: Treatment protocol for diabetes mellitus

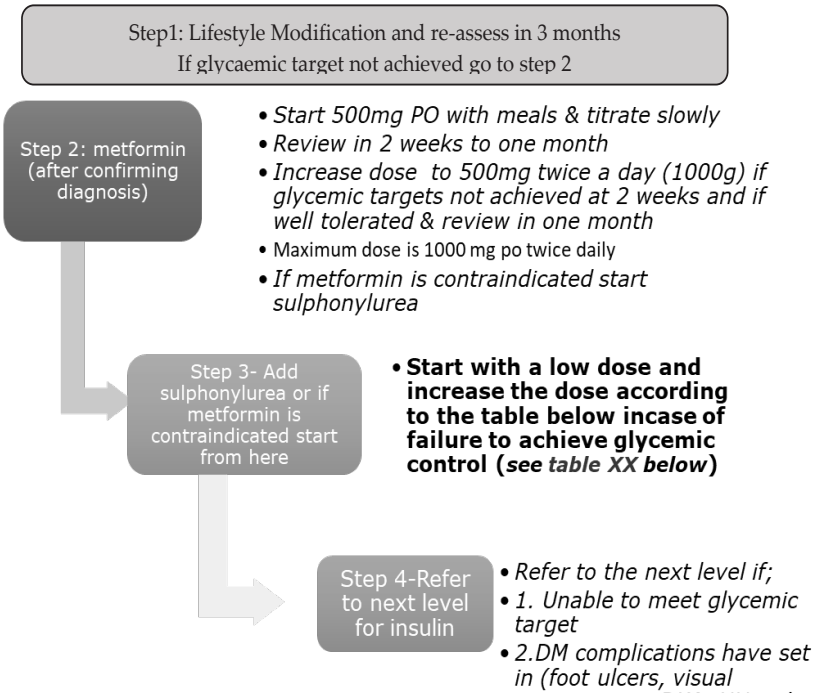


Table 55: Sulfonylurea oral glucose lowering agents with starting and escalating doses

Medication	Start-ing dose	Next dose if glucose target not met	Next dose if glucose target not met	Next dose if glucose target not met	Next dose if glucose target not met	Range of daily dosage (mg)
Glimepiride	2mg	4mg	6mg			1-6
Gliclazide controlled release	30 mg	60 mg	80 mg	160	320	30-320
Glipizide						2.5-20
Gliben-clamide	2.5 mg	5 mg	10 mg	12.5 mg	15 mg	2.5-151

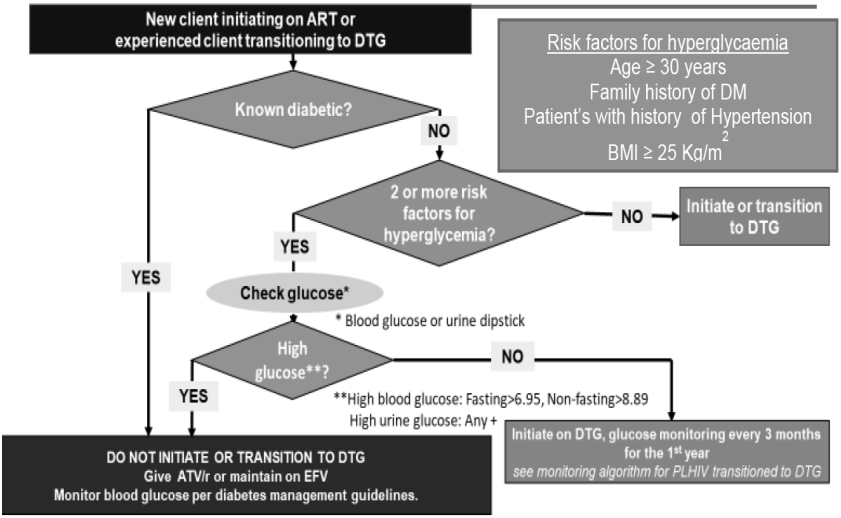
Figure 40: Contraindications for Metformin and Glibenclaminde

Metformin is contraindicated in:
•people with chronic kidney disease (estimated glomerular filtration rate (eGFR) <30 mL/minute/1.73m2)
•people with severe reduced liver function
•people with acute cardiac insufficiency
•people with respiratory insufficiency
•people who abuse alcohol

Glibenclamide is not recommended in:
•people aged 50 years or older
•people with severe liver disease
•in patients for whom hypoglycemia is a concern (people who are at risk of falls, who have impaired awareness of hypoglycemia, who live alone)
•people who drive or operate machinery as part of their job.

INTERACTIONS OF METFORMIN MEDICINE WITH DTG
Metformin and DTG**: a lower dose of metformin may be needed with closer monitoring of blood glucose

Figure 44: DM Screening Algorithm for PLHIV Transitioning to DTG

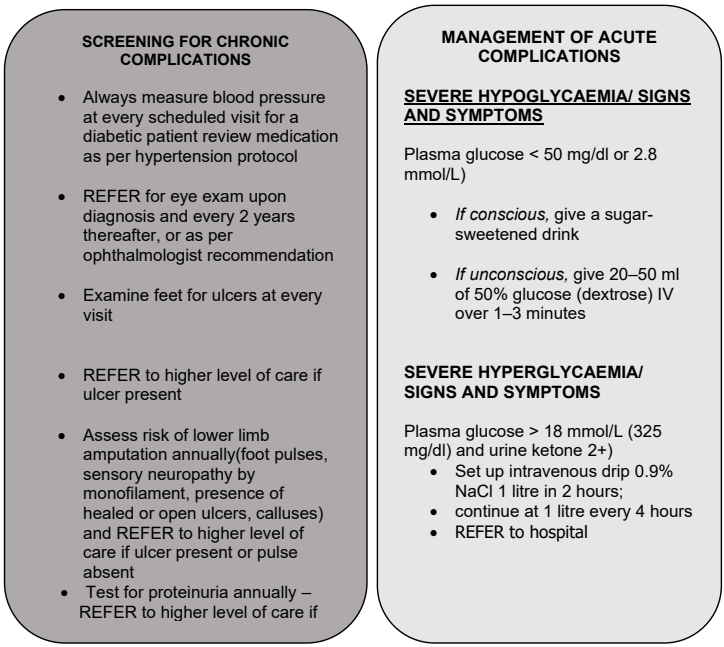


Screening and management of complications of Diabetes Mellitus

Good control of diabetes results in the reduction of occurrence of complications such as retinopathy (visual problems), nephropathy (kidney problems), Neuropathy (problems of the nerves of extremities),

cardiovascular disease including hypertension. It is therefore important for a healthworker to encourage the patient to adhere to treatment for glycemic control and be screen as often as possible for early identification and management

Figure 45: Screening for Complications with DM



Screening, Diagnosis and Management of Obesity

According 2021 global nutrition, 10.4% of the adult women (>18 years) and 2.3% of the adult males are obese in Uganda and yet the country has shown little progress towards achieving diet related NCD targets. Obesity is a preventable medical disorder involving excessive body fat and often increases the risk of health problems/diseases such as heart disease and diabetes

Risk factors for obesity

Although there are genetic, behavioural, metabolic and hormonal influences on body weight, obesity occurs when you take in more calories than you burn through normal daily activities and exercise. The risk factors that can be modified include; an unhealthy diet i.e high in calories, lacking in fruits and vegetables, b. inactivity: Sedentary lifestyle, c. Stress, d. some medical conditions can lead to weight gain

Figure 46: WHO classification of weight status and calculation of BMI

WHO CLASSIFICATION OF WEIGHT STATUS	
WEIGHT STATUS	**BODY MASS INDEX (BMI), kg/m^2**
Underweight	<18.5
Normal range	18.5 – 24.9
Overweight	25.0 – 29.9
Obese	≥ 30
Obese class I	30.0 – 34.9
Obese class II	35.0 – 39.9
Obese class III	≥ 40

BMI is calculated to classify a person's weight and diagnose obesity. For example, for a person with weight 70Kg and Height 170cm:

BMI = 70/ (1.7)2 = 24.2 (Normal BMI)

Prevention and Management: Lifestyle modification

Advise patients to do the following:

- Eat a healthy balanced diet: rich in fresh fruits and vegetables, avoid carbonated beverages, reduce alcohol intake or quit alcohol
- Increase physical activity to equivalent of 30 minutes of aerobic exercise a day, at least 5 days every week
- Consistency and discipline are Key

5.4.7.2 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, dyslipidemia, history of adverse cardiovascular event like stroke and heart attack and unhealthy diet at every visit. They should also have their blood pressure (BP) measurement at every clinic visit. Note that protease inhibitors can also contribute to increased cardiovascular disease risk. Persistently high resting BP defined as >140/90mmHg on at least two measurements five minutes apart with the patient seated should be managed as guided by the algorithm (Figure 47). People with any risk factor identified should be advised to modify lifestyle as described below.

Figure 47: Algorithm for diagnosis and management of hypertension

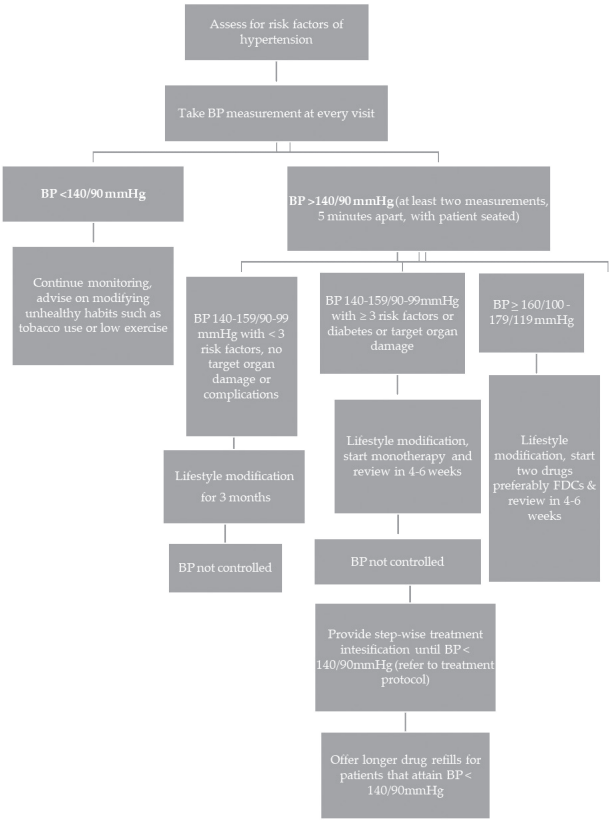


Table 56: Hypertension Treatment Protocol

	Preferred drugs	Alternative 1	Alternative 2	Least Level of care
Step 1: If BP is ≥ 140-159/90-99 mmHg with < 3 risk factors, no target organ damage. Follow-up in 3months	Offer Lifestyle modification			HC2

Step 2: If BP is ≥ 140/90mmHg, Follow-up in 4 weeks	Amlodipine 5mg	Amlodipine 5mg	Bendroflu-methiazide 2.5mg once daily	HC3
Step 3: If BP is ≥ 140/90mmHg, Follow-up in 4 weeks	Amlodipine 5mg + Valsartan 80mg	Amlodipine 5mg + Losartan 25mg	Bendroflu-methiazide 5mg once daily	HC3
Step 4: If BP is ≥ 140/90mmHg, Follow-up in 4 weeks	Amlodipine 10mg + Valsartan 80mg	Amlodipine 10mg + Losartan 25mg	Bendroflu-methiazide 5mg + Nifedipine 20mg bd	HC3
Step 5: If BP is ≥ 140/90mmHg, Follow-up in 4 weeks	Amlodipine 10mg + Valsartan 160mg	Amlodipine 10mg + Losartan 50mg	Bendrofl-umethiazide 5mg + Nifedipine 40mg bd	HC3
Step 6: If BP is ≥ 140/90mmHg, Follow-up in 4 weeks	Amlodipine 10mg + Valsartan 160mg + Hydrochl-orothiazide 12.5mg	Amlodipine 10mg + Losartan 50mg + Hydrochl-orothiazide 12.5mg	Bendrofl-umethiazide 5mg + Nifedipine 40mg bd + Captopril 50mg tds	HC4
Step 7: If BP is ≥ 140/90mmHg: Refer to a hospital for further management Note: Maintain lifestyle modification with treatment; assess and offer adherence support				

Figure 48: Lifestyle Modification Counselling for Hypertension

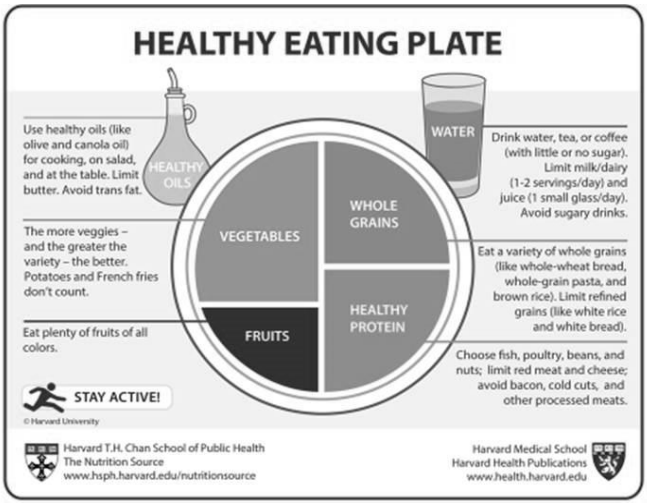
Lifestyle Counselling

- **Tobacco smoking cessation**: Ceasing to smoke reduces the risk of, uncontrolled hypertension, diabetes, heart disease, stroke and chronic lung diseases.
- **Regular physical activity**: Persons should be advised to have aerobic exercises for at least 30 minutes a day, 5 days a week. Health care workers should help patients find activities that they enjoy because this increases adherence.
- **Healthy diet**: Eat a diet high in fruits and vegetables and low in fat
    - Limit processed and fast foods.
    - Reduce refined sugar intake.
- **Salt reduction**: Reduce sodium intake to <1.5 g/day (less than one teaspoon)
- **Weight control**: Maintain a normal body weight of a body mass index of 18 – 25kg/m^2 and or a waist circumference of < 82cm for females and < 102cm for males.

Adherence counselling for integrated HIV Hypertension and diabetes Care

- The goal of treatment is blood pressure <140/90mmHg, Diabetes is FBG < 7mmol/l and viral load< 200copies/ml
- Patients with uncontrolled hypertension and blood sugar may suffer complication such as heart attack, stroke, chronic kidney disease, blindness, numbness of limbs and heart failure,
- Hypertension, diabetes and HIV/ART treatment is lifelong.
- Hypertension often has no symptoms, HIV patients with unsuppressed viral loads may initially show no symptoms but they will appear in the worst form and those with high blood sugar will show symptoms immediately
- ART, diabetes and hypertension medicines can be taken at the same time.
- Maintain lifestyle modification and risk reduction with treatment.
- Adherence to ARTminimizes complications of HIV infection on the blood vessels.
- Explain potential side effects of hypertension medicines.

LIFESTYLE MODIFICATION



Monitoring treatment for Hypertension and diabetes among PLHIV

- Measure blood pressure on every clinic visit.

Figure 49: Laboratory Monitoring for PLHIV on Hypertension Medications

LABORATORY MONITORING FOR PLHIV ON HYPERTENSION MEDICINES

6 months	12 months	2 years
• Fasting blood sugar • Urine protein • Potassium and Sodium (if on diuretic or ACEI/ARB) • Creatinine (if on ACEI/ARB)	• Lipid profile	• ECG • Fundoscopy

ACEI – Angiotensin converting enzyme inhibitors; **ARB** - Angiotensin receptor blockers

Drug-Drug interactions and common side effects of some of the NCD drugs

PLHIV with co-morbidities often take multiple drugs some of which interact and may increase or decrease each other's level affecting the outcome. It is important that a health worker pays attention to the different types of drugs a patient is receiving. This way there will be minimal effect on the outcome and less side effects (see tables 57 and 58).

Table 57: Interactions of hypertension medicine

INTERACTIONS OF HYPERTENSION MEDICINE WITH ARVs

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

LPV/r - Lopinavir/ritonavir, **ATV/r** – Atazanavir/ritonavir, **DRV/r** – Darunavir/ritonavir, **PIs** – Protease Inhibitors

Table 58: Potential side effects of hypertension medicine

POTENTIAL SIDE EFFECTS OF HYPERTENSION MEDICINES		
Drug	**Common Side Effects**	**Management**
Amlodipine/ Nifedipine	• Lower limb edema (1-10%)	Observe on treatment. Consider alternative medicine if excessive or persistent after using a diuretic.
	• Headache (7%), • Palpitations (1-3%)	Usually self-limiting, observe on treatment.
	• Male sexual disorder (1-2%)	Explore for other causes and reassure.
	• Muscle cramps	Usually self-limiting, observe on treatment.
Valsartan/ Losartan	• Hypotension with dizziness (10%)	Monitor blood pressure and consider dose reduction if systolic BP is < 100mmHg or person is frail.
	• Hyperkalemia (4-10%)	Monitor potassium and creatinine. Stop drug when potassium is > 5.5mmol/L and or eGFR <30ml/min.
	• Angioedema (rare)	Stop immediately and provide alternative medicine.
Captopril	• Hyperkalemia (1-11%)	Monitor potassium and creatinine. Stop drug when potassium is > 5.5mmol/L and or eGFR <30ml/min.
	• Pruritus (2%)	Usually self-limiting, observe on treatment.
	• Cough (1-2%)	Monitor on treatment and consider alternative medicine if persistent
Hydrochlorothiazide	• Hyperuricemia • Hyperlipidemia	Monitor while on treatment.
	• Hypercalcemia • Photosensitization	
	• Exacerbation of gout	Consider alternative medicine if persistent after diet modification.

Management of Clinic Reviews for Stable HIV Patients with NCDs

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

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

5.4.7.3 Assessment and Management of Common Mental Disorders Amongst PLHIV

Assessment and management of depression

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

Screening for depression, anxiety, substance and alcohol use disorder

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

- When newly diagnosed with HIV or at disclosure of HIV status to family and friends.
- Occurrence of any physical illness, recognition of new symptoms/ progression of disease or hospitalization or diagnosis of AIDS.
- Initiation of medication.
- Death of a significant other.
- Necessity of making end of life and permanency planning decisions.
- Major life changes,e.g., childbirth, pregnancy, loss of a job, end of a relationship.

Procedure for Mental Health assessment at TRIAGE

Procedure for mental Health assessment of Triage

- General health education on common Mental Health disorders to all attending patients.
- Educate about the signs & symptoms of common mental health disorders.
- Identify and sort out patients that report any of the signs & symptoms.
- Set up a private corner at triage point.
- Use the screening tools provided to assess the patients individually.
- Ensure the triage nurse/ peer is well trained to screen for Mental health.
- Use language which is most comfortable and understandable for the patient.
- Document in the patient file

- Escort patients with positive screen to clinician for farther assessment & management.

Tools for screening for depression, anxiety, Substance and Alcohol Use disorder

a. Self-Reporting Questionnaire 20(SRQ-20)
b. SAD PERSONS Scale
c. AUDIT – C +1 question on other substance abuse

Figure 50: Self-Reporting Questionnaire Screening Tool

SELF-REPORTING QUESTIONNAIRE (SRQ)

NTD TOOLKIT – Body functions and structures

Participant ID number: _____

The following questions are related to certain pains and problems, that may have bothered you in the last 30 days. Ifyou think the question applies to you and you had to describe the problem in the last 30 days, answer YES. On the other hand, if the question does not apply to you and you did not have the problem in the last 30 days, answer NO.

1. Do you often have headaches?	Yes (1)	No (0)
2. Is your appetite poor?	Yes (1)	No (0)
3. Do you sleep badly?	Yes (1)	No (0)
4. Are you easily frightened?	Yes (1)	No (0)
5. Do your hands shake?	Yes (1)	No (0)
6. Do you feel nervous, tense or worried?	Yes (1)	No (0)
7. Is your digestion poor?	Yes (1)	No (0)
8. Do you have trouble thinking clearly?	Yes (1)	No (0)
9. Do you feel unhappy?	Yes (1)	No (0)
10. Do you cry more than usual?	Yes (1)	No (0)
11. Do you find it difficult to enjoy your daily activities?	Yes (1)	No (0)
12. Do you find it difficult to make decisions?	Yes (1)	No (0)
13. Is your daily work suffering?	Yes (1)	No (0)
14. Are you unable to play a useful part in life?	Yes (1)	No (0)
15. Have you lost interest in things?	Yes (1)	No (0)
16. Do you feel that you are a worthless person?	Yes (1)	No (0)
17. Has the thought of ending your life been on your mind?	Yes (1)	No (0)
18. Do you feel tired all the time?	Yes (1)	No (0)
19. Do you have uncomfortable feelings in your stomach?	Yes (1)	No (0)
20. Are you easily tired?	Yes (1)	No (0)

Duration of interview:_____minutes

If the person scores 6 or more on the SRQ- 20, then they are further assessed for suicide using a SAD PERSONS scale (see below).

SAD PERSONS scale

- S – Sex: 1 if male; 0 if female; (more females attempt, more males succeed)
- A – Age: 1 if < 20 or > 44
- D – Depression: 1 if depression is present
- P – Previous attempt: 1 if present
- E – Ethanol abuse: 1 if present
- R – Rational thinking loss: 1 if present
- S – Social Supports Lacking: 1 if present
- O – Organized Plan: 1 if plan is made and lethal
- N – No Spouse: 1 if divorced, widowed, separated, or single
- S – Sickness: 1 if chronic, debilitating, and severe

Figure 51: Degree of Risk after Assessment using the SAD PERSON's Scale

Total points	Risk
0 – 4	Low suicide risk
5 – 7	Moderate suicide risk
8 – 10	High suicide risk

Figure 52: AUDIT-C tool for substance and alcohol use disorder

	0	1	2	3	4	Score
1. How often have you taken a drink containing alcohol to cope with stress?	Never	Monthly	2-4 times/ month	2-3 times/ week	4 or more times a week	
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more	
3. How often do you have six or more drinks on one occasion?	Never	Less than a monthly	monthly	weekly	Daily or almost daily	
Do you currently use any substance?	Never					

Scoring and interpreting AUDIT-C

Add the scores (shown in the top line) for each of the three questions for a total score out of 12. The following total scores provide an indication of whether to advise no alcohol use and/or refer the woman to a specialist addiction treatment service. They are a guide only.

- 0-3 Low-risk drinking (advise no use)
- 4-5 Moderate-risk drinking (advise no use and use professional judgement to consider referral to a specialist addiction service)
- ≥5 High-risk drinking (definite referral to a specialist addiction

Management of Depression and Anxiety

First line treatment includes psychotherapy or counseling through which the affected person is provided with knowledge and a variety of skills to help them overcome depression. If there is no improvement, psychotherapy is combined with medications, as shown on Table 59. The psychotherapy can be group (GSP) or individual psychotherapy.

Table 59: Psychotherapy and Medications for Anxiety and Depression

Psychotherapy (Mild-Moderate depression)	Medications (Severe depression)
• Teach skills to; • Acknowledge stressful situations • Cope with stressful situations. • Replace unhelpful ways of thinking with helpful ways of thinking. • Practice new skills • Connect with other people • Positive creative visualization, • Express gratitude. • Practice positive self-talk • Practice spirituality • Engage in helping acts. • Maintain good nutrition, and general physical health.	• The drugs for treatment of depression are called antidepressants. • The common antidepressants are; Fluoxetine, amitriptyline and imipramine. Dosage • Fluoxetine 20mg once daily in the morning is preferred • Start with 10mg in the elderly • If not better after 4-6 weeks, increase to 40mg • Amitriptyline or Imipramine 50mg at bed time is the alternative • Increase by 25mg every week aiming at 100-150mg in divided doses or single bedtime dose by 4-6 weeks of treatment. NB: • Continue for at least 9-12 months if patient is responding to medication. • Consider stopping if patient has been without depressive symptoms and able to carry out normal activities for at least 8 months. • Counsel the patient about withdrawal symptoms (dizziness, tingling, anxiety, irritability, nausea, headache, sleep problems) • Counsel the patient about possibility of relapse and when to come back

Referral

Please refer the patient to a mental health worker (Psychiatric Nurse, Psychiatric Clinical Officer, Psychologist, Psychiatrist) at closest health center if the following happens:

- Acute aggressive behavior
- Alcohol withdrawal symptoms
- High suicide risk (SAD PERSONS score >7)
- Hearing voices of people they cannot see (auditory hallucinations)
- Seeing things that others do not see (visual hallucinations)
- Persisting suicidal ideation after 4 sessions of psychotherapy

Management of Alcohol and Substance Use Disorder

Motivational interviewing (brief intervention) for alcohol and substance use:

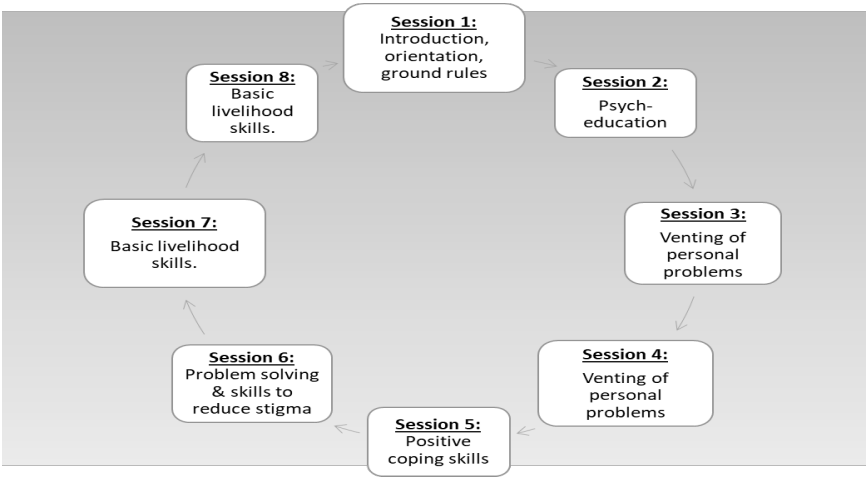
- Provide personalized feedback to the person about the risks associated with their pattern of substance use
- Encourage the person to take responsibility for their substance use choices, and the choice of whether to seek assistance for their substance use.
- Ask the person the reasons for their substance use
- Ask about their perception of both the positive and negative consequences of their substance use
- Ask about the person's personal goals, and whether their substance use is helping them or preventing them from reaching these goals.
- Have a discussion with the person based on the statements about their substance use, its causes, consequences, and their personal goals, allowing exploration of apparent inconsistencies between the consequences of substance use and the person's stated goals.
- Discuss options for change based on the choice of realistic goals and try to find a mutually agreed course of action.
- Support the person to enact these changes by communicating your confidence in them to make positive changes in their life

Management of Mental Health Disorders using Group Support Psychotherapy (GSP)

What is group support psychotherapy?

