Sierra Leone

Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care in Sierra Leone

October, 2020.

ACRONYMS

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine aminotransferase also known as SGPT
ANC	Antenatal Clinic
ARV	Antiretroviral
ART	Antiretroviral Therapy
CBC	Complete Blood Count
CBO	Community Base Organization
CD4	T lymphocyte Cells
CITC	Client Initiated Testing and Counselling
CPHRL	Central Public Health Laboratory
CNS	Central Nervous System
CPT	Cotrimoxazole Preventive Therapy
CrAg	Cryptococcal antigen
CTX	Cotrimoxazole
CSF	Cérébrospinal Fluid
DOT	Directly Observed Treatment
DHMT	District Health Management Team
DLL	Didanosine
DSD	Differentiated Service Delivery
DTG	Dolutegravir
EFV	Efavirenz also abbreviated as EFZ
EID	Early Infant Diagnosis
ELISA	Enzyme Linked Immunosorbent Assay
eMTCT	Elimination of Mother to Child Transmission
ETWG	Expanded Technical Working Group
FBO	Faith Base Organization
FTC	Emtricitabine
FP	Family Planning
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
INH	Isoniazid
IPT	Isoniazid Preventive Therapy
IRS	Immune Reconstitution Syndrome
LPV	Lopinavir
MCH	Maternal and Child health
MoHS	Ministry of health and sanitation
M&E	Monitoring and Evaluation
MTCT	Mother-to-child transmission of HIV
NACP	National HIV/AIDS Control Program
NGO	Non-Governmental Organization

NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NsRTI	Nucleoside Analog Reverse Transcriptase Inhibitor
NtRTI	Nucleotide Analog Reverse Transcriptase Inhibitor
NVP	Nevirapine
ICAP	ICAP Columbia University
OI	Opportunistic Infection
OVC	Orphan and Vulnerable Children
PCP	Pneumocystis jiroveci Pneumonia
PCR	Polymerase Chain Reaction
PEP	Post Exposure Prophylaxis
PI	Protease Inhibitor
PIH	Partners in Health
PO	Per OS
PrEP	Pre Exposure Prophylaxis
PMTCT	Prevention from Mother to Child Transmission
PITC	Provider Initiated Testing and Counselling
QA	Quality Assurance
QI	Quality Improvement
RNA	Ribo Nucleic Acid
RNMCAH	Reproductive newborn child and Adolescent Health
RTV /r	Ritonavir
RTV-PI	Ritonavir Boosted Protease Inhibitor
RPR	Rapid Plasma Reagent
SLDHS	Sierra Leone Demographic Health Survey
SP	Sulfamethazole and Pyrimethamine
SGPT	Serum Glutamic Pyruvic Transaminase, also known as ALT
SOLTHIS	Therapeutic Solidarity and Initiatives against AIDS
STI	Sexually Transmitted Infection
TB	Tuberculosis
TLC	Total Leucocyte Count
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nation Children Fund
VL	Viral Load
WHO	World Health organization
ZDV	Zidovudine, also known as AZT

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FOREWORD

The need to develop a National HIV Consolidated Guidelines for Sierra Leone is in response to the National Strategic Plan (NSP) on HIV/AIDS 2016-2020 to achieve zero new infection, zero discrimination and zero AIDS-related deaths with the main strategy to Test All, Treat All, and Retain All. It is based on the global targets of increasing access to treatment with the aim of ending the AIDS epidemic as a public health threat by 2030 and to achieve the 90–90–90 targets.

The consolidated guidelines provide new opportunities, as well as new imperatives for strengthening HIV prevention and care efforts, increasing access to Antiretroviral Treatment (ART) for people in need and treatment monitoring for people on antiretroviral (ARV) drugs. This opportunity further allows the country to develop a comprehensive public health response to the HIV epidemic that integrates prevention, care and treatment.

These guidelines provide a simplified framework for healthcare workers, District Health Management Teams, HIV, TB and RMNCAH programs and all partners. They also act as a reference tool Ministry of Health and sanitation, implementing partners, training institutions, researchers, civil society organizations and the entire community of people living with HIV.

The guidelines also provide information on the use of Dolutegravir; and clarification on the use of ARVs in other conditions such as hepatitis and, prevention of HIV acquisition through the use of pre-exposure prophylaxis (PrEP).

The National HIV/AIDS Control Programme through the Ministry of Health and Sanitation and its partners will ensure the availability of necessary commodities and drugs that will guarantee quality care for recipient of care at all levels. They will also support the implementation of differentiated service delivery in order to ensure retention of clients on ART. Other models of care with established benefits will be taken to scale in all applicable communities.

I wish to recognize the role played by the leadership of the National HIV/AIDS Control Programme in the Ministry of Health and Sanitation in providing coordination for the development of these guidelines and the roles of implementing partners. It is hoped that this guidelines will serve its purpose of contributing to the national effort to achieve the global targets. I, therefore, call upon all stakeholders in the fight against HIV and AIDS in-country to support the successful implementation of these guidelines.

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ACKNOWLEDGEMENT

This consolidated guideline was developed through several months of work with the contribution of experienced professional medical practitioners in HIV prevention, treatment care and support in Sierra Leone. It is also based on current evidence documented over the years by the World Health Organization.

Many people and organizations contributed to the revision of these guidelines. The contribution of the World Health Organization in providing Technical assistance is of immense importance in arriving at national specific treatment guidelines.

I would therefore wish to commend the team of professionals who spent relentless time to compiled this guideline most especially Mr. Tamba (M&E Officer-NACP) who developed the first draft to set the pace and basis for the completion of the document and Dr. Alren O. Vandy the ART Coordinator who took the lead in the entire process.

The role of the Expanded Technical Working Group (ETWG) including all development and implementing partners in the completion of this guideline was immense.

At this point I would like to especially express special thanks to all partners; SOLTHIS, AHF, ICAP, KSLP, PIH, WHO, UNICEF, UNAIDS.

I also acknowledge the contributions provided by Dr. Sulaiman Lakoh, Mrs Martha Sentho Kamara and all others from the Ministry of Health and Sanitation.

Finally, I must thank the Government of Sierra Leone, the UN Family, National HIV/AIDS Secretariat and Global Fund for their continuous support to the National HIV/AIDS Control Programme to develop and produce these guidelines. It is my fervent hope that the guidelines would be useful and will contribute to improving the quality of care delivered to people living with HIV/AIDS in Sierra Leone.

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INTRODUCTION

Since the recognition of the first case of Human Immunodeficiency Virus (HIV) in Sierra Leone in 1987, the number of people living with HIV/AIDS has steadily increased with the prevalence of HIV estimated at 1.7 percent among adults age 15-49 with 2.2 and 1.1 percent in women and men respectively (DHS 2019). HIV prevalence in urban areas is twice that in rural areas, at 2.3 percent in urban areas compared with 1.2 percent in rural areas. The Western region has the highest HIV prevalence (2.5 percent), about twice the level compared with the other regions. By district, Western Rural has the highest HIV prevalence, at 3.4 percent (DHS 2019).

The government has undertaken urgent actions through the National HIV/AIDS Secretariat (NAS) and the National HIV/AIDS Control Programme (NACP) and partners over the years, and a stabilisation of the epidemic has been seen with the national prevalence remaining at 1.5 between the 2008 SLDHS and the 2013 SLDHS. However, result of the 2019 SLDHS shows an increase in prevalence of 1.7%.

People living with HIV/AIDS in Sierra Leone have access to free antiretroviral drugs. Over the years, global platforms and partnerships have led to increased commitment towards making these drugs available to all HIV infected persons, which has been effective in reducing HIV related morbidities and mortalities.

The goal of the Sierra Leone National Strategic Plan (NSP) on HIV/AIDS 2016-2020 is to achieve zero new infection, zero discrimination and zero AIDS-related deaths with the main strategy to Test All, Treat All, and Retain All. The NSP is aligned to global targets of expanding access to treatment with the aim of ending the AIDS epidemic as a public health threat by 2030; as well as the 90–90–90 targets: 90% of the people living with HIV know their HIV status, 90% of the people who know their HIV status receiving ART and 90% of the people receiving ART having suppressed viral loads.

In this regard, the country has deemed it fit to develop a consolidated guideline in line with the World Health Organization (WHO) recommendations, to provide guidance on the diagnosis of HIV infection, the care of people living with HIV and the use of antiretroviral (ARV) drugs for treating and preventing HIV infection. The guidelines are structured along the continuum of HIV testing, prevention, treatment, and care.

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

These guidelines also provide operational and service delivery guidance to health care workers to implement new approaches, including:

- Guidance on 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, and
- Retention and adherence to treatment and, adolescent-friendly and responsive health services.

Objectives of the Integrated Guidelines

- To provide a standardized approach and simplified guide for HIV testing services (HTS).
- To provide an updated, evidence-based and simplified guide for the provision of ARV drugs for HIV treatment and prevention to all age groups and populations.
- To provide a standardized and simplified guide on infant and young child feeding for HIV-infected or exposed infants and children.
- To provide guidance on key operational and service delivery issues in order to increase access to HIV services and strengthen the continuum of HIV care.
- To serve as a training tool and a reference material for health care providers, program managers, and people living with HIV/AIDS (PLHIVs).

Target Audience

The primary audience for these guidelines will include:

- Healthcare workers and District Health Management Teams (DHMTs), CHWs, M2M, peer navigators
- HIV Program Managers, RMNCAH, TB program, Directorate of drugs and medical supplies.
- AIDS development, implementing partners, training institutions, researchers, civil society organization and community of PLHIV.

Process of the Guidelines Development

These guidelines were developed by the technical team of the National HIV/AIDS Control Programme (NACP), Ministry of Health and Sanitation (MoHS) with inputs from technical partners. The development process was comprehensive, involving technical review, adaptations of the guidelines, approval of the adaptation and final validation.

Components of the guidelines

These guidelines are structured along the continuum of HIV Testing, Prevention, Treatment, and Care.

1. DIAGNOSIS OF HIV AND LINKAGE TO CARE AND TREATMENT

1.1 Introduction

The term HIV testing services (HTS) is used in this guideline to embrace the full range of services that should be provided together with HIV testing including counselling (pre-test information and post-test counselling); linkage to appropriate HIV prevention, treatment and care services and other clinical services; and coordination with laboratory services to support quality assurance and the delivery of correct results. The aim of HIV Testing Services (HTS) is to make early and correct diagnoses to ensure early access to prevention, treatment and support services.

An estimated 77,072 (Spectrum, 2020) were living with HIV in Sierra Leone, only 47% knew their HIV status and 32% of these were receiving antiretroviral treatment (MoHS, 2018).
To improve access and efficiency, HTS should be made available to all persons at risk of HIV infection using cost-effective and high-impact approaches. HTS service delivery includes a range of activities and services that are described in the pathway below.

This section guides the provision of focused and targeted HTS for reaching populations at risk of HIV infection.

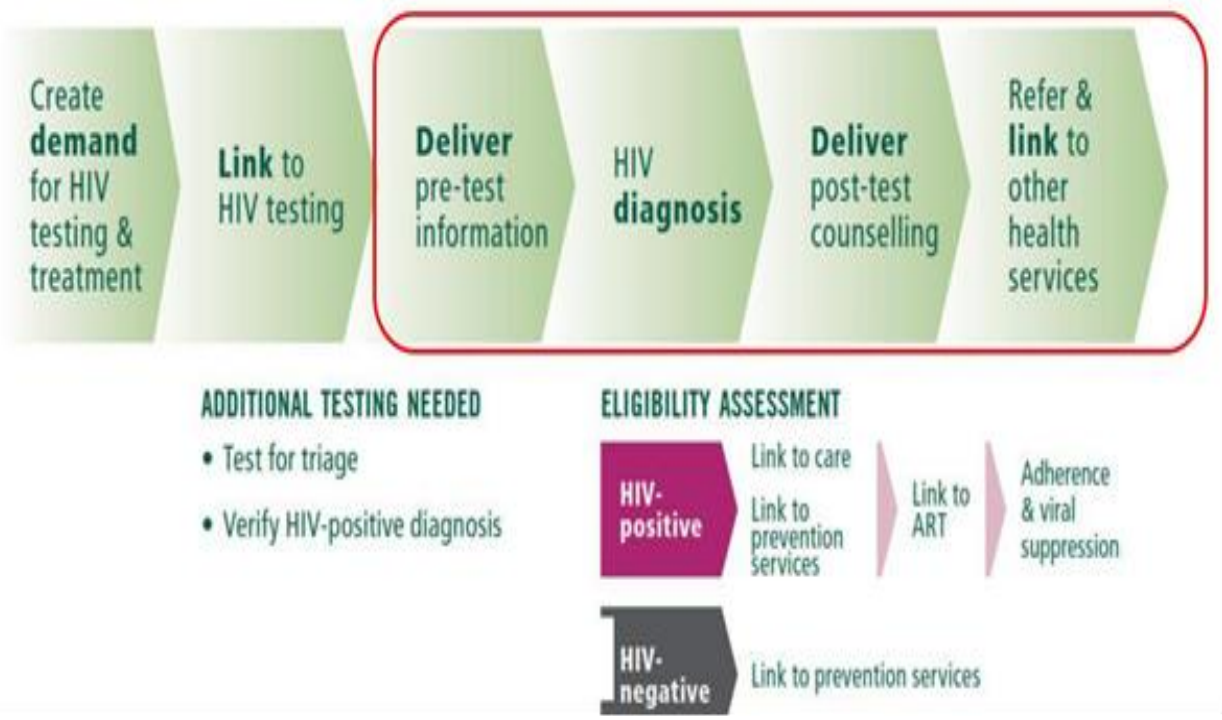


Figure 1: HIV Testing Services Pathway

Adapted from WHO consolidated guidelines on HTS, 2015

1.2 Principles of HIV Testing Services (HTS)

The HTS Guidelines use public health and human rights-based approach to delivering HTS. All forms of HIV testing should adhere to the World Health Organization's (WHO) Five Cs (WHO, 2015):

Informed Consent: *Permission granted in full knowledge of the possible consequences, typically that which is given by a patient/client to a service provider with knowledge of the possible risks and benefits. (Should be taken to key definitions)*

Consent: People receiving HTS must give informed consent to be tested and counselled. Informed consent is the permission granted to the service provider by patients/clients with the full knowledge of the possible outcomes of HIV testing services. They should be informed of the process for HIV testing and counselling, their right to decline to test, and the availability and benefits of treatment. Verbal consent is sufficient. For children below 18 years, consent is required from their guardian/parents. The three crucial elements in obtaining informed consent in HIV testing are:

- Providing pre-test information on the purpose of testing, prevention, treatment and support services available based on the outcome of HIV testing
- Ensuring understanding
- Respecting the individual's autonomy

Only when these elements are in place will individuals be able to make an informed decision on whether or not to be tested. In situations where consent cannot be obtained, the parent or guardian (of a child), next of kin or legally authorised person should consent. Mandatory HIV testing is not acceptable; it denies the individual's choice and violates the right to obtain informed consent and maintain confidentiality.

Confidentiality: HTS must be confidential, meaning that discussions between the service provider and the client will not be disclosed to anyone without the expressed consent of the client. Confidentiality should be respected, but it should not reinforce secrecy, stigma or shame. Service providers should discuss, among other issues, whom the person may wish to inform and how they would like this to be done. Shared confidentiality with health care providers for purposes of additional support and management is highly beneficial.

Counselling: Pre-test information can be provided individually or in a group setting. For group settings, clients should have the opportunity to ask questions in private if they so wish. All HIV testing must be accompanied by appropriate and high-quality pre and post-test counselling. Quality assurance (QA) mechanisms, as well as supportive supervision and mentoring systems, should be in place to ensure the provision of high-quality counselling.

Correct test results: All HIV testing should follow the validated national testing algorithm and should have appropriate QA and quality improvement (QI) mechanisms in place. Providers of HIV testing should strive to provide high-quality testing services. QA mechanisms should ensure that people receive a correct diagnosis.

QA may include both internal and external measures and should receive support from the national reference laboratory.

Connection (linkage to prevention, treatment and care services): Linkage to prevention, treatment and care services should include condoms, lubricants, PEP VMMC, eMTCT, ART and other referral services Providing HTS where there is no access to care, or poor linkage to care, including ART, has limited benefit for those with HIV.

1.3 HTS Approaches

It is recommended that HTS is made available through a range of approaches, both in facilities and in the community.

HTS at Health Facilities

Client initiated HIV testing and counselling (CITC): This involves a person(s) voluntarily seeking HIV counselling and testing services either in a health facility.