Group support psychotherapy (GSP) is a culturally sensitive counseling intervention that aims to treat depression by enhancing social support, teaching positive coping skills, and income-generating skills.

Figure 53: Structure of GSP



Interactions between ARVs and antidepressants

Interactions between ARVs and antidepressants are summarized in Table 61.

Table 60: Interactions between ARVs and common antidepressants, and recommended management

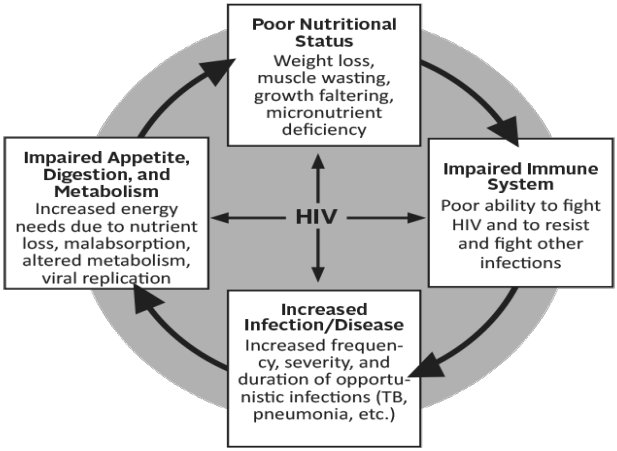
ARV	Antidepressant	Interaction	Management
Ritonavir	Amitriptyline	Increased amitriptyline levels/ effect	Monitor and adjust amitriptyline dose as indicated
	Fluoxetine	Increased ritonavir effects	No dose adjustment required
Efavirenz	Bupropion	Decreased bupropion effects	Monitor for signs and symptoms of depression and titrate bupropion dose to effect
Lopinavir/ ritonavir	Bupropion	Decreased bupropion effects	Monitor for signs and symptoms of depression and titrate bupropion dose to effect
	Trazodone	Increased trazodone levels/ effects	Use with caution; if benefits outweigh risk, start with low dose of trazodone

ARV	Antidepressant	Interaction	Management
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

5.5 NUTRITION CARE AND SUPPORT FOR PLHIV

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

Figure 40: The Cycle of Under nutrition and HIV/AIDS



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

Nutrition Assessment Counseling and Support (NACS) is an important component of comprehensive care for PLHIV. NACS therefore, should be

conducted in PLHIV from enrolment and extended throughout the care continuum.

5.5.1 Steps In Implementing NACS

NACS should be implemented in HIV care settings using the "The Seven Steps" approach in Table 51.

Table 51: Seven steps approach for implementing NACS

Step	Activities
Step 1: Nutrition and health education	Create awareness on benefits of proper nutrition Sensitize clients on how to ensure proper nutrition and monitoring of nutritional status
Step 2: Nutrition assessment	**Anthropometry**: Take and record the anthropometric measurements (weight, length/height, or MUAC) of PLHIV at each visit. Routinely monitor and promote growth for children <5 years
	Biochemical analysis: Monitor micronutrient deficiencies such as haemoglobin level. Conduct Lipid profiling for ART clients annually.
	Clinical assessment: Check for signs of under nutrition including bilateral pitting oedema, wasting, hair changes, anemia (pale conjunctiva, gums, nails, skin), breathlessness, and rapid pulse. Assess for symptoms that affect food intake (diarrhea, nausea, vomiting, anorexia, mouth/throat sores and oral thrush).
	Dietary assessment: Collect information about the types and amounts of food consumed, appetite, and eating behaviours
	Living environment: Assess for the cleanliness and sanitation of the client's environment, access to and use of safe water, food hygiene especially for immune-compromised HIV patients.
	Lifestyle practices: Smoking, alcohol and drug abuse can affect food intake and decrease effectiveness of some medications.

Step	Activities
Step 3: Nutrition classification	Classify nutritional status and decide on care plan, see Figure 40.
Step 4: Nutrition counselling	Encourage clients to consume a variety of locally available, high-energy and nutrient dense foods; increased feeding frequency and intake per meal; high-protein intake (especially animal); frequent hydration; intake of fats and sugar in moderation; exercise, hygiene, and sanitation.
Step 5: Nutrition therapy	Severe acute malnutrition (SAM) with complications Manage in inpatient therapeutic care (ITC) using F75, F100
	Severe acute malnutrition (SAM) without complications Counsel and manage in outpatient therapeutic care (OTC) using ready to use therapeutic food (RUTF) for children 6-59 months or nutrient rich/enhanced food for older children, adolescents and adults.
	Moderate acute malnutrition (MAM) Counsel and refer to supplementary feeding program or livelihood programs
	Micronutrient deficiencies Provide appropriate micronutrient (iron, folate, vitamin A, zinc) supplements, see The Micronutrient Guidelines for Uganda, Ministry of Health 2013
	Food and drug interactions Manage complications that affect food intake/utilization, drug adherence, and efficacy, Integrated Nutrition Assessment, Counselling and Support into Health Service Delivery, Reference Manual, 2016
Step 6: Follow-up for nutrition care and support	Follow-up all clients with acute malnutrition Routine and scheduled follow-up for clients on nutrition treatment: where appropriate, synchronize with other services

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

5.5.2 Dietary Recommendation For PLHIV

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

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

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

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

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

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

5.5.2.1 Nutrition Support for PLHIV

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

Management of Severely malnourished PLHIV

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

Justification: Adolescents and adults rarely associate wasting or oedema with their diet except in famine conditions resulting in disbelief that altering their diet will help them. Even in famine conditions, they are often very reluctant to eat anything except traditional foods, which they view as perfectly satisfactory. They are often reluctant to take formula feeds and/or RUTF unless they can be persuaded that such feeds are a form of medicine. This problem is one of the most difficult aspects of treating adolescents and adults.

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

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

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

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

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

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

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

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

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

Management of PLHIV with over nutrition (overweight/obese)

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

1. Controlling energy intake by increasing intake of low- energy foods such as vegetables and high fiber diets; whole grains are excellent sources of fiber and nutrients essential for weight control.
   - Restricting intake of sugar, fats and oils, and salt.
   - Excess intake of fats/oils and sugar increases the risk of overweight/obesity.
   - Excess intake of salt increases the risk of high blood pressure
   - Reduce intake of processed drinks like sodas and sugar added drinks
   - Read food labels to be able to make healthy food choices
2. Increasing daily water intake.
3. Ensuring regular exercise/physical activity.
   - Adults should engage in 30mins of moderate intense physical activity per day.
   - Children and adolescent should engage in 60mins of moderate intense physical activity per day

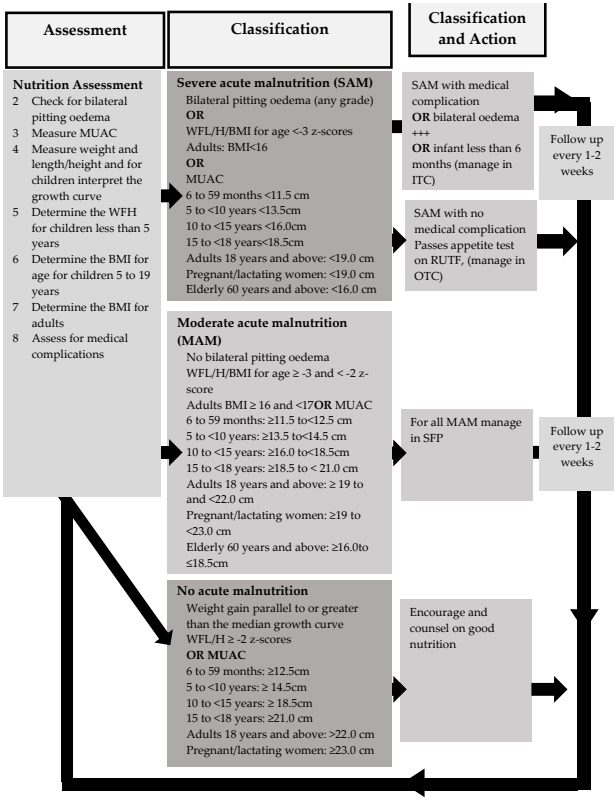
- Examples of moderate intense physical activities include walking, climbing stairs, domestic work, gardening, jogging, aerobics, cycling and sports.

4. Ensure regular medical check- up.

Regular medical check-up is crucial for the benefit of general wellbeing and overall health as it helps to detect any upcoming health issues that can be diagnosed and treated properly. It is therefore important to go for regular medical check-up every 6 months for:

- Body Mass Index
- Blood pressure
- Blood sugar levels
- Cholesterol levels
- Cancers like, breast, prostate, cervical

Figure 41: Algorithm for nutrition assessment, classification, and care plan of acute malnutrition



5.6 SEXUAL AND REPRODUCTIVE HEALTH SERVICES

5.6.1 Screening and Management of Sexually Transmitted Infections (STIS)

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

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 52).

Table 52: STI screening tool

Syndrome	Key Symptoms
URETHRAL DISCHARGE	• Discharge from the urethral opening or vagina • In men, blood in the semen or urine • Difficulty starting urination
GENITAL ULCER DISEASE	For men: a genital sore is any sore or lesion that appears on the • Penis • Scrotum • Urethra • Perineum • Anal and perianal region For women: a genital sore is any sore or lesion that appears on the • Skin surrounding the vulva, • Labia • Vagina • Perineum • Anal and perianal region

ABNORMAL VAGINAL DISCHARGE	Fungal cause: • Vaginal discharge that is thick, white, cheesy Bacterial cause: • Vaginal discharge that is white, gray, or yellow and may have a fishy or foul odor
LOWER ABDOMINAL PAIN (PID)	• Dull pain in the stomach or lower abdomen • Pain during sex

STI Management

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

Cervical Cancer Screening

Over 90% of the incident cervical cancer cases occur in the less-developed regions of the world, where access to prevention, screening, and treatment services are severely limited. In Uganda, cervical cancer contributes 6,959 (20%) of the new global cancer cases annually and 4,607 (20%) of all global cancer deaths annually. It is the leading cause of cancer related deaths in Uganda for all sexes combined. HPV is the recognized necessary cause of 99.7% of all cervical cancers and is sexually transmitted. Women living with HIV have a higher risk for cervical cancer compared to their counter parts that are HIV negative. Cervical cancer screening using HPV testing is the primary cervical cancer screening method in Uganda .. Additionally visual inspection with acetic acid (VIA)where HPV testing is not available or Pap smear for especially post-menopausal women is also recommended .The cervical screening should be repeated every three years. Patients with pre-cancerous cervical lesions should be managed using Ablative (destroying abnormal tissue by heating it with thermal coagulation or freezing it with cryotherapy) or Excisional (surgically removing abnormal tissue with LEEP (Loop Electrosurgical Excision Procedure) or cold knife conization (CKC)

Table 53: Eligibility criteria for cryotherapy/ thermocoagulation

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

If lesion is more than 2mm beyond its edges use LEEP

* Refer for further management

Prevention of cervical cancer

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

Table 54 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

5.8 VACCINES FOR PEOPLE LIVING WITH HIV

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

BCG VACCINE

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

HBV VACCINE

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

HPV VACCINE

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

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/mm3.Itis recommended during yellow fever outbreaks and for those intending to travel to high-risk areas for yellow fever. The single vaccine gives lifetime coverage.

Box 8: Key highlights in Care and Support for people living with HIV.

- PLHIV should be educated, encouraged and supported to improve their nutrition, regularly assessed and screened for malnutrition and linked to appropriate management. PLHIV should be encouraged to practice proper personal and food hygiene and ensure water safety.
- PLHIV with Advanced HIV disease (CD4<200cells/mm3, WHO stage 3 and 4) should be screened for OIs (especially TB and Cryptococcal Meningitis) and appropriately receive prophylaxis or treatment before initiation of ART. Initiate treatment for diagnosed OIs and defer ART initiation for at least 2 weeks to decrease risk of IRIS.

- TB/HIV co-infection: If patient is already on ART, start TB treatment and modify the ART regimen appropriately. If Patient is ART naïve, start TB treatment and initiate ART 2 weeks after (earlier than 2 weeks in adult patients with CD4 <50 cells/mm3).
- ARV and/or TB regimen adjustments may be made in the treatment of TB-HIV co-infection to address drug interactions and ensure optimization of both the ART and TB medication.
- TB Preventive Therapy (TPT): All PLHIV with a negative TB screen, and children and pregnant women/adolescent girls with history of TB contact should be given TPT. Do not initiate TPT and ART concurrently.
- In children and pregnant women/adolescent girls with exposure to person with active TB: Initiate TPT immediately and delay ART initiation or ART optimization.
- In pregnant women/adolescent girls without TB exposure, defer TPT until 3 months postpartum.
- In PLHIV initiating ART or optimizing ART regimens: defer TPT until 3 months after ART initiation or ART optimization.

5.9 PSYCHOSOCIAL CARE AND ADHERENCE SUPPORT FOR PLHIV

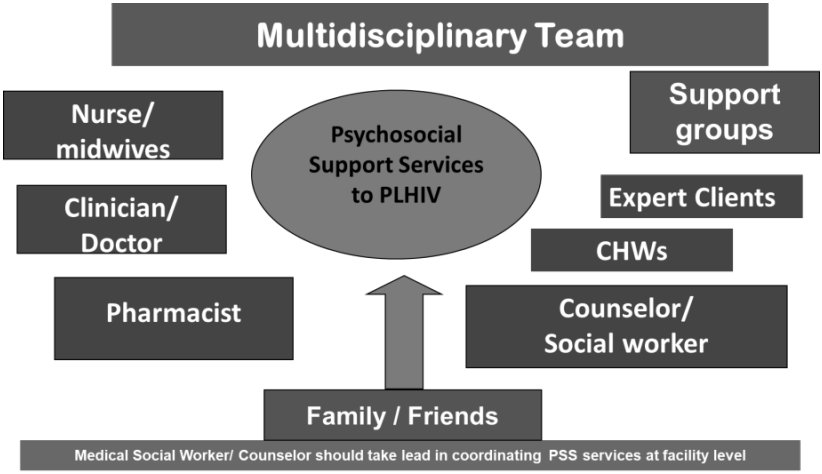
With implementation of "test and treat", the need for psychosocial care and support is more critical to enhance adherence, retention and viral suppression. This section of the guidelines highlights the key interventions to guide adherence support and provision of psychosocial care. Psychosocial care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

5.9.1 Who Should Provide Psychosocial Support (PSS) to PLHIV?

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

1. Ensuring PSS services are well coordinated within the facility and community.
2. A strong and effective referral and linkage system is established and maintained
3. Documentation of PSS services is accurately done.
4. Ensuring routine reporting for PSS services.
5. PSS services should be provided by a multi-disciplinary team that interacts with the client throughout the process of care as shown in Figure 55 below.

Figure 54: Who to provide Psychosocial Support Services to PLHIV



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

5.9.2 Psychosocial Care and Support Service Package

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

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

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

Table 61: Minimum Standards for Providing Psychosocial Support Services

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

Standard	What should be done

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

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

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

5.9.3 Adherence Preparation, Monitoring and Support

Good adherence to ART is key for sustained HIV viral suppression, reduced risk of drug resistance, improved overall health, quality of life, and survival, as well as decreased risk of HIV transmission. Conversely, poor adherence is the major cause of ART treatment failure. Adherence should be routinely

assessed and reinforced by everyone in the clinical team (physicians, counselors, nurses, pharmacists, peer educators,etc.) at each of the patient's visits to the clinic. This section will cover how to prepare patients for ART, and monitor and support them to adhere to ART.

ADHERENCE PREPARATION

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

Health workers should provide information on circumstances where delays in starting ART can have negative consequences, particularly for people with tuberculosis (TB), advanced immune suppression, and/or who are at high risk of death. The healthcare team should use the 5As principles for chronic care as a guide to offer pre-ART adherence counseling and psychosocial support. These are Assess, Advise, Assist, Agree and Arrange Table 62.

Table 62: 5As for adherence preparation support

Guide	Components
Assess	Goal: To assess patients' knowledge of HIV,ARVs and potential barriers to adherence 1. Knowledge about HIV and ARVs 2. Myths and misconceptions about HIV and ARVs 3. Potential barriers to adherence 4. Patient psychosocial concerns and needs that may hinder adherence to ART 5. Patient willingness and commitment to take medicines correctly 6. Patient readiness to honor subsequent appointment for treatment support 7. Patient's support systems at family and community level 8. Disclosure status and implications

Guide	Components
Advise (information giving)	Goal: To provide the patient with knowledge about HIV/ ARVs to enable themdecide to initiate treatment • Give information about HIV and ARVs • Provide information on adherence to ART. Include information on the 5 Rs (taking the right medicine, at the right time, right dose, right way, and right frequency) • Demonstrate how the ARVs are taken • Provide information about side effects of ARVs, improved quality of life while on ART, changes that may occur in a person's life once on treatment • Explain the benefits of disclosure and support systems to adherence • Explain to the patient how often they will be monitored once on treatment; other ways of assessing adherence and response to treatment including pill counts • Emphasize the importance of attending all the clinic appointments for review and support • Discuss the Positive Health, Dignity, and Prevention package • Explain the implication of not adhering to ARV treatment • Explain what VL test is and the meaning of suppressed and unsuppressed viral load
Assist	Goal: To support client identify possible barriers and consider different options of dealing with the barriers. The client: • Evaluates the possible barriers to adherence and how to overcome them • Identifies the support systems that will enable the client to take his drugs and to regularly come to the facility such as treatment supporter, social support groups • Consider disclosing to a trusted person of their choice such as a treatment supporter, social support group, etc.

Guide	Components
Agree on	Goal: To guide the client to develop a realistic individual adherence plan. The client considers and where possible documents: An adherence plan (Table 47) Family and community support systems (expert client in the community) Possibility of home visit and consent Possibility of testing other family members including sexual partner and children Assess client's readiness to start ART (see Table 48: ART readiness assessment form)

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

Table 63: Checklist for developing an adherence plan

Question
• How many pills of the medicine will you take/give per day? • (client demonstrates as you observe)
• What time will you take/give the medicine?
• How will you remember to take/give the medicine?
• Where will you keep the medicine?

Question
• What will motivate you to take/give the medicine?
• Whom have you disclosed to/plan to disclose to?
• Who is your or your child's treatment buddy?
• Who will pick your/your child's medicine if you cannot come to the clinic?
• How will you ensure you keep your appointments as scheduled?
• What challenges/factors may affect your adherence? (Explore for non-disclosure, alcohol and substance abuse, sexual partner(s), and stigma)

Table 64: ART readiness assessment checklist

A. Psychosocial/knowledge criteria (applies to patients and caregivers)	**Yes**	**No**
1. Understands how HIV affects the body and benefits of ART?		
2. Has screened negative for alcohol or other drug use disorder?		
3. Is willing to disclose/has disclosed HIV status to a sexual partner and significant other?		
4. Has received demonstration of how to take/administer ART and other prescribed medication?		
5. Has received information on predictable side effects of ART and understands what steps to take in case of these side effects?		
6. For patients dependent on a caregiver: caregiver is committed to long-term support of the patient, daily administration of ART, and meets the criteria above?		
7. Other likely barriers to adherence have been identified, and there is a plan in place to address them (e.g. frequent travel for work, plan to deal with unexpected travel, distance from clinic, etc.)?		
8. Patient/caregiver has provided address and contact details?		
9. Patient/caregiver feels ready to start ART today?		

10. Has identified convenient time/s of the day for taking ART?		
11. Has treatment supporter been identified and engaged in HIV education, or will attend next counseling session?		
12. Is aware of the support group meeting time/s?		
13. Has enrolled into SMS reminder system? (If facility has reminder system)		
14. Are other support systems in place or planned (e.g. setting phone alarm, pill box)?		
15. Patient newly diagnosed with TB: Start TB treatment Defer ART until 2 weeks after starting TB treatment		
16. Patient diagnosed with cryptococcal meningitis or has symptoms consistent with cryptococcal meningitis (headache, the presence of seizures, altered consciousness, photophobia, neck stiffness, and a positive Kernig's sign): Treat cryptococcal meningitis Defer ART until 4-6 weeks after initiating treatment for cryptococcal meningitis		

5.9.4 Monitoring Adherence to ART

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

Viral Load Monitoring

Viral load monitoring is considered the gold standard for monitoring adherence and confirming treatment response. All HIV-infected patients should receive a viral load test 6 months after initiating treatment and annually thereafter. Following an initial high viral load (>200 copies/ml and >400 copies/ml) for plasma and DBS samples respectively), enhanced/intensive adherence counseling should be carried out before conducting a repeat viral load test.

- Three consecutive IAC sessions with scores >95% is recommended before a repeat VL test is done.
- However, if scores persistently remain <95%, then initiate a Directly Observed Therapy or treatment supporter at the 4th, 5th, and 6th IAC session and conduct a repeat VL thereafter.
- Irrespective of the adherence scores at the 6th IAC session, conduct a repeat VL where two samples are withdrawn with an anticipation of conducting HIV DR in case the repeat VL result is unsuppressed.

Self-Reporting

Self-reporting is rapid, inexpensive, easily carried out in clinical settings and is frequently used in routine care. It involves asking questions regarding missed doses to establish adherence. It is essential that these questions be posed in as non-threatening and sensitive a way as possible. All patients, especially adolescents should be encouraged to speak openly, and they should be reassured that many people find it difficult to take all their medications. When using self-report, use the four guide questions to determine adherence and reasons for not adhering to ART (Table 65).

Table 65: Question guide for reviewing an adherence plan

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

Use the number of missed ARV doses in the past month to determine adherence level and appropriate action (Table 66).

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:

% adherence=

After computing % adherence, use Table 66 to determine the adherence level and support the client accordingly.

Table 66: Determining adherence levels from self-report and pill count and recommended action

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

What should be done in case a PLHIV forgets taking his or her dose; -The principle of drug half-life should apply.

For drugs taken twice a day, take the forgotten dose within 6 hrs of remembering. For drugs, taken once a day, the forgotten dose can be taken within 12 hrs of remembering. Beyond 6 and 12 hrs respectively for defer the forgotten dose and continue with the next dose.

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.

5.9.5 Adherence Support

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

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

5.9.6 Intensive Adherence Counseling and Support for Patients with Detectable Viral Load

Intensive Adherence Counseling (IAC) and support refers to a targeted and structured counseling and support intervention offered to patients on ART with a non-suppressed viral load (patients with viral load >200 and >400 copies/ml respectively for plasma and DBS samples). IAC is offered systematically and routinely as per scheduled appointments; one month apart. IAC helps a client develop a comprehensive plan for adhering to ARVs by identifying their barriers to adherence, gaining insight of the barriers, exploring possible ways to overcome barriers and planning to adhere to medicine. Provision of IAC requires a multidisciplinary team including clinicians, nurses, counselors, family members, peers, etc. It may also require consultations from experts or referrals to address the issues related to stigma, disclosure, mental health and nutrition.

How to offer IAC

The 5As counseling framework applies to provision of intensive adherence counseling and psychosocial support. Key messages at every step are summarized below in Table 67 below.

Table 67: 5As for adherence support for people with non-suppressed viral load

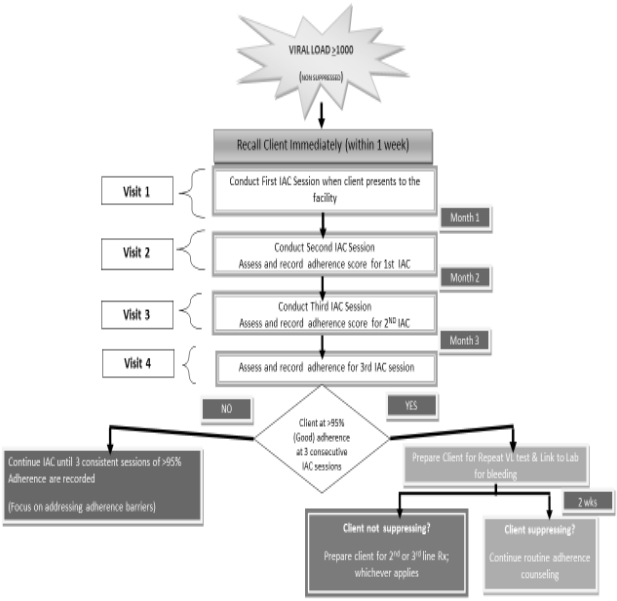
Guide	Components
IAC Session 1	
Assess	Explain purpose of session Disclose VL test results to client and explain the meaning of suppressed and non-suppressed VL Explain reasons for non-suppressed VL results (non-adherence to drugs or drugs may not be working well) Discuss implications of non-suppressed results to the client Determine adherence levels Calculate the adherence score using the adherence percentage formula Assess client's barriers to adherence Use the adherence assessment checklist to ascertain client's adherence practices. Identify barriers to client's adherence (arising from the assessment)

Guide	Components
Advise	Identify information gaps from assessment Educate client in relation to specific barriers identified Review benefits of good adherence Assess client's knowledge of benefits Provide correct and complete information on Discuss consequences of non-adherence Assess client's knowledge on the dangers of non-adherence Educate client on the consequences of non-adherence
Assist	Evaluate the underlying causes of the identified barriers Prioritize the barriers Identify possible root causes of each barrier (where applicable) Identify client specific strategies to overcome identified barriers Discuss possible options to address key barriers Provide information about available support systems e.g. CBOs, peer support groups etc Discuss the pros and cons of each strategy/option
Agree on	Agree on client's action points to address the key barriers Identify appropriate strategies Provide relevant and necessary information Evaluate each action point using the 5 Ws and 1H What, where, when, who, which, how? Document agreed upon action points on the IAC session form Develop and document a new adherence plan on the IAC session form

Guide	Components
Arrange	Summarize the session Review the action points Review the new adherence plan Arrange for ART refill Explain the schedule for IAC intervention Explain the number of sessions Emphasize appointment keeping Schedule the 2nd IAC session Document the next appointment date on the IAC session form Remind client to bring remaining pills at next visit Refer and link to other services as appropriate
IAC Session 2	
Assess	1. Assess adherence levels a. Document the adherence score b. Compare current score with the previous 3. Assess progress in dealing with barriers Identify what worked a. Identify what did not work b. Discuss new strategies 3. Assess compliance to adherence plan a. Identify what worked b. Identify what did not work c. Discuss new strategies 4. Assess for possible new barriers to adherence Use adherence assessment checklist
Advise	Do as in IAC Session 1
Assist	Do as in IAC Session 1
Agree on	Do as in IAC Session 1
Arrange	Do as in IAC Session 1
IAC Session 3	
Assess	Do as in IAC Session 2
Advise	Do as in IAC Session 1
Assist	Do as in IAC Session 1
Agree on	Do as in IAC Session 1

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

Figure 55: Flow-chart for offering IAC to non-suppressed Adult PLHIV



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

Due to the high levels of pre-treatment NNRTI resistance in Uganda (see Section 13.14.3), these guidelines recommend optimization of ART for children. Children and adolescents whose viral load are not suppressed should receive IAC following the recommendations below:

- All children and adolescents on NNRTI-based regimens with a non-suppressed viral load:
  - Switch immediately to second line ART without waiting for a repeat viral load result.
  - IAC should be initiated immediately and provided monthly.
  - IAC should be continued until child/adolescents stabilizes on their new regimen for a maximum of 6 months.
  - Resume routine adherence support aligned to clinic appointments.
- Children and adolescents on DTG or PI-based regimens: DTG and PIs have a high barrier to resistance, so poor adherence is a more likely cause for an unsuppressed VL than resistance. Therefore, for children and adolescents on DTG or LPV/r-based first line regimens with non-suppressed VL:
- Conduct IAC and repeat VL after 3 months.
- If repeat VL is still not suppressed after 3C good IAC interventions with scores>95%, conduct HIV DR to guide the next course of action.
- Adherence scores persistently <95%, initiate a Directly Observed Therapy or treatment supporter at the 4th, 5th, and 6th IAC session and conduct a repeat VL thereafter.
- Irrespective of the adherence scores at the 6th IAC session, conduct a repeat VL where two samples are withdrawn with an anticipation of conducting HIV DR in case the repeat VL result is unsuppressed.