Provider-initiated testing and counselling (PITC): This type of HIV counselling and testing is initiated by healthcare providers as a standard component of medical care. PITC can be offered in the following approaches as diagnostic and routine HIV testing
Diagnostic Testing. This shall be carried out on individual as deemed necessary by the attending health care team with the purpose of better patient management such situation may include symptomatic (TB Clients, sick and malnourished children), 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
Routine HIV testing. This shall be carried out for individual likely to pose a risk of HIV infection to others. The following shall be offered routine testing, among others:

- Pregnant and breastfeeding women
- Partners of pregnant and breastfeeding women
- Donors of blood, body tissue and organs
- Sexual offenders and survivors.
- Those attending sexual health services
- Key populations and key affected populations

Index Case Testing/ Assisted Partner Notification/Partner Notification Services and Family-Based Testing: Is a case-finding approach that focuses on eliciting the contacts of an HIV positive client. The aim of the index case partner testing is to offer HIV testing to everyone exposed to HIV by the index, thereby breaking the chain of transmission.

There are several approaches, including partner and assisted partner notification and family-based testing.

i. Partner notification is where the client is empowered with information and skills on how to disclose to a partner; this is purely done by the client him/herself.
ii. Assisted partner notification is where the client is joined or supported by healthcare worker or person of choice in disclosing their status to the partner

iii. Family testing is when testing is taken or done to family members of a particular index client basing on eligibility. Testing the family of adult or child 'index' cases can serve as an entry point for identification of children living with HIV not identified through PMTCT program testing. This type of index case approach to HIV testing and service delivery enables parents and their children to access care as a unit. Such approaches may improve retention and offer convenient service for families affected by HIV.

Community-based HTS: HTS is provided within the community to individuals, couples or families from a community site.

Home-based HTS: is HIV testing offered in clients' homes by trained lay counsellors and healthcare workers. Other approaches to home-based testing include door-to-door that aims for high coverage of HIV testing services within a specific community or geographic location

Mobile outreach HTS: Includes outreach to community sites targeting hard to reach populations. It complements facility-based approaches which often do not reach most at-risk population or those in remote areas that lack health facilities. The approach is aimed at improving access to the utilization of HTS services and linkage to care.

HIV Self-Testing: 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. This approach will target population with unmet needs in Sierra Leone context. These will include key population, adolescents and men who are often disproportionately reached with HTS. Clients with positive results should be linked to health facilities for confirmatory HIV test.

HTS campaigns: HTS campaigns are nationwide efforts to increase access and uptake of HTS. Campaigns are implemented in many different ways, some focusing on the provision of referrals for testing in facilities; others provide HTS immediately and some combining the two. Either way, these campaigns should adhere to the HTS screening eligibility criteria and the standard operating procedures for service provision. Campaigns can be done in collaboration with other health services (i.e. maternal and child health week campaigns).

HTS in workplace and tertiary institutions: Seeks to provide formally employed men and women with access to testing. This people may have limited access to outside clinical services and may lose wedges if they must leave work to seek health care. Workplace testing has been implemented with high levels of uptake and linkage to HIV and TB services, particularly in high burden settings. Workplaces include higher institutions, mining companies, factories seaports and private sectors. HTS should always be done in a way that protects and promotes the right to autonomy and dignity of all clients and must follow the prescribed national protocols.

1.4 Target Population for HTS

In order to achieve the 90-90-90 targets, HTS should be offered to persons of all age groups. However, special attention should be paid to population that remain undiagnosed, including prioritizing implementation in specific geographical areas or clinical settings as defined by country epidemiology.

Population for HTS consideration include Key and priority populations:

- Partners and family members of people with HIV (index testing).
- Partners in discordant relationships
- Children attending tuberculosis (TB) or other infectious disease clinics, malnutrition services and/or admitted to the paediatric or adult hospital wards.
- Adults attending tuberculosis (TB) or other infectious disease clinics, other clinics like Family Planning or admitted to hospital wards
- Orphans and vulnerable children (OVC)
- Adolescents and young people
- Pregnant and breastfeeding women
- Miners
- Fisherfolks
- Long-distance truck drivers
- Correctional services inmates
- men with unknown status (e.g. Tricycle and motorbike Riders)
- people living with disabilities
- Other vulnerable population

Key Populations often have limited access to HTS due to stigma and discrimination, including criminalization of their activities. They include:

i. Sex workers and their clients
ii. Men who have sex with men
iii. Transgender people
iv. People who inject drugs

Prisoners and other people in enclosed setting Country strategies should adopt evidence-based practices to reach key populations. These include HIV self-testing, mobile outreach testing, workplace testing, and index case testing.

Partners and family members of people with HIV (index testing). Members of married or unmarried couples infected with HIV, including their families, should be provided with HTS. This is an efficient and effective way of identifying additional people living with HIV who also can benefit from treatment. Couple and home-based HIV testing should be promoted to improve access to partners and family members.

Partners in discordant relationships - a pair of sexual partners in which one is HIV positive, and the other is not. Access to HTS should be improved for partners in discordant relationships through index case testing and promotion of couple counselling.

Orphans and vulnerable children (OVC) – This is a child under the age of 18 whose mother, father, or both parents and primary caregiver died, and who is in need of care or protection. In a generalized epidemic context like Sierra Leone, routine HTS and focused HTS should be provided to orphans and vulnerable children.

Men - are disproportionately reached with HTS because of their poor health-seeking behaviour. Conscious effort should be made to reach men. Strategies such as mobile outreach HTS, home-based HIV testing, workplace HIV testing, facility-based HIV testing in adjusted hours (e.g. evening hours) HIV self-testing, male involvement in eMTCT should be promoted

Adolescents - Adolescents are age group 10 - 19 years. They can acquire HIV through vertical transmission, SGBV, FGM, sexual intercourse or injection drug use. Engaging adolescents in HIV testing, as well as prevention, treatment and care, requires specific strategies. These may include facility or community-based strategies. The service provided should be based on adolescent-friendly principles to ensure that psychological and physical needs are addressed.

Pregnant and breastfeeding women- For early diagnosis and prevention, PITC is recommended among pregnant and breastfeeding women.

Communities

Other Groups at risk:

i. Survivors of sexual and gender-based violence
ii. Uniformed personnel
iii. Fisherfolk
iv. Long distant truck drivers
v. Migrant workers
vi. Mineworkers
vii. Displaced persons

Routine and focused HTS should be provided to this population group

HTS should be guided by Country Epidemic Shift and can be focused on a particular:

Geographical areas: Communities (e.g. Fishing and landing sites), border towns, cities and districts, with high burden and unreached population should be targeted for HTS provision

Health facility: Facilities with wider catchment coverage, including those located within high HIV burden communities.

1.5 Steps in HIV Testing Services

Table 1 provides the steps involved in HTS and highlights of the description of each step.

Table 1: Steps involved in HIV Testing Services

Step	Activity	Description
1	Pre-test information (counselling)	Offering or recommending HIV testing to a client, couples or a group of clients includes providing clear and concise information on: ▪ Basic information about HIV ▪ The benefits of HIV testing ▪ The meaning of an HIV-positive and an HIV-negative diagnosis ▪ The services available in the case of an HIV-positive diagnosis, including where ART is provided ▪ The potential for a false-negative result if a person is on ART ▪ That negative result may imply that you are in the window period or you are free from HIV ▪ A brief description of prevention options and encouragement of partner testing ▪ The fact that the test result and any information shared by the client is confidential ▪ The fact that the client has the right to refuse to be tested and that declining testing will not affect the client's access to HIV-related services or general medical care ▪ Potential risks of testing to the client in settings where there are legal implications for those who test positive and/or for those whose sexual or other behaviour is stigmatized ▪ Potential benefits of testing which include the fact that ART is both lifesaving and can decrease the risk of spread of HIV to sexual partners ▪ Risk assessment ▪ Explain the testing procedure to the client ▪ An opportunity to ask the providers questions ▪ Consent sought for the individual to be tested ▪ An option to start ART on the same day if HIV positive

Step	Activity	Description
2	HIV Testing	▪ The testing algorithm indicates the combination and sequence of HIV tests to be used. All specimens are first tested with Determine and specimens that are non-reactive are considered HIV negative and reported as such. Any specimens that are reactive on the Determine assay should be re-tested using a separate and distinct second assay (Bioline). Specimens that are reactive on both the first- and second-line assays (Determine+; Bioline+) are reported as HIV positive and referred for antiretroviral therapy (ART). ▪ Specimens that are reactive on the first-line assay (Determine+) but non-reactive on the second-line assay (Bioline) should then be tested using the tie-breaker assay (Unigold). If the result of the third assay is non-reactive (Determine+; Bioline; Unigold-), then the test is inconclusive. The client should be asked to return in 14 days for re-testing. If the result of the third assay is reactive (Determine+; Bioline -; Unigold+), then the test result is considered positive, and the Bioline assay should be redone to establish type
3	Post-test counselling (Individual/Couples)	▪ A guiding principle of HIV counselling and testing is that all clients should receive post-test counselling regardless of their HIV status. The HIV test result should always be given in person, not otherwise. ▪ Assess readiness to receive results, give results; address concerns, discuss disclosure and partner testing, risk reduction, condom demonstration and re-emphasize basic information on HIV ▪ Provide information on HIV care and ART including benefits of ART and, consequences of delaying ART ▪ Discuss disclosure (Who, When, When and How) ▪ Discuss readiness to start ART ▪ Complete the post-test form and HTS register. ▪ Link to ART

1.6 HIV Testing Algorithm

1.6.1 Serial HIV Testing Algorithm for persons above 18 months of age (or 6 weeks after cessation of breastfeeding)

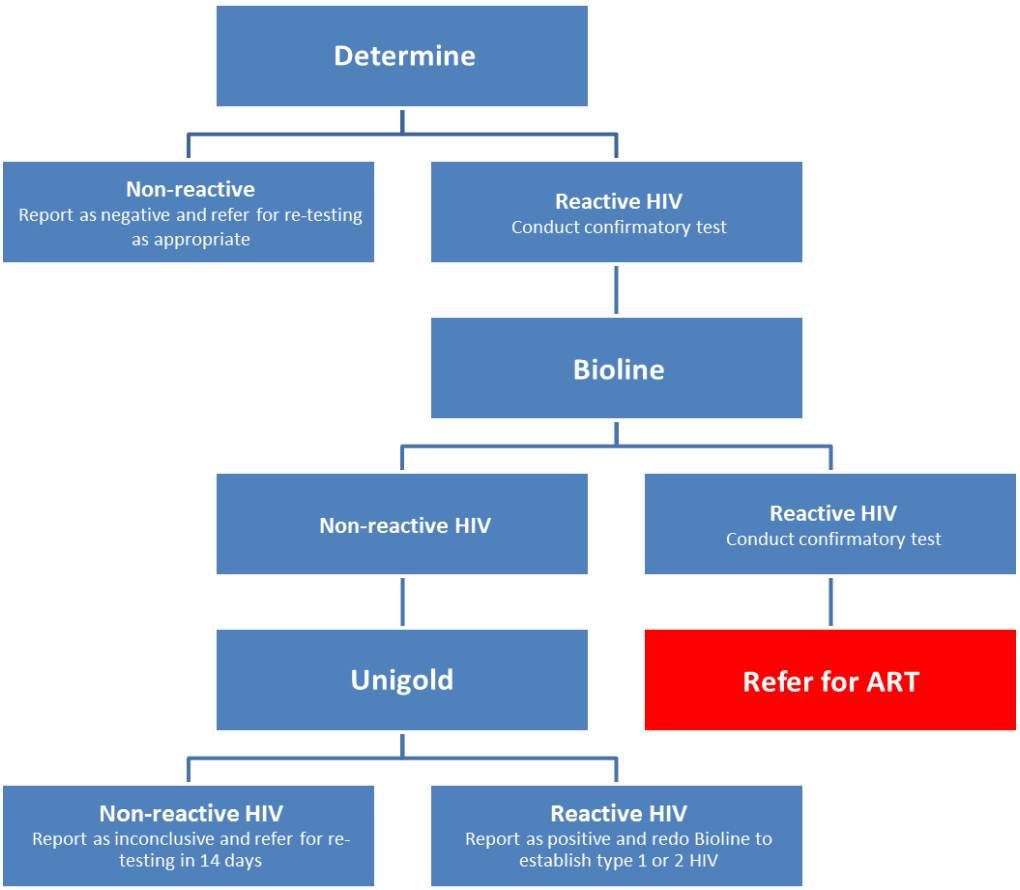


Figure 2: Serial HIV Testing Algorithm for persons above 18 months of age

Inconclusive results after re-testing

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

1.6.2 HIV Testing Algorithm for Pregnant Women (Reviewed Feb.2019)

Specimens are first tested with HIV/syphilis duo. Specimens that are non-reactive for both HIV and syphilis are reported as negative. Specimens that are reactive for syphilis are reported as syphilis positive and treatment provided for the client and his/her partner(s). Specimens that are HIV reactive should be retested using Determine. Specimens that are reactive on both assays (Duo+; Determine+) should be tested with Bioline to establish the type of HIV. Reactive samples (Duo+; Determine+ and Bioline+) are reported as positive and referred for ART.

Specimens that are non-reactive on the second-line assay (Duo+; Determine-) should be re-tested using Unigold. Specimens that are positive on the tie-breaker test (Duo+; Determine- and Unigold+) should then be tested with Bioline to establish type 1 or 2 HIV. Specimens which are negative on the tie-breaker test (Duo+; Determine-; and Unigold-) are considered indeterminate (inconclusive), and the clients should be referred for re-testing in 14 days. If the same result is obtained after retesting, the sample should be referred to CPHRL for confirmatory testing.