5.9.7 Positive Health, Dignity and Prevention (PHDP)

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

Table 68: Positive health, dignity, and prevention intervention

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

5.10 OVC CARE AND SUPPORT

Programming for children orphaned and made vulnerable by HIV/AIDS contributes to the achievement of an AIDS-free generation by responding to the social, economic and emotional consequences of the disease on children, their families, and communities that support them. Health workers therefore should screen all children and adolescents for vulnerability and appropriately link them to OVC services within the facility's catchment area.

A standardized screening tool for vulnerability within health facilities is provided in Table 69 below.

Table 69: OVC Vulnerability screening tool

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

6. ANTIRETROVIRAL THERAPY FOR PEOPLE LIVING WITH HIV

6.1 THE GOAL OF ART

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

6.2 COMPOSITION OF ART

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

6.3 WHEN TO START ART

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

Rationale for treating all people living with HIV

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

6.4 THE PROCESS OF STARTING ART

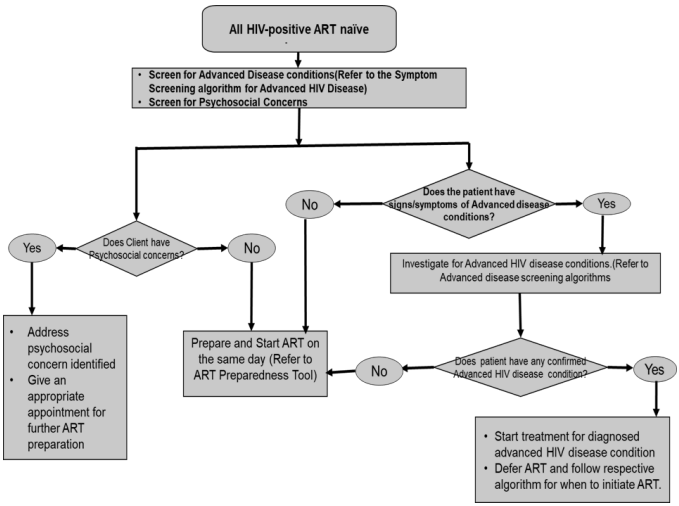
Although the program recommends starting all PLHIV on ART, health workers should do the following:

- Assess all clients with the Symptom Screen for Advanced Disease Pathway (Figure 33) any evidence of opportunistic infections (OIs) especially TB and cryptococcal meningitis. If the patient has TB or cryptococcal meningitis, ART should be deferred and initiated after starting treatment

for these OIs as outlined in Chapter 7. Treatment for other OIs and ART can be initiated concurrently.

- For patients without TB or cryptococcal meningitis, offer ART on the same day through an opt-out approach. In this approach, patients should be prepared for ART on the same day according to the guidelines in Section 7.5.2 and assessed for readiness to start ART using the readiness checklist (Table 64).
- 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 56 for the process of evaluating patients for ART.
- For institutions starting patients on ARTS for research purposes, there should be a clear post ART access plane for approved drugs but not yet accessible in the public facilities
- Post-Trial Access: Research institutions should collaboratively work with its partners to ensure post trial/Research access to efficacious/safe study HIV treatment regimens for HIV positive clients enrolled for study purposes until the drugs become available through the national supply chain. If the patients can afford prescribed ART regimens but are not available on the essential drugs list and not accessible through the national supply chain system, facilitate access to options of these new generation drugs

Figure 56: How to evaluate patients for ART initiation



6.5 FIRST-LINE ART REGIMENS FOR PATIENTS INITIATING ART

Principles for selecting the ARV regimens (treatment optimization):

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

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

DOLUTEGRAVIR (DTG) is an integrase inhibitor and is recommended for use as the anchor ARV in the preferred first, second- and third-line treatment regimens for all recipients of care such as children, adolescents, men, women including pregnant women, breastfeeding women, adolescent girls and women of childbearing potential).

RATIONALE FOR USING DOLUTEGRAVIR (DTG)

a. High Circulating levels of resistance to NNRTI-containing First-line Therapy
NNRTI-containing combinations have been used as first-line regimens for adults in Uganda since the start of ART services in 2005. However, there are growing concerns of increasing levels of transmitted drug resistance, mostly to NNRTIs, in Uganda and elsewhere. A study by the Uganda Virus Research Institute (UVRI) conducted in Uganda in 2016/2017 revealed high levels of pre-treatment drug resistance (PDR) estimated at 15.9% to NNRTIs, exceeding the threshold of 10.0% set by WHO for first line ARVs.

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

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

d. Higher genetic barrier to resistance
The higher genetic barrier of DTG means patients are less likely to develop resistance and therefore postponing the need for superior line treatment

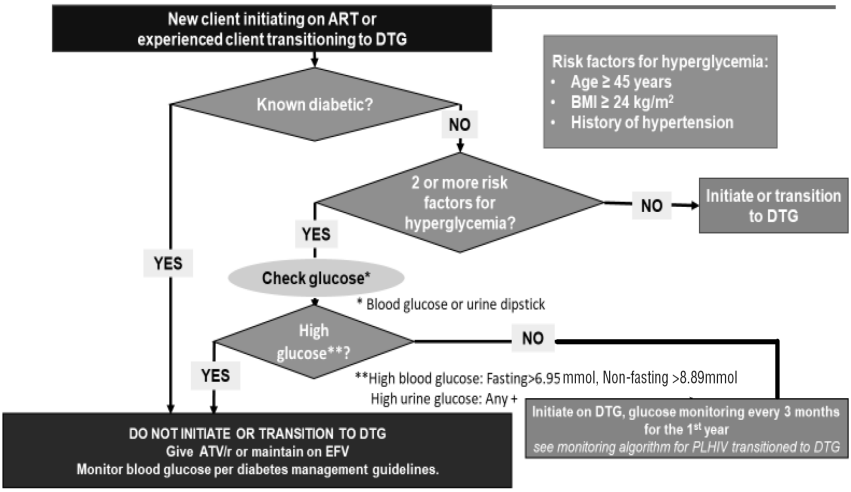
6.6 SCREENING FOR RISK FACTORS PRIOR TO INITIATING DGT

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

- Age ≥ 40 years
- BMI≥ 24 kg/m2
- History of hypertension

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

Figure 57: Screening Algorithm for PLHIV initiating or transitioning to DTG



6.6.1 Rationale for Using EFV400

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

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

All eligible HIV-infected adults and adolescents weighing ≥ 30kg should be initiated on Tenofovir or tenofovir alefenamide, Lamivudine and Dolutegravir (TDF + 3TC +DTG or TAF+FTC+DTG) (Table 74).

6.7 WHEN TO USE ALTERNATIVE FIRST LINE REGIMENS

When to use TDF+ 3TC+EFV400 or TAF+FTC+EFV400

Adults and adolescents should only be initiated on TDF+3TC+EFV400 if they are ineligible for DTG i.e. Table 74.

- If weight does not allow for use of the currently available DTG formulations (containing 50mg).
- Diabetic patients.
- An EFV based regimen may also be considered if the client needs concurrent TB treatment and doubling the dose of DTG is not an option (See Chapter 6, Table 39 and Table 40).

When to use TDF+3TC + ATV/r or TAF+FTC+ATV/r

Adults and adolescents should only be initiated on TDF+3TC+ATV/r if they are ineligible for DTG and EFV (Table 74).

When to use ABC+3TC + DTG or TAF +FTC+DTG

Adults and adolescents eligible for DTG should only be initiated on ABC+3TC+DTG if TDF is contraindicated (Table 74), including the following conditions:

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

When to use ABC+ 3TC +EFV400 or TAF +3TC+EFV400

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

- If TDF is contraindicated and they are ineligible for DTG (Table 78).
- If the client requires concurrent TB treatment and doubling the dose of DTG is not an option (Tables 30 and 31).

6.8 PREGNANT AND BREATSFEEDING WOMEN NEWLY INITIATING ON ART

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

6.8.1 When to use Alternative Firstline Regimens

When to use TDF +3TC + EFV400 or TAF +FTC+EFV400

Pregnant and breastfeeding women will only be initiated if DTG is contraindicated (Table 74).

When to use ABC+3TC +EFV400 or TAF +FTC+EFV400

Pregnant or breastfeeding women should only be initiated on ABC+3TC+EFV if TDF and DTG are contraindicated (Table 74).

When to use TDF + 3TC + ATV/r or TAF +FTC+ATV/r

Pregnant or breastfeeding women should only be initiated on TDF+3TC+ATV/r if EFV and DTG are contraindicated (Table 74).

PREGNANT AND BREATSFEEDING WOMEN ALREADY ON FIRST LINE ART

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

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

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

RECOMMENDED FIRSTLINE REGIMEN: ABC or TAF +3TC+DTG

All HIV-infected children weighing between 20kg to less than 30kg should be initiated on Abacavir or Tenofovir alefenamide + Lamivudine+ Dolutegravir (ABC or TAF +3TC+DTG) (Table 74)

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 or TAF +3TC+DTG can be given as once a day dose which may improve adherence.

6.9 WHEN TO USE ALTERNATIVE FIRSTLINE REGIMENS

When to use ABC+3TC+LPV/r

Children who weigh between 20kg to <30kg should only be initiated on ABC+3TC+LPV/r if DTG is contraindicated or not tolerated (Table 78).

When to use TAF/3TC/DTG

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

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

RECOMMENDED FIRSTLINE REGIMEN: ABC+3TC+DTG
All HIV-infected children weighing less than 20kg should be initiated on Abacavir + Lamivudine + Dolutegravir (ABC + 3TC + DTG) (Table 74) If DTG is contra-indicated, initiate on Abacavir + Lamivudine+ Ritonavir-boosted Lopinavir (ABC+3TC+LPV/r).
LPV/r syrup, pellets or tablets should be prescribed/dispensed on the basis of the individual child's ABILITY to CORRECTLY take the specific formulation. As soon as the child is able to take pellets, these will be prescribed instead of syrup. Likewise, as soon as a child is able to swallow tablets without breaking, crushing or chewing them, these will be prescribed instead of pellets.

6.11 WHEN TO USE ALTERNATIVE FIRSTLINE REGIMENS

All PLHIV on raltegravir should be immediately transitioned to DTG irrespective of the VL status.

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

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

Table 74: Recommended first-line ARV regimens in Children, adolescents, adults and pregnant or breastfeeding women

Patient Category	Preferred regimens	Alternative regimens
ADULTS AND ADOLESCENTS		
Adults and adolescents ≥ 30Kg	TAF + FTC + DTG or TDF + 3TC + DTG	Pregnant and breastfeeding women: TDF + 3TC + EFV400 or TAF + FTC +EFV400 If DTG is contraindicated1: TDF + 3TC + EFV400 or TAF + FTC +EFV400 If TDFor TAF is contraindicated 2: ABC + 3TC +DTG If both TDF or TAF and DTG are contraindicated: ABC +3TC +EFV400 If EFV and DTG are contraindicated: TDF +3TC + ATV/r or TAF + FTC +ATV/r or ABC + 3TC + ATV/r
Pregnant and breastfeeding women	TAF +FTC + DTG or TDF +3TC+ DTG	
CHILDREN		
Children ≥20Kg-<30Kg	ABC + 3TC + DTG	If DTG is contraindicated: ABC + 3TC + LPV/r (tablets) If ABC is contraindicated: AZT + 3TC + DTG or TAF + 3TC + DTG (TAF in children> 6 years and ≥25Kg)
Children<20Kg	ABC + 3TC + DTG3	If intolerant or appropriate DTG formulations are not available: ABC +3TC + LPV/r Granles. If intolerant to LPV/r: ABC + 3TC + EFV (in children > 3 years and >10Kg) If ABC is contraindicated: AZT + 3TC + DTG or LPV/r

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

*Refer to Table 78 for complete list of ARV adverse effects/toxicities and recommended drug substitutions.

6.12 MONITORING RESPONSE 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. The purpose of monitoring patients on ART is to assess:

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

Monitoring adherence to ART is covered in Chapter 11. The visit schedule and the recommended clinical and laboratory monitoring are in Table 77.

What should be done in case a PLHIV forgets taking his or her dose; -The principle of drug half-life should apply.

For drugs taken twice a day, take the forgotten dose within 6 hrs of remembering. For drugs, taken once a day, the forgotten dose can be taken within 12 hrs of remembering. Beyond 6 and 12 hrs respectively, defer the forgotten dose and continue with the next dose.

6.12.1 Clinical Monitoring

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

Table 75: Components of a comprehensive clinical assessment of PLHIV

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

6.12.2 Laboratory Monitoring

Viral load monitoring

Uganda adopted viral load monitoring as the preferred approach for monitoring response to antiretroviral therapy (ART) and to diagnose/ confirm ART treatment failure, defined as two consecutive viral load results of >1,000 copies/mL. Compared to clinical or immunological monitoring,

virological monitoring provides an early and more accurate indication of treatment failure and indicates the need to switch from first line to second-line drugs, and from second- line to third-line drugs, toward reducing accumulation of drug-resistance mutations and improved clinical outcomes.

Dolutegravir (DTG)-based regimens (e.g., tenofovir/lamivudine/dolutegravir [TLD]) have increased viral load suppression (VLS) rates to unprecedented levels, hence a need to actively monitor patients for low-level viremia to keep DTG a durable treatment option for as long as possible.

Furthermore, low-level viraemia monitoring can enhances monitoring of achieving and sustaining HIV epidemic control, as viral load of >200 copies/mL is associated with potential risk of sexual transmission as well as subsequent virologic non-suppression and treatment failure.

Given the above background and taking into consider the 2021 World Health Organization guidance to monitor low-level viremia, the guidelines have been designed to carter for health facilities with capacity to utilize plasma and dried blood spot (DBS) samples at suppression cut off points of 200 copies/mL and 400 copies/mL respectively, as shown in Figure 58.

A patient who has been on ART for more than 6 months and is responding to ART is considered virally suppressed at VL <200 copies/mL and <400 copies/mL for plasma and DBS samples, respectively. Facilities should constitute a multidisciplinary VL review committees to review, track, and make decisions to optimize ART regimen by switching to second-line, third-line, or a more potent regimen. At the minimum, the committee should consist of a healthcare worker and a lay provider (e.g. expert client, counselor, peer education, VHT) who knows the client.

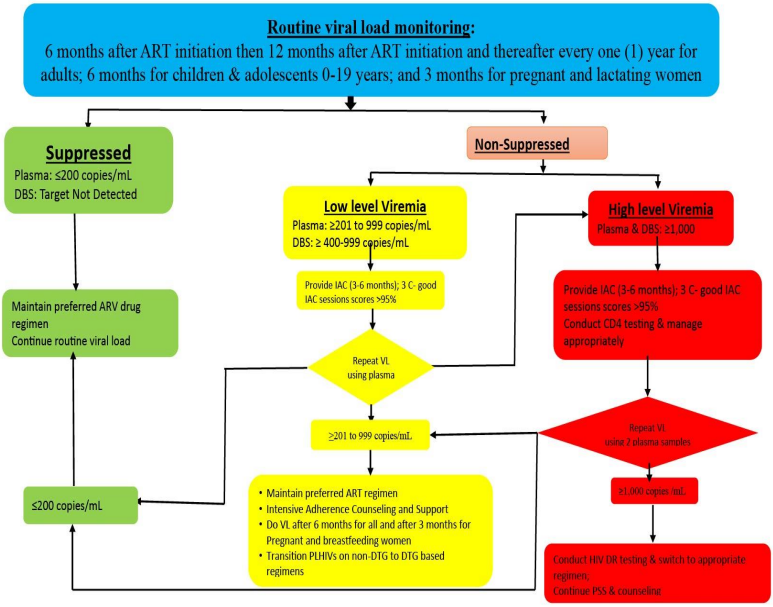
6.12.3 Frequency of viral load monitoring

1. Children and adolescents under 19 years of age: the first VL test should be done at 6 and 12 months after initiating ART, if it is suppressed, every 6 months thereafter. If not suppressed, follow the algorithm in Figure 58.
2. Adults: the first VL test should be done 6 months after initiation of ART. The second VL following the first suppressed viral load should be done at 12 months after initiation of ART and thereafter every 12 months if it is suppressed. If not suppressed, follow the algorithm in Figure 58.
3. HIV positive pregnant and breastfeeding women: If newly initiated on ART at ANC, conduct a VL test at 3 months on ART. If VL supressed

repeat VL every 3 months throughout pregnancy and until cessation of breastfeeding. If not suppressed, follow the algorithm in Figure 58.

4. HIV-positive pregnant and breastfeeding women already on ART at ANC1 or MBCP: If HIV+ woman is already on ART at ANC1 or enrolled at MBCP, conduct a VL test at first ANC or MBCP visit. If VL is supressed repeat VL every 3 months throughout pregnancy until cessation of breastfeeding. If not suppressed, follow the algorithm in Figure 58.
5. After every switch in treatment (after failure): The VL test should be done at 6 months after a switch to second- and third-line ART.
6. Third line ART patients: The VL test should be done every 6 months. If VL is un-suppressed, then genotype testing is recommended.

Figure 58: VL testing algorithm for children, adolescents and adults for health facilities using plasma and DBS samples



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

1. Engage multidisciplinary switch team at health facilities to discuss failing patients.
2. Sort viral load results from the laboratory as suppressed vs non-suppressed (NS) for rapid action by the ART clinic.

3. Apply the red stickers for non-suppressed clients to flag non-suppressed client files.
4. Conduct a first intensive adherence counselling within 7-30 days of result return.
5. Record IAC sessions on HIV care card to support completion of 3 consecutive IAC sessions.
6. Form viral load focal teams with clinical–lab interface for routine review of non-suppressed files.
7. Utilization of non-suppressed registers.
8. Integrate viral load monitoring talks into routine health education sessions.
9. Linkage with community structures for peer support and client tracking.
10. VL CQI site-level initiatives for managing non-suppressed patients.

Genotype testing

HIV genotypic resistance test is a qualitative test that detects mutations associated with ARV drug resistance. The test evaluates if the HIV strain infecting the individual has developed resistance to one or more ARV drugs. This is useful in identifying a combination of ARVs to which the HIV strain is susceptible. There is documented high level of pre-treatment drug resistance to Nevirapine and Efavirenz in Uganda (15.4% in the general population and 35.7% among infants of HIV infected mothers).

As a priority, eligible PLHIV on non-DTG based regimens should be transitioned to DTG and monitored appropriately. In the era of DTG as an anchor drug with high resistance barrier, genotype testing is the recommended approach for PLHIV switching from one regimen to a superior regimen after 3-consecutive IAC with scores ≥95% and a non-suppressed repeat VL.

CD4 monitoring

CD4 cell count testing can be performed using point of care technologies such as laboratory based CD4 analyzers and device -free semi-quantitative rapid tests. If a CD4 cell count is not readily available onsite, draw a sample and send to the nearby hub laboratory for testing.

CD4 cell count is recommended in the following scenarios:

- At baseline when initiating ART; Baseline CD4 helps to screen for risk for opportunistic infections, e.g. cryptococcal infection in patients with CD4 less than 200 cells/mm3.

- ART patients with non supressed VL and/or WHO clinical Stage 3 or 4 disease.
- PLHIV re-engaging in care after interrupting treatment for 3 or more months.
- PLHIV who are on treatment or prophylaxis for cryptococcal infection to inform decision on when to stop fluconazole.

Other laboratory tests

Other laboratory tests should be done when clinically indicated (Table 76).

Table 76: Follow-up lab tests and their clinical indication

Test	Indication
CrAg	(CD4<200cells/mm3)
Urine TB LAM	(CD4<200cells/mm3)
Complete blood count (CBC)	Patients at risk of anaemic conditions, e.g. patients on AZT, anti-cancer drugs, chronic renal disease, etc.
Lipid profile and blood glucose	If PLHIV has comorbidities (diabetes mellitus, hypertension) or lifestyle risk factors or on ART for more than five years or is ≥ 45 years
TB tests	If TB is suspected
RFTs: Serum creatinine	If PLHIV has comorbidities (DM, hypertension)
LFTs: ALT, AST	Compromised liver function, e.g. Hepatitis B or C infection, ART hepatotoxicity

Table 77: Follow-up schedule for PLHIV and monitoring components

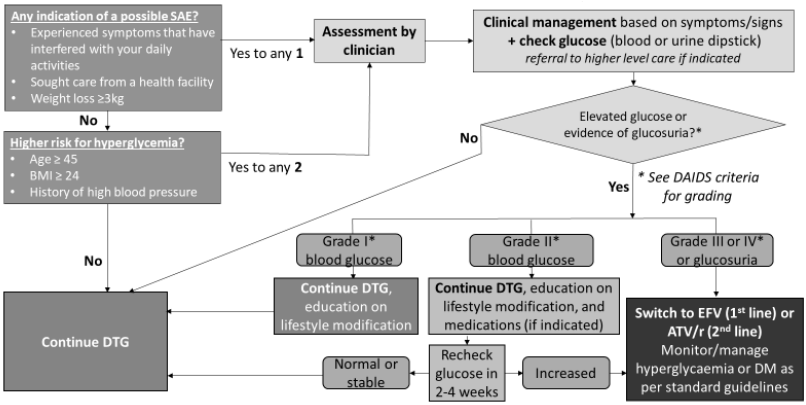
Time	Before ART	During ART								
					DSD from 6 months			After 12 months on ART		
	Baseline	1 month	2 months	3 months	6 months	9 months	12 months	3 monthly	6 monthly	12 monthly
Clinical assessment										
Comprehensive clinical assessment (Table57)	X	X	X	x	X	X	x	X	X	x
Prepare for ART (refer to Section 7.5)	X									
Assess readiness for ART (refer to Section 6.5)	X									
Provide CTX	X	X	X	x	X	X	x	x**	x**	x**
Provide FP if required	X									
Assess for drug intolerance, side effects/ toxicities		X	X	x	X	X	x	X	X	x
Assess for Immune reconstitution inflammatory syndrome (IRIS)		X	X	x	X					
Adherence assessment, monitoring, and support		X	X	x	X	X	x	X	X	x
ART and CTX refill (in children adjust dose based on weight)		X	X	x	X	X	x	X	X	x

FP refill		X	X	x	X	X	x	X	X	x
TB Screening	X							X	X	x
Follow up review: If the patient is clinically well:										
Give ONE month refill and appointment		X	X	x						
Give THREEmonths refill and appointment					X	X	x	X		
Laboratory tests										
Viral Load					x*		x*		x**	x
CD 4	X									
HBsAg,	X									
CrAg if CD4 <200,	X									
TB LAM if CD4 <200,	X									
FBS/RBS (especially adults at risk on DTG)	X			x	X	X	X		X	
LFTs	X									
Do other lab tests if clinically indicated (Table 58)	X	X	X	x	X	X	X	X	X	x
Cervical cancer screening										x

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

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

Figure 59: Monitoring patients initiated or transitioned to DTG



6.13 PHARMACOVIGILANCE

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

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

IMPORTANT OF PV

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

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

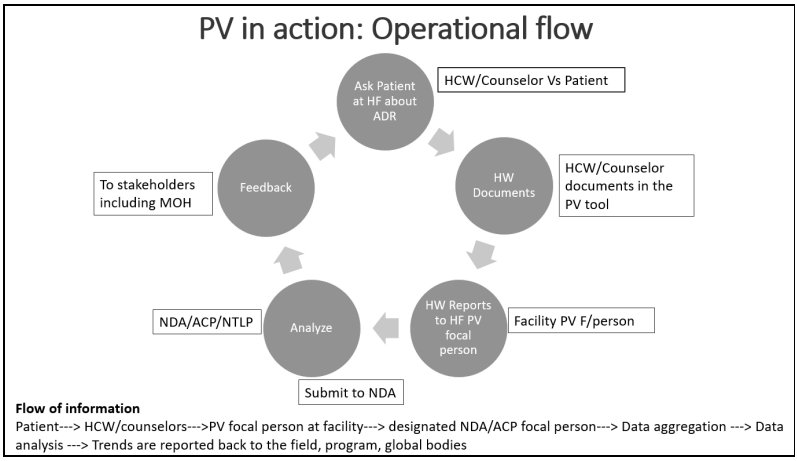
MAJOR AIMS OF PV

a. Early detection of previously unknown adverse reactions and interactions.
b. Detection of increase in known adverse drug reactions.
c. Identification of predisposing risk factors and possible mechanisms underlying adverse reaction.
d. Estimation of quantitative aspects of risk/ benefits analysis and dissemination of needed information to improve drug prescribing, use and regulation.

METHODS OF PV

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

Figure 63: Steps and key players in Pharmacovigilance



PHARMACOVIGILANCE STRATEGY FOR THE ART PROGRAM IN UGANDA

The program adopted active PV as part of the routine standard of care in all HIV and TB facilities. The strategy for active PV implementation shall apply in all HIV and TB clinics, and will include:

- Screening for any suspected ADRs as per screening tool at triage area
- Clinical evaluation of the reported signs and symptoms
- Baseline Laboratory screening to detect the presence or absence of adverse drug reactions

- Routine Laboratory screening for adverse drug reactions to monitor ARV and TB drug toxicities to better understand the risks of taking the drug regimen under conditions of programmatic use
- Management of severity of adverse drug events in a timely manner
- Systematic and standardized recording and reporting of AEs

ACTIVE PHARMACOVIGILANCE

Active PV, in contrast to spontaneous PV, seeks to ascertain completely the extent of adverse events through a continuous systematic process. To complement spontaneous reporting, active PV enables enhanced monitoring & data capture of ADRs including management of adverse events for improved treatment outcomes.

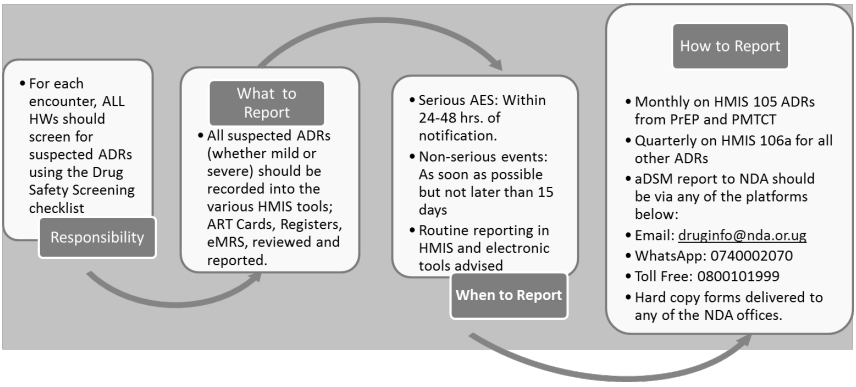
The processes of Active PV implementation will be as follows:

a. All RRHs, some District Hospitals and centres of excellency that act as HUBs for delivery of active PV services shall be sentinel sites for active PV services delivery.
b. Sentinel sites shall pro-actively follow-up patients to detect drug reactions and, conduct the following laboratory screening for all Recipients of Care (RoC):
    i) Baseline laboratory investigations for suspected adverse drug event in addition to clinical screening as per the guidelines
    ii) Routine laboratory investigations for suspected or confirmed adverse drug event in addition to clinical screening as per the guidelines
    iii) Both laboratory and clinical screenings shall be conducted for patients during treatment to detect ADRs and AEs even when the patient has no signs and symptoms
c. Non- sentinel sites (Spokes) shall conduct risk-based screening to determine what laboratory tests are to be done. For patients who screen positive to a minimum of two questions on the screening tool shall be eligible for relevant laboratory tests.
    i) Samples for relevant laboratory tests to investigate for suspected adverse drug events shall be transported to the nearby Hub using laboratory Hub transport system
d. For each encounter, the health worker should screen for any suspected ADRs as per screening tool above at triage.
e. Clinicians should further evaluate reported signs and symptoms.
f. Where applicable the clinician should request for additional tests (including laboratory and radiological) for patients with signs or symptoms suggesting ADRs.

g. Routine Screening for active PV: Clinicians/ Health workers shall request for tests at baseline and periodically thereafter as described in Table 64 below.
h. All AEs detected should be managed according to severity in accordance to the guidelines
i. All suspected ADRs should be recorded on the relevant tools: Patient care cards, Registers, entered in eMRS, and aDSM report form. All suspected ADRs/AEs data should be reviewed at the site by the facility pharmacovigilance team. The aDSM report form should be relayed to the NDA either online or as a hard copy (Annex 15).
j. Data on ADRs and AEs from ART and TB medicines should regularly be analyzed by the NDA to inform regulatory decision and stakeholders feedback in quarterly aDSM technical working group meetings.

Procedure of reporting an adverse drug reaction

Figure 64: Showing reporting process of adverse drug reaction



As soon as an ADR is suspected/detected, health worker should:

- Immediately and adequately assess the patient for adverse drug events/ reactions
- Record the diagnosis in the client care card, OPD/IPD register and eMRS.
- Fill the aDSM report form, collect all the filled forms, tally, and enter the record into relevant registers, and reported into HMIS database that include; HMIS Form 105 for ADR from PrEP and PMTCT and HMIS Form 106a for all other ADRs
- The suspected ADR should concurrently be recorded on the Active Drug Safety Monitoring (aDSM) form in Annex 15. The aDSM form should be filled in duplicates; - Original copy submitted to the National Pharmacovigilance Centre at the NDA secretariat, the duplicate (blue

copy) stays at the Health Unit/Facility. A validly filled aDSM report should have the following minimum information a) Source of information, b) Patient details, c) Drug details d) Reaction details.

- Ensure relevant tests are conducted
- The report is then submitted to the pharmacovigilance focal person within the facility, or if no such person exists, to the regional referral within your catchment area or to the nearest NDA office, or directly to the national Pharmacovigilance Centre at the NDA head office
- For reports on serious adverse events, within 24 to 48 hours of detection/diagnosis.
- For non-serious adverse events report as soon as possible but, in any case, not later than 15 days.
- Follow up of the ADR should be done appropriately and any emerging supplementary/additional information should be forwarded immediately. The tally data for the previous month (collected from HMIS 105 and HMIS 108) should be entered into the HMIS database. NB: – Use a separate form for each event.

Alternative methods of reporting may include:

1. Telephone/WhatsApp line; a reporter can call the National Drug Authority or Regional Pharmacovigilance Centre or send a WhatsApp message. The essential information is captured or transcribed on to the suspected ADR reporting form for follow-up.
2. Toll free line: 0800101999
3. WhatsApp: on 0740002070
4. Email: druginfo@nda.or.ug

Screening tool for Active Pharmacovigilance

This tool (see below) is to be placed in the recipient of care's file and should be used as a checklist to screen for side effects of ART or TB medicines at the triage point.

Figure 65: Screening tool for Active Pharmacovigilance

Screening tool for Active Pharmacovigilance in ART/TB clinics

To be used at the triage point for screening all patient at every visit

Name: ……Clinic……Patient Clinic No…… Facility Name: …… District: …… Sex …… Age…… Initial assessment Date …… Regimen: ……..

Since you began taking your medicines, have you noticed any changes in the following (Ensure to ask about all the adverse events) Actions to take:
Tick ☑ if any symptom/complaint is present, or ☐ if absent
Record Adverse Event in patient's card and refer to clinician
Clinician/Nurse will take all necessary actions to address the Adverse Event and fill the aDSM form which should be submitted to NDA

	Does the patient have any of the following symptoms or complaints?	Month of Visit											
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Neuropsychiatric symptoms (bad dreams, convulsions, suicidal thoughts, insomnia, headaches, anxiety, nervousness, memory or mood changes) (e.g. CS, EFV, DTG) Younger children: Ask for irritability (in addition to the above symptoms)												

2	Peripheral neuropathy (numbness, tingling, feeling of pins and needles, burning sensation in hands and/or feet) Younger children: Ask for pain in hands and feet, regression in motor milestones - refusal to crawl, walk or run, reduced playfulness (in addition to the above symptoms) (e.g. H, DTG, LZD)												
3	Abdominal symptoms (nausea & vomiting, diarrhea, abdominal pain) (e.g. ETO)												
4	Hepatotoxicity (nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes) (e.g H, PZA, ETO, BDQ, CFZ, Rifabutine, FLQ, Z, DTG)												
5	Musculoskeletal symptoms (muscle cramps, joint pains, tiredness, weakness, inability to move limb/s) (e.g LZD, Z, LFX, ETO, TDF)												
6	Eye symptoms (blurred vision, double vision, redness, tearing) (LZD, E)												
7	Kidney symptoms (lower limb swelling, facial puffiness, reduced urine output) (e.g. AMK,TDF)												

8	Blood disorders (Aneamia, leucopenia, Thrombocytopeania) Bruising or bleeding (subcutaneous, mucosal petechia, nose or gum bleeding) (e.g. LZD, AZT, 3TC)												
9	Cardiac symptoms (palpitations, fainting, easy fatigability) (e.g. BDQ, AZT)												
10	Skin changes (new skin rashes or skin discoloration, dermatitis) (e.g. CFZ, H)												
11	Breast enlargement (painful bilateral male breast enlargement) (e.g. ETO, EFV)												
12	Thyroid symptoms (weight gain, constipation, dry skin, fatigue, neck swelling, cold intorelence, hoarse voices) (e.g. ETO)												
13	Hearing disturbance and vestibular toxicity (hearing loss, tinnitus, dizziness, nausea and vomiting, loss of balance) (e.g. Kanamycin)												

14	Hyperglycemia or diabetes. (Increased appetite, increased thirst, and excessive urination). (e.g. DTG). Younger children: Ask for irritability (in addition to the above symptoms)												
15	Fever (e.g. LZD)												
16	Abnormal weight gain (e.g. DTG)												
17	Sexual dysfunction (increased or low libido) indicate type in remarks (e.g. ETO, DTG)												
18	Congenital Anomaly/Birth Defect												
19	Other SEs. Specify; _____ _____ _____												
	Sign (initials)												

Key to the abbreviation:

AMK: Amikacin
BDQ: Bedaquiline
CM: Capreomycin
CFZ: Clofazimine
LFX: Levofloxacin
CF: Clofazimine
CS : Cycloserine
DTG: Dolutegravir
DLM: Delamanid
MFX: Moxifloxacin
ETO: Ethionamide
FLQ: Fluoroquinolones
H: Isoniazid
LZD:Linezolid
RFB: Rifabutine

Table 83: Laboratory monitoring for Active Pharmacovigilance in non-sentinel sites

Category of Patient	Drugs	Screening procedures
ART naïve or experienced patient being initiated or switched to DTG or starting Isoniazid preventive therapy	At the time of starting/switching to DTG or starting INH	
	DTG	1. Review eligibility for DTG (Figure25) 2. Perform Baseline Random or Fasting Blood Glucose for those eligible according to the DTG eligibility screening tool (Figure 22).
	Isoniazid /3HP	1. Review eligibility for INH/3HP 2. Perform risk-based baseline Liver Function Tests checked against any previous values (Minimum AST and ALT) 3. Hepatitis B test
	After initiating/switching to DTG or starting INH/3HP	
	DTG	1. Screen using screening tool to identify any developing signs and symptoms. 3. Perform RBS every 3 months for those at high risk for hyperglycaemia in the first 12 months, then thereafter use clinical indication to determine need for tests.
	Isoniazid/ 3HP Prophylaxis	1. Screen using screening tool to identify any developing signs and symptoms. 2. Do Liver Function Tests based on clinical indication.
	TDF	1. Do Serum creatinine & eGFR for naïve patient initiating ART with TDF back borne at base 2. Do Serum creatinine & eGFR for experienced patient on TDF every 12 months

Patients on other regimens and not on this table	Any ART	1. Screen using screening tool to identify any developing signs and symptoms. 2. Perform laboratory and radiological investigations based on clinical indication.

Table 84: Laboratory monitoring for Active Pharmacovigilance in sentinel sites

Category of Patient	Drugs	Screening procedures
ART naïve or experienced patient being initiated switched to DTG or starting Isoniazid preventive therapy	At the time of starting/switching to DTG or starting INH	
	DTG	1. Review eligibility for DTG (Figure 57) 2. Perform Baseline Random or Fasting Blood Glucose checked against any previous values
	Isoniazid /3HP	1. Review eligibility for INH/3HP 2. Baseline Liver Function Tests checked against any previous values (Minimum AST and ALT) 3. Hepatitis B test
	After initiating/switching to DTG or starting INH	
	DTG	1. Screen using screening tool to identify any developing signs and symptoms. 3. Routine RBS every 3 months in the first 12 months, then thereafter use clinical indication to determine need for tests.
	Isoniazid/ 3HP Prophylaxis	1. Screen using screening tool to identify any developing signs and symptoms. 2. Routine Liver Function Tests at 3 months after initiating INH/3HP

Category of Patient	Drugs	Screening procedures
	TDF	1. Do Serum creatinine & eGFR for naïve patient initiating ART with TDF back borne at base 2. Do Serum creatinine & eGFR for experienced patient on TDF every 12 months
Patients on any other regimens and not on this table	Any ART	1. Screen using screening tool to identify any developing signs and symptoms. 2. Perform laboratory and radiological investigations based on clinical indication

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

6.14 COMMON DRUG TOXICITIES IN HIV CARE

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

Drug-related side effects while on ART can occur immediately (soon after a drug has been administered), early (within the first days or weeks of treatment) or late (after months or years of treatment). Adverse reactions may be specific to a particular drug, or they may be generic to the class of drugs in use. Toxicity is a concern because it can be life-threatening, can cause non-adherence to ARVs, and may be disfiguring like lipodystrophy. See Table 78 for common ARV side effects and toxicities.

Managing ARV and TB Drug Toxicity

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

- Determine the seriousness of the toxicity.
- Evaluate concurrent medications and establish whether the toxicity may be attributable to an ARV or TB medicine, or to any other medication taken at the same time.
- Consider other disease processes. Not all problems that arise during treatment are caused bymedicines.
- Manage the side effects and toxicities according to severity (Table 85).
- Report the event using the Adverse Drug Reaction form.

Table 85: Management of ARV side effects/toxicities

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

Table 86: Symptomatic and Laboratory Severity Grading for common ADRs

Parameter	Grade 1: Mild	Grade 2: Moderate	Grade 3: Severe	Grade 4: Potentially life threatening
Note: For all symptoms reported as potential ADRs, grade them according to the criteria above.				
Symptomatic grading	Mild symptoms causing no or minimal interference with usual social & functional activities with intervention not indicated	Moderate symptoms causing greater than minimal interference with usual social & functional activities with intervention indicated	Severe symptoms causing inability to perform usual social & functional activities with intervention or hospitalization indicated	Potentially life-threatening symptoms causing inability to perform basic self-care functions with intervention indicated to prevent permanent impairment, persistent disability, or death
Note: Use the reference ranges below to grade the severity of events where laboratory investigations are available. For laboratory investigations not included, refer to DAIDS Grading tables for grading: https://rsc.niaid.nih.gov/clinical-research-sites/daids-adverse-event-grading-tables				
Random Blood Sugar	116 to 160 mg/dL 6.44 to < 8.89 mmol/L	> 160 to 250 mg/dL 8.89 to < 13.89 mmol/L	> 250 to 500 mg/dL 13.89 to < 27.75 mmol/L	≥ 500 mg/dL ≥ 27.75 mmol/L
Fasting Blood Sugar	110 to 125 mg/dL 6.11 to < 6.95 mmol/L	> 125 to 250 mg/dL 6.95 to < 13.89 mmol/L	> 250 to 500 mg/dL 13.89 to < 27.75 mmol/L	≥ 500 mg/dL ≥ 27.75 mmol/L
Glycosuria (random collection tested by dipstick)	Trace to 1+ or ≤ 250 mg	2+ or □ 250 to ≤ 500 mg	> 2+ or > 500 mg	N/A

Parameter	Grade 1: Mild	Grade 2: Moderate	Grade 3: Severe	Grade 4: Potentially life threatening
LFTs (Transaminases) ALT or SGPT and AST or SGOT	1.25 to < 2.5 x ULN (For any) *ULN=Upper limit of Normal	2.5 to < 5.0 x ULN (For any)	to < 10.0 x ULN (For any)	≥ 10.0 x ULN (For any)
RFTs (Creatinine)	N/A	< 90 to 60 ml/min or ml/min/1.73 m2 OR 10 to < 30% decrease from participant's baseline	< 60 to 30 ml/min or ml/min/1.73 m2 OR 30 to < 50% decrease from participant's baseline	< 30 ml/min or ml/min/1.73 m2 OR ≥ 50% decrease from participant's baseline or dialysis needed
Cholesterol, Fasting, High ≥ 18 years of age	200 to < 240 mg/dL; 5.18 to < 6.19 mmol/L	240 to < 300 mg/dL; 6.19 to < 7.77 mmol/L	≥ 300 mg/dL; ≥ 7.77 mmol/L	N/A
LDL, Fasting, High ≥ 18 years of age	130 to < 160 mg/dL; 3.37 to < 4.12 mmol/L	160 to < 190 mg/dL; 4.12 to < 4.90 mmol/L	≥ 190 mg/dL; ≥ 4.90 mmol/L	NA
Triglycerides, Fasting, High	150 to 300 mg/dL; 1.71 to 3.42 mmol/L	>300 to 500 mg/dL; >3.42 to 5.7 mmol/L	>500 to < 1,000 mg/dL; >5.7 to 11.4 mmol/L	> 1,000 mg/dL; > 11.4 mmol/L

Drug substitutions for ARV drug toxicity

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

However, after six months on ART, a viral load test may be required to rule out treatment failure before a drug is substituted in a failing patient. If the viral load is not suppressed, it is possible the patient may be failing on treatment. Follow the viral load algorithm to rule out treatment failure. In a failing patient, the ART regimen should be switched to 2nd line. See Table 78 for side effects of commonly used ARVs and recommended substitutions.

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

Co-administration of ART and TPT/TB medicines increases the likelihood of toxicities especially hepatotoxicity. Health workers should therefore take care to adequately screen patients for TPT eligibility prior to initiation of TPT. Once toxicity occurs, it should be managed appropriately according to the grading (refer to Table 86 for grading).

Contraindication for TPT:

- Presence of acute liver disease
- History of alcohol abuse
- Known hypersentivity to INH
- Presence of mental illness
- Presence of seizures
- Presence of severe neuropathy
- Newly initiated on DTG (within the last 3 months)

Co-administration with Nevirapine. Note, for patients transitioning from NVP, ensure to wait for at least 2 weeks before starting TPT.

Box 11: Key highlights in Pharmacovigilance

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

WHAT TO EXPECT IN THE FIRST MONTHS OF ART

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

- Clinical and immunological improvement and viral suppression are expected when individuals adhere to ART.
- Opportunistic infections (OIs) and immune reconstitution inflammatory syndrome (IRIS) may develop, as well as early adverse drug reactions, such as drug hypersensitivity, especially in the first three months of treatment.
- ART significantly decreases mortality overall, but death rates are also highest in the first three months of ART. These complications are most common when the people starting ART already have advanced HIV

disease with severe immunodeficiency and existing coinfections and/or comorbidities, severely low hemoglobin, low body mass index, and very low CD4 cell counts or are severely malnourished.
- More frequent visits and monitoring can help reduce this mortality.
- Poor adherence in this period is also associated with the risk of early treatment failure and rapid development of drug resistance.

IMMUNE RECONSTITUTION INFLAMMATORY SYNDROME (IRIS)

IRIS is a spectrum of clinical signs and symptoms thought to be associated with immune recovery brought about by a response to ART. It is a widely recognized phenomenon that occurs among 10–30% of the people initiating ART, usually within the first 4–8 weeks after initiating therapy. IRIS should be considered only when the presentation cannot be explained by a new infection, the expected course of a known infection, or drug toxicity. The most serious and life-threatening forms of IRIS occur in patients co-infected with TB, Cryptococcus, Kaposi's sarcoma and herpes zoster. BCG vaccine–associated IRIS (localized and systemic) may occur in infants infected with HIV in settings where BCG immunization is routine.

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

Managing IRIS

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

Steps to reduce development of IRIS

1. Diagnose HIV early and initiate ART before CD4 declines to below 200 cells/mm3.
2. Screen and optimally manage opportunistic infections before initiating ART, especially TB and Cryptococcus.
3. The timing of ART in people with opportunistic infections requires balancing a greater risk of IRIS after early initiation against continuing high mortality if ART is delayed.

Table 78: Toxicities/side effects of commonly used ARVs and recommended substitutions

	MAJOR ADVERSE/ TOXICITY EVENTS	PRESENTING SIGNS/ SYMPTOMS	SUGGESTED MANAGEMENT
REGIMENS FOR ADULTS AND ADOLESCENTS			
DTG	• Hyperglycaemia • Insomnia • Hepatotoxicity • Hypersensitivity reactions	• Excessive drinking/eating, excessive urination • Difficulty falling asleep • Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes • Skin itching (localized or diffuse), dizziness, faintness, difficulty breathing, nausea, vomiting, diarrhoea, and abdominal cramping	Do RBS to confirm hyperglycaemia then substitute with EFV Insomnia: Ensure patient is taking DTG during the day if it persists then substitute with EFV If EFV is contraindicated: Substitute with ATV/r
EFV	• Persistent central nervous system toxicity • Convulsions • Hepatotoxicity • Severe skin and hypersensitivity reactions • Gynecomastia	• Dizziness, insomnia, abnormal dreams, or mental symptoms (anxiety, depression, mental confusion, suicidality) • New-onset seizures • Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes • New-onset skin rash • Breast enlargement in men	In case on EFV 600mg • Lower the dose of EFV to 400mg. In case on EFV 400mg • Reassure, • If symptoms persist Substitute EFV with DTG If DTG is contraindicated: substitute with ATV/r

	MAJOR ADVERSE/ TOXICITY EVENTS	PRESENTING SIGNS/ SYMPTOMS	SUGGESTED MANAGEMENT
TDF	• Chronic kidney disease, acute kidney injury and Fanconi syndrome • Decreased bone mineral density • Lactic acidosis or severe • Hepatomegaly with steatosis	• Lower back pain, change in urine volume • Bone aches, spontaneous fractures • Exhaustion or extreme fatigue, muscle cramps or pain, headache. • Abdominal pain or discomfort, decrease in appetite.	Do LFTs and RFTs. If deranged (elevated liver enzymes and/or GFR is < 60mls/min) then substitute with ABC If ABC is contraindicated: substitute with AZT
ABC	• Hypersensitivity reaction	• Skin itching (localized or diffuse) dizziness, faintness, difficulty breathing, nausea, vomiting, diarrhoea, and abdominal cramping	Substitute with TDF If TDF is contraindicated: substitute with AZT
AZT	• Severe anaemia, neutropenia • Lactic acidosis or severe hepatomegaly with steatosis • Lipoatrophy, lipodystrophy, myopathy • Severe vomiting	• Easy fatigability, breathlessness, recurrent infections • Exhaustion or extreme fatigue, muscle cramps or pain, headache. • Abdominal pain or discomfort decrease in appetite. • Persistent vomiting resulting in severe dehydration	Do Hb (if < 8mg/dl): Substitute with TDF If TDF is contraindicated: substitute with ABC
NVP	• Acute symptomatic hepatitis • Hypersensitivity reaction, Stevens-Johnson Syndrome (severe or life-threatening rash, mucosal involvement)	• Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes • Severe or life-threatening rash with mucosal involvement (ulcers in the mouth or eyes)	Substitute or switch to appropriate regimen NOTE: NVP is not recommended in ART regimens. NVP should be substituted even in absence of ARs/ toxicity OR regimen switched if client is failing

	MAJOR ADVERSE/ TOXICITY EVENTS	PRESENTING SIGNS/ SYMPTOMS	SUGGESTED MANAGEMENT
ATV/r	• Electrocardiographic abnormalities (PR and QRS interval prolongation) • • Elevated Lipid • Indirect hyperbilirubinemia (clinical jaundice) • History of nephrolithiasis	• Dizziness or fainting • Refer to Blood Lipid levels in Table 68 • Yellowing of eyes, dark yellow urine, yellow stools • Severe lower back pain that comes in waves and fluctuates in intensity, pain on urination, cloudy or foul-smelling urine.	Do ECG; Use with caution in people with pre-existing conduction disease or who are on concomitant drugs that may prolong the PR or QRS intervals, pre-existing coronary disease or previous stroke. Jaundice is clinically benign but potentially stigmatizing. Do LFTs and Lipid profile. If deranged: Substitute with DTG or LPV/r
DRV/r	• Hepatotoxicity • Severe skin and hypersensitivity reactions	• Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes • Skin itching (localized or diffuse) dizziness, faintness, difficulty breathing.	Do LFTs if deranged Substitute with ATV/r or LPV/r. When it is used in third-line ART, limited options are available. For hypersensitivity reactions, substitute with another therapeutic class.
ETV	• Severe skin and hypersensitivity reactions	• Skin itching (localized or diffuse) dizziness, faintness, difficulty breathing.	Substitute with another therapeutic class (integrase inhibitors or boosted PIs).
LPV/r	• Electrocardiographic abnormalities (PR and QRS interval prolongation, torsades de pointes) • Hepatotoxicity • Pancreatitis • Dyslipidemia • Diarrhoea • Unable to tolerate taste	• Dizziness, fainting • Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes • Upper abdominal pain that feels worse after eating, fever, rapid pulse, nausea and vomiting. • Refer to Blood Lipid levels in Table 86. • ≥3 watery stool motions/ day.	Do ECG; Use with caution in people with pre-existing conduction disease or who are on concomitant drugs that may prolong the PR or QRS intervals, pre-existing coronary disease or previous stroke. Do LFTs, Serum Amylase and Lipid profile: if deranged: Substitute with DTG or ATV/r

	MAJOR ADVERSE/ TOXICITY EVENTS	PRESENTING SIGNS/ SYMPTOMS	SUGGESTED MANAGEMENT
REGIMENS FOR CHILDREN 0-10 YEARS			
ABC	Hypersensitivity reaction	Skin itching (localized or diffuse) dizziness, faintness, difficulty breathing.	Substitute with AZT.
EFV	• Persistent central nervous system toxicity (such as dizziness, insomnia, abnormal dreams) or mental symptoms (anxiety, depression, mental confusion) • Convulsions • Hepatotoxicity • Severe skin and hypersensitivity reactions • Gynecomastia	• Dizziness, insomnia, abnormal dreams, or mental symptoms (anxiety, depression, mental confusion, suicidality) • New-onset seizures • Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes • New-onset skin rash • Breast enlargement	Reassure, If symptoms persist, substitute EFV with DTG or LPV/r (if appropriate DTG formulation is not available)
NVP	• Acute symptomatic hepatitis • Hypersensitivity reaction, Stevens-Johnson Syndrome	• Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes • Severe or life-threatening rash with mucosal involvement (ulcers in the mouth or eyes)	Substitute with DTG or LPV/r NVP is not recommended in ART regimens. NVP should be substituted even in absence of ARs/toxicity OR regimen switched if treatment failure confirmed NOTE: NVP will continue to be used for prophylaxis in EMTCT

	MAJOR ADVERSE/ TOXICITY EVENTS	PRESENTING SIGNS/ SYMPTOMS	SUGGESTED MANAGEMENT
LPV/r	• Electrocardiographic abnormalities (PR and QRS interval prolongation, torsadesde pointes) • Hepatotoxicity • Pancreatitis • Dyslipidemia • Diarrhoea • Unable to tolerate taste	• Dizziness, fainting • Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes • Upper abdominal pain that feels worse after eating, fever, rapid pulse, nausea and vomiting. • Refer to Blood Lipid levels in Table 66. • ≥3 watery stool motions/ day • Changes in taste of food, low appetite	Do ECG; Use with caution in people with pre-existing conduction disease or who are on concomitant drugs that may prolong the PR or QRS intervals, pre-existing coronary disease or previous stroke. Do LFTs, Serum amylase and Lipid profile. If deranged: Substitute with DTG If DTG contraindicated: (formulation not available): Substitute with RAL If RAL contraindicated and child is >3 years: Substitute with DRV/r
AZT	• Severe anemia, neutropenia • Lactic acidosis or severe hepatomegaly with steatosis • Lipoatrophy, lipodystrophy, myopathy • Severe vomiting	• Refer to Blood Counts. • Exhaustion or extreme fatigue, muscle cramps or pain, headache. • Abdominal pain, discomfort or decrease in appetite. • Persistent vomiting resulting in severe dehydration	Do Hb (if < 8mg/dl) Substitute with ABC
RAL	• Rhabdomyolysis, myopathy, myalgia • Hepatitis and hepatic failure • Severe skin rash and hypersensitivity reaction	• Severe muscle pain, muscle wasting • Nausea, vomiting, right upper quadrant abdominal pain, yellow urine or eyes • Skin itching (localized or diffuse) dizziness, faintness, difficulty breathing	Do LFTs if deranged and child is > 3 years: Substitute with DRV/r If child is <3 years: Substitute with LPV/r

Table 79: 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. • It's important to note that the major criteria for switching ART in Uganda is Virologic failure with switch guided by HIV DR testing		
Virologic failure	Two consecutive viral loads above 1000 copies/ml, done at least 3-6months apart, with adherence support following the 1st VL test.	The patient should have been on ART for at least six months
Clinical failure	Adults, adolescents and children: New or recurrent WHO clinical stage 3 or stage 4 event (except TB) in a patient who has been on effective ART regimen for at least six months.	The condition must be differentiated from IRIS occurring after initiating ART

6.15 CHILDREN WITH A NON-SUPPRESSED VIRAL LOAD

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

If the child is on a DTG or LPV/r-based first line ART regimen, conduct IAC and repeat VL after 3 months. DTG and PI have high resistance barrier so poor adherence is a m vore likely cause for an unsuppressed VL than resistance. If VL is still not suppressed after IAC interventions, conduct HIV drug resistance to guide the next cause of action.