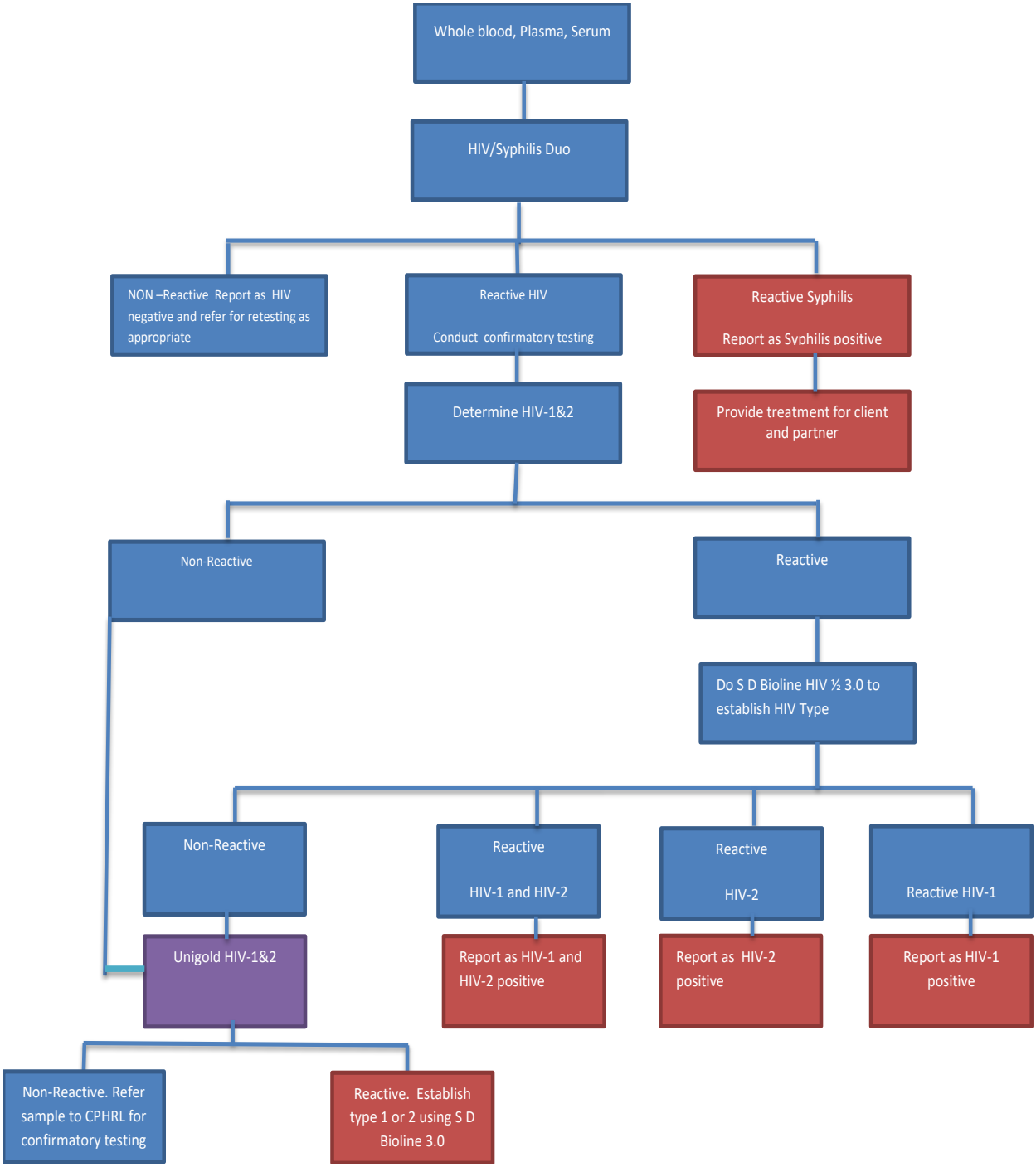


Figure 3: Serial HIV Testing for Pregnant Women

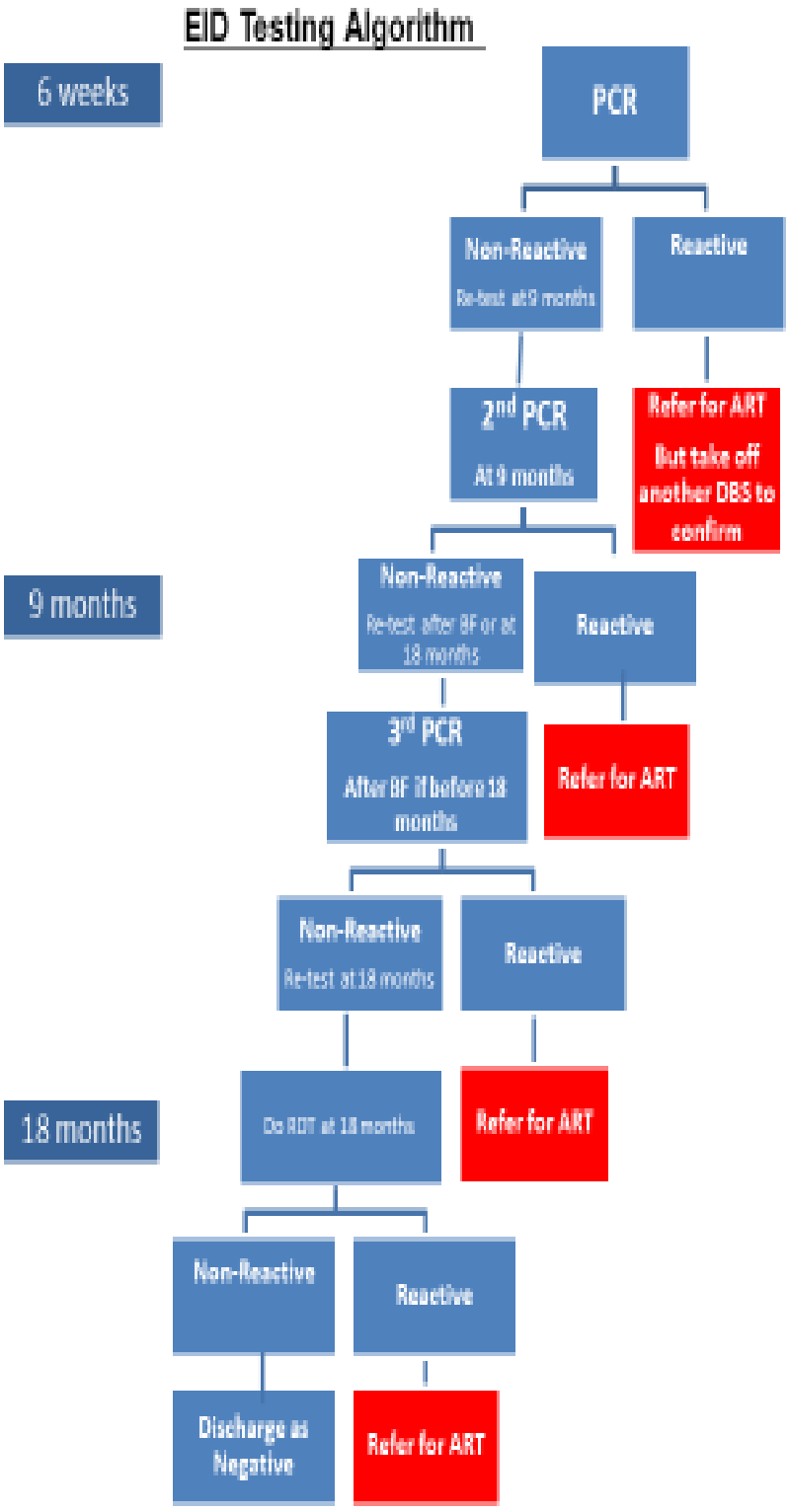


Figure 4: EID Testing Algorithm for Exposed Infants

Retesting of individuals with HIV negative status

The vast majority of individuals do not require retesting to verify an HIV negative status, particularly in the absence of any ongoing risk.

However, certain individuals who test HIV negative warrant retesting:

- An individual with an indeterminate HIV status (Determine +, Bioline -, Unigold -)
- If an individual has previous or ongoing risk for HIV infection (i.e. key populations, people who currently inject drugs, sex workers, or men who have sex with men, transgender and people in prisons or closed settings) those having a high-risk or known HIV positive partner; having clinical indications for re-testing such as newly acquired STI or viral hepatitis; persons with confirmed or presumptive TB diagnosis; persons who can identify a specific incident of HIV exposure in the three months prior to HIV testing (i.e. history of occupational exposure, unprotected sex with a known HIV positive person, sharing injecting equipment with a known HIV positive person)
- Pregnant women who have tested HIV negative in the first or second trimester of pregnancy should be re-tested in their third trimester or at delivery.
- Outpatients with clinical conditions indicative of HIV infection.

1.6.3 Linkage to ART, and other Services

There are several approaches to strengthening the links between HTS, ART, STI and other services.

Linkage to a service is when a referred client/patient takes up the service for which he/she is referred to (treatment, prevention and care). All referrals and linkages should be documented using the existing referral tools with clear evidence of feedback.

All clients who test HIV positive should be linked to care and initiate ART same day or within ***seven days.*** We highly recommend the use of health care workers and Community Health Workers (CHWs) as linkage facilitators.

Good Practices for linkage to care for HTS sites

- Prepare standard operating procedure for inter and intra- facility service outlets referral linkage systems
- Establish site-level support groups to improve escorting/accompanying referrals and feedback practices for intra-facility referral
- Conduct linkage audits to monitor clients' engagement to care and treatment services
- Map and establish network between available HTS, chronic care and other support services within the area (linkage directories)

Inter-facility referrals and linkage – Refers to connecting a client with another facility for HIV treatment, care and support services.

Intra-facility referrals and linkage- Connecting clients to services within the same facility

1.7 Quality Assurance and Quality Control

Quality assurance (QA) is an overall program of activities throughout the entire testing process. Quality control (QC) is one part of the QA program.

Here are definitions for both terms:

Term	Definition and activities performed
Quality Assurance	Planned and organized activities to help ensure that certain requirements for quality will be met.
Quality Control	Operational techniques or tasks that are in place to find and correct problems that might occur.

Even though rapid tests are simple to use, things can go wrong. To help find and prevent problems, the basic elements of a QA program should be in place before offering HIV diagnostic testing. The basic elements of a QA program and are as follows.

- Organization of the QA program
- Testing personnel
- Process control
    i. Before testing
    ii. During testing
    iii. After testing
- External quality assessment
- Documents and records
- QA evaluation and troubleshooting

1.7.1 Establishing the Quality Assurance program

A QA program, no matter how simple, requires resources. Someone who must oversee the program and ensure the necessary personnel and supplies are available. Each organization must:

- Identify the person(s) responsible for managing the QA program (this could be a senior staff member or a network of persons who oversee different aspects of the QA program).
- Verify the testing process.
- Write site-specific procedures (step-by-step instructions) and make them available to all personnel involved in testing.
- Ensure personnel know how to perform each of the procedures.
- Create mechanisms for communication so that personnel are informed about problems when they are identified.
- Develop and implement mechanisms to ensure the site meets all applicable, State, and other regulatory requirements, including requirements for biohazard safety

1.7.1.1 Verifying the testing process

Before offering the test to clients or patients, service providers should ensure and verify that the testing process works as planned.

Verifying the process includes: ensuring that personnel have been trained and are able (competent) to perform their assigned tasks, the test kits work as expected (e.g. give accurate results for a referenced panel of nonreactive, weakly reactive, and reactive specimens), and that logistics are in place for providing confirmatory testing of preliminary positive test results and handling biohazardous waste.

1.7.1.2 Providing written testing instructions (Standard Operating Procedures/ Job AIDS)

Service providers must follow instructions provided by the manufacturer. It is strongly recommended that step-by-step, written instructions (SOP) be made available to all personnel performing tests. The test kit package insert provides text that can be used as a procedure for steps in the testing process, as shown in table 2.

Table 2: Procedures for HIV Testing

Procedure	Describes how to...
Pre-test information	Provide required pre-test information to test subject.
Materials and storage	Maintain sufficient supplies of unexpired test and control kits and adhere to the manufacturer's temperature ranges for storage and testing areas.
Test performance	Collect specimens, perform the test, interpret and report test results, resolve problems (troubleshoot) before reporting results.
Quality control	check performance of new test kit lots and shipments, frequency of routine QC testing, and actions to take if controls do not work

Recommended site-specific written procedures

Site-specific procedures describing other operations should be written and available to help ensure personnel know how to perform additional QA tasks.

Table 3: Specific-Site Procedures for HIV Testing

Procedure	Describes how to...
Personnel training and competency	Train and assess competency of new employees; periodic competency assessment of all testing personnel.
Safety	Use gloves and other personal protective equipment (PPE); safely dispose of biohazard waste, including used lancets or other sharps used for blood collection.
Reporting	Report results, including confirmatory results, if applicable.
Confirmatory testing	Refer specimens or test subjects for confirmatory testing; manage test results.
Documentation	Keep records and timelines for review, retain and destroy when outdated.

1.7.1.3 Testing Personnel

Having qualified, trained personnel who perform and supervise rapid HIV testing and the various activities in the QA program is one of the most important factors for ensuring accurate and reliable results. Key aspects of this element include:

- Personnel qualifications
- Training
- Competency assessment (To assess how well they are doing their job)

Personnel Qualifications

Service providers should consider the following when selecting personnel to perform rapid HIV antibody test.

- Sincerity and commitment – A dedication to performing testing accurately, according to defined procedures.
- Literacy – The ability to read instructions and record results is critical.
- Organizational skills – The level of skill necessary will depend on the number and complexity of tasks an individual performs in the testing process. If test volume is high, and the individual performing testing is doing several tests or managing several other tasks simultaneously, organizational skills can be critical.
- Decision-making skills – Testing personnel should be able to interpret results and be able to recognize and handle problems that might arise.
- Communication skills – If the person performing the test also is the one who shares results or other information with the person being tested, being able to communicate clearly is important.

Components of training

Training is crucial to ensuring quality testing. Personnel should be fully trained on how to perform their assigned tasks and responsibilities. Training should be documented for each individual, and using a training checklist is necessary. Key components to include in a training program are as follows:

- The importance of QA and the elements of the site's QA program
- How testing is integrated into the overall program
- How to perform the test, including procedures performed before, during, and after testing.
- The use and importance of blood and body fluid precautions and biohazard safety.

Competency Assessment

Before a trainee is permitted to perform testing alone for the first time, his or her ability to conduct the test should be demonstrated and documented. This assessment should also be carried out at periodic intervals after training, such as every six months or other intervals as determined by the testing site.

Competency assessment can be carried out in many ways, but regardless of the method, every task for which an individual is responsible should be evaluated. A supervisor or trainer should perform the assessment, using a combination of methods to determine competency.

- If the frequency of reactive rapid test results is low, the trainee should be observed collecting blood specimen from a volunteer staff member and demonstrate how it is processed for confirmatory testing.
- Verify that confidentiality is maintained

1.7.1.4 Process Control

Process control refers to the activities and techniques that are carried out to ensure that the testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to produce accurate and reliable results.

Steps in the testing process

Steps in the testing process follow the path of workflow, beginning with tasks before testing, followed by those conducted during and after testing. This path of workflow and the associated steps are shown in table 4.

Table 4: HIV Testing Services Workflow

Before testing (Pre – analytic)	During testing (Analytic)	After testing (Post – analytic)
• Check storage and room temperatures daily • Check inventory and test kit lots, as needed • Receive request for testing • Provide HIV/AIDS test information to the test subject (HIV counsellor) • Set up test area, label test device • Perform external QC according to the manufacture's and the site's instructions	• Follow biohazard safety precautions • Collect the blood specimen • Perform the test • Interpret the results	• Document results • Report results to test subject • Collect, process, and transport confirmatory test specimens or refer clients/patients for follow-up • Clean up and dispose of biohazardous waste • Manage confirmatory test results • Participate in periodic external quality assessment

1.7.1.5 Documents and Records

One of the hallmarks of an adequate QA program is comprehensive documentation. Sites using rapid HIV tests should have policies and procedures describing what QA records are required.

Having a supervisor review records periodically is recommended. QA records include the following:

- Training documentation
- Temperature logs
- External control result logs
- Standardized test result logs
- Specimen transfer logs (Chain of custody)

1.7.2 Quality control

Rapid HIV tests include two types of Quality Control, which are described in Table 5.

Table 5: Quality Control for Rapid HIV Tests

Type of quality control	Description of activity
Internal controls	Controls built into each testing device can verify that specimen was adequate, and the solution flowed through the device as intended. Functions of internal controls vary by device.
External controls	Known reactive and nonreactive liquid or lyophilized samples. It is either provided in each test kit or purchased separately from the manufacturer. External controls are surrogate samples used to evaluate the integrity of the test system and whether the person conducting the test performs it correctly.

External quality control

To verify that test devices accurately detect antibodies to HIV, external positive and negative controls must be tested from time to time. The test kit manufacturer provides external controls containing HIV antibody-negative (nonreactive) and positive (reactive) specimen compatible with its test system.

External Quality Assessment

External quality assessment is an evaluation of the testing process by an impartial outside source, as a way to evaluate how well and reliably testing is being performed. It can help to identify existing or potential problems. Moreover, information gathered can provide an educational tool to improve performance.

2. COMBINATION PREVENTION

Introduction

Prevention is fundamental to the reversal of the devastating effects of the epidemic. In Sierra Leone, the goal of HIV prevention is to halt and reverse the spread of HIV infection in the general and key population, and to achieve the elimination of mother to child transmission (eMTCT). Important ways to address HIV prevention include:

- Behavioural Prevention
  - Behavioural Change Communication (BCC) including Information, Education and Communication (IEC)

2.1 Biomedical Prevention

- HIV testing and counselling (HTS)
- EMTCT
- Safe blood transfusion and tissue transplantation
- Universal Precautions – IPC (including PEP for occupational exposure)
- Condom promotion and Voluntary medical male circumcision (VMMC)
- Post Exposure Prophylaxis (PEP)
- Prevention of STIs
- Interventions for key populations
- Pre-exposure prophylaxis (PrEP)
- Treatment as prevention (TasP)
- HIV and STI surveillance
- TB/HIV collaboration

2.2 Structural Prevention

- Gender-Based Violence/ Intimate Partner Violence
- Legal and Policy Review

This section will provide guidance on how to implement interventions that reduce the acquisition of new infections among HIV-uninfected youth and adults, as well as key and priority populations.

2.3 Behaviour Prevention

Behaviour Change

A comprehensive BCC strategy that includes IEC is considered central to efforts to reduce the spread of HIV. BCC and IEC messages should, therefore, include information for the general, and other specific populations. The BCC strategy takes cognizance of :

- Age, key cultural and family values, sexual orientation, social settings and gender specificities
- Appropriately informed HIV-related ethical and human rights issues;
- Scientific and evidence-based ;

- Participatory methods that are appropriate for key populations, vulnerable, general population and other groups
- Stigma and discrimination in any form;
- Integration into the spheres of social, economic and religious activities of individuals, communities and organizations;
- The critical role that the media (both traditional and modern), plays in informing and educating the public about practices that either promote or hinder the spread of HIV and AIDS and

The behavioural change interventions that aim at progressive transition from general awareness to knowledge of a person's serostatus and prevention **Biomedical Prevention**

2.4 HIV Testing Services (HTS)

Good quality HIV Testing and Counselling (HTC) should be available and accessible to each person seeking these services. Adequate information must be provided before testing, and post-test counselling should be provided when test results are received. Clients who test positive must be made fully aware through counselling of their responsibility to prevent onward transmission to others. HTC should also be promoted as a major entry point into care and treatment services.