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

Second line for adults, adolescents and children will be guided by HIV genotyping.

Table 80: Recommended NRTI sequence from first-line to second-line

First line NRTIs	Second line NRTIs
Adults and adolescents ≥30Kg	
TDF+3TC or TAF+FTC	AZT+3TC
ABC+3TC or TAF +FTC	TDF +3TC
AZT+3TC	TDF + 3TC or TAF +FTC

Children <30Kg	
ABC+3TC	AZT+3TC
AZT+3TC	TAF*+FTC
AZT+3TC	ABC+3TC

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

6.16.1 Second Line ARVs In Adults And Adolescents ≥30Kg, Including Pregnant and Breastfeeding Women

RECOMMENDED 2ndline REGIMEN:
2NRTIs + DTG
(if client failed on a PI- or NNRTI-based 1st line ART regimen)
or 2 NRTIs + ATV/r
(if client failed on a DTG-based or NNRTI-based 1st-line ART regimen)
The choice of NRTI should be determined based on the NRTI the patient was previously on (For NRTI sequencing see Table 62 and for 2nd line regimens see Table 63

Rationale for using ATV/r

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

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

LPV/r should only be used for second line in adults and adolescents if ATV/r or DTG are contraindicated.

6.16.2 Second Line ARVs In Children ≥20Kg – 30Kg

RECOMMENDED 2ndline REGIMEN: 2NRTIs + DTG*
(If child failed on a PI- or NNRTI-based 1st line ART regimen)
Or 2NRTIs + LPV/r
(If child failed on a DTG- or NNRTI-based 1st line ART regimen)
The choice of NRTI should be determined based on the regimen the patient was previously on (for NRTI sequencing see Table 80 and for 2nd line regimens see Table 81).

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

WHEN TO USE ALTERNATIVE 2ND LINE REGIMEN: TAF+FTC+ DTG or LPV/r

For children who have failed on AZT+3TCNRTI backbone, give TAF+FTC NRTI backbone as part of second line ART regimen.

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

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

6.16.3 Second Line ARVs In Children <20Kg

RECOMMENDED 2nd line REGIMEN: 2NRTIs + DTG*
(If child failed on a PI- or NNRTI-based 1st line ART regimen)
or 2NRTIs + DRV/r
(If child failed on a DTG-based or NNRTI 1st line ART Regimen)
The choice of NRTI should be determined based on the regimen the patient was previously on (For NRTI sequencing see Table 80 and for 2nd line regimens see Table 81).

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

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

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

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

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

Table 81: First-Second- and third-line ART regimens for patients failing on treatment:

Population	Failing first line regimens	Recommended second line regimen; guided by HIV DR	Alternative second line regimen	Third line regimens[1,2]
Adults and adolescents ≥ 30Kg, including pregnant and breastfeeding women	TAF + FTC + EFV or TDF + 3TC+EFV or TDF+3TC+NVP	**AZT+3TC+DTG**	**AZT+3TC+ DRV/r or ATV/r**	**All third line regimens to be guided by HIV DR resistance testing.** **In case of susceptibility to all drugs, use the table to guide the preferred or alternative choices.**
	TAF + FTC + DTG or TDF+3TC+DTG	**AZT+3TC+DRV/r**	**AZT+3TC+ATV/r**	
	AZT+3TC+NVP AZT+3TC+EFV ABC/3TC/NVP ABC+ 3TC+ EFV	**TAF + FTC + DTG or TDF+3TC+DTG**	**TAF + FTG + ATV/r or TDF+3TC+ATV/r**	
	AZT+3TC+DTG ABC+3TC+DTG	**TAF+ FTC + DRV/r or TDF+3TC+ DRV/r**	**TAF+ FTC +ATV/r or TDF+3TC+ATV/r**	
Children ≥ 20Kg - <30Kg	ABC+3TC+EFV ABC+3TC+NVP	**AZT+3TC+DTG**	**AZT+3TC+LPV/r**	*NOTE: For details on the third-line ART, please see the third-line ART implementation guides.*
	ABC+3TC+LPV/r	**AZT+3TC+DTG**	**AZT+3TC+DRV/r**	
	ABC+3TC+DTG	**AZT+3TC+DRV/r**	**AZT+3TC+LPV/r**	
	AZT+3TC+EFV AZT+3TC+NVP	**TAF + FTC + DTG or ABC+3TC+DTG**	**TAF+ FTC +LPV/r or ABC+3TC+LPVr**	
	AZT+3TC+LPV/r	**TAF + FTC +DTG or ABC+3TC+DTG**	**TAF+ FTC + DRV/r or ABC+ 3TC+DRV/r**	
	AZT+3TC+DTG	**TAF+FTC + DRV/r or ABC+3TC+ DRV/r**	TAF + FTC +LPV/r or ABC+3TC+ LPV/r	

Children <20Kg	ABC+3TC+EFV ABC+3TC+NVP	**AZT+3TC+DTG**	**AZ-T+3TC+LPV/r**	
	ABC+3TC+LPV/r	**AZT+3TC+DTG**	**AZ-T+3TC+DRV/r**	
	ABC+3TC+DTG	**AZT+3TC+ DRV/r**	**AZT+3TC+ LPV/r**	
	AZT+3TC+EFV AZT+3TC+NVP	**ABC+3TC+DTG**	**AB-C+3TC+LPV/r**	
	AZT+3TC+LPV/r	**ABC+3TC+DTG**	**AB-C+3TC+DRV/r**	
	AZT+3TC+DTG	**ABC+3TC+ DRV/r**	**ABC+3TC+ LPV/r**	

All PLHIV should receive resistance testing to inform the prescription of 2nd and 3rd-line medicines

- In case of susceptibility to all drugs, use the table to guide the preferred or alternative choices.
- Since all 3rd-line PLHIV will have prior PI Exposure, DRV/r will be taken twice a day.
- For recipients of care on NNRTI-based First Line regimen whose VL is not suppressed, switch without a second VL but conduct IAC to improve adherence to new regimen.
- All PLHIV on raltegravir should be immediately transitioned to DTG if there are no contra indications irrespective of the VL status.

6.16.4 Programmatic Drug Substitution on 2nd Line Regimens

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

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

Although simplification of regimens including once-a-day dosing is a main goal of ART optimization, children and adolescents who are virally

suppressed and stable on 2nd line regimens containing twice-daily LPV/r will be maintained on their regimens so as to preserve their options for 3rd line regimens. Drug substitutions may be considered on a case by case basis especially in children and adolescents in whom twice-daily dosing may hinder adherence.

6.17 THIRD-LINE ART REGIMENS

6.17.1 Eligibility for Third-Line ART

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

- If they have a detectable viral load test result >1000 copies/ml at the repeat viral load test following intensified adherence counseling.
- The patient should have had three intensified adherence counseling sessions one month apart after the initial detectable viral load.
- The patient has three consecutive scores of adherence >95% as determined by adherence support team. In case the 3 scores are less than 95%, then do DOTs for three months and repeat VL irrespective of adherence scores.

6.17.2 When a patient on second line has suspected resistance to secondline ART

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

- Two samples of venous blood should be taken off and sent to CPHL (Central Public Health Laboratories).
- The samples should be accompanied by the combined viral load and HIV drug resistance form. The first sample will be used by CPHL to conduct the repeat viral load test. Once the result is > 200 or 400 copies/Ml for plasma and DBS respectively, CPHL will proceed to facilitate the geno typing process either by CPHL, JCRC or UVRI as may be deemed necessary
- The resistance test results will be dispatched by CPHL to respective regions for action. The regional teams will review the results alongside the patient details and make the decision to switch or not to switch the patient to third-line ART. Please refer to Figure 63 for the third-line ART flow chart.
- The case discussion and decision reached will always be instituted in the HIV DR data base for monitoring by the National team.

- The health facility team will follow up the patient to initiate them on third-line ART.

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

The recommended anchor drug for third-line regimens for adults, adolescents and children will be ritonavir-booster Darunavir (DRV/r). DTG will be considered for children <20Kg who utilized DRV/r for their second-line regimen. However, selection of third-line ART regimens will be guided by resistance profiling of the antiretroviral drugs. In the initial phase of implementation of the third-line ART program within the national system, the drugs will be kept at the regional referral hospitals to which the health facilities will make their orders. For details on guidance on how to order for and report on third-line ART, refer to Chapter 13.

Figure 62: Third-Line ART Flow Chart

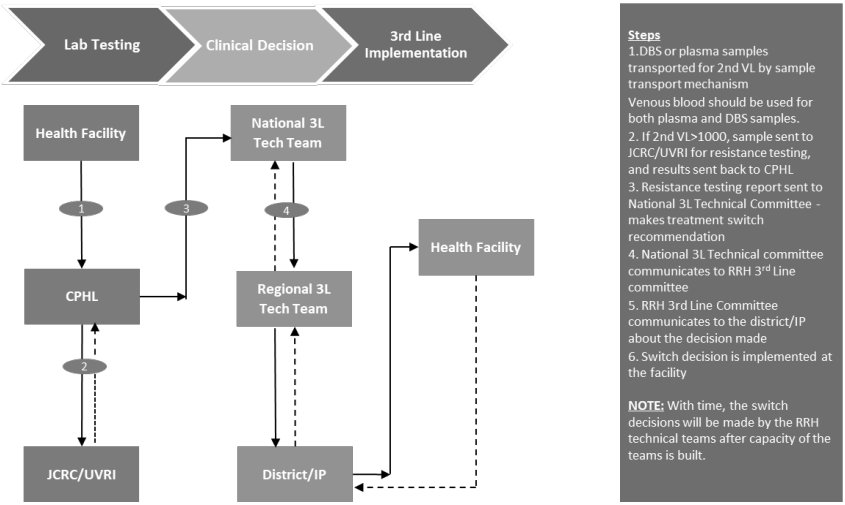


Table 82: Drug interactions

Drug Family	ARV Drug	Interaction	Action
Anti-TB medicines	NVP	Rifampicin decreases NVP concentrations in blood. Could cause liver toxicity	Do not co-administer NVP and rifampicin See Table 39 and Table 40 for TB/ARV co-management
	DTG	Rifampicin lowers DTG levels	Adjust DTG dose to twice daily
	ATV/r, LPV/r, DRV and RTV	Rifampicin boosts metabolism of PIs	If given together with LPV/r increase the dose of RTV to achieve 1:1 ratio
Combined oral contraceptive pills, hormonal implants (etonogestrel)	EFV or ATV/r, LPV/r, DRV and RTV	Risk of contraceptive failure due to increased metabolism of contraceptives	Use additional barrier method or Use Depo-Provera or IUDs
Anxiolytics, e.g. midazolam, diazepam	ATV/r, LPV/r, DRV and RTV	Risk of respiratory depression (midazolam) Increased sedation (diazepam)	Reduce dose of midazolam or diazepam
Antifungals, e.g. ketoconazole	NVP	Risk of hepatotoxicity	Use fluconazole
Simvastatin, rosuvastatin, atorvastatin	ATV/r, LPV/r, DRV and RTV	Inhibition of CYP450 3A4 (reduced metabolism of statins)	Use atorvastatin with lowered dose and monitor for side effects like muscle pains

Drug Family	ARV Drug	Interaction	Action
Anti-epileptics, e.g. carbamazepine, phenobarbital, and phenytoin	EFV, DTG, Etravirine,	Carbamazepine decreases DTG levels by 30-70%	Use valproic acid
Drugs for acid reflux or ulcers, e.g. omeprazole, esomeprazole, lansoprazole, pantoprazole	ATV/r	Reduced concentrations of Atazanavir	Use alternatives like ranitidine, cimetidine, etc.
Polyvalent cation products containing Mg, Al, Fe, Ca, Zn (e.g. vitamin supplements and antacids)	DTG	Reduce DTG levels	Use DTG 2 hours before or 6 hours after the product to avoid interaction
Antimalarial drugs: artemether/lumefantrine, halofantrine	ATV	Both could prolong QT interval	When given with artemether/lumefantrine monitor closely for undesired effects Halofantrine: do not give together (contraindicated)
Metformin	DTG	DTG increases metformin levels. May increase risk of hypoglycemia and metabolic acidosis	Close follow-up (routine electrolytes, BUN and Creatinine, Random Blood Sugar tests) recommended

Box 10: Key highlights in Antiretroviral Therapy for people living with HIV

- Optimization of ART regimens with more efficacious and durable drugs and simplified dosing is recommended for improved long-term viral suppression.
- The preferred first-line ART for all adults, adolescents and children is Dolutegravir-based.
- PLHIV on NNRTI-based first-line regimens should have their viral loads assessed. If virally suppressed, their ART should be transitioned to optimal preferred first-line regimens. If not suppressed, the patients should be switched to second-line ART with IAC.
- PLHIV initiated on DTG should be longitudinally monitored for adverse effects following recommended pharmacovigilance protocols.
- Newly diagnosed pregnant and breastfeeding women shall be initiated on TDF+3TC+DTG or TAF+FTC+DTG.
- Pregnant and breastfeeding women already on TLE should be maintained on this regimen until 6-9 months postpartum when they should be transitioned to TLD if the VL within the past 6 months is suppressed.
- Women becoming pregnant while on DTG-based regimens shall be maintained on the regimen.
- Treatment should be monitored by measuring viral load 6 months after initiation of ART and every 6-12 months or when clinically indicated.
- A repeat viral load of >1000cells/mm3 suggests treatment failure and is indication for HIV DR and appropriate switch after ruling out adherence challenges.
- The preferred second-line ART for adults, adolescents and children are either DTG-based or PI-based, depending on the failing first-line regimens.
- Second and third line regimens shall be guided by genotype (resistance) testing.

7 SERVICE DELIVERY APPROACHES

This chapter will discuss differentiated service delivery for PLHIV including children, adolescents and Adults, the comprehensive community service delivery approach and continuous quality improvement in DSD.

7.1 DIFFERENTIATED SERVICE DELIVERY (DSD)

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

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

This section presents the recommended differentiated service models for HTS, care and treatment for PLHIV and TB for adoption by the facilities and communities managing PHLIV. The details on how the differentiated care models will be implemented in Uganda are described in the Implementation guide for Differentiated Service Delivery Models (DSDM) for HIV and TB services in Uganda (version November 2022).

7.1.1 Core principles of differentiated service delivery

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

a) Client-centered care

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

b) Health system efficiency

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

7.1.2 Why differentiated service delivery is needed

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

7.1.3 The Target Groups For Differentiated Service Delivery

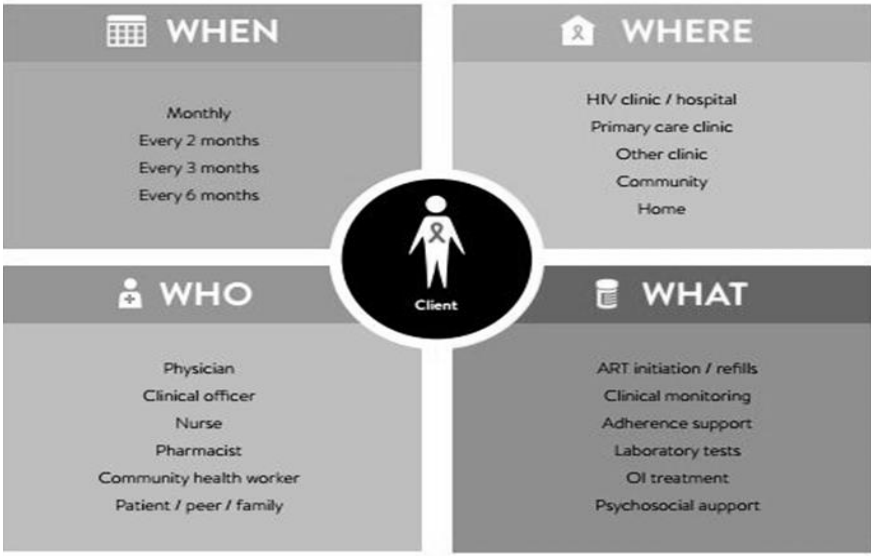
The DSD will meet the different care and treatment needs of different groups of clients including clients newly initiating ART, children, adolescents, pregnant and lactating women, adult men and women, key populations and patients with advanced disease. All these groups will be served either at facility or in the community depending on their preferred model.

7.1.4 Building Blocks for Differentiated Delivery

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 66 below summarizes these building blocks which include:

1. The type of services delivered – WHAT
2. The location of service delivery - WHERE
3. The provider of the services – WHO
4. The frequency of the services – WHEN

Figure 66: The building blocks for differentiated service delivery



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

7.1.5 The 5 A's criteria to choosing a preferred DSD approach

In DSD it is important for the health care worker (HCW) to guide the client to make an informed decision and choose a DSD model that is appropriate for their needs. HCWs should use their knowledge of the client's needs and limitations and guide them using the 5 A's criteria.

1. Assess
    a. Explain the purpose of the session
    b. Assess the client's barriers to adherence to DSD approaches
2. Assist
    a. Evaluate the underlying causes of the identified barriers
    b. Identify client-specific strategies to overcome identified barriers
    c. Discuss the pros and cons of each strategy/option(s)
3. Advise

a. Give necessary information about the different approaches
b. Review benefits of good adherence in relation to DSD
c. Discuss consequences of non-adherence

4. Agree on
   a. Agree on the client's action points to address the key barriers
   b. Evaluate each action point
   c. The document agreed upon action points
5. Arrange
   a. Summarize the session
   b. Arrange for ART refill in the agreed upon approach
   c. Schedule and Document the next appointment date on the visit session form
   d. Refer and link to other services as appropriate

7.1.6 Recommended differentiated services

The two services for adopting differentiated models are:
- Differentiated HIV testing services.
- Differentiated HIV care and treatment services.

DIFFERENTIATED HIV TESTING SERVICES

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

Definition

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

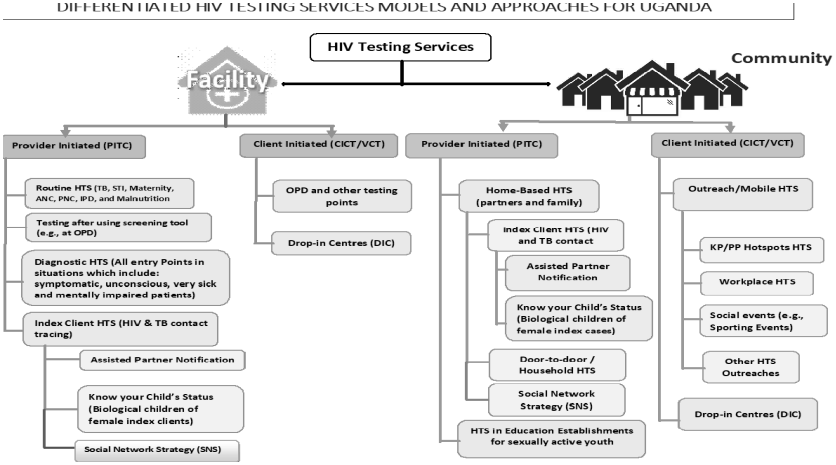
The recommended models and approaches

The recommended ways of differentiating HIV testing and screening include 1) facility-based models and 2) community-based models, summarized under Chapter 4 as well as in Figure 67 below.

HTS services will be offered in the facility (facility-based HTS model) or in the community (community-based HTS model). Facility-based HTS includes provider-initiated HTS (i.e. Routine HTS, OPD testing, Diagnostic HTS and Index client HTS) and client-initiated counseling and testing (i.e.at

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

Figure 67: Recommended differentiated HTS delivery models



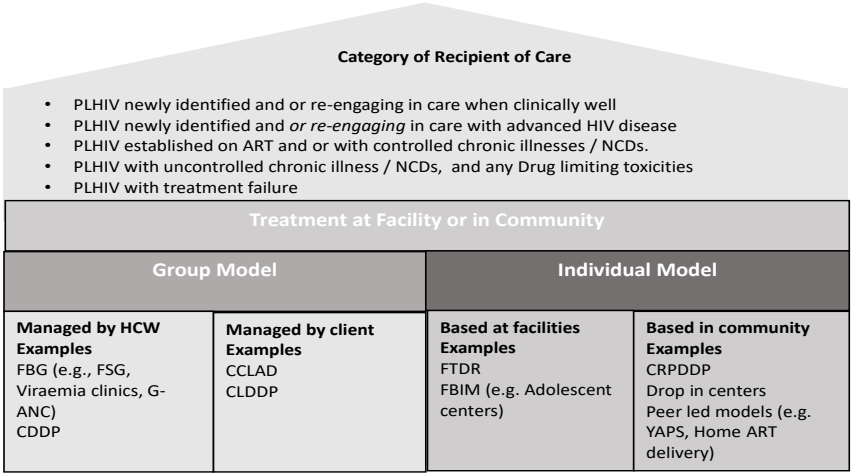
7.1.7 Differentiated Care and Treatment Services

Differentiated HIV treatment and care refers to a strategic mix of approaches to address the specific requirements of a subgroup of clients living with HIV. It includes approaches aimed at modifications of client flow, schedules and location of HIV treatment and care services for improved access, coverage, and quality of care.

The recommended models and approaches

The recommended ways of differentiating HIV treatment and care include 1) facility-based models and 2) community-based models, summarized in the Figure 67.

Figure 68: Recommended differentiated care and treatment service delivery models and their respective target populations



CATEGORIZATION OF CLIENT CHARACTERISTICS FOR DSD

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

1. PLHIV newly identified and or re-engaging in care when clinically well
2. PLHIV newly identified and or re-engaging in care with advanced HIV disease
3. PLHIV established on ART and or controlled chronic illness / NCDs
4. PLHIV with uncontrolled chronic illness / NCDs and any Drug limiting toxicities
5. PLHIV with treatment failure

Table 88: Definition of the DSD Categories

PLHIV newly identified and or re-engaging in care when clinically well	PLHIV newly identified and or re-engaging in care with advanced HIV disease	PLHIV Established on ART and or with Controlled chronic illnesses / NCDs	PLHIV with uncontrolled chronic illness / NCDs and any Drug limiting toxicities	PLHIV with Treatment Failure

• CD4≥ 200 Cells/mm3 • WHO stage 1 and 2	• CD4 <200 cells/ mm3 • WHO stage 3 or 4 at presentation for care • Children < 5 years	• Receiving ART for at least 6 months • No current illness • Controlled chronic health conditions • Good understanding of lifelong adherence • Evidence of treatment success (at least one suppressed VL in the last 6 months) • No ART limiting drug toxicity	• FBG ≥ 7mmol • RBG ≥ 11mmol • HTN ≥ 140/90mmhg • SRQ≥ 6 • Audit-C > 3 • HPV/VIA positive clients	• 2 consecutive Non suppressed VL ≥ 1000 copies • Has current or history of WHO stages 3 or 4 event within the past one year.

DSD MODELS

DSD will continue to be implemented both at the facility and in the community. There will be broadly two models namely; group model and Individual model. Each of these, will be further divided into two i.e. Group model managed by health care worker or client and individual model based at facility or community, with the different approaches listed in the schemer above.

Table 89: Client categories for HIV Care and Treatment services under the various differentiated categories

ROC Categories	Group Model		Individual Model	
	Managed by HCW	Managed by client	Based at the facility	Based in the community
PLHIV newly identified and or re-engaging in care when clinically well	✓	✓	✓	✓
PLHIV newly identified and or re-engaging in care with advanced HIV disease	✓		✓	

PLHIV established on ART and or with Controlled chronic illness / NCDs	✓	✓	✓	✓
PLHIV with uncontrolled chronic illness / NCDs, and any Drug limiting toxicities	✓		✓	
PLHIV with treatment failure	✓		✓	

Note: Eligibility criteria for RoC to be enrolled into any of the DSD approaches of their choice have been removed.

Unsuppressed clients can now also receive care from a community based approach like CDDPs

For the less intensive approaches, a RoC can change from one approach to another if they have a suppressed viral load in the last 12 months.

DSD APPROACHES

The approaches will be implemented at the facility and the community as shown in Figure 67.

Facility approaches

These include:

1. Facility-Based Individual Management (FBIM), where RoC gets a comprehensive assessment on every visit at the facility (Clinical assessment, review of results and other services like PSS)
2. Facility-Based Groups (FBGs), usually for clients that require peer support or special attention like PBFW, children, unsuppressed clients. These are usually for 15-40 clients meeting monthly or quarterly. Examples include FSG, Viraemia clinics, G-ANC.
3. Fast track drug refill (FTDR), where clients are fast tracked to get their drug refills after being triaged for adherence, TB, Nutrition etc.

Community Approaches

These include:

1. Community Client Led ART Delivery (CCLAD), that comprises of 3-6 people who will provide peer support to each other and alternate drug refill pickups at the facility. These clients stay in the same community for easy access to each other.
2. Community Drug Distribution Points (CDDPs), where ART is delivered to the community by both health workers and peers through outreach sites to reach hard to reach populations or poor accessibility to health facilities. For CDDPs managed by health workers, these guidelines allow even the non- suppressed clients, children and adolescents to be part of the CDDPs with agreed upon visit times to the CDDP. A comprehensive care package should be given while at the CDDP site.

CDDP can be subdivided into the following:

- Drop-in Centers. This is the movement of services to a site nearer to the population to be served.
- Community Retail Pharmacy Drug Distribution Point. Where a private retail pharmacy, is attached to a parent health facility to service eligible clients for this approach to improve convenience as these work past ART clinic hours and even on weekends.
- Eligibility criteria for CRPDDP
  - Not pregnant
  - Not breastfeeding
  - On ART for 1+ years
  - Age 20+
- Client Led Drug Distribution Points. Where the clients demand for facility services from a nearby health facility. These communities will use some of their savings to facilitate transport and facilitation of the health workers and the services will be integrated to include FP,SRH, Lab.
- Home delivery. This will be done by a peer support or where possible a health care worker in the community.
- Peer led Models like YAPS.

7.2 MULTI- MONTH PRESCRIPTIONS

Multi-month prescriptions apply to clients in the different approaches. This is defined as prescriptions for 3- or 6-months. Previous guidelines recommended 3 months prescriptions for clients on stable approaches like i.e., FTDR, CDDP and CCLAD. These guidelines recommend the

introduction of 6 months prescription to all eligible clients for MMDs in their respective approaches.

7.2.1 Frequency of clinical visits and ART pick up

PLHIV established on ART should be offered clinical visits and or ART refills every 3–6 months, preferably every six months if feasible, which have been associated with improved outcomes compared with monthly schedules.

7.2.2 DSD for children and adolescents

With the new categorization, children and adolescents can now be served through both group and individual models together with their parents / guardians. Previous guidelines restricted differentiation of HIV/TB services for children to FBIM or FBG while the adolescents were restricted to FBIM, FBG or FTDR. These guidelines recommend the expansion of DSD approaches for children and adolescents to be with their caregivers and are eligible to community-based approaches.

7.2.3 DSD implementation in the context of ART optimization

All stable PLHIV transitioning to other regimens due to policy changes (e.g. ART optimization) shall be retained in their current DSD approaches if all other factors stay constant. Efforts should be made to strengthen pharmacovigilance in all DSD models and approaches.

- Providing patient education about side effects and when to return to facility
- Scheduling a clinical review one-month post regimen change with a one month refill of the new regimen
- If no major concerns are identified during the clinical review one-month post regimen change, RoC can resume multi-month refills (MMRs) and reassessed for DSD approach

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

Regimen change done by clinician at the CDDP

Patient education about side effects and when to return to facility provided at the CDDP

3 or 6 -months refill provided

Clinical review scheduled at 1 month later at the facility. If no major concerns identified the client is referred back to the CDDP for the next scheduled visit

Clients enrolled into the Community Retail Pharmacy Drug Distribution Point (CRPDDP) approach shall have their regimen optimization done as follows:

- Facility will inform the pharmacy about eligible clients for ART optimization and send them back to the facility.
- Facility will also inform the eligible clients to come to the facility on their next visit.
- Regimen change done by clinician at the facility.
- Patient education about side effects and when to return to facility provided at the facility and CRPDDP
- 3 or 6 -months refill provided
- Clinical review scheduled at 1 month later at the facility or CRPDDP.

7.2.4 Provision of TPT Within DSD Models And Approaches

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

7.2.5 TPT initiation

TPT should be initiated by a clinician regardless of which DSD approach the client is on. Efforts should be undertaken to have baseline tests done (i.e. LFTs) prior to initiation of TPT.

TPT should be initiated at the health facility and community for all clients receiving ART services through FBIM, FBG, FTDR, CRPDDP and CCLAD.

For clients enrolled onto CDDPs, TPT should be initiated from the CDDP during the clinicians visit. Efforts should be undertaken to have baseline tests done (i.e. LFTs) at the time of initiation of TPT.

Patient education about side effects and when to return to the facility should be provided at the time of TPT initiation regardless of DSD approach.

TPT and ART refills should be aligned

7.2.6 Monitoring clients on TPT

Clinical monitoring of clients on TPT should be done at every clinical encounter regardless of DSD approach the client is on:

Monitoring can be done through history taking and physical examination for signs suggestive of hepatic injury (i.e. Yellowing of eyes, body itching, body rash)

Monitoring can also be done through follow up phone calls to the clients. During the phones calls health workers should explore for signs of liver injury, adherence to treatment and provide client education.

LFTs should be done at baseline and at 3 months

7.2.7 How to Introduce DSD Models

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

During and immediately following the training of health care workers on DSD, MoH recommends the stepwise approach detailed in Table 90 to be followed in your facility to introduce differentiated models of service delivery. This approach will facilitate effective implementation and coordination of DSDM.

Table 90: Stepwise approach to introduce differentiated models of service delivery

Step 1: Establish a committee to coordinate DSDM activities
Strengthen an existing committee to undertake DSDM activities. At a minimum they should include:

- ART In Charge
- HTS Focal Person
- HMIS/Data Clerk
- Logistics Focal Person
- QI Focal Person
- PMTCT/EID Focal Person
- Community Representative (Health Assistant, CDO, VHTs, CHEWs)
- TB Focal Person
- Laboratory Focal Person

NOTE:

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

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

Step 2: Conduct assessments to:

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

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

Step 4: Assess resource needs

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

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

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

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

NOTE:

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

Step 6: Document best practices
- Documentation for best practices should be detailed enough, addressing aspects such as:
- Processes that were undertaken
- Structures/systems that were developed and/or strengthened
- Positions that were designated for key DSD activities
- Resources used, including how they were mobilized - from who or which organization and whether they fostered TB/HIV collaboration efforts
- Networks that were developed – within the community, across facilities etc. and how this was done
- Successes attained
- Challenges encountered and how they were addressed or attempted to be address (if the challenges still exist); etc.

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

Box 12: Key highlights in Service Delivery Approaches

The core principle for differentiating care is to make it client-centered by providing ART service delivery in a way that acknowledges specific barriers identified by clients and empowers them to manage their disease with the support of the health system.

Determining the type of DSD bases on the category of patients (adults, adolescents, children, pregnant and breastfeeding women, key and priority populations), clinical status of patients (stable or unstable) and the context (rural or urban).

DSD may be provided in the facility and in the community. Unstable patients will receive facility-based DSD interventions while stable patients may receive community-based DSD interventions.

Multi-month prescriptions for ART and other medications for up to 6 months are recommended for eligible stable clients in whom frequent drug pickups may compromise their adherence to ART including key populations, migratory and those in hard to reach settings.

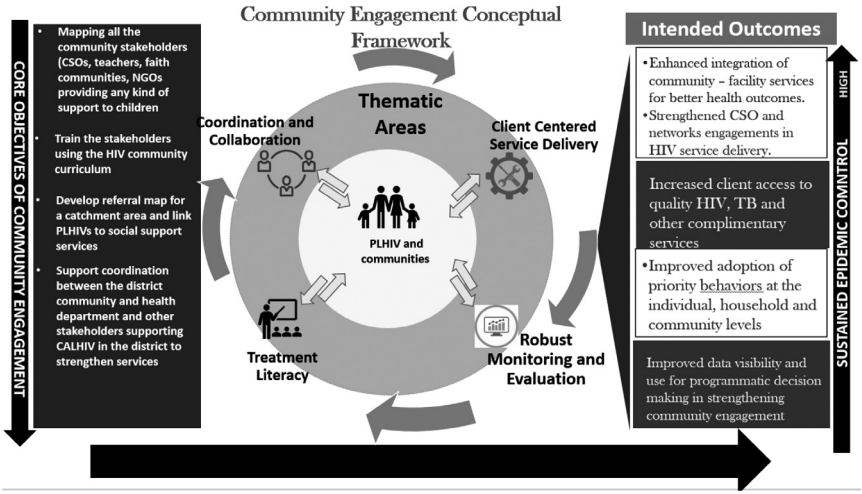
Community structures and systems play a key role in completing the continuum of care by increasing demand, uptake and continuous utilization of HIV prevention, HTS, care and treatment services both in facilities and community. A coordinated system of referral and linkage between community structures and health facilities should be established to ensure access to services and optimal outcomes.

7.3 COMMUNITY SYSTEMS AND STRUCTURES IN OPTIMIZING DELIVERY OF HIV/TB SERVICES

Community engagement aims at ensuring inclusiveness and involvement of all stakeholders such as the community based, community led organizations and other stakeholders in the delivery of services to ensure that services respond to the needs of clients, gender responsive and informed by and respond to an analysis of equity.

The National Community Health Strategy provides guidance to all stakeholders on the strategic direction and implementation of community interventions and the community engagement framework is hinged on the above strategy intended to define the implementation of community services in HIV/TB geared at achieving epidemic control.

Figure 73: Community Engagement Conceptual Framework



Guided by the above conceptual framework, the framework is intended to define the standard package of community based services relevant to all People Living with HIV and communities based on principles of personal centeredness, community leadership, and enabling linkages with existing services. The framework stipulates four pillars that should be implemented by the health facility to achieve maximum support towards achieving epidemic control as explained below.

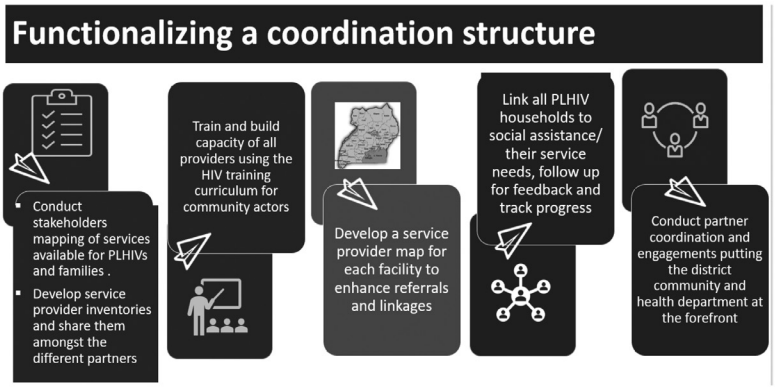
7.3.1 Coordination and Collaboration of all Community Stakeholders in Delivery of Services to Communities

At all levels of support, structures should be established with a mechanism for coordinating the different stakeholders to ensure clients receive a continuum of services.

A comprehensive service mapping should be conducted to operationalize the coordination at all level. This exercise is geared to establish, build and strengthen functional beneficiary referral networks at all levels. The exercise will enable all districts to establish the existing community resources and service delivery structures to generate data that facilitates the building of strong and formal partner service linkages and networks. The establishment of strong formal linkages and referral networks will scale up accessibility and utilization of core services, and expand the case management approach to build long term sustainability. Through enhanced coordination, user-friendly directories, effective follow-up mechanisms and improved service provider capacities, People Living with HIV who access one key core service will be linked to multiple core services that pave the way to sustained health outcomes and graduation from social assistance.

These structures should be operationalized at national, regional and community level as explained below.

Figure 74: Functionalizing a Coordination Structure



At national level

The Ministry of Health will provide overall strategic policy direction and guidance together with key line Ministries and other national level

stakeholders through the National Community Technical Working Group. Additionally, the Ministry of Health will provide technical assistance through the regional referral hospital community health department to operationalize coordination for all the partners in the regions.

Regional level

The Regional Referral Hospitals' through the Community Health Department shall work with the regional partners to functionalize a regional coordination structure.

District Level

The District Community Development Office together with the District Health Office will spear head planning, coordination, monitoring and supervision of the implementation of the community interventions beginning with mapping of all stakeholders with in their catchment area.

The District will monitor and supervise activities that provide an enabling environment for smooth implementation of the community interventions. The District will also ensure the functionality of multi sectoral coordination committees at both sub-county, parish and community levels.

Health facility level

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

The health facility should map children on ART and in organized settings such as (education institutions, institutional homes and foster homes) to ensure they receive a continuum of services they require to adhere to treatment. Staff working in these institutions should be trained using the MOH community HIV training curriculum and equip them with the treatment literacy handbooks to support the CALHIV in schools as well as linking them to nearby health facilities for additional support. The operational step by step SOP can be found in the treatment literacy handbook

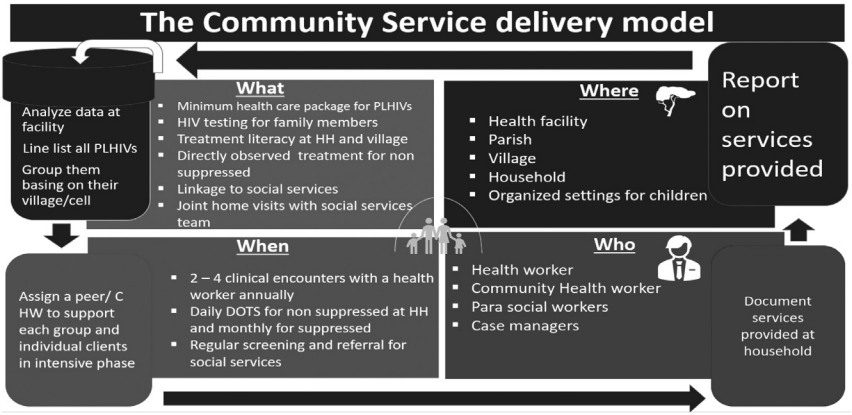
Community Level

Community based organizations and other organized groups including People Living with HIV networks, peer support groups, Expert Clients, male action groups, youth and adolescent groups provide services to the target populations as guided by the core package of community-based services and established Memorandum of Understanding with implementing partners and facilities as appropriate. The organizations will periodically compile and report on the community- based care activities to the district.

7.3.2 Client-Centered Service Delivery

Integrated client centered service delivery aims at promoting a Family-centered approach which is community led, promotes participation of people living with HIV and empowers patients to take responsibility and ownership of their health for HIV epidemic control.

Figure 75: Integrated Community Service Delivery Model



How does the approach work?

This family centered approach to care is applicable for all Recipient of Care and their family members or caregivers at household and community (village) level. People living with HIV are grouped according to their villages into cells for provision of the minimum package of services. The approach offers a platform for clinical support and linkage to other support services using the 4 building blocks to ultimately improve the quality of clinical care and social wellbeing.

How to operationalize the model

At the Facility

- Update the EMR and other primary data sources
- Conduct a mapping exercise of non-suppressed clients;
  - Line list all people living with HIV in the facility by District, Sub county, Parish and villages where they live.
  - Zone the people living with HIV according to the villages of residence. Follow up the line listed people living with HIV by their villages passively for those returning within one month and actively for those with an appointment longer than a month to return to the health facility on a scheduled date for the inception meeting.
  - Map the community Health Workers from the same villages where the non-suppressed are coming from.
  - Attach community health workers (peer mother, client linkage facilitators, caregiver mentor, para- workers, safe space leader) depending on village/safe space of abode.
- Conduct HIV training for Community health workers using the Ministry of Health training curriculum for community actors.
- Conduct meeting between community health workers and the non-suppressed to be supported at health facility.
- Give information on the model, obtain a written consent
- Zone household of the non-suppressed per villages/cells into groups of 5-10 families and agree on the day and central meeting place in the community
- Introduce package to be offered
- Provide 3 months refill to non-suppressed and 6 months refill to suppressed clients and family members in the community.
- Synchronize clinical appointments for care and drug refills for the clients and the community health worker (Safe space leader) at health facility.

In the community

Pre safe space meeting preparations

- The health worker uses service gap identifier tool to offer services to eligible for all people living with HIV and their family members.
- Safe space lead conducts pre appointment reminders to patients on the agreed location and date
- The safe space lead prepares and delivers play materials

At the quarterly safe space meeting

- Safe space lead mobilizes clients for services
- Health worker or safe space lead gives health information
- The health worker updates service gap identifier tool to offer services to eligible people living with HIV and their family members.

At the monthly safe space meeting

- Safe space lead gives health information
- Skills building and economic strengthening
- Saving and Loans schemes activities
- Provide play materials for children at the spaces in the community
- Schedule appointments

Daily safe space visits (at the agreed meeting point)

The second 2 weeks after household Directly Observed Treatment and support the treatment supporter will move with the non-suppressing people living with HIV to the agreed meeting point. This is intended to ensure that the people living with HIV is taking the medicine the right way as guided by the safe space lead.

The safe space lead will;

- Give health information
- Conduct Directly Observed Treatment and support
- Do Pill count
- Provide Intensive Adherence Counselling support
- Link clients to social services

Daily household visits

The safe space leader will conduct daily Directly Observed Treatment and support at household level for the first 2 weeks (14 days) during the intensive phase of the Directly Observed Treatment and support to improve adherence on treatment for the non-suppressed people living with HIV.

- Health workers will conduct an initial joint home visit with the Community Health Worker (Safe space lead) and Orphans and Vulnerable Children team to each of the household of a non-suppressed. They will conduct a root cause analysis (RCA) and develop a joint care plan including.
- 2 weeks of daily contact
- Cell lead gives health information (treatment literacy)
- Directly Observed Treatment
- Pill count
- Intensive Adherence Counselling and support

- Linkage to other social services

7.3.3 Treatment Literacy

Treatment literacy is one of the challenges causing the slow progress to the achievement of the global 95-95-95 targets. This has been observed in how care givers administer treatment to children. There is limited knowledge on the importance of timely viral load bleeding and there remains significant stigma and discrimination in the community and households.

As guided by the community framework, the Ministry of Health developed a treatment literacy pillar to address the gaps in knowledge and understanding of HIV among the different sub populations.

Treatment literacy translates medical information on Antiretroviral Treatment (ART) into languages and formats that are understandable by all. It is defined as understanding the major issues related to an illness or disease – such as the science, treatment, side-effects, and guidelines – *so that the patient can be more responsible for their own care* and will demand their rights when proper care is not available to them.

Treatment literacy encompasses a matrix of approaches and stakeholders at national, regional, district and community level. These approaches link to each other and engage a wide number of stakeholders as shared in the Community Engagement Framework.

7.4 INTEGRATING CONTINUOUS QUALITY IMPROVEMENT INTO HIV CARE

The Ministry of Health recommends the use of continuous quality improvement (CQI) as means to ensure the provision of high-quality health services and attainment of the 90-90-90 HIV targets. CQI is an approach to improvement of service systems and processes through the routine use of health and program data to meet patient, and program needs. The basis of CQI is a continuous measurement of the actual performance against the desired performance as per set national standards. The Ministry of Health recommends a combination of work environment organization using 5Ss (Sort, Set, Shine, Standardize, Sustain) and CQI methodologies to achieve Total Quality Management (TQM).

The health sector quality improvement framework clearly spells out quality improvement roles and responsibilities at the different levels of the health system from national level through regional, district, health sub-district,

health facility to work improvement team levels.The functionality of these structures is crucial to the integration of CQI in health care services. This chapter will describe the process of using CQI to improve HIV service delivery through addressing the service delivery gaps.

7.4.1 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 93** below describes the steps involved in using CQI to address HIV service delivery gaps. Steps 1 and 2 describe the process of forming teams while steps 4 and 5 describe how the teams implement CQI. Steps 3–5 should be followed for each performance gap and regularly repeated (at least monthly) until the performance gap has been closed**.**

Table 93: Steps to use CQI to improvement HIV service delivery gaps

Step	Description
Establish the health facility QI team	Team should have leader. They will supervise the HIV work improvement teams (WIT) for different care processes.
Set up HIV work improvement teams (WIT)	• WIT should be set up for the different care processes along the HIV continuum of care. • They will dedicate time to understanding their current process for providing HIV care services, identify gaps and bottlenecks. • They will use the CQI approach through applying the principles of an iterative cycle of improvement (Plan, Do, Study, Act [PDSA] Cycle).
Identify gaps	• WIT should regularly review performance and HIV QI indicators. • WIT should analyze the data and identify performance gaps by comparing current performance to set targets.
Gap analysis to get root causes	• Use QI tools such as brainstorming, flow charting, five whys, cause and effect analysis to identify the root causes of the performance gaps.
Develop possible solutions	• Use QI tools like the driver diagram to develop possible solutions to address the performance gaps

Step	Description
Prioritizing solutions to address performance gaps	• Use a prioritization matrix to prioritize the solutions to be implemented. • Look for solutions that give maximum benefit at relatively low cost.
Developing improvement projects using the documentation journal	WIT will: • Develop improvement aims from the prioritized gaps. • List all the activities in a particular process targeted for improvement. • Use the activities to develop a flow chart for the process. • Use the flow chart to identify the individuals who will perform the different activities and include them in the WIT for the process. • Develop an improvement objective from the prioritized performance gap with the aid of the HIV QI indicator manual. • Document the data in the graph template of the documentation journal. • Develop an action plan indicating the changes that the team agreed to test or redesigning the service delivery model.

7.4.2 Monitoring of CQI Implementation

- Work improvement teams working on a particular improvement project should regularly review performance data (in the documentation journals) resulting from the implementation of changes targeting the improvement.
- Health facility QI teams and QI focal person should jointly review the teams' documentation journals and provide guidance as necessary regularly (at least monthly).
- District QI committees should supervise and guide QI implementation at health facilities.
- Regional QI Committees should mentor and supervise district and selected facility QI implementation.

7.4.3 The following documents provide more guidance on implementing CQI:

a. Health Sector Development Plan (HSDP) 2015/16-2019/20 (Ministry of Health)
b. Health Sector Quality Improvement Framework and Strategic Plan (QIF & SP) 2015/16 - 2019/20 (Ministry of Health).

c. CQI training curriculum for health workers 2020
d. The clinical Audit tool

Box 13: Key highlights in Service Delivery Approaches

- The core principle for differentiating care is to make it client-centered by providing ART service delivery in a way that acknowledges specific barriers identified by clients and empowers them to manage their disease with the support of the health system.
- Determining the type of DSD bases on the category of patients (adults, adolescents, children, pregnant and breastfeeding women, key and priority populations), clinical status of patients (stable or unstable) and the context (rural or urban).
- DSD may be provided in the facility and in the community. Unstable patients will receive facility-based DSD interventions while stable patients may receive community-based DSD interventions.
- Multi-month prescriptions for ART and other medications for up to 6 months are recommended for eligible stable clients in whom frequent drug pickups may compromise their adherence to ART including key populations, migratory and those in hard-to-reach settings.
- Community structures and systems play a key role in completing the continuum of care by increasing demand, uptake and continuous utilization of HIV prevention, HTS, care and treatment services both in facilities and community. A coordinated system of referral and linkage between community structures and health facilities should be established to ensure access to services and optimal outcomes.

7.4.4 Monitoring and Evaluation of the Strategy

All programs will be required to monitor and track progress towards achieving the four major pillars of the framework. Data should also be used to build a knowledge base on effective two-way referrals, linkages and quality service delivery between facilities and communities, including implementation of differentiated service delivery. This will help identify strengths and key areas for improvement, and to define and implement quality improvement activities.

Community Led Monitoring will be used as a client feedback mechanism to generate information for improvement of quality of HIV services.

Community Led Monitoring is a social accountability and advocacy strategy with the primary objective of contributing to improvement of quality of HIV and TB services by holding duty bearers and healthcare service providers accountable for the quality of HIV and TB services offered.

The primary purpose of Community Led Monitoring is to engage community stakeholders affected by HIV and TB to use data to improve the quality of client-centered care.

Community Led Monitoring is led by civil society organizations representing communities living with, affected by and at high risk of HIV and TB to independently conduct systematic and routine monitoring of facility and community service delivery sites and to use their findings to advocate for improvements in the quality and accessibility of HIV and TB services

8 HEALTH PRODUCTS MANAGEMENT

8.1 INTRODUCTION

This section describes the health products management to support the scale-up of HIV prevention, care and treatment services for Uganda to attain the 95-95-95 targets. This includes product selection in line with the updated guidelines and patient regimens, aspects of quantification, ordering and reporting as well as commodity management by health facilities.

8.2 PRODUCT SELECTION, QUANTIFICATION AT THE CENTRAL LEVEL

At the National level, products are selected according to the consolidated guidelines for HIV prevention, care, and treatment. New commodities, formulations, strengths, and pack sizes are adopted as recommended in the guidelines while obsolete ones are equivocally dropped. The Essential Medicines and Health Supplies List of Uganda (EMHSLU) is reviewed periodically, and such changes considered.

The Department of Pharmaceuticals and Natural Medicines through the Quantification and Procurement Planning Unit (QPPU) in consultation with the ACP is responsible for the national level quantification, supply planning and ensuring reliable and uninterrupted supply of HIV commodities at National Medical Stores and Joint Medical Store.

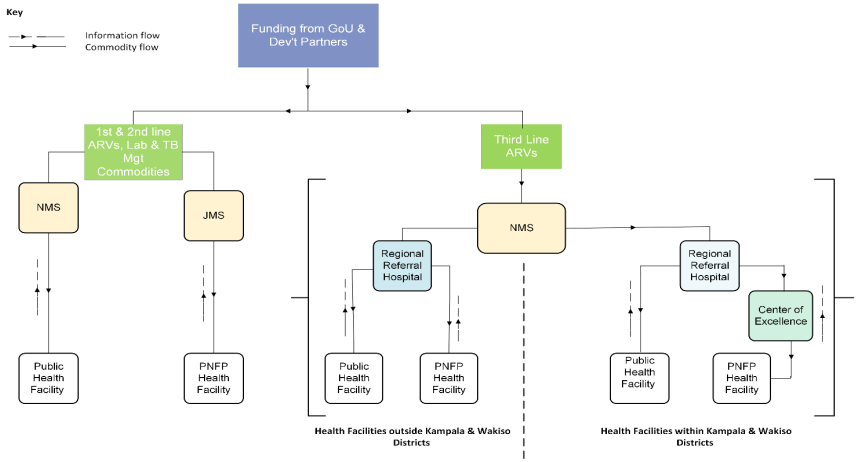
Table 94: New Formulations being introduced.