2.5 Condom promotion

Encourage education on methods to prevent HIV acquisition and provision of female or male condoms, lubricants and guidance on their use.

2.6 Voluntary Medical Male Circumcision (VMMC)

VMMC provides about 60% risk reduction for HIV transmission. Counsel and refer clients who require VMMC services to the appropriate service providers.

2.7 Safe blood transfusion and tissue transplantation

The virtual elimination of blood-transmissible HIV infection should be facilitated by ensuring that health facilities and health care workers obtain blood for transfusion that is screened with p24 antigen for HIV and other blood transmissible infections. Blood and blood products should be obtained from reputable sources, including the National Blood Transfusion Service (NBTC).

2.8 Elimination of Mother to Child Transmission (EMTCT)

Transmission of HIV from mother to child can occur during pregnancy, during delivery, or through breastfeeding. Mother-to-child transmission of HIV represents one of the major causes of morbidity and mortality among children less than five years old.

In view of the desired objective of saving children's lives and reducing the impact of HIV on families and communities, the use of ART **(Option B+)** to reduce the risk of MTCT is to be promoted and adhered to by all health care providers.

EMTCT and Improving Maternal, Newborn, Child, Adolescent and Youth Health (MNCAYH)
Globally, about 90% of children get HIV from their mothers during pregnancy, delivery, and breastfeeding.

Mother-to-Child Transmission (MTCT) of HIV is a major problem in Sub–Saharan Africa which is home to more than 75% of all women of reproductive age living with HIV/AIDS (PLHIV) globally.

In Sierra Leone, the Prevention of Mother-to-Child Transmission (PMTCT) programme started in 2004 and has been rolled out with the aim of achieving national coverage, but only 51% coverage has been reached. Currently, HIV prevalence among pregnant women has reduced from 3.2% in 2010 to 2.8% in 2018 **(ANC, 2018).**

The country embraces the UN four-prong approach in the provision of PMTCT services including; primary HIV prevention among women and girls of reproductive age, prevention of unintended pregnancies among women living with HIV, prevention of HIV transmission from women living with HIV to their children, and treatment, care and support for women living with HIV, their children, and families.

Following the 2009 global call for the virtual elimination of MTCT and new paediatric HIV infections by 2015; which when effectively implemented will reduce MTCT rates of less than 2% in non-breastfeeding populations and 5% in breastfeeding populations; Sierra Leone adopted the elimination strategy and started its implementation process in 2011.

2.8.1 EMTCT Approach

The overall goal of the EMTCT strategy is to contribute to the improvement of maternal health and child survival through accelerated provision of comprehensive services. The strategy also comprises of a package of interventions summarized are to be offered simultaneously within the platform of RMNCAYH services along the life course and throughout the continuum of EMTCT services.

Table 6: EMTCT Interventions

Element	Target Population	Additional Information
Prong 1. **Primary Prevention of HIV**	**Women and men of reproductive age including adolescent and youths**	This prong aims to prevent HIV in men, women of reproductive age and adolescents and youths. Interventions include: ▪ Sensitize the general population on HIV services ▪ Routine HIV testing services for all pregnant women attending in the context of PMTCT ▪ Routine HIV testing services for pregnant and non-pregnant adolescents ▪ All women identified HIV negative receive information on risk reduction (including condom use and partner referral). ▪ All communities surrounding PMTCT facilities are provided with information to facilitate the utilization of the services. ▪ Screening of male partners for HIV. ▪ Couple counselling and testing & targeted retesting for the HIV negative ▪ Behavioural change communications and risk reduction counselling to avoid high-risk sexual behaviour including. ▪ Safer sex practices, including condom protection
Prong 2. **Prevention of unintended pregnancies**	**Women including adolescents and youths living with HIV and their partners**	This prong will focus on: Women living with HIV enrolled in PMTCT care, and treatment receives family planning services (either on-site or through referral) ▪ Ensure sexual partners of women living with HIV are offered HIV testing ▪ FP counselling & voluntary services (informed choice) ▪ Safer sex practices, including dual protection (contraception and HIV prevention through condom promotion)
Prong 3. **Prevention of HIV transmission from women living with HIV**	**Pregnant and breastfeeding women including adolescents living with HIV**	This prong will focus on: ▪ Integrated and quality prenatal antenatal, labour and delivery and postnatal care ▪ Safe delivery practices to decrease the risk of infant exposure to HIV ▪ Access to HTS during ANC, Labour, delivery, and

to their infants		postpartum period ▪ Early initiation of ARVs for prevention of HIV transmission and for the mother's health ▪ Adherence counselling and support ▪ Offer peer education and support such as Mother Mentors to do follow-up for retention monitoring ▪ Viral load testing and monitoring ▪ Encourage facility delivery ▪ ARV prophylaxis for HIV-exposed infants ▪ Infant and young child feeding counselling. ▪ Community outreach and efforts to support partner involvement and testing. ▪ TB screening, diagnosis, and treatment ▪ INH prophylaxis ▪ Syphilis screening and treatment for both partners Nutritional assessment counselling and support to HIV positive mothers
Prong 4 Treatment, care and support to women infected with HIV, their children and their families	**HIV positive women and their families**	<u>Package of services for mothers includes</u>: ▪ Lifelong ART ▪ Co-trimoxazole prophylaxis ▪ TB screening, diagnosis, and treatment ▪ INH prophylaxis ▪ Prevention, diagnosis, and treatment of malaria ▪ Continued infant and young child feeding, counselling, and support ▪ Nutrition assessment counseling and support ▪ Sexual and reproductive health services including FP and condom provision ▪ STI screening and treatment ▪ Adherence and Psychosocial support ▪ Risk reduction counseling ▪ CD4 and routine viral load monitoring ▪ Routine follow-up, ARV refills and other routine MCH services ▪ Effective referrals and linkages to other services (community and facility) ▪ Symptom management and palliative care between the ANC, Labour ward, postnatal and under five and other services <u>Package of services for HIV-exposed and infected children</u> ▪ ARV prophylaxis ▪ OI prophylaxis ▪ CTX

		▪ INH prophylaxis ▪ for TB exposed ▪ Routine immunization, growth monitoring, nutritional care ▪ HIV testing (EID) ▪ Prevention, screening & management of infections ▪ Psychosocial care and support ▪ Routine follow up and refills and provision of age-appropriate supplements ▪ Effective referrals and linkages to other services (community and facility) ▪ ART for HIV-infected children <u>Package of services for partner and the family</u>: ▪ Family index testing: HIV testing of partners, children and other family members and linkage to prevention & care services ▪ ART for family members living with HIV ▪ Co-trimoxazole prophylaxis for HIV-positive family members ▪ TB screening, diagnosis, and treatment and advice on TB infection control in the family. ▪ INH prophylaxis ▪ Sexual and reproductive health services including FP and condom provision ▪ STI screening and treatment ▪ Adherence and Psychosocial support ▪ Risk reduction counseling ▪ Routine CD4 and viral load monitoring for the HIV-positive ▪ Routine follow-up, ARV refills, and other services ▪ Effective referrals and linkages (community and facility) ▪ Symptom management and palliative care

2.8.2 Integrating EMTCT into RH/MNCA&YH Services

EMTCT interventions should be integrated into the RH/MNCAYH services which include but not limited to the ANC, Labor and Delivery, Post Natal Care, Special Care Baby Unit (SCBU), Under-fives clinic, EPI, Sick child clinic, nutrition and AYCC at health facilities and in community.

The section defines which services in each EMTCT prong are offered in each of the RH/MNCAYH services continuum; before pregnancy, antenatal, labour and delivery, postnatal and in communities.

Table 7: The EMTCT Continuum of Services

Non Pregnant women	During Pregnancy	Labour and Delivery	Post-Partum
▪ Primary Prevention of HIV infection ▪ HIV testing services (HTS) including provision of /linkages to ART if living with HIV ▪ Prevention of unintended pregnancy	▪ HIV testing and counseling - (PITC). ▪ ART for mother & Basic HIV care (CPT, ITNs) ▪ Infant feeding counseling and support ▪ VL testing and monitoring for women living with HIV ▪ Provision of ANC services throughout pregnancy	▪ PITC (offer PITC if unknown or tested negative more than 3 months prior) ▪ Safer delivery practices to decrease the risk of infant exposure to HIV ▪ ART & CTX refill and Adherence counseling ▪ ARVs to the newborn / NVP prophylaxis ▪ Routine vaccination	▪ PITC (offer PITC if never tested or tested negative more than 3 months). ▪ Testing exposed newborn, initiate NVP prophylaxis *(Refer to EID Section)* ▪ Routine Immunization, Growth monitoring, Infant and young child feeding support ▪ Early Infant Diagnosis (EID) & ART for infected infants ▪ ART & CTX refill and adherence counselling ▪ Family planning counselling and choice with methods
Community EMTCT			

2.8.2.1 Services for Non-Pregnant Women

HIV prevention among non-pregnant women of reproductive age eliminates the risk of HIV infection in infants as MTCT is the major route of HIV transmission among infants. Initiation of ART before pregnancy in women living with HIV provides better outcomes for preventing MTCT.

Table 8: Prevention of HIV Infection among non-pregnant women of Reproductive age

Service	Description
Routine HTS	▪ Provide HTS to all non-pregnant women of reproductive age and their partners. ▪ Link all women who test HIV positive to care and treatment services. ▪ Offer counseling and other services to all women who test HIV **negative to encourage them to stay negative**
BCC	▪ Safer sex practices, dual protection including condom promotion and FP ▪ Delay of onset of sexual activity
Other Services	▪ Offer PEP to eligible women of reproductive age in line with the guidelines ▪ Special consideration should be given to women and adolescents in discordant relations who desire to get pregnant
STI	Treat all STIs according to national guideline (both partners)

2.8.2.2 Prevention of Unintended Pregnancy among HIV Positive Women

Family planning is part of a comprehensive public health strategy to prevent MTCT. All women living with HIV and their partners should receive family planning counselling and have access to and choice for effective contraceptive methods in order to avoid unintended pregnancies. For best results, Dual protection is recommended: the use of birth contraceptive method and condoms (male or female).

Table 9: Process of providing family planning services to HIV-infected women

Service	Explanation
Counsel women routinely for FP	Provide routine FP information and counseling to women attending ANC, PNC, ART services Information provided during counseling should cover; ▪ Family planning methods, medical – eligibility criteria, advantages, and side effects. ▪ Common misconceptions about family planning ▪ Advantages of dual protection and also how to negotiate for condom use. ▪ What to do when pregnancy occurs ▪ Provide empowerment for the woman to make an informed decision on the method of choice for FP. ▪ Encourage HIV-infected women to discuss their RH choices and support them as appropriate. ▪ All pregnant women and their partners (HIV infected and uninfected) should be encouraged to use condoms during pregnancy to prevent STIs (and/or re-infection) and HIV infection ▪ Every woman living with HIV who intends to stop use of contraceptives and become pregnant should be provided with adequate counselling on PMTCT Address misconceptions
After counselling, offer FP on a one-on-one basis	For HIV-positive women/couples who desire to become pregnant Discuss strategies to: ▪ Reduce the likelihood of HIV transmission to infants. ▪ Among discordant couple, reduce the risk of transmission to the partner through conception strategies including Initiating and adhering to ART for ensuring viral suppression and/or PrEP for the HIV negative partner For HIV-positive women/couples who do not desire to become pregnant. ▪ Offer effective contraception. ▪ Encourage dual contraception (use of both hormonal contraception and condoms) to prevent pregnancy, STIs (infection and/or re-infection), and HIV transmission ▪ The choice of contraceptive methods in HIV-infected women is much the same as in non-HIV women. However, IUCD use is discouraged due to increased risk of STIs. ▪ Consider some drug interactions between HIV medicines and contraceptives when offering FP methods to women on ART
Ongoing support for women when Using FP	▪ Assess for possible side effects and manage accordingly. ▪ Clients on Nevirapine-based ART and Injectable (Depo-Provera) should be counselled to return for injection on appointment date or before if they can't make it on that date.

Table 10: Family Planning Commodities for Women Living with HIV

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

2.8.2.3 During Pregnancy

This section outlines ANC services for all pregnant women, specific services for the HIV-infected pregnant woman and HIV-negative pregnant woman.

Table 11: Services offered during Pregnancy

Service	Description
Provide HTS and syphilis testing during ANC	▪ Offer routine HTS and testing for syphilis to pregnant women and their Partner(s) with same-day results. ▪ Offer HTS through PITC, VCT and couple testing should be encouraged with support for mutual disclosure ▪ Link all HIV-positive seroconcordant and serodiscordant couples to ART services. Offer PrEP to the negative partner in the discordant couple and treatment to the positive partner. ▪ For HIV-negative pregnant women, retest in the third trimester, or during labour, or shortly after delivery, because of the high risk of

	acquiring HIV infection during pregnancy. ▪ Re-test the following HIV negative pregnant women after risk assessment within six weeks of the first test o STI's or TB- infected pregnant women o Those with a specific incident of HIV-exposure within the past three months. o Re-test HIV-negative pregnant women in a discordant relationship every 3months. • Provide risk-reduction counseling to HIV-negative women.
Antenatal care package for all pregnant women (regardless of HIV status	**General care:** ▪ All pregnant women should have at least 8 ANC visits. Encourage and support mothers to start ANC in the first trimester. ▪ Routinely provide iron, folic acid, and multivitamin supplements ▪ Deworm in the 2nd trimester using Mebendazole. ▪ Provide appropriate feeding counseling. ▪ Counsel and encourage to deliver at the health facility. ▪ Screen for TB ▪ Routine examination: Take Weight and BP at every visit **Laboratory services:** ▪ Screen and treat for syphilis, HIV, Hep B, other STI's and anemia. Use syndromic approach to treating STI's. ▪ Perform urinalysis to detect a urinary tract infection (UTI), protein in the urine (proteinuria), or blood in the urine (hematuria) indicating kidney damage, or sugar in urine suggesting diabetes. ▪ Perform a blood group test in anticipation of possible need for blood transfusion.
Laboratory investigations specific to HIV-Positive Pregnant Women	▪ For HIV-positive women, perform a baseline CD4 count. The test result is not required for ART initiation ▪ Do HB test for women beginning AZT-based ART at baseline and four weeks after initiating ART. ▪ For HIV-positive pregnant women already on ART, do VL during first ANC visit, then follow the National VL testing algorithm. ▪ For newly diagnosed HIV-positive pregnant women, do VL test 6 months after initiating ART and then follow the National VL testing algorithm.
Comprehensive care for pregnant women with HIV	At each visit provide: ▪ Comprehensive clinical evaluation. ▪ Provide Cotrimoxazole Preventive Therapy (CPT). Pregnant women on CPT should not be given sulphadoxine-pyrimethamine for intermittent preventive treatment for malaria (IPT) ▪ Screen for TB ▪ INH for eligible women. ▪ Screening and Management of Opportunistic infection
ART	▪ All women living with HIV identified during pregnancy, labour or while breastfeeding should be started on lifelong ART (option B+) irrespective of CD4 counts or WHO clinical stage. ▪ ART should be initiated on the same day or as soon as possible after diagnosis, and adherence counselling should be initiated and sustained intensively for the first three months then maintained for life. ▪ Initiate mother on once-daily TDF+3TC+DTG or TDF+3TC+EFV(400mg)

	see section 4.3.1 ▪ All women should receive Pre-ART adherence before initiating ART and ongoing adherence support after that. ▪ ART should be initiated and maintained in the Mother-Baby care point in MCH.	
Risk reduction counselling and support	Encourage consistent and correct condom use ▪ Encourage women to deliver at the health facilities ▪ For negative pregnant women – Offer other prevention services and FP	
Visit schedules for HIV-infected pregnant and breastfeeding women	HIV Positive pregnant and breastfeeding woman already on ART and stable: Stable pregnant and breastfeeding clients Viral suppression Adherence above 95% On ART for more than one year Stage T1 and no active OIs Not due for vital lab tests in the next two months, e.g., viral load Has disclosed to significant other/ household member/ family member	Initiating ART in ANC (New clients) Unstable pregnant and breastfeeding clients: Recently initiated on ART (less than one year on ART) Poor Viral suppression: most recent VL of above 1000copies/ml Adherence less than 95% Stage 3,4 and active OIs Comorbidities/ co-infection CD4 less than 500 Due for vital lab tests in the next two months, e.g., viral load Has not disclosed to significant other/ household member/ family member
	8 ANC visits ▪ Synchronize ART refills and adherence support with the ANC visits	Two weeks after initiating ART ▪ After that, monthly until delivery ▪ Follow routine MCH schedule after delivery together with the exposed infant.