#	Item Description	Dosage form
1	Tenofovir alafenamide /Emtricitabine/Dolutegravir 25/200/50mg - TAF/FTC/DTG 25/200/50mg)	Tablet
2	Darunavir/Ritonavir 400/50mg (DRV/r 400/50mg)	Tablet
3	Lopinavir/Ritovir 40/10 mg - LPV/r 40/10 Granules	Granules
4	Dapivirine 25mg vaginal ring	Ring
5	Cabotegravir 600mg/3ml – Long Acting (CAB-LA)	Injection

The timing for the introduction of each of the formulations will be communicated by MoH.

8.3 FLOW FOR COMMODITIES USED IN THE PREVENTION, CARE AND TREATMENT FOR HIV.

Figure 76: Flow for Commodities used in the Prevention, Care and Treatment for HIV.



Except for antiretroviral medicines meant for clients on third line and a few special distribution commodities, Supply of Commodities Used in the Prevention, Care and Treatment for HIV follows the **one warehouse one health facility policy** and **the 2012 ART rationalization guidelines** where every health facility is allocated one central warehouse for supply and resupply of Essential Medicines and Health supplies as illustrated above and emphasized below.

- National Medical Stores is responsible for supplying commodities to all ART accredited health facilities within the public sector while.
- Joint Medical Store supplies the ART accredited health facilities within the Private Not for Profit (PNFP) sector.
- Newly accredited facilities should refer to the accreditation letter for information on warehouse allocation.

Flow for Antiretroviral medicines meant for Third line Clients.

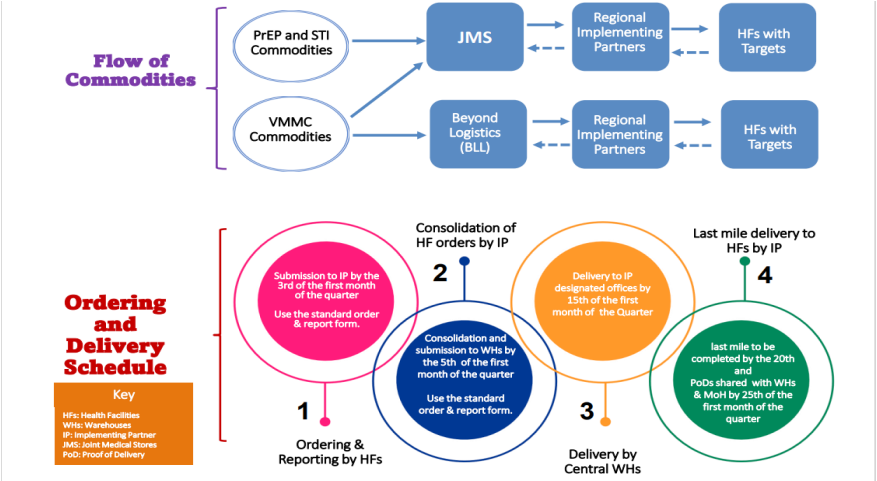
- Flow of third line commodities follows the current recommended support structure for third line programing which is provided through the regional referral hospitals (RRHs).

- Currently, National Medical Stores is the only warehouse that supplies commodities meant for third line. These are supplied to RRHs which later supply to the health facilities and or Centers of Excellence (CoEs) under their support.
- PNFP health facilities in Kampala and Wakiso access third line ARVs from the CoE that directly supports them.

Special Distribution Commodities.

- The include commodities meant for Pre-exposure Prophylaxis (PrEP), Voluntary Medical Male Circumcision (VMMC), Medication Assisted Therapy (MAT) and STI medications funded specifically for HIV programing usually donor specific.

Figure 77: Commodity Flow, Ordering and Reporting Timelines for PrEP, STI and VMMC commodities



Note

- Given the restrictions associated with handling the MAT commodities, they are delivered straight to the sites offering MAT services that have strong rooms and adequate training to avoid misuse.
- Plans to integrate above commodities into the National supply chain are underway, MoH will provide further guidance.

8.4 SELECTION OF HEALTH PRODUCTS AT FACILTY LEVEL

In general, all health facilities should select antiretroviral drugs and related commodities for both existing and new patients in line with the current Consolidated Guidelines for the Prevention, Care and Treatment for HIV and AIDS in Uganda (see Chapter 3).

- It is recommended that the overall number of ARV- formulations and related commodities be minimized to optimize treatment.
- A health facility should select and order for formulations which have clients benefiting from them.
- Guidance for introduction for new formulations will always be given by MoH.
- Health facility teams should constantly monitor and review formulations with clients and those which no longer have clients taking them should be deleted from the facility list to avoid ordering and accumulation of either obsolete or unnecessary items.
- For third line ART program, only health facilities designated to order for third line ARVs (RRHs) should select and order for third line ARVs.

8.5 ORDERING AND REPORTING BY THE HEALTH FACILITIES

All facilities are required to quantify their need for HIV commodities (ARVs, OI medicines, PrEP, HIV test kits, laboratory monitoring reagents. etc.) required for all existing and new patients to ensure uninterrupted availability. The number of patients on treatment, rate of consumption of the various commodities should inform the quantities of commodities to be ordered, putting into consideration the recommended minimum and maximum stock levels.

General Guidance

- Ordering and reporting of medicines and HIV test kits and related laboratory reagents at health facilities is a multi-disciplinary task that should involve the pharmacist, dispenser, clinician, the laboratory officer, the M&E officer, and inventory officers where applicable.
- Ordering processes should be coordinated and led by a pharmacist or a dispenser or a person designated to manage medicines and health supplies in the facility.
- Facilities should order medicines and HIV test kits on a bi-monthly basis following schedules provided by their respective central warehouses. Complete, correct, and timely orders should always be submitted.

- Health facilities should order for ARVs, Fluconazole, Cotrimoxazole, Dapsone, L-Amphotericin B and Flucytosine using the ARV Medicine order and Patient report form (HMIS PHAR - 017)
- Isoniazid and Rifapentine should be ordered using the Health Facility Order Form for First Line TB Drugs (HMIS PHAR-026).
- HIV test kits should be ordered using the bimonthly report and order calculation form for HIV test kits (HMIS PHAR-021)
- Other laboratory commodities should be ordered using the general laboratory order form (HMIS PHAR-023)
- All paper orders should be fed into the electronic ordering platform (NMS CSSP for public sector facilities and electronic Logistics Management Information Systems (eLMIS) App in DHIS 2 for PNFP health facilities).
- The Ministry of Health revised all logistics management information system (LMIS) tools to accommodate changes in the 2022 treatment guidelines. Health facilities should obtain copies of updated LMIS from the warehouses.

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 logistics management information systems if available and consistently used.
- Stock on hand of commodities obtained from the stock cards after conducting a physical count. Stock on hand should include balance of commodities in the dispensary and any other units where medicines are stored or dispensed.

Facility patient data including:

- The number of existing patients on treatment aggregated by age and treatment regimens at the beginning of the reporting period obtained from the ART registered or the Electronic Medical Records (EMR).
- The number of new patients enrolled in the reporting period including those patients switching to other lines of treatment regimens obtained from the ART registered or the Electronic Medical Records (EMR).

Other considerations when ordering include:

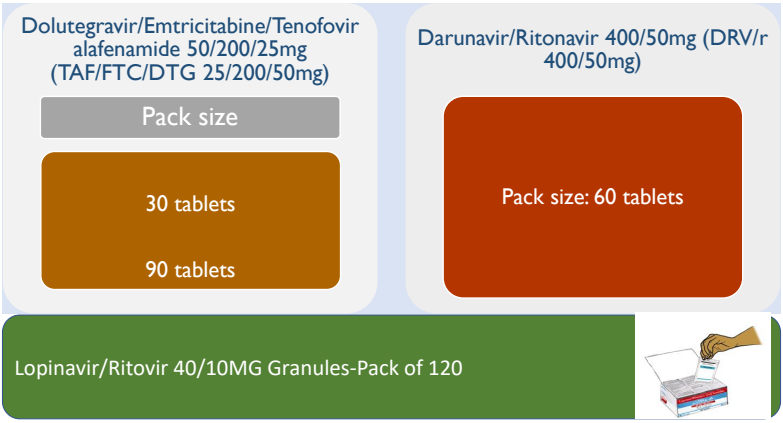
- The minimum and maximum stock levels
- The required delivery date for new orders
- Any anticipated risk of expiry

- Transition of patients should be planned to take into consideration the available stock and lead time for the next cycle delivery to avoid stock out and wastage of existing formulations.

Submitting the bi-monthly order

- Health facilities should submit timely orders and reports to the appropriate warehouse in line with their ordering and delivery schedules.
- Health facilities should first compile the bi-monthly order using the hard copy of the appropriate HMIS PHAR tool, have it reviewed by the teams for any errors, make all necessary correction to have a final order that is representative of the facility need.
- The final orders should be submitted electronically through the recommended electronic systems (NMS CSSP for public sector facilities and electronic Logistics Management Information Systems (eLMIS) App in DHIS 2 for PNFP health facilities).
- A hard copy of the final order should be always filed for quick reference and validation.

NEW FORMULATIONS INTRODUCED



8.6 GUIDANCE ON ORDERING AND REPORTING FOR THIRD-LINE ART MEDICINES

Ordering and reporting for third line ARVs is currently restricted to regional referral hospitals. This means only regional referral hospitals will be ordering and reporting on the consumption and usage of third line ARVs. The RRHs shall aggregate the medicines need for all patients in the region and submit a consolidated third line ARV order for the entire region. Once medicines

are received at the RRHs, they should be distributed through the same mechanism.

The referral hospitals shall use the standard ARV ordering and reporting forms to order and report on third line ARV following the bi monthly ordering and reporting cycle. This should be done alongside other ARVs. Orders should be submitted through the NMS CSSP before the order deadline.

Table95: How To Access Third Line ARV Medicines.

Facility	Source Of Third Line Medicine
All public health facilities	Regional referral hospital for the respective region
Centers of Excellence	Regional referral hospital for the respective region
PNFP health facilities **outside** Kampala and Wakiso.	Regional referral hospital for the respective region
PNFP health facilities **within** Kampala and Wakiso.	Centers of Excellence that directly support them.

8.7 ISSUING THIRD LINE ARVS TO FOLLOW-UP FACILITY

At the regional referral hospital

- The regional referral hospital is responsible for issuing third line ARVs to all lower-level health facilities within the region even when their other ARVs are provided through a different mechanism.
- The implementing partner in coordination with the district should facilitate the movement of the ARVs from the RRH to the lower facility.
- The RRH should consider ARVs issued to the lower-level facility as consumed and therefore should proceed and update the stock card.
- This information should be used to prepare the next ARV order and report.

At the facility

- Once the third line ARVs have reached the lower facility, the medicine should be entered into a stock card.
- The facility should then follow the issuing procedures prescribed in the Uganda Essential Medicines and Health Supplies Management Manual.
- Once the medicine is dispensed to the patient, the dispensing log should be updated immediately.

8.8 GUIDANCE FOR STOCK MANAGEMENT AT HEALTH FACILITY

- Medicines and medical supplies should be received at the facility store according to the recommended receipt procedure.
- The facility should then follow the issuing procedures prescribed in the Uganda Essential Medicines and Health Supplies Management Manual.
- The person receiving the supplies should enter them into the facility stock cards and store them under recommended storage conditions.
- Stock cards should be updated whenever stock is issued from the health facility main store.
- Monthly physical counts should be done and reasons for any discrepancy noted.
- All documents related to medicines transactions should be filed and kept for future reference.

8.9 DISPENSING MEDICINES

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

- Ensure availability of dispensing tools at all dispensing points.
- Ensure medicine shelf life is long enough to cover the treatment duration.
- Dispensing to all patients should preferably be done using the primary packaging.
- Record all transactions in the medicine dispensing log.
- Provide all the necessary information that the client needs to appropriately take the medicines. Double check to assess understanding.

Stock Redistribution

- Redistribution should be triggered if the facility is overstocked with more than four months of stock, there is risk of expiries or when is the either an eminent or actual medicine stock out.
- The stock should be redistributed in line with the Uganda National Redistribution Guidelines for Prevention of Expiry and Handling Expired Medicines and Health Supplies, 2019.
- It is important to note that redistribution does not lead to financial loss to the affected health facility since HIV commodities are non-credit line items.
- It instead mitigates financial loss due to expiries and additional cost of treatment incurred due to stock outs.
- Stock monitoring and reporting in real time is recommended to inform redistribution.

8.10 RATIONAL MEDICINES USE

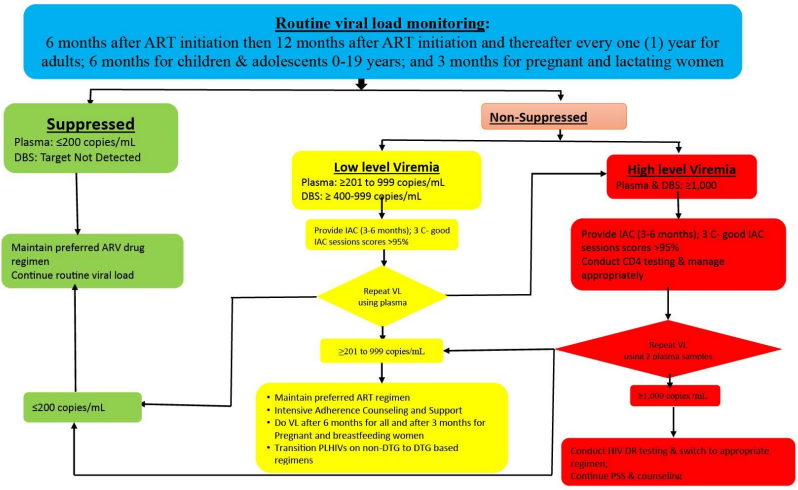
Rational medicines use ensures patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements for an adequate period, and at the lowest cost to them and their community.

The principles of rational medicines use are as follows:

a. Rational prescribing

Healthcare workers should prescribe medicines according to the following principles:

- Prescribe medicines according to the treatment guidelines.
- Prescribe doses that are age and weight appropriate.
- Use the correct combination of drugs.
- Prescribe medicines for the correct treatment duration.
- Counsel patients on how to take the medicines.
- Counsel patients on substituting or switching treatment regimens.
- Counsel patients on safety and use of medicines



Special Considerations for LPV/r 40/10mg Granules

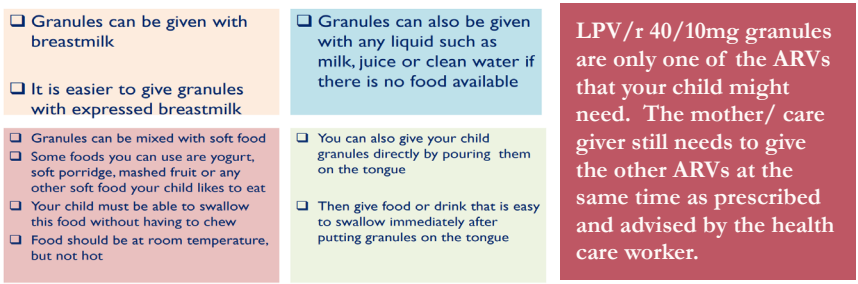
- LPV/r 40/10 granules is one of the new ARV formulations introduced in the new guidelines. The LPV/r 40/10 mg granules are recommended over pellets because.
- They can be used right from 2 weeks of age as opposed to the pellets which are recommended to start at 3 months,
- and they are easier to administer compared to the pellets.

Table 96: Dosing for LPV/r 40/10mg Granules

	Number of sachets	
	Morning	**Evening**
3.0 - 5.9	2	2
6.0 - 9.9	3	3
10.0 - 13.9	4	4
14.0 - 19.9	5	5

The LPV/r 40/10mg Granules are prescribed according to body weight. The Number of sachets to be dispensed are as highlighted in the table above.

Figure 78: Administration of LPV/r 40/10mg Granules.



b. Rational dispensing

Healthcare workers should dispense medicines according to the following principles:

- Dispense the correct quantity, dose, and dosage formulation to the correct patient. Fixed-dose combinations are preferred.
- Provide explanation on how patients should take their medicines and always double check to assess understanding.
- Appropriately label the medicine packs to include medicine name and strength, patient's name, and dose and dosage.
- Package and label medicines for individual patients that are for distribution under the community drug delivery points.
- Offer further explanation/counseling to patients on multiple medicines because of other co-morbidities. Communicate possible drug interactions and adverse effects.
- Effectively introduce new formulations to patients while taking into consideration medication branding.
- Counsel patient on adherence

Dispensing of medicines to patients under facility-based DSD models.

These are the clients who are receiving ARVs and other form of care directly from the health facility. Health care workers should do the following while dispensing ARV and other medicines;

- Ensure adequate medicines are requisitioned from facility store for dispensing.
- Medicines shelf life should be long enough to cover duration of use by the client.
- Preferably issue 3 months of stock for Multi-Month Dispensing using multi-month packs where applicable
- In some stable patients who fit eligibility criteria (see section 10.1.11), 6 months of stock of drugs may be prescribed and dispensed.
- Supply medicine to newly initiating patients for a duration determined by the clinician.
- Appropriately record all medicines issued in appropriate logistics HMIS tools.

Dispensing of medicines to Community-based clients

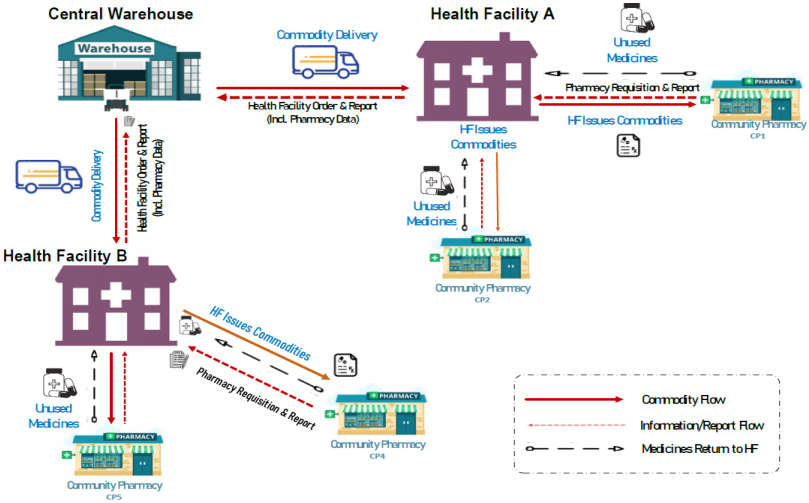
These are clients receiving ARVs and other form of care from the communities where they live. Health care workers should:

- Take into consideration recommendations for dispensing medicines to facility-based clients above.
- Dispense medicines to the CCLAD representative using the patient held card for each CCLAD member.
- Use the ART medicines return forms and the CCLAD monitoring forms to ensure traceability.
- For the CDDP, ensure that medicines for CDDP are prepacked, labeled according to the expected client refill list for each of the CDDP. These medicines should be given to the health worker or the peer leader for that CDDP. Once medicines are issued to the client, the patient file should be updated accordingly.
- This information should be transferred to the appropriate dispensing log on return to the facility.

8.11 CRPDDP APPROACH

The Ministry of Health adopted the extended Differentiated Service Delivery (DSD) as a model to optimize service delivery to community. Under this DSD model, Implementing Partner (IP) organizations, district local governments, health facilities, and Community pharmacies implement the Alternative Drug Distribution Point (ADDP) approach; Community Retail Pharmacy Drug Distribution Point (CRPDDP).

Figure 79: Flow for Commodities Under the CRPDDP Approach.



Key Supply Chain considerations under CRPDDP:

- The Community Retail Pharmacy is an extension of the health facility (i.e., extra dispensing point), therefore the overall responsibility for the commodities that move to the CRP remains with the supporting health facility.
- The CRP should have all the necessary hard copy tools as back bout for system malfunctioning. The tools include, the requisition and issue voucher, stock card, and ART dispensing log.
- Use of the electronic platform (ART Access) should take prioritized in undertaking supply chain activities including ordering, receiving, and dispensing of commodities, hard copies should only be used in case of the system malfunction.

- The CRP team should ensure that adequate medicines are requisitioned from the facility for the clients on appointment.
- Medicines shelf life should be long enough to cover duration of use by the client.
- A maximum of 6 months of stock of drugs may be prescribed and dispensed to clients depending on stock availability.
- Documentation should be on a transactional basis for any activity undertaken.
- Recommended minimum and maximum stock levels are 2 and 4 weeks of stock respectively.

9 MONITORING AND EVALUATION

9.1 INTRODUCTION

A comprehensive and well-functioning monitoring and evaluation (M&E) framework is essential to ensure that Uganda's program to prevent and treat HIV using ART is effective and efficient. This module provides a highlight of the HIV/AIDS programme monitoring and plan for monitoring the roll out of the revised guidelines.

The module is aligned to the guidance contained in the National HIV and AIDS Strategic Plan 2015/2016–2019/2020, Health Sector HIV and AIDS Strategic Plan (HSHASP)2018/19 -2022/23 and Health Sector HIV and AIDS Monitoring and Evaluation Plan 2018/19 – 2022/2023.

9.2 OVERVIEW OF HIV/AIDS PROGRAMME MONITORING

9.2.1 Pateint Data Recording

The current patient monitoring system uses paper-based tools and electronic medical records system. However, the primary data collection method at facilities is paper-based, and includes pre-primary, primary and secondary tools as detailed in the Ministry of Health HMIS Manual, 2020. Paper-based records are used to update electronic medical record systems where they exist.

9.2.2 Patient Data Reporting

Health facilities should submit timely reports of aggregated patient data on a weekly, monthly and quarterly basis. The monthly and quarterly reports shall be consolidated and entered into DHIS-2. Table 94 below shows the different reports and frequency of submission. An online dashboard to track the implementation of the consolidated guidelines will be developed.

NB: non -ART REFILL/ absence from the health facility visits for 28 Days or more is considered a lost followup

Table 97: Routine reports and their frequency

Report	Description	Source documents	Frequency
HMIS 106A: Health Unit Quarterly Report	Reports the quarterly attendance figures for HIV care/ART, ART outcomes, nutrition, and TB services	Registers: Linkages and Pre-ART, ART, PEP, EID, TB, DSD, SMC, PrEP, CrAg, Viral Load .	Quarterly
HMIS 105: Health Unit Outpatient Monthly Report	Reports the monthly attendance figures for OPD, OPD diagnoses, MCH, HIV/AIDS service data, EID, laboratory data, stock-out of essential drugs and supplies and financial data	HCT Register, EID Register, Safe Male Circumcision Register, Laboratory Tests Daily Summary	Monthly
HMIS 033B: Health Unit Weekly Epidemiological Surveillance Report	Reports cases of notifiable diseases after the first few cases have been notified.	HIV Laboratory Tests Log and eMTCT Drug Dispensing Log	Weekly

Note: Indicators for routine monitoring have been updated and can be found in the Monitoring plan for the HSHASP 2018-2023. Facility ARV stock and orders shall be monitored via the Web-Based ARV Ordering System (WAOS).

9.2.3 Other programme data sources

The following sources complement the data generated from routine HIV/AIDS programme data

- Surveys (population based, ANC surveillance, case-based surveillance, other special surveys including size estimations, modes of transmission, etc.)
- Programme Evaluations (PMTCT Impact evaluation, eMTCT validation, etc.)

Operational research

Special studies and assessments (Cohort studies, HIV drug resistance, etc.)

9.2.4 Programme Data Quality and Use

The programme has institutionalised interventions that geared to ensure that programme data is of high quality to inform planning and decision making. These include but not limited to; standardised HMIS manual with indicator descriptions and definitions, annual data quality assessments, integrated and technical supervisions.

At national, sub national (region and district) and health facility levels, use of programme data generated from HMIS is emphasised. This is done through;

- Dashboards – tools that summarize and display aggregated data (VL, EID, B+, HIV stituation room, WHO DHIS2 App, etc.)
- Routine data/performance reviews
- Continous Quality Improvement projects

9.3 MONITORING ROLL OUT OF REVISED GUIDELINES

9.3.1 Tracking progress of roll out

Rolling out of the revised guidelines at health facilities and training of Health workers to ensure effective utilization of the guidelines will be tracked using the training reports, that will be entered into the online training database.

Data will be summarized as follows; weekly for the first three months and bimonthly thereafter. Summaries generated will be disseminated to key stakeholder to provide an update on the roll out of the guidelines.

9.3.2 Supervision on implementation of revised guidelines

This will be conducted at the following planned intervals;

- 3 months from onset of roll out amongst the health facilities that would have rolled out;
- One month after completion of national roll out of the revised guidelines at health facilities

This supervision exercises are aimed at assessing whether the HIV/AIDS services are provided based on the revised guidelines as well as identifying challenges encountered during in the utilization of the revised guidelines.

9.3.3 Review of the guidelines

The process of reviewing these guidelines will be informed by new emerging facts mainly from recommendations from WHO, results of operational research, programme evaluations and revised national strategic plans.

9.3.4 Indicator matrix

The Health Sector HIV and AIDS M&E plan 2018/19 – 2022/23 provides a comprehensive plan that tracks programme implementation and sustainable HIV control at national and sub national levels. Whereas several indicators pertaining to the revised guidelines are already covered in the sector HIV AIDS M&E plan, there are some process indicators, key to monitoring this roll out that are not catered for by the broader M&E plan. A list of indicators has been developed to track efficient implementation of the revised guidelines.