2.8.2.4 During Labour and Delivery

Labour and delivery are the period of highest risk of transmission and should be handled with universal precautions and extra care to avoid transmission from mother to the child. This section outlines specific services to be offered during that period.

Table 12: Services Offered during labour and delivery

Service	Description
Ascertain HIV status, offer PITC for the partner	▪ Offer HTS and syphilis testing to all women with unknown status. ▪ Link all HIV-negative mothers to prevention services ▪ Retest HIV negative women after 6 weeks
Safe obstetric practices	Safe obstetric practices help to reduce the risk of HIV transmission during labour and delivery and reduce maternal and infant morbidity and mortality. They include: ▪ Use a partogram to allow for early detection and management of prolonged labour. ▪ Avoid routine (artificial) rupture of membranes (ARM). If prolonged labour

	is due to poor uterine contraction, perform ARM at ≥6cm cervical dilation and augment with oxytocin (Pitocin)or misoprostol ▪ Do not perform routine episiotomy except for specific obstetric indications ▪ Avoid instrument delivery including vacuum extraction only when necessary ▪ Avoid frequent vaginal examinations ▪ Umbilical cord-cutting 1-3 minutes after delivery, Do not 'milk' the umbilical cord before cutting ▪ Actively manage the third stage of labour: Active management reduces the risk of postpartum hemorrhage. Active management of the third stage of labour involves three important components: ✓ Giving oxytocin within 1 minute following the birth of the baby ✓ Delivery of the placenta using controlled cord traction ✓ Massaging the uterus after delivery of the placenta
ART for the mother	**Give ART:** for mothers on treatment, continue the same ART regimen. Initiate ART for mothers not yet on treatment. Continue to provide HIV care services to the mother.
ARV prophylaxis for the HIV-exposed infant	Initiate NVP prophylaxis for the infant at birth. ▪ Low risk: counsel mother and provide NVP syrup for six weeks ▪ High risk: Counsel mother and provide NVP syrup for up to 12 weeks.
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.
At discharge	▪ Counsel the mother and provide an appointment date to return for postnatal services and exposed infant testing and care at six weeks. ▪ Infants should return for six weeks follow up for these key services: Early infant diagnosis, routine immunizations, withdrawal of Nevirapine syrup (except for infants whose mothers received ART less than 1 month before delivery), and initiation of Cotrimoxazole syrup. ▪ If the mother is not going to receive services at this facility, link the mother to HIV care services in facility of their choice. ▪ Provide or link to FP services starting with counselling before discharge.

2.8.2.5 During Post-Partum

After delivery of HIV-infected women, address their treatment, care and support needs, and those of their children and families. The HIV-infected mother should continue to receive her care in the mother-baby care point until the baby is 18 months of age. Provide family planning services and continue to prevent HIV incidence in women who were tested negative during pregnancy, labour, and delivery.

This section will describe services for the mothers after delivery, services for infant including care for the HIV-exposed infant and Infant and young child feeding counselling.

Table 13: EMTCT Services during the post-partum period

Postnatal services for all mothers regardless of HIV status	It is important that postnatal follow-up services be scheduled at six weeks as this coincides with the baby's immunization schedules and exposed infant testing for HIV positive mothers, at this visit: ▪ Check for sepsis, anaemia, high blood pressure, etc. and provide of vitamin A ▪ Offer family planning counselling and services. ▪ Review of ART regimen and provide adherence support ▪ Re-enforce safe infant feeding practices ▪ Screen for TB and treat if infected. ▪ Breast health and cancer screening ▪ Cervical cancer screening
HIV and syphilis testing services	▪ Provide HTS and syphilis testing for breastfeeding women who have never tested and their partner. ▪ Provide repeat HIV testing to women who were negative at ANC, labour and delivery. ▪ Provide ART for all women newly diagnosed at PNC visit according to the national guideline ▪ Continue to provide risk-reduction counselling and support to HIV-negative women
HIV care and management for the HIV infected mother and family	Antiretroviral therapy (ART) accompanied by ▪ Provide Co-trimoxazole prophylaxis ▪ Regular TB screening and provide INH prophylaxis if eligible. ▪ Continued infant feeding counselling and support ▪ Nutritional counselling and support ▪ Sexual and reproductive health services including FP ▪ Psychosocial support ▪ Adherence counselling and support ▪ Monitor retention in care. ▪ Assess all women who delivered outside the facility for OIs, provide appropriate care and initiate ART.
Psychosocial support services	Link the mother to support groups and other services.

2.8.2.6 Care of the exposed infant/child

In the absence of PMTCT interventions, up to 40% of infants born to HIV-positive mothers are infected during pregnancy, delivery, and breast-feeding. Without treatment, one in five HIV-infected infants dies before 6 months, more than a third die by 1 year, and more than half die before 2 years. It is, therefore, critical to identify HIV exposed infants and provide ARV prophylaxis and ART to improve child survival. An HIV exposed infant may be identified through the documentation on the child health card (CHC) that is given to the mother during ANC services. The HIV exposure status may also be determined from reports on birth summary by noting the mother's HIV result.

Therefore, HIV-exposed infants should receive care together with their mothers (mother-baby care) until they are 18 months of age. The goals of HIV-exposed infant care services include:

- Prevention of the infant from being HIV infected through MTCT and the care of the HIV exposed uninfected child

- Early diagnosis of HIV infection among those who become infected and initiation of ART treatment.
- Offer child survival interventions to prevent early death from preventable childhood illnesses.

Visit schedule for HIV exposed infants

Regular follow-up is the backbone to caring for HIV-exposed and infected or uninfected children.
It ensures optimal health care and psychosocial support to the family. The HIV exposed infants should receive care together with their mother in the mother-baby care point in the MCH setting until the infant is 18 months of age.

The HIV exposed infant, and the mother should consistently visit the health facility at least nine times during that period. The mother-baby pair should be supported to adhere to the visit schedule. The visits are synchronized with the child's immunization schedule.

Table 14: HIV-Exposed infant care services

Service	Description
Identification of HIV-exposed infant	▪ Identify all HIV-exposed infants ▪ Document the HIV status of the mother in the child card ▪ For infants whose HIV status is not documented or is unknown should be offered a rapid HIV test; including those whose mothers did not receive eMTCT services or have become newly infected after pregnancy. ▪ The entry points for identification of HIV-exposed babies include PMTCT, OPD, inpatient pediatric wards, TFC, EPI 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 to test and interpret the test results.** ▪ Provide 1st PCR within 6 - 8 weeks or the earliest opportunity thereafter ▪ Provide 2nd PCR 6 weeks after cessation of breastfeeding. ▪ Do a DNA PCR test for all HIV exposed infant who develops signs/symptoms suggestive of HIV during follow-up, irrespective of breastfeeding status. ▪ Conduct rapid HIV test at 18 months for all infants who test negative at 1st or 2nd PCR.
Routine immunization	▪ HIV-infected children are more susceptible to diseases preventable by immunization than their HIV-uninfected counterparts. ▪ HIV-infected and uninfected infants and children can safely receive most childhood vaccines if given at the right time. ▪ All HIV-infected and uninfected exposed children should be immunized as per EPI immunization schedule ▪ Review their immunization status at every visit ▪ Some special considerations/ modifications **BCG: Children with Symptomatic HIV infection should not receive BCG.**

	Measles: Although the measles vaccine is a live vaccine, it should be given at nine and 15 months, even when the child has symptoms of HIV. The measles illness from the vaccine is milder while that from the wild measles virus is more severe and likely to cause death. **Yellow Fever:** Do not give yellow fever vaccine to symptomatic HIV-infected children; asymptomatic children in endemic areas should receive the vaccine at nine months of age. ▪ Vitamin A supplementation ▪ Routine de-worming (from 12 months of age)
Growth monitoring and nutritional assessment	▪ Growth and child nutrition should be monitored using weight, length/height, and MUAC. ▪ At every clinic visit with a child, weight and length/height should be taken and recorded on the growth monitoring Card. ▪ MUAC should only be measured starting at six months of age. – **Failure to gain weight or height, slow weight or height gain and loss of weight may be an indication of HIV infection in an infant/young child** ▪ Failure to thrive affects as many as 50% of HIV-infected infants and children. HIV-infected infants and children who are failing to thrive have a significantly increased risk of mortality. ▪ Counsel the mother/ caregiver on the child's growth trend and take appropriate action where necessary
Development monitoring	**At each visit assess the infant's age-specific developmental milestones** ▪ 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 Include:** ▪ The child may develop some milestones and after never progress to develop others ▪ Child may develop milestones and lose them after some time ▪ Child may fail to develop milestones at all ▪ Test children with developmental delay for HIV and if infected initiated on ART ▪ Measure the infant's head circumference
NVP prophylaxis	▪ Provide NVP syrup to HIV exposed infant from birth until six weeks of age ▪ For high-risk babies; give NVP syrup from birth until 12 weeks of age **High-risk babies are breastfeeding infants whose mothers** ▪ Have received ART for four weeks or less before delivery; or ▪ Have VL >1000 copies in 4 weeks before delivery; or ▪ Diagnosed with HIV during 3rd trimester or breastfeeding period (Postnatal)
Opportunistic Infection Prophylaxis	**Cotrimoxazole prophylaxis:** Cotrimoxazole (CTX) prophylaxis significantly reduces the incidence and severity of Pneumocystis jiroveci pneumonia. It also offers protection against common bacterial infections, toxoplasmosis, and malaria. ▪ Provide CTX prophylaxis to all HIV-exposed infants from 6 weeks of age until they are proven to be uninfected ▪ Infants who become HIV infected should continue to receive

	Cotrimoxazole prophylaxis for life. ▪ If Cotrimoxazole is contraindicated, offer Dapsone at a dose of 2mg/kg once daily (up to 100mg) **Isoniazid (INH) preventive therapy(IPT)** ▪ Give INH for six months to HIV exposed infants 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 HIV exposed infants and HIV-infected children should receive ITNs and Cotrimoxazole. Using both reduces the risk of malaria.
Actively look for and treat infections early	**HIV exposed infants are susceptible to common infections and OIs.** ▪ Counsel caregivers to seek care to receive timely treatment. ▪ At every visit, assess HIV exposed infants for signs and symptoms of common childhood illnesses using the IMNCI guidelines and provide treatment. ▪ Document & use 'exposed infant' clinical care chart
Counselling and feeding advice	Provide infant feeding counseling advice according to national guidance
Educate the caregiver and family	**HIV exposed infants depend on their caregivers to receive care** ▪ Provide information to the caregivers about the care plan including what to expect and how to provide care for the infant ▪ Caregivers should participate in making decisions and planning care for the child, including decisions about therapy and where the child should receive care. ▪ Empower caregivers to be partners with the health facility and provide key aspects of home-based care for the child, including: ✓ Dispensing prophylaxis and treatment ✓ Maintaining adherence ✓ Complying with the follow-up schedule ✓ Good personal and food hygiene to prevent common infections ✓ Seeking prompt treatment for any infections or other health-related problem ▪ The most important thing for the child is to have a healthy mother. Ensure the mother/ infected caregiver is receiving their care. If the mother is sick, the infant will not receive care. ▪ Ensure mother/caregiver and baby pair (same day appoint) if mother/caregiver is HIV positive.
Referrals and Linkage	Link the caregiver and exposed infant to appropriate services like OVC care, the psychosocial support and other community support groups
ART for Infected Infants	Initiate ART in Infants who become infected according to national guidance

2.8.3 Community EMTCT

Introduction

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

2.8.3.1 Minimum Package of Community EMTCT Services

These services include:

1. Community sensitization and mobilization for reproductive health and EMTCT services

2. Identification, counselling, and referral of pregnant/ lactating mothers for comprehensive ANC services including screening for Tb symptoms, skilled delivery, EMTCT services for mother and baby including EID, Post Natal Care, IYCFC, and FP.

3. Identification of partners and children of pregnant and breastfeeding women in communities and ensuring that they know their HIV status, either through outreaches/home-based HCT or through referral.

4. Male involvement, including all males such as community leaders in the community.

5. Addressing social and behavioural factors that affect the uptake of EMTCT services, including stigma, disclosure, discrimination, GBV, etc.

6. Providing adherence support.

7. Support for Follow-up, linkage, tracking and tracing of mother-infant pairs through at least 18m post-partum and the infant's final survival and HIV-status is known.

8. Community ART and cotrimoxazole refills.

9. Provision of psychosocial support through Family Support Groups or other community-based PLHIV support groups, OVC programs, household economic strengthening/income-generating activities, CBOs

10. Assessing all EMTCT families for eligibility for OVC programs

11. Promote family index testing, treatment & support including from treatment support who are not part of the family.

12. Health education and advocacy for EMTCT services

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

2.8.3.2 Establishing/Strengthening Community EMTCT services

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

1. **Establish partnership and Networks with a community-based organization, NGOs and 'networks of PLHIV for community service delivery.**

The networks and partnerships should be established by;

a. Conducting or updating community mapping of resources, identify referral trigger factors, develop referral directories and support documentation of referral processes.
b. Connecting with the Community Development Officers, CBO, FBO, and NGO's and networks of PLHIV and other networks involved in community-based eMTCT and meeting to agree on a common objective and agenda.
c. Establishing and strengthening of comprehensive referral network systems and coordination of two-way referrals between community and health facilities. Also, establish mechanisms for assessing the performance of these systems
d. Promoting the integration of eMTCT and HIV into reproductive health, MCH, and other programs
e. Identification of and collaboration with relevant sectors for community empowerment and economic strengthening activities to reduce gender inequalities as well as increase women's access to assets
f. Promoting partner support by using different strategies to engage Male Partners

2. Identify, train and facilitate community health workers

a. Community health workers, including peer educators and M2M volunteers (mother mentors) in the catchment area, should be identified, trained and facilitated to implement the community eMTCT minimum package.

3. Establish coordination mechanism

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

3. MATERNAL, INFANT AND YOUNG CHILD FEEDING

Introduction

Feeding Infants Born to HIV-Infected Mothers

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

In Sierra Leone, MCH services promote and support breastfeeding by HIV infected mothers until the baby is 12 months of age with exclusive breastfeeding for the first 6 months. WHO recommends:

- Exclusive breastfeeding from birth to 6 months for all babies, regardless of the mother's HIV status.
- Breastfeeding should continue as an important source of nutrition from 6 to 12 months of age with the introduction of complementary foods for all babies from 6 months.
- Breastfeeding HIV-infected mothers should be given triple lifelong ART.
- If an HIV-infected mother is unable to take ARV medications but continues to breastfeed, the baby should be given daily extended Nevirapine prophylaxis until one week after the cessation of breastfeeding (generally at 12 months of age).
- Even if ARV drugs are not immediately available, breastfeeding should be recommended while ARV interventions are being scaled-up.

Infant feeding in the context of HIV has implications on child survival. Balancing the risk of infants' HIV infection through breast milk with a higher risk of death from malnutrition, diarrhoea, and pneumonia among non-breastfed infants is a challenge.

Protecting the infant from the risk of death from these causes is as important as avoiding HIV transmission through breastfeeding. Current evidence indicates that exclusive breastfeeding and the use of antiretroviral drugs greatly reduce MTCT. The effectiveness of ARV interventions with continued breastfeeding by HIV-infected mothers until the infant is 12 months of age capitalizes on the maximum benefit of breastfeeding to improve the infant's chances of survival while reducing the risk of HIV transmission.

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

- Promote optimal feeding for the HIV-exposed children to ensure HIV-free survival
- Minimize HIV transmission through breastfeeding
- Ensure a healthy mother

Table 15: National Infant Feeding Recommendations according to HIV status

Client situation	Feeding recommended for the first 6 months	Feeding recommended >6 months
HIV-negative woman	Exclusive breastfeeding	Introduce complementary foods while continuing to breastfeed until 2 years of age and beyond
A woman living with HIV	Exclusive breastfeeding	Introduce complementary foods while continuing to breastfeed (receiving ARVs) to 12 months of age. At 12 months: • **If the child is either HIV-uninfected or of unknown HIV status** — breastfeeding should stop gradually if a nutritionally adequate and safe diet without breast milk can be provided. • **If the child is known to be HIV-infected** — continue breastfeeding until 2 years of age and beyond
Woman of unknown HIV status	Exclusive breastfeeding	Breastfeeding and complementary foods until 2 years and beyond Encourage this group of women to test for HIV
Mixed feeding during the first 6 months of life is never recommended and should be avoided by all women, regardless of HIV status.		

Exclusive breastfeeding means that there are no added foods or liquids, not even water. Vitamin or mineral supplements should be provided only when medically appropriate.

3.1 Interim Feeding Strategies

- HIV infected mothers may consider expressing and heat-treating breast milk as an interim feeding strategy under the following special circumstances:
  - In the neonatal period, if the infant is born with low birth weight or is otherwise ill and unable to breastfeed;
  - The mother is unwell and temporarily unable to breastfeed, or has a temporary breast health problem such as mastitis;
  - Antiretroviral drugs are temporarily not available

- Some mothers may also consider using expressed and heat-treated breast milk, if feasible, to assist them to stop breastfeeding if the baby is younger than six months of age.

- Mothers choosing to utilize these interim feeding strategies should receive appropriate instruction from HCWs describing the appropriate procedure for heat-treating breast milk to ensure that the milk retains its full nutritional benefits for the infant

Table 16: Nutrition Counselling messages and services for pregnant women

Service	Description
Diet	HIV positive mother's nutrition before, during, and after pregnancy can influence her own health and the risk of transmitting HIV to her child. Good nutrition for pregnant and breastfeeding mothers is important for the survival and wellbeing of the developing infant. HIV positive mothers are at higher risk of malnutrition and illness while pregnant and breastfeeding. During pregnancy and lactation, the mother's need for energy and nutrients increases to meet the demands of: • Adequate weight gain due to pregnancy • Development of the baby • Milk production Therefore, in order to maintain good health, HIV positive mothers need additional food to meet the extra energy and nutrient needs associated with HIV, pregnancy and lactation. Food intake for pregnant women should include a variety of foods to meet both macro and micronutrient requirements as prescribed in the National Nutritional Guidelines for PLHIVs ▪ Add extra meals during pregnancy and breastfeeding ▪ Drink adequate fluids ▪ Eat plenty of fruits and vegetables ▪ Eat foods rich in vitamin C to enhance iron absorption ▪ Avoid tea or coffee close to (less than 1 hour) or with meals as this may interfere with the absorption of iron ▪ Use iodized salt to prevent pregnancy complications (abortions, miscarriages and stillbirths), fetal growth retardation, and maternal goiter ▪ Maintain high levels of personal and food hygiene and food safety to prevent infections ▪ Avoid alcohol, narcotics or tobacco products and medicines not prescribed by a trained health care provider Adolescent mothers may require more care, food and rest than other mothers since they are still growing Note ▪ Nutritional status and weight should be monitored and recorded at each ANC visit. Inadequate weight gain or weight loss can be a sign of advancing AIDS disease or Opportunistic Infections. ▪ All pregnant women living with HIV should have an assessment of nutritional status and be provided with counselling and support ▪ Healthcare workers should discuss specific dietary choices that make up a healthy diet for the mother and her infant. ▪ Nutritional supplements, ferrous sulphate, folic acid and multivitamins should also be given according to national guidelines ▪ With option B+, the mothers are not asked to make a choice of feeding option. National Breastfeeding guidelines will apply regardless of HIV status.
Medications during pregnancy	▪ Supplemental iron to prevent anaemia and to reduce the risk of low birth ▪ folic acid to prevent fetal brain and spinal cord congenital disabilities ▪ De-worming tablets to treat worms infestation and prevent anaemia ▪ Provide 60mg of elemental iron (200mg of ferrous sulphate) and 400ug folic acid OR combined iron (150mg with 0.5mg folic acid) after three months of gestation and continue to take them daily for six months ▪ Take supplement with food to overcome side effects ▪ Give iron 120mg + 4000ug folic acid daily for three months to pregnant

	women with mild to moderate anaemia. After completing this treatment, continue with routine supplementation for three months.
Malaria prevention	▪ Malaria may cause anaemia, therefore: ▪ Mothers should sleep under an insecticide-treated mosquito net ▪ HIV-infected pregnant women on cotrimoxazole **should not** receive intermittent preventive treatment (IPT) for malaria with Sulfamethoxazole-Pyrimethamine (SP)
Attend ANC	▪ Counsel and educate mothers to attend ANC at least eight times during pregnancy and follow your health worker's recommendations

3.2 Initiative to Promote Active Breast Feeding

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 status.
- Link the mothers to support groups such as mother to mother support groups on discharge from the hospital or clinic.
- Demonstrate to mothers how to position infants when breastfeeding, and how to maintain lactation should they be separated from their infants.
- Pay particular attention to the prevention of conditions such as cracked nipples, mastitis that increase the risk of HIV transmission.

During Labour and Delivery

- Help mothers initiate breastfeeding within half an hour of birth, including cases of caesarean section.
- Newborn infants should be fed on only colostrum (the first milk) and not be given pre-lacteal feeds such as glucose, dill/ gripe water, mushroom soup; herbal extracts, etc.
- Continue to counsel on-demand feeding, Exclusive breastfeeding, ways of holding and putting the baby to the breast (positioning and attachment) to enhance breastfeeding
- Mothers should continue supplementation with Iron 1 tablet/day and Folic acid 400ug for three months after delivery in addition to intake of iron-rich foods

During Postnatal Period

Table 17: Feeding a Child (0-6 Months)

HIV-exposed but uninfected infants/unknown HIV status	▪ HIV-infected mothers should exclusively breastfeed (EBF) their infants for the first six months of life, introducing appropriate complementary foods after that, and continue breastfeeding for the first 12 months of life while being fully supported for ART adherence. ▪ Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided. ▪ Establish the HIV exposure status of those infants with unknown status

HIV-infected infants	▪ HIV-infected mothers should exclusively breastfeed (EBF) their infants for the first six months of life, introducing appropriate complementary foods after that, and continue breastfeeding until 24 months of life while being fully supported for ART adherence

3.3 Complementary Feeding

Feeding a child (6-12 months)

- After six months of age, appropriate complementary foods should be introduced while continuing to breastfeed until 12 months.
- The mother should be encouraged to breastfeed as often as the infant wants (on demand).
- Counselling messages on complementary feeding are summarized below

Table 18: Counselling messages on complementary feeding

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 500mls (167mls).
T= Thickness (consistency	Mothers should mash and soften the food for easy swallowing and digestion. Use animal milk or margarine/oil (not water) to soften and enrich the food.
V = Variety	Encourage mothers to include at least one type of food from the different food groups (carbohydrates, plant/animal protein, vegetables, fruits and fats/oils.
A = Active/ responsive feeding	Mothers should be encouraged to patiently and actively feed their infants and young children and to use a separate plate for the infant to ensure adequate intake.
H = Hygiene	Counsel Mothers on hygienic food preparation and handling to avoid food contamination leading to diarrhoea and illness. Use of clean open cups. Discourage use of feeding bottles, teats or spouted cups as they are very difficult to clean

3.4 Replacement feeding options

- Recommended for mothers who are HIV positive and choose not to breastfeed.
- Recommended for mothers who are HIV positive who meet the AFASS conditions.
- Replacement feeding options include Commercial infant formula, modified animal's milk, full cream milk powder.
- Mixed feeding (combination of breastfeeding and replacement feeding) should be avoided as this may lead to gut inflammation or irritation that could increase the risk of HIV passage from breast milk to the child.

Table 19: 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. ▪ Encourage mothers to feed their children five times a day - 3 main meals and two extra foods between meals (snacks). Encourage mothers to give a variety of foods prepared from the family meal for children above 24 months.

Additional Support Messages

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

Mechanism of transition includes:

- Expressing breast milk and feeding infant/child by a cup
- Substituting the expressed breast milk with suitable replacement feed gradually
- Replacement feeding (using alternative milk other than breast milk in the first six months of life) should be recommended only in extreme circumstances such as mother absent, dead or mentally challenged, following the regulations on the marketing of Infant and Young Child Foods.
- Follow up all HIV-exposed infants, and continue to offer infant feeding counselling 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.

4. ANTIRETROVIRAL THERAPY FOR PEOPLE LIVING WITH HIV

4.1 The Goal of ART

The aim of Antiretroviral Therapy is to suppress viral load levels amongst all PLHIV to undetectable levels and reduce the risk of morbidity and mortality associated with HIV, as well as to reduce the transmission of HIV.

4.2 When to start ART

ART should be initiated at the earliest opportunity in all people with confirmed HIV Infection regardless of WHO clinical staging or CD4 count.

4.2.1 Test and Treat Approach

All PLHIVs should be initiated on ART as soon as possible after the HIV diagnosis either the same day or within 7 days. The role of the healthcare worker is to assess the readiness of the client to start ART. ART should be encouraged at the earliest opportunity in order to reduce mortality/morbidity in accordance with best practice guidelines. Considerations for healthcare workers during initial assessment when starting clients on ART:

- Assess all clients for opportunistic infections - especially TB and Cryptococcal meningitis.
- If the patient has TB or Cryptococcal meningitis, ART should be deferred and initiated after starting treatment for these OIs. Treatment for other OIs and ART can be initiated concurrently. (For advice on OI management and ART initiation see section on OIs).
- For patients without TB or Cryptococcal meningitis, offer ART on the same day. The client may not be ready to receive ART on the same day; the healthcare worker should counsel the client on the risks and benefits of treatment, to assist the client in decision making. In this approach, the patients should be prepared for ART on the same day according to the guidelines and assessed for readiness to start ART.
- 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 as soon as possible (preferably within 7 days).

4.3 What ARV to Start with

4.3.1 First-line ART regimen

This section describes the recommended ART to start in:

- Adults and adolescents
- Pregnant and breastfeeding women
- And those with TB and Hepatitis B co-infection.

It is recommended to initiate Antiretroviral Therapy in ART-naïve patients (i.e. patients who have not yet been treated with ARVs) using a combination of two nucleoside reverse transcriptase inhibitors (NRTIs) and an integrase inhibitor (INI) or a non-nucleoside reverse transcriptase

inhibitor (NNRTI). Fixed combinations containing the above drugs achieve fast viral load suppression; they are strongly recommended because they are cheap, user-friendly and facilitate better adherence because of low pill burden.

Table 20: Recommended First-Line ART for Adults and Adolescents in Sierra Leone

What ART Regimens to start with			
Topic and population	Preferred first-line regimen	Alternative first-line regimen	*Special circumstances
Adults and adolescents (Above 30kg)	• TDF + 3TC + DTG*	TDF + 3TC + EFV 400mg	ABC + 3TC + DTG AZT + 3TC + DTG
Pregnant and breastfeeding women	TDF + 3TC + DTG*	TDF + 3TC + EFV 400mg	ABC + 3TC + DTG AZT + 3TC + DTG

* Note of caution using DTG during the preconception period among women and adolescent girls of childbearing potential as may be associated with neural tube defects amongst infants. Women in this group should be offered contraception and be allowed an informed choice between TLD and TLE.

Table 21: Recommended First-Line ART for children in Sierra Leone

What ART Regimens to start with			
Topic and population	Preferred first-line regimen	Alternative first-line regimen	Special circumstances
Children >20 kg	ABC + 3TC + DTG*	AZT + 3CT + DTG* ABC + 3TC + EFV AZT + 3TC + EFV	
Children <20 kg	ABC + 3TC + LPV/r	AZT + 3TC + LPV/r AZT + 3TC + EFV ABC + 3TC + EFV	AZT + 3TC + NVP** ABC + 3TC + NVP** **Only for use in children who cannot tolerate LPV/r *or* who are <10kg
Infants <3kg	AZT + 3TC + NVP When infants >3kg switch to AZT + 3TC + LPV/r		

*DTG is approved for use among children older than six years and weighing more than 15kg and is currently available for children weighing at least 20kg who can take 50mg film-coated adult tablets. °EFV can be given only in children >10 kg or >3 years of age.

Note: If you cannot use the preferred first-line or alternative first-line regimen – go to the special circumstances.

Table 22: Recommended First-Line ART for Children with HIV-2

HIV 2 What ART Regimens to start with		
Topic and population	Preferred first-line regimen	Alternative first-line regimen
Children >20 kg	ABC + 3TC + DTG*	AZT + 3TC + DTG* AZT + 3TC + LPV/r ABC + 3TC + LPV/r
Children <20 kg	ABC + 3TC + LPV/r	AZT + 3TC + LPV/r

*DTG is approved for use among children older than six years and weighing more than 15kg and is currently available for children weighing at least 20kg who can take 50mg film-coated adult tablets.

4.4 Second Line Antiretroviral Regimen

This regimen is recommended in circumstances involving treatment failure (see section 2.11 for recommendations on changing regime due to toxicity). The preferred second-line regimen is dependent on the constituents of the failing first-line regimen. Failing NNRTI regimens should be switched to an INSTI based regimen whilst failing INSTI regimens should be switched to a boosted PI regimen.

Table 23: Second Line ART Regimen for adolescents and adults

DTG based regimen is recommended as first-line ART in pregnant and breastfeeding women

Second-line ART: what ARV regimen to switch to			
Topic and population	Failing first-line regimen	Preferred second-line regimen	Alternative second line
Adults and adolescents including pregnant and breastfeeding women	TDF + 3TC + EFV (or NVP)	recommended as the preferred approach AZT + 3TC + DTG*	AZT + 3TC + ATV/r (or LPV/r or DRV/r) (Note: ATV/r can only be used for clients >35kg)
	AZT + 3TC + EFV (or NVP)	TDF + 3TC + DTG*	TDF + 3TC + ATV/r (or LPV/r or DRV/r) ABC + 3TC + ATV/r (or LPV/r or DRV/r)
	ABC + 3TC + EFV (or NVP)	AZT + 3TC + DTG*	AZT + 3TC + ATV/r (or LPV/r or DRV/r)
	TDF + 3CT + DTG*	AZT + 3TC + ATV/r	AZT + 3TC + LPV/r (or DRV/r)
	ABC + 3TC + DTG*	AZT + 3TC + ATV/r	AZT + 3TC + LPV/r (or DRV/r)
	AZT + 3TC + DTG*	TDF + 3TC + ATV/r	TDF + 3TC + LPV/r (or DRV/r) ABC + 3TC + ATV/r (or LPV/r or DRV/r)

Women of childbearing potential who intend to become pregnant or who are not otherwise using or accessing effective contraception can receive DTG based regimens if they have been informed of the potential increase in the risk of neural tube defects (at conception and up to the end of first trimester). The alternative regimen for these women is TDF + 3TC + EFV.

Table 24: Second line ART Regimen for children

☆DTG is approved for use among children older than six years and weighing more than 15 kg and is widely available for children weighing at least 20kg who can take 50mg film-coated adult tablets.

Second-line ART: what ARV regimen to switch to			
Topic and population	Failing first-line regimen	Preferred second-line regimen	Alternative second line
Children >20 kg	ABC + 3TC + DTG☆	AZT + 3TC + LPV/r (or ATV/r) (Note: ATV/r in children >35kg)	AZT + 3TC + DRV/r
	AZT + 3TC + DTG☆	ABC + 3TC + LPV/r (or ATV/r) (ATV/r in children >35kg)	ABC + 3TC + DRV/r
	ABC + 3TC + EFV	AZT + 3TC + DTG☆	AZT + 3TC + LPV/r (or ATV/r) (Note: ATV/r in children >35kg)
	AZT + 3TC + EFV	ABC + 3TC + DTG☆	ABC + 3TC + LPV/r (or ATV/r) (Note: ATV/r in children >35kg)
Children <20 kg	ABC + 3TC + LPV/r	AZT + 3TC + RAL☆ *In these cases seek NACP expert opinion	
	AZT + 3TC + LPV/r	ABC + 3TC + RAL☆ *In these cases seek NACP expert opinion	
	AZT + 3TC + EFV	ABC + 3TC + LPV/r	ABC + 3TC + DRV/r* *Only in children above 15kg
	ABC + 3TC + EFV	AZT + 3TC + LPV/r	AZT + 3TC + DRV/r* *Only in children above 15kg

4.5 Classes of Antiretroviral Drugs and their functions

There are currently over 20 approved Antiretroviral Drugs for the treatment of HIV in Sierra Leone that includes Reverse Transcriptase Inhibitors (Nucleoside Reverse Transcriptase Inhibitors (NRTIs), Nucleotide Reverse Transcriptase Inhibitors (NtRTIs), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs), Integrase Inhibitors and Protease Inhibitors (PIs). The list below is a general list of ARVs including those in Sierra Leone and outside.