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

Visit schedule	Birth	6wks	10wks	14wks	5mo	6mo	9mo	12mo	15mo	18mo	24mo
Immunization	X	X	X	X	-□		X		-□		-□
Clinical assessment	X	X	X	X	X	X	X	X	X	X	X
Growth and development	X	X	X	X	X	X	X	X	X	X	X
CTX and ARV prophylaxis	Stable motherc- Give baby Nevirapine prophylaxis for 6weeks Unstable motherd – Give baby Nevirapine prophylaxis for 12 weeks Cotrimoxazole should be started at six weeks of age or thereafter and continued until infant is determined to be HIV-negative										
Infant diagnosis testinge	None	Do 1stPCR at 6 weeks of age or as soon as infant is identified Do 2ndPCR at 9 months Do 3rdPCR 6 weeks after cessation of breastfeeding								Do antibody test at 18 months	
Counseling and feeding advice	X	X	X	X	X	X	X	X	X	X	X
Mother's care and treatment	X	X	X	X	X	X	X	X	X	X	X

a - At every visit, the EID card, EID register, mother's HIV care/ART card and ART register should be updated as well the Open MRS/EID database where it exists

b – The standard is starting Nevirapine at birth and cotrimoxazole at 6 weeks of age

c – Stable mother

d – Unstable mother

e - Infants should come every month until test results are given to the caretaker

Annex 2: WHO staging for HIV infection and disease in adults and adolescents

Clinical Stage I: • Asymptomatic • Persistent generalized lymphadenopathy • Performance Scale 1: Asymptomatic, normal activity
Clinical Stage II: • Moderate weight loss (less than 10% of presumed or measured body weight) • Minor mucocutaneous manifestations (seborrhoeic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular stomatitis) • Herpes zoster within the last five years • 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: • Severe weight loss (more than 10% of presumed or measured body weight) • Unexplained chronic diarrhea for more than one month • Unexplained prolonged fever, intermittent or constant, for more than one month • Oral candidiasis • Oral hairy leukoplakia • Pulmonary tuberculosis (current) • Severe bacterial infections such as pneumonia, pyomyositis, empyema, bacteremia or meningitis • Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis • Unexplained anemia (<8gm/dl), neutropenia (<0.5× 109 per liter), or chronic thrombocytopenia (<50× 109 per liter) And/or Performance Scale 3: Bed-ridden for less than 50% of the day during the last month

Clinical Stage IV:

- HIV wasting syndrome – weight loss of more than 10%, and either unexplained chronic diarrhea for more than onemonth or chronic weakness or unexplained prolonged fever for more than one month
- Pneumocystis pneumonia (PCP)
- Recurrent severe bacterial pneumonia
- Toxoplasmosis of the brain
- Cryptosporidiosis with diarrhea for more than one month
- Chronic Isosporiasis
- Extrapulmonary Cryptococcosis including meningitis
- Cytomegalovirus infection (retinitis or infection of other organs)
- Herpes simplex virus (HSV) infection, mucocutaneous for more than one month, or visceral at any site
- Progressive multifocal leukoencephalopathy (PML)
- Any disseminated endemic mycosis such as histoplasmosis, coccidioidomycosis
- Candidiasis of the oesophagus, trachea, bronchi or lungs
- Atypical mycobacteriosis, disseminated
- Recurrent non-typhoid salmonella septicemia
- Extrapulmonary tuberculosis
- Lymphoma
- Invasive cancer of the cervix
- Kaposi's sarcoma
- 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
- Atypical disseminated leishmaniasis
- Symptomatic HIV-associated nephropathy or symptomatic HIV-associated cardiomyopathy

And/or Performance Scale 4: Bed-ridden for more than 50% of the day during the last month

Annex 3: WHO staging for HIV infection and disease in infants and children

Clinical Stage I:

1. Asymptomatic
2. Persistent generalized lymphadenopathy

Clinical Stage II:

- Unexplained persistent hepatosplenomegaly
- Papular pruritic eruptions
- Extensive wart virus infection
- Extensive molluscum contagiosum
- Recurrent oral ulcerations
- Unexplained persistent parotid enlargement
- Linear gingival erythema
- Herpes zoster
- Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis)
- 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/L3) or chronic thrombocytopenia (<50 x 109/ L3)

Clinical Stage IV:

- Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy
- Pneumocystis pneumonia (PCP)
- Severe recurrent bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)
- Chronic herpes simplex infection; (oral, labial or cutaneous of more than one month's duration, or visceral at any site)
- Extrapulmonary TB
- Kaposi's sarcoma
- Oesophageal candidiasis (or Candida of trachea, bronchi or lungs)
- Toxoplasmosis of the brain (after the neonatal period)
- HIV encephalopathy
- Cytomegalovirus (CMV) infection (retinitis or infection of other organs) with onset at age over one month
- Extrapulmonary cryptococcosis (including meningitis)
- Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiomycosis)
- Chronic cryptosporidiosis (with diarrhea)
- Chronic isosporiasis
- Disseminated non-tuberculous mycobacteria infection
- Cerebral or B-cell non-Hodgkin lymphoma
- Progressive multifocal leukoencephalopathy
- 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

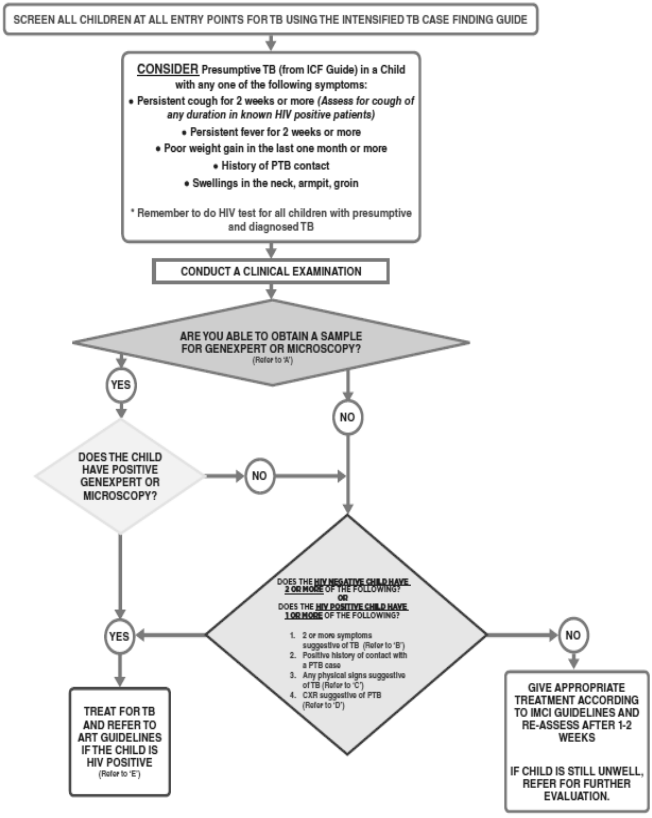
**For Children who are unable to produce sputum, refer to clinician for further investigations*

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:

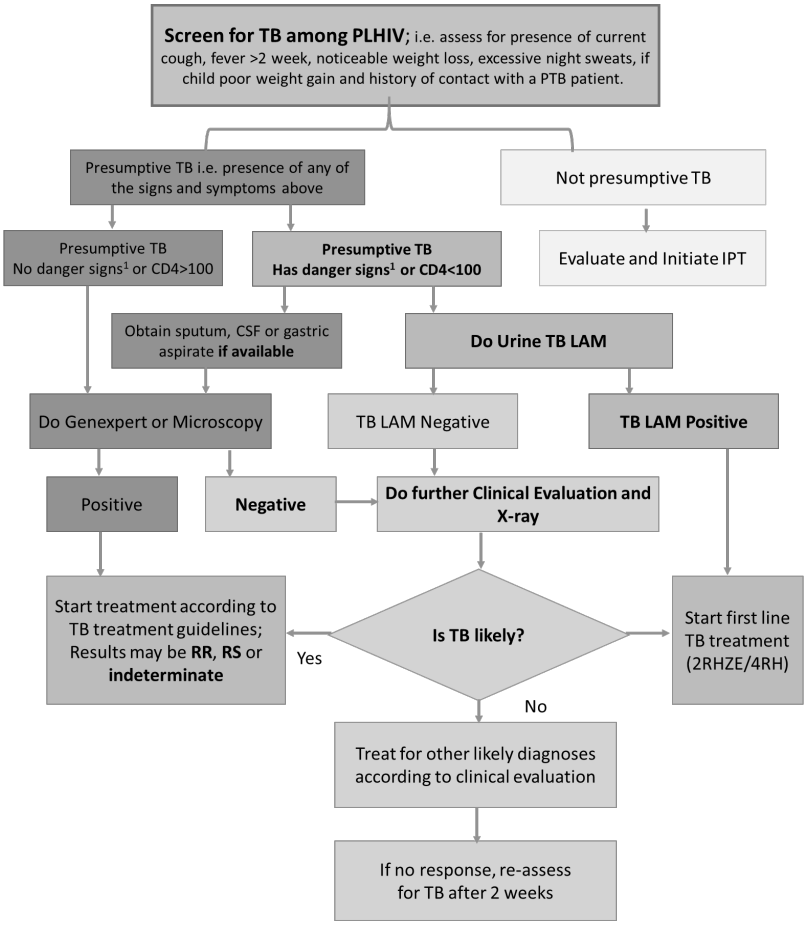
- Miliary picture
- Hilar adenopathy
- Cavitation

C PHYSICAL SIGNS SUGGESTIVE OF TB

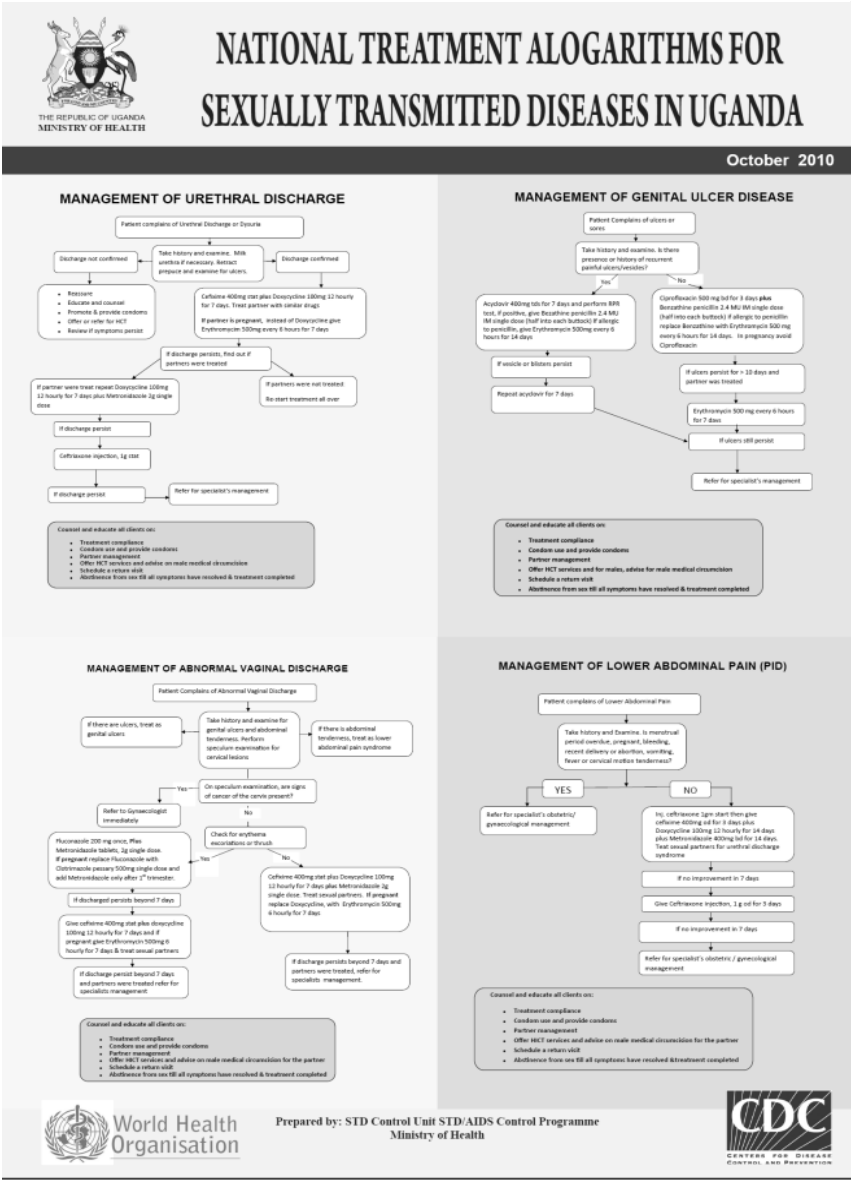
- Severe malnutrition
- Enlarged lymph nodes around the neck or the arm pit (TB adenitis).
- Acute pneumonia not responding to a complete course of appropriate broad spectrum antibiotics.
- Recurrent pneumonias (defined as at-least 2 episodes of pneumonia in a year with at-least 1 month of clinical recovery 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 HIV positive 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/ Clinical O□ cer	Nurse/ Midwives	Trained Nursing Assistants	Pharmacists/ Pharm Technicians/ Dispensers/ Nurses/ storekeepers	Laboratory Technicians/ Laboratory Assistants	Lay providers (Expert Clients, VHTs, CHEWS, Mentor Mothers), CBOs and CSOs working with PLHIV VHT	Health Information Assistants/ Data Clerk
Comprehensive clinical services including, NACS, symptom screening for NCDs, TB, STIs and hepatitis	X	X					
Prescription of ART, initiation and follow up for adults, adolescents and children	X	X					
Switching and substituting ART regimens by a multidisciplinary 'switch team'	X						
Management of complicated cases(e.g. cryptococcal meningitis (CCM); second line treatment failure etc.)	X						

	Doctor/ Clinical O□ cer	Nurse/ Midwives	Trained Nursing Assistants	Pharmacists/ Pharm Technicians/ Dispensers/ Nurses/ storekeepers	Laboratory Technicians/ Laboratory Assistants	Lay providers (Expert Clients, VHTs, CHEWS, Mentor Mothers), CBOs and CSOs working with PLHIV VHT	Health Information Assistants/ Data Clerk
TB initiation of smear or gene X-pert positive cases for adults, adolescents and children	X	X					
TB initiation for adults and adolescents requiring chest x-ray (CXR) interpretation, and for children where no sputum is available	X						
HIV testing services	X	X	X	X	X	X	X
Health Education	X	X	X			X	
Registration and filling of appointment diaries		X	X	X	X		
Performing vital signs (triage)	X	X	X				
Dried blood spot (DBS), VL sample collection, testing and results delivery	X	X	X		X	X	

	Doctor/ Clinical O□ cer	Nurse/ Midwives	Trained Nursing Assistants	Pharmacists/ Pharm Technicians/ Dispensers/ Nurses/ storekeepers	Laboratory Technicians/ Laboratory Assistants	Lay providers (Expert Clients, VHTs, CHEWS, Mentor Mothers), CBOs and CSOs working with PLHIV VHT	Health Information Assistants/ Data Clerk
Coordinating and supervising the community groups	X	X	X				
Linkage facilitation	X	X	X			X	
Pre-packing medicines, picking drug refills, distribution of refills, Forecasting and ordering of commodities from the warehouses, Dispensing, Filling/updating the dispensing log and tracking tools		X	X			X*	X
ART preparation and adherence counselling for adults, adolescents, children and pregnant women including treatment failure	X	X	X		X	X	X
Defaulter tracing		X	X		X	X	X

	Doctor/ Clinical O□ cer	Nurse/ Midwives	Trained Nursing Assistants	Pharmacists/ Pharm Technicians/ Dispensers/ Nurses/ storekeepers	Laboratory Technicians/ Laboratory Assistants	Lay providers (Expert Clients, VHTs, CHEWS, Mentor Mothers), CBOs and CSOs working with PLHIV VHT	Health Information Assistants/ Data Clerk
Client records management/data entry & updating registers (for area of service)		X	X		X	X	X
Phlebotomy	X	X			X		
Reporting on community activities/client groups, support; coordinate and supervise their peers						X	
Community – facility referrals and vice versa						X	

*These service providers will be supervised while undertaking these tasks

**Lay clients include; expert clients, VHTs, CHEWS, andmentor mothers

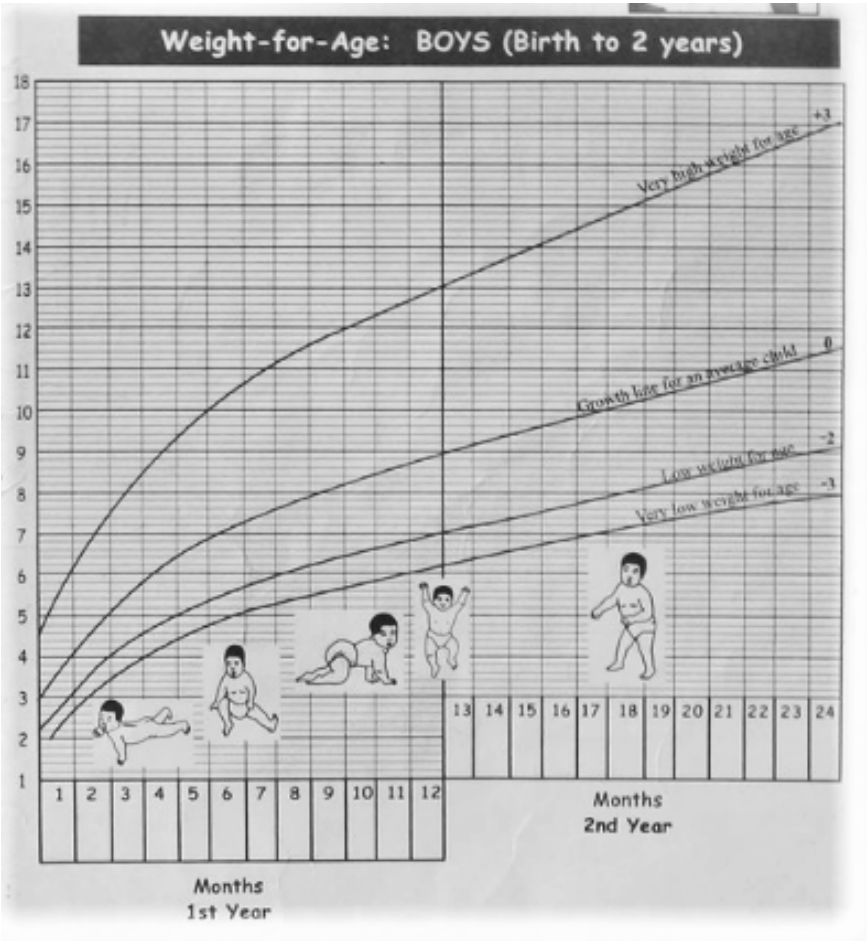
Annex 9: Home education/eating/exercise activities drugs/depression sexuality suicidality/safety assessment tool in adolescents

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 ahome environment? • Have they disclosed their HIV status? If yes, with whom? If not, what are the reason?	
Education and employment	• School/grade performance--any recent changes? Any past dramatic changes? • Favourite subjects--worst subjects? (include grades) • Any years repeated/classes failed? • Suspension, termination, dropping out? • Future education/employment plans? • Any current or past employment? • Relations with teachers, employers--school, work attendance?	

HEADSS ASSESSMENT TOOL		
Component	Area of assessment	Assessment results
Activities	• On own, with peers (what do you do for fun? where? when?) • With family? • Sports--regular exercise? • Religious attendance, clubs, projects? • Hobbies--other activities? • Reading for fun--what? • TV--how much weekly--favourite shows? • Favourite music? • Doestheyoung person have acar, use seat belts? • History of arrests--acting out--crime?	
Drugs / tobacco/ alcohol	• Use by peers? Use by a young person? (include tobacco, alcohol) • Use by family members? (include tobacco, alcohol) • Amounts, frequency, patterns of use/ abuse, and car use while intoxicated? • Source—how theypaid for them?	
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?	

HEADSS ASSESSMENT TOOL		
Component	Area of assessment	Assessment results
Suicide / Depression	• Sleep disorders (usually induction problems, also early/frequent waking or greatly increased sleep and complaints of increasing fatigue) • Appetite/eating behavior changes • Feelings of 'boredom' • Emotional outbursts and highly impulsive behaviour • History of withdrawal/isolation • Hopeless/helpless feelings • History of past suicide attempts, depression, psychological • History of suicide attempts in family or peers • History of recurrent serious 'accidents' • Psychosomatic symptomology • Suicidal ideation (including significant current and past losses) • Decreased affect at theinterview, avoidance of eye contact--depression posturing Preoccupation with death (clothing, media, music, art)	

Annex 10: Child health card



Annex 11: Patient Health Questionnaire-9 (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Over the last two weeks, how often have you been bothered by any of the following problems? (Use "□ " to indicate your answer)

Question	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or yourfamilydown	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
• 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
• Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Column total		___	+_____	+___

Add totals together = _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all Somewhat difficult Very difficult
Extremely difficult

Annex 12: ARV Dosing Tables

	Formulations and strengths	3.0–5.9kg		6.0–9.9kg		10.0–13.9kg		14.0–19.9kg		20.0–24.9kg		25.0–34.9kg		Adolescents and adults >35kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Fixed Dose Combination Tablets/Granules	**ABC/3TC** 120/60mg	–	1	–	1.5	–	2	–	2.5	–	3	-	-	-	-
	ABC/3TC 600/300mg	-	-	-	-	-	-	-	-	-	-	–	1	–	1
	AZT/3TC 60/30mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	-	-	-	-
	AZT/3TC 300/150mg	-	-	-	-	-	-	-	-	-	-	1	1	1	1
	TDF/3TC 300/300mg	-	-	-	-	-	-	-	-	-	-	-	-	–	1
	TDF/3TC/EFV 300/300/400mg	-	-	-	-	-	-	-	-	-	-	-	-	-	1
	TDF/3TC/DTG 300/300/50mg	⌐-	-	-	-	-	-	-	-	-	-	-	-	1	-
	TAF/FTC/DTG 25/200/50mg	-	-	-	-	-	-	-	-	-	-	1	-	1	-
	ABC/3TC/DTG 600/300/50mg	-	-	-	-	-	-	-	-	-	-	1	-	1	-
	ABC/3TC/DTG 60/30/5mg	2	-	3	-	4	-	5	-	6	-	-	-	-	--
	ABC/3TC/LPV/r 30/15/40/10mg	2	2	3	3	4	4	5	5	6	6	-	-	-	-

	Formulations and strengths	3.0–5.9kg		6.0–9.9kg		10.0–13.9kg		14.0–19.9kg		20.0–24.9kg		25.0–34.9kg		Adolescents and adults >35kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Fixed Dose Combination Tablets/Pellets/Syrups	DTG 50mg	-	-	-	-	-	-	-	-	1	-	1	-	1	1
	DTG 10mg	1	-	1.5	-	2	-	2.5	-	3	-	-	-	-	-
	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
	DRV/r 400/50mg	-	-	-	-	-	-	-	-	-	-	-	-	2	-
	ATV/r 300/100mg	-	-	-	-	-	-	-	-	-	-	-	-	–	1
	Raltegravir 25mg Chewable Tablet	-	-	-	-	3	3	-	-	-	-	-	-	-	-
	Raltegravir 100mg Chewable Tablet	-	-	-	-	-	-	1	1	1.5	1.5	-	-	-	-
	Raltegravir 400mg	-	-	-	-	-	-	-	-	-	-	1	1	1	1
	DRV 75mg Tablets[3]	-	-	-	-	3 +RTV 0.5ml	3 +RTV 0.5ml	5 +RTV 50mg	5 +RTV 50mg	5 +RTV 50mg	5 +RTV 50mg	-	-	-	-
	DRV 150mg	-	-	-	-	-	-	-	-	-	-	4 +RTV 100mg	4 +RTV 100mg	4 +RTV 100mg	4 +RTV 100mg
	DRV 600mg[4]	-	-	-	-	-	-	-	-	-	-	1 +RTV 100mg	1 +RTV 100mg	1 +RTV 100mg	1 +RTV 100mg
	RTV 25mg	-	-	-	-	-	-	2	2	2	2	-	-	-	-
	RTV 100mg	-	-	-	-	-	-	-	-	-	-	1	1	1	1
	ETV 200mg	-	-	-	-	-	-	-	-	-	-	-	-	1	1

1. For children≥10kg that are able to swallow tablets, give LPV/r 100/25mg tablet.
2. tablets of LPV/r 100/25mg can be substituted with 1 tablet of LPV/r 200/50mg in order to reduce the pill burden. These tablets should be administered fully intact/whole i.e. not cut or crushed.
3. DRV must be administered with 0.5mL of RTV 80mg/mL oral suspension in children <15kg, with 2 tab of RTV 25mg in children 15 to 25kg and 3 tab of RTV 25mg in children above 25kg. DRV is always taken with food.
4. DRV 600mg must be co-administered with RTV 100mg.

Annex 13: Dosing of RUTF

Weight (kg)	Sachets/ day	Sachets/ week	Sachet/two weeks	Sachets/ month
3.0 - 3.4	1.25	9	18	35
3.5 - 3.9	1.5	11	22	44
4.0 - 5.4	2	14	28	56
5.5 - 6.9	2.5	18	35	70
7.0 - 8.4	3	21	42	84
8.5 - 9.4	3.5	25	49	98
9.5 - 10.4	4	28	56	112
10.5 - 11.9	4.5	32	63	126
≥ 12.0	5	35	70	140
14 years and above	6	42	84	168

Source: Integrated Management of Acute Malnutrition Guidelines

Annex 14: Suspected Adverse Drug Reaction Reporting form

CONFIDENTIAL

REPUBLIC OF UGANDA
MINISTRY OF HEALTH

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

A. PATIENT DETAILS

Patient name	Patient Number	Sex: M/F*
Age at time of onset(yrs)*	Health Facility	Last Menstrual Period
Weight (kg)	District	Trimester (if pregnant)

B. SUSPECTED DRUG (S) DETAILS

Generic Name*	Brand Name	Dose ,Route Frequency	Date* started	Date stopped	Prescribed for	Expiry date	Batch No

C. SUSPECTED REACTIONS

Please describe the reaction as observed and any treatment given to manage the reaction

Outcome

Recovered ☐ Recovering ☐ Continuing ☐ Death due to reaction ☐

Date reaction started*	Date reaction stopped	Date of notification

SERIOUSNESS OF THE REACTION

Patient died ☐ Prolonged inpatient Hospitalization ☐ Involved disability ☐ Life Threatening ☐
Congenital abnormality ☐

D. CONCOMITANT DRUGS

Please give information on the drug(s) the patient has been taking together with the suspected drug including those taken for chronic diseases (include self medication and herbal preparations)

Generic Name Brand Dosage Date started Date stopped Indication(prescribed or OTC)

Relevant laboratory tests including dates	Additional relevant information (medical history, allergies, failure of efficacy)

E. REPORTER'S DETAILS

Name/designation*	Telephone and Email Address	Date of reporting	Health facility

* Mandatory field