Integrase strand transfer inhibitors: Integrase strand transfer inhibitors (INSTIs) works by interfering with one of the three enzymes responsible for HIV replication, the enzyme Integrase. Examples are Dolutegravir (DTG), Raltegravir (RAL) and Elvitegravir (EVG).
List of Antiretroviral Drugs and their Dose

Table 25: Integrase Inhibitor (INSTI)

Generic name	Trade name	Presentation	Recommended Adult Doses	Diet Restrictions	Side Effects	Storage Requirements
Dolutegravir (DTG)	Tivicay®	10mg; 20mg; 50mg	50mg daily (double dose if being used with Rifampicin TB treatment) With light meal	With light meal	Rash Liver dysfunction Headache Sleep disorder Weight gain	Room Temperature

Table 26: Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTI)

Generic Name	Trade Name	Presentation	Recommended Adult Doses	Diet Restrictions	Side Effects	Storage Requirements
Zidovudine (AZT)	Retrovir®	Capsules: 100, 250, 300mg Oral solution 10mg/ml IV formulation: 10mg/ml	250-300mg BID	None	Myelosuppression (anaemia and/or neutropenia), lactic acidosis or steatosis (Hepatomegaly, fatty liver), lipodystrophy, myopathy, gastrointestinal intolerance	Room temperature
Tenofovir (TDF)	Viread®	Tablets: 150, 200, 250, 300mg	300 mg once daily	None	Chronic kidney disease, acute kidney injury and Fanconi syndrome, hepatomegaly with steatosis, lactic acidosis, decreased bone mineral density	Room temperature
Abacavir (ABC)	Ziagen®	Capsules 300mg Oral solution : 20mg/ml	300 mg BID or 600mg once daily	None	Hypersensitivity reaction	Room temperature
Lamivudine (3TC)	Epivir®	Capsules 150mg Oral solution : 10mg/ml	150 mg BID or 300mg once daily	None	Peripheral neuropathy	Room temperature
Didanosine (ddI)	Videx®	Tablets: 25, 50, 100, 150, 200mg Enteric coated capsules: 125, 200, 250, 400mg	>60 kg: 400 mg once daily <60 kg: 250 mg once daily	Yes (fasting)	Pancreatitis, hyperuricemia, peripheral neuropathy, gastrointestinal intolerance	Tablets/capsules: room temperature. Oral solution is stable after reconstitution for 30 days if refrigerated
Emtricitabine (FTC)		200mg tablet	200mg daily			Room temperature

Table 27: Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)

Generic Name	Trade Name	Presentation	Recommended Adult Doses	Diet Restrictions	Side Effects	Storage Requirements
Nevirapine (NVP)	Viramune®	Tablets 200mg Oral suspension 50mg/ml	200 mg once daily for 14 days, followed by 200 mg twice daily	None	Rash, including rare severe reactions such as Stevens-Johnson/ TEN, hepatotoxicity. More common in high CD4.	Room temperature
Efavirenz (EFV)	Sustiva® Stocrin®	Capsules 50, 100, 200, 600 mg	600 mg once daily at night	None	CNS side effects (dizziness, insomnia, somnolence, abnormal dreams, depression, psychosis), convulsions, skin rash, hepatotoxicity	Room temperature

Table 28: Protease Inhibitors (PIs)

Generic Name	Trade Name	Presentation	Recommended Adult Doses	Diet Restrictions	Side Effects	Storage Requirements
Lopinavir/ Ritonavir (LPV/r)	Kaletra®	Capsules 133.3 + 33.3mg; 200/50mg; 100/25mg Oral solution80mg+20mg/ml	400/100mg BID (double dose if being used with rifampicin TB treatment)	With light meal	Arrhythmias, hepatotoxicity, pancreatitis, dyslipidaemia, gastrointestinal disturbance	Capsule: Stable for 30 days at room temperature. Oral Solution: Store Kaletra oral solution* in a refrigerator (2°C to 8°C).
Atazanavir/ Ritonavir (ATV/r)	Reyataz ®	300/100 mg	300/100 mg daily	With light meal	Arrhythmias, indirect hyperbilirubinaemia (clinical jaundice), nephrolithiasis	Room temperature
Indinavir + ritonavir (IDV/r)	Crixivan®	Capsules 200-400mg	800 mg + 100 mg twice daily	Fasting if not boosted	Nephrolithiasis Gastrointestinal intolerance Hyperbilirubinemia	Room temperature
Saquinavir + ritonavir (SQV/r)	Invirase® Fortovase® (SGC)	Hard gel capsules 200 mg **or** Soft gel capsules 200 g	(HGC) 600 mg TID **or** (SGC) 1200 mg TID	With light meal	Gastrointestinal intolerance (Diarrhoea) Headaches	Room temperature

**Kaletra oral solution can also be stored at room temperature (less than 25°C), but then it should be used within 2 months. Keep the oral solution away from high heat.*

Table 29: Fixed-Dose Combination in Sierra Leone

Generic Name	Trade Name	Strength	Dosage	Storage
Tenofovir + Lamivudine + Dolutegravir	Generic product	300/300/50 mg	1 tablet daily	Room temperature
Tenofovir + Lamivudine + Efavirenz	Generic product	300/300/600 mg	1 tab at night	Room temperature
Tenofovir + Lamivudine	Generic product	300/300 mg	1 tab daily	Room temperature
Tenofovir + Emtricitabine	Truvada	300/200 mg	1 tab daily	Room temperature
Zidovudine + Lamivudine + Nevirapine*	Duovir-N, ZIDOLAM-N	300/150/200 mg	1 tab 12 hourly	Room temperature
Zidovudine + Lamivudine + Nevirapine	Duovir-N baby, ZIDOLAM-N baby	60/30/50 mg	According to body weight	Room temperature
Zidovudine + Lamivudine + Abacavir	Trizivir	300/150/300 mg	1 tab 12 hourly	Room temperature
Zidovudine + Lamivudine + Abacavir	Trizivir	60/30/60 mg	According to body weight	Room temperature
Zidovudine + Lamivudine	Duovir	300/150 mg	1 tab 12 hourly	Room temperature
Zidovudine + Lamivudine	Duovir baby	60/30 mg	According to body weight	Room temperature
Abacavir + Lamivudine	Kivexa	600/300 mg	1 tab daily	Room temperature
Abacavir + Lamivudine	Kivexa	60/30 mg	According to body weight	Room temperature

* Nevirapine should be started at half dose in the first 2 weeks: 1 tab (AZT+3TC) in the morning and 1 tab (AZT+3TC + NVP) at night.

4.6 Patients with TB co-infection: Drug Interactions

First Line Regimen

ART Regimen – first line	**Neonates AZT + 3TC + NVP**	**Children <20kg ABC + 3TC + LPV/r (AZT + 3TC + NVP)**	**Children >20kg ABC + 3TC + DTG**	**Adults & Adolescents TDF + 3TC + DTG**
Significant drug interaction	**Rifampicin + NVP**	**Rifampicin + LPV/r**	**Rifampicin + DTG**	
Measures to counteract drug interactions with Rifampicin	Seek expert advice	LPV/r tablets: Double dose LPV/r oral solution and pellets: super-boost with RTV	Boosting of DTG required The dosing frequency of DTG should be increased to 50mg 12-hourly. If on TLD FDC, then add DTG 50mg 12 hours after TLD dose.	

Second-line regimen

ART Regimen – second line	**Children <20kg ABC (or AZT) + 3TC + LPV/r***	**Children >20kg AZT (or ABC) + 3TC + DTG AZT (or ABC) + 3TC + LPV/r**	**Adults & Adolescents DTG, or LPV/r based regimens**
Significant drug interaction	**Rifampicin + LPV/r**	**Rifampicin + DTG Rifampicin + ATV/r**	**Rifampicin + DTG Rifampicin + LPV/r**
Measures to counteract drug interactions with Rifampicin	LPV/r tablets: Double dose LPV/r oral solution and pellets: super-boost with RTV	Boosting of DTG required The dosing frequency of DTG should be increased to 50mg 12-hourly. If on TLD FDC, then add DTG 50mg 12 hours after TLD dose. ATV/r is contraindicated with Rifampicin – substitute ATV/r with LVP/r LPV/r tablets: Double dose LPV/r oral solution and pellets: super-boost with RTV	Boosting of DTG required The dosing frequency of DTG should be increased to 50mg 12-hourly. If on TLD FDC, then add DTG 50mg 12 hours after TLD dose. ATV/r is contraindicated with Rifampicin – substitute ATV/r with LVP/r LPV/r tablets: Double dose

*If on RAL based regimen seek NACP expert opinion

4.7 Hepatitis B/HIV co-infection and HIV 2 regimens for adults & adolescents

Recommended first-line regimen in HIV/Hepatitis B co-infection

Preferred: TDF + 3TC + DTG
Alternative: TDF + 3TC + EFV

Recommended second-line regimen in HIV/Hepatitis B co-infection

HIV/Hepatitis B co-infection should be treated as per the normal adult population recommendations with hepatotoxicity monitoring if using DTG containing regimen due to side effect profile.

Population	Failing first-line regimen	Preferred second-line regimen
HIV/Hepatitis B co-infection	TDF + 3TC + DTG*	TDF + 3TC + (ATV/r or lopinavir/ritonavir (LPV/r))
	TDF + 3TC + EFV	TDF + 3TC + DTG
HIV 2**	TDF + 3TC + DTG	AZT + 3TC + LPV/r TDF + 3TC + LPV/r

*TDF should not be initiated in patients with eGFR<50mL/min (patients with kidney disease) However, laboratory testing is not mandatory to initiate treatment with TDF if there is no reason to suspect renal dysfunction. Renal disease should be attended to by a doctor, CHO or the most senior health personnel in the facility. Please refer appropriately.

** All HIV-2 and HIV1+2 should be confirmed, ideally at a higher-level health facility/laboratory (Refer to HIV testing guidelines for additional guidance). For HIV1/HIV-2 dual infection, treat as HIV2. ***For further management refer to Hepatitis Guidelines***

4.8 The Process of providing Pre-Exposure Prophylaxis (PrEP)

PrEP is when people take an HIV medication to reduce their chance of getting infected while they are at risk of acquiring HIV. Currently, PrEP is recommended for use daily for both men and women who are at substantial risk of acquiring HIV. PrEP does not provide 100% protection, but it is highly effective and provide a great deal of protection against HIV.

Eligibility for PrEP in Sierra Leone

PrEP is provided for:-

- Key Population (MSM, PWID, FSW)
- People in correctional centres
- Discordant couples, especially if the HIV positive partner is not on ART or on ART but not virally suppressed, or has been on ART for less than six months.

Screening for PrEP eligibility

After meeting the eligibility criteria, the following screening tests should be done before initiating PrEP.

- Confirm HIV-negative status
- Assess for hepatitis B infection
- Assess for contraindications to TDF

Steps to initiate PrEP

Provide risk-reduction and PrEP medication adherence counseling,

- Provide condoms and education on their use for STI prevention
- Initiate a medication adherence plan
- Prescribe a once-daily pill of TDF (300mg) and FTC (200mg).
- Initially, provide a 1-month TDF/FTC prescription (1 tablet orally daily) together with a 1-month follow-up date.
- Counsel client on side effects of TDF/FTC.

Follow-up monitoring of clients on PrEP

After the initial visit, subsequent clinic visits should be every three months

- Perform an HIV antibody test every three months.
- For women, perform a pregnancy test based on clinical history
- Review the patient's understanding of PrEP, any barriers to adherence, tolerance to the medication as well as any side effects
- Review the patient's risk exposure profile and perform risk reduction counseling
- Evaluate and support PrEP adherence at each clinic visit
- Evaluate the patient for any symptoms of STI s at every visit and treat as needed

Discontinuing PrEP

When the patient:

- Has changed life situations resulting in lowered risk of HIV acquisition
- Has intolerable toxicities and side effects
- Is unable to adhere to the prescribed dosing regimen despite efforts to improve daily pill-taking
- Test positive for HIV infection (at that point the patient should be linked to HIV treatment)
- If HIV positive partner is virally suppressed and there is no significant risk of transmission

4.9 Post Exposure Prophylaxis

Medical personnel caring for HIV infected patients may be at risk of acquiring HIV infection through contact with HIV-infected blood and body fluids. In persons who have been accidentally exposed to HIV through needle stick inoculation or through contamination of mucous membranes by secretions, like rape victims, it has been shown that immediate administration of antiretroviral may prevent infection from occurring.

It should be emphasized that, the risk varies with on the type of exposure. A percutaneous injury resulting from a needle prick has a risk of 0.3% (3 in a 100) of resulting in HIV infection.

Healthcare workers are at significant risk of HIV through exposure in occupational settings. They as well as people who have a sexual exposure to HIV should receive post-exposure prophylaxis as part of a broader care package of care, including first-line support, emergency contraception and prophylaxis for sexually transmitted infections in combination with psychological interventions.

Body fluid and materials with a risk of HIV transmission

- Amniotic fluid and genital secretions
- Blood
- Cerebrospinal fluid
- Semen
- Synovial fluid
- Pericardial, peritoneal and pleural fluid

Occupational exposures with risks of HIV transmission

- Percutaneous injury from a known contaminated source
    - needle sticks
    - instruments
    - bone fragments
    - bites
- Exposure of broken skin
- Exposure of mucous membranes, including the eyes, nose and mouth, or contact
- with chapped, abraded or inflamed skin.
- Risk increases with exposure to
    - large volume of blood
    - High circulating viral load
    - Advanced stages of illness
    - Severity of the exposure (ex: type of injury...)

Occupational exposures posing no/low risk of HIV transmission

- Exposure of intact skin to potentially infectious body fluids
- Exposure to non-infectious body fluid
    - faeces
    - saliva
    - urine
    - sweat
    - vomit
- An exposure to a known HIV negative source

Managing HIV Occupational Exposure

Step 1 – Immediate measures
Step 2 - Report to concern authority
Step 3 - Testing & Counselling
Step 4 - Use of PEP

Immediate measures after exposure

- Wash the exposed site with soap and water
- Free gentle bleeding of puncture wounds. Encourage bleeding from the site but do not scrub or cut the site
- Thoroughly flush **exposed mucous membranes (eyes, nose or oral cavity)** with water or saline

Report to concern Authority

- All exposures should be documented
- A ledger should be provided for documentation
- Proper documentation and reporting of event and patient management

Testing and Counselling

- Both the source and exposed health worker need to be counselled for HIV-testing
- Assess the HIV status of the source of exposure
- Assess the HIV status of exposed health worker
- Positive result should be confirmed by another test of different kit
- Negative result should be repeated for the source and exposed health worker at 6 weeks, 3 months and at 6 months for person exposed.

4.9.1 Use of Post Exposure Prophylaxis

Criteria for initiating PEP

- Not already known to be HIV positive
- Exposures with risks of HIV transmission to body fluid and materials with a risk of HIV transmission (see above for guidance)
- The source patient is known to be HIV positive OR status unknown OR impossible to identify the source patient

Timeframe

- Initiate the 1st dose within 1 hour of exposure if possible
- The latest initiation of PEP should be within 72 hours of exposure
- Full course: 28 days

Choice of ARVs for PEP in adults and children

Table 30: Choice of ARVs for PEP in Adults and Children

	Recommended	Alternative
Children (≤10 years)	**AZT + 3TC + LPV/r** **OR** **ABC+3TC+ LPV/r**	**ABC + 3TC + DTG***
Adult and Adolescent	TDF + 3TC + ATV/r** OR TDF+ 3TC + LPV/r	TDF +3TC +DTG*

*DTG is approved for use among children older than six years and weighing more than 15 kg and is widely available for children weighing at least 20kg who can take 50mg film-coated adult tablets.
**ATV/r can only be used in adolescents >35kg.

Dosing of all drugs is the same as in ART. The course should be continued for 28 days. Enhanced adherence counselling is important for patients.

Note: PEP is not 100% effective; therefore, counselling of exposed persons to consistently and correctly use a condom until a negative result at 6 weeks is recommended.

Post-exposure management of sexual assault

- Provide appropriate first aid and emotional support
- Provide baseline and follow up counselling for HIV test
- Offer PEP as appropriate
- The first doses should not be delayed by baseline HIV Testing. However, testing should be done as soon as available.
- Treatment should not be continued if status of the patient remains undetermined
- Offer emergency contraception in women at risk of pregnancy
- Document clinical evidence of assault
- Provide STI prophylaxis and consider hepatitis B vaccination if indicated
- Offer trauma counselling
- Alert authorities as appropriate
- Refer as appropriate for legal services

4.9.2 Prevention of Occupational Exposure in Health Facilities

All health facilities in the private and public sector should adopt a policy for the prevention of accidental occupational exposure to bloodborne pathogens. Health facilities should implement universal precautions for the prevention of exposure to potentially infectious material.

The Programme should include:

- Training of all employees in handling and safe disposal of infectious materials.
- Provision of guidelines for prevention and control of infections within the facilities.
- Provision of equipment and supplies necessary for prevention and control of infections such as educational materials, disposable gloves, disposable needles and syringes and sharp bins.

All personnel should be made aware of the risks involved in proper handling of such material, and the steps necessary for preventing exposure should be clearly displayed in posters. Messages should promote avoiding recapping of needles, using sharp boxes for disposal of sharp objects, and exercising caution in performing any risky procedures.

4.9.3 Summary of steps to be taken after an Occupational Exposure

Post-exposure prophylaxis must be initiated within 72 hours of exposure.
The immediate steps to be taken after an occupational exposure include:

- Use soap and water to wash any wound or skin site that came into contact with infected
  blood or fluid
- Flush exposed mucous membranes with water
- Irrigate an open wound with sterile saline or disinfectant solution
- Eyes should be irrigated with clear water, saline or sterile eye irrigants
- Report to the concerned authority
- Counselling- Ascertain the HIV status of the patient and the injured health worker after appropriate counselling

Use antiretroviral immediately after exposure. These should be started within 1 hour if possible and at the latest within 72 hours of the exposure.

5. SEXUAL AND REPRODUCTIVE HEALTH SERVICES

5.1 Screening and Management of Sexually Transmitted Infection (STI)

Introduction

STIs increase the risk of HIV transmission and often coexist with HIV. HIV may alter the natural history of STIs by increasing recurrences and severity of STIs. It is, therefore, important to screen and appropriately manage STIs among PLHIVs irrespective of whether the patient is on ART or not. All pregnant women living with HIV should have RPR (TPHA)/VDRL at the first antenatal visit. Those who are positive should have a confirmatory test (TPHA).

5.1.1 Screening for STI

All sexually active adults, adolescents and young people with HIV should be screened for STIs at every clinic visit using the protocol in Table 31:

Table 31: Protocol for Screening STIs

SYNDROME	KEY SYMPTOMS
Urethral Discharge	▪ Discharge from the urethral opening or vagina ▪ In men, blood in the semen or urine ▪ Painful urination
Genital Ulcer Diseases	**For men:** Any genital sore is any sore or lesion that appears on the Penis Scrotum Male urethra **For Women:** Genital Ulcer Sores in Females involving; the skin surrounding the vulva, labia vagina perineum perianal anal regions
Abnormal Vagina Discharge	**Fungal cause:** Thick, white, cheesy vaginal discharge **Bacterial cause:** White, grey, or yellow with fishy odour vaginal discharge
Lower Abdominal Pain (PID)	Dull pain in the stomach or lower abdomen Pain during sex

5.1.2 Management of STI

Refer to National STI Guidelines.

5.1.3 Cervical Cancer Screening

Screening for cervical cancer using visual inspection with Acetic acid (VIA)/Cytology using Conventional Pap smear/HPV testing is recommended for all girls (18 years old and above) and women living with HIV and history of sexual activity at enrolment into HIV care; as they are of higher risk of developing the condition. The screening should be done at the enrolment into care, 6monthly in the 1st year and then annually if normal. Patients with pre-cancerous cervical lesions should be managed using cryotherapy as guided by the eligibility criteria below.

5.1.4 Management of Cervical Cancer

Refer to Gynaecologist for further management

5.1.5 Prevention of cervical cancer

HPV vaccine is more effective against cervical cancer among young girls and young women before the onset of sexual activity. HPV vaccine can therefore be recommended for young girls aged 9-13 years in Sierra Leone. Two vaccines will be offered.

6. PREVENTION, SCREENING AND MANAGEMENT OF CO-INFECTIONS

This section will provide guidance on how to prevent, screen and manage TB, Cryptococcal meningitis, Pneumocystis Jiroveci Pneumonia, Hepatitis B and C virus co-infections and STIs.

6.1 Tuberculosis (TB) Screening, Treatment, and Prevention

Introduction

Among people living with HIV, TB is the most frequent life-threatening opportunistic infection and a leading cause of death. Also, patients with TB and HIV have poorer treatment outcomes (such as death) compared to patients with TB alone. In Sierra Leone, about 13% of all TB cases in clinical settings are co-infected with HIV (Global TB Report, 2019).

6.1.1 HIV testing in TB

All patients with presumptive and/or confirmed TB in Sierra Leone should be offered an HIV test.

6.1.2 Screening for TB in PLHIV

People living with HIV are around 20 times more likely to develop TB disease than those without HIV infection and should be routinely evaluated for active TB using a clinical algorithm at every visit.

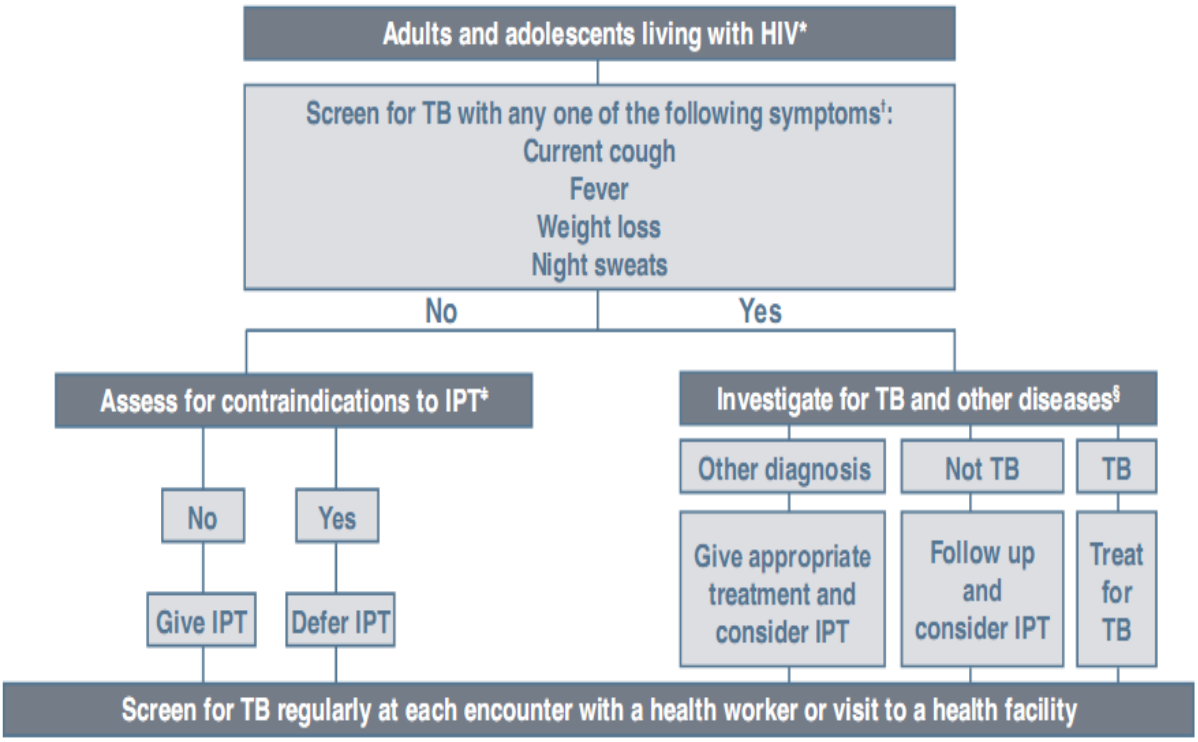


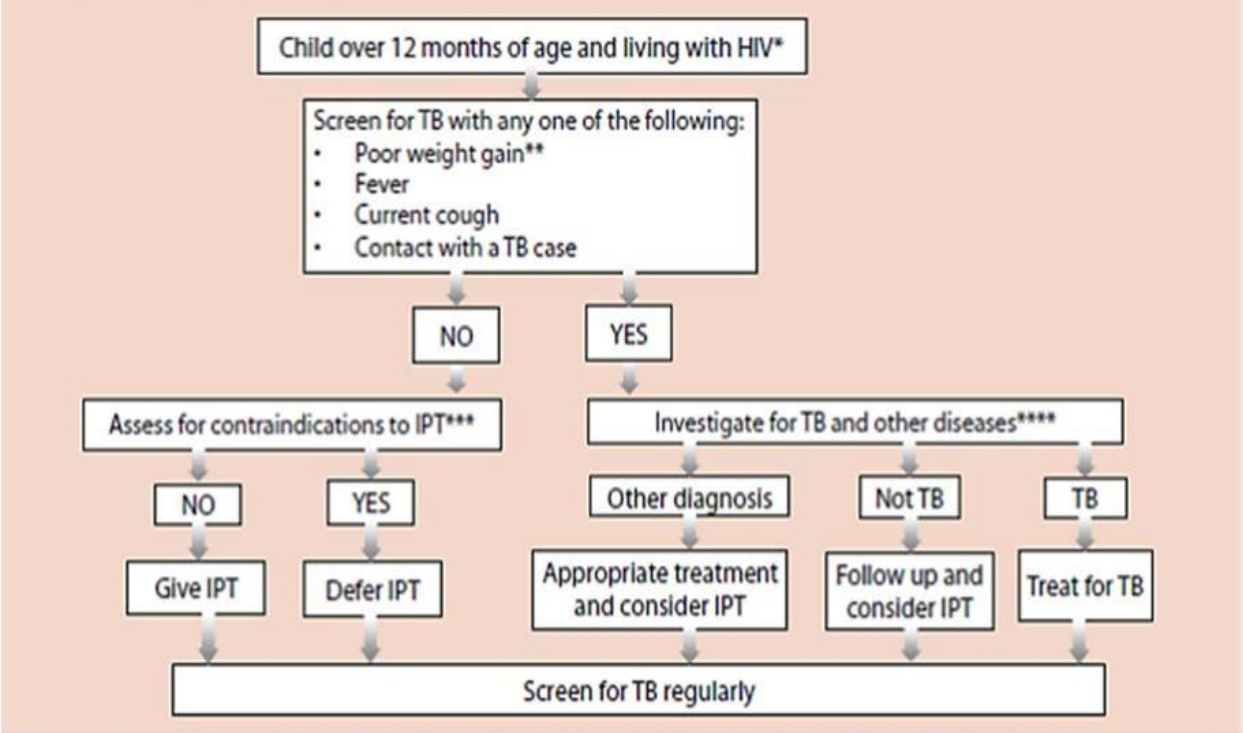
Figure 5: Algorithm for TB Screening among adults and adolescents living with HIV

Adults and adolescents living with HIV should be asked if they have any symptoms of current cough, fever, weight loss or night sweats. Those who report any of these symptoms are likely to have active TB and should go on to have sputum testing. GeneXpert is recommended as a primary diagnostic test for all PLHIV with presumptive TB. Where the GeneXpert MTB/RIF is not available, use sputum smear microscopy and/or a chest X-ray if available (refer to the national TB guidelines for TB diagnostic algorithms).

Urine lateral flow urine lipoarabinomannan assay (LAM) is recommended for HIV patients with CD4 less than 100cells/microL.

Infants and Children

Infants and children living with HIV should be screened for poor weight gain, fever, current cough or contact history with a TB case; if any of these are positive, they should be investigated for active TB.



* All children and infants less than one year old should be provided with IPT if they have household contact history with a TB case.
** Poor weight gain is defined as reported 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
*** Contraindications include: active hepatitis (acute or chronic) and symptoms of peripheral neuropathy. Past history of TB should not be a contraindication for starting IPT. Although not a requirement to initiate IPT, TST may be done as part of eligibility screening in some settings.
**** Investigations for TB must be done in accordance to existing national guidelines

Figure 6: Algorithm for TB Screening in children more than one year old and living with HIV

Infants aged < 12 months 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 should receive TB preventive treatment.

6.1.3 TB Diagnosis

GeneXpert should be performed as the preferred TB diagnostic test for all HIV patients with presumptive TB who can produce sputum. If not available, sputum smear microscopy test should be performed. Those with negative sputum test but suspicious TB symptoms, chest x-ray, is recommended where available. Urine LAM is recommended for all HIV patients with CD4 less than 100cells/microL for TB testing.

Note: diagnosis using smear and GeneXpert can be applied to other body fluids/tissues as appropriate.

6.1.4 TB Treatment

Refer to National TB Treatment Guidelines

6.1.5 ART for TB/HIV Co-infected patients

Refer to ART Section

Note: Patients newly diagnosed with HIV and TB should start TB treatment first, followed by ART as soon as possible within 2- 8 weeks of TB treatment. If patient is already on ART at the time of TB diagnosis, they should continue with ART.

6.1.6 TB Prevention

The following principles should be applied for the prevention of TB:

- Vaccination with BCG to prevent severe forms of TB in children. However; BCG should be avoided in children with active HIV diseases who were not previously immunised because of risk of BCG related TB
- Early identification and prompt treatment of TB patients
- Providing isoniazid preventive therapy
- Implementation of infection control practices within the health facility and community settings

6.1.7 TB Preventive Therapy (TPT)

TPT prevents the progression of TB infection to active TB disease, therefore, TPT should be considered in all patients with HIV who do not have active TB disease, irrespective of the degree of immunosuppression, whether they are on ART, whether they have previously been treated for TB, and including pregnant and breastfeeding mothers. Providing IPT to people living with HIV does not increase the risk of developing isoniazid-resistant TB. Therefore,

concerns regarding the development of Isoniazid (INH) resistance should not be a barrier to providing TPT.

Eligibility for TPT

- HIV-positive children (≥ 12 months of age), adolescents and adults (including pregnant women) living with HIV with no signs active TB
- Infants less than 12 months living with HIV who are in contact with a person with active TB.
- All children living with HIV who have successfully completed treatment for TB disease.

Adult	300mg once daily for 6 months
Children	Isoniazid 10 mg/kg (Max 300mg) daily for 6 months (see dosing chart below)

***Pyridoxine (25mg daily for adults, 10mg daily for children) while taking isoniazid is recommended to reduce the risk of peripheral neuropathy.**

Body weight (kg)	**Isoniazid tablet 100 mg** Crush the appropriate fraction and dissolve in water or multi-vitamin syrup
2 – 3.4	1/4 tab
3.5 – 6.9	½ tab
7 – 9.9	1 tab
10 – 14.9	11/4 tabs
15 – 19.9	11/2 tabs
20 – 24.9	2 tabs
25 – 29.9	2½ tabs
> 30	3 tabs

Contraindications to TPT

- Active hepatitis (acute or chronic)
- Regular and heavy alcohol consumption
- Symptoms of peripheral neuropathy

6.2 Cryptococcal Infection

Introduction

Based on a recent prospective study on cryptococcal diseases in Connaught Hospital, Cryptococcal meningitis (CM) associated mortality is about 62.5% after 18 weeks of follow up. Patients with a CD4 cell count of <100 are at the highest risk of CM. Currently, the prevalence of cryptococcal antigenaemia is 4.7% among PLHIV with CD less than 100 cells/mm^3 in Sierra Leone.

6.2.1 Screening and Management of Early Cryptococcal Infection

6.2.1.1 Screening

Routine CD4 cell count remains an important parameter and should be done in PLHIVs to guide screening for cryptococcal disease.

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

- All HIV-infected adults with CD4 <100 cells/mm3
- All PLHIV on ART suspected or confirmed to have treatment failure, i.e. Viral Load > 1,000 copies/ml with stage III or IV disease.

6.2.1.2 Testing for cryptococcal disease

Cryptococcal antigen (CrAg) test using the Lateral Flow Assay (LFA) on plasma, serum or finger-prick blood. The result will inform the next steps below:

Patients with positive serum CrAg should be assessed for signs of cryptococcal meningitis. Lumbar puncture for CSF CrAg is recommended for all patients with positive serum CrAg. If CSF CrAg is positive, then the patient has cryptococcal meningitis.

6.2.1.3 Signs and Symptoms of Cryptococcal Meningitis

- Persistent headache
- Fever
- Presence of seizures
- Altered consciousness
- Photophobia (Burden vision)
- Neck stiffness
- Positive Kernigs' sign.

6.2.1.4 Diagnosis of Cryptococcal Meningitis

This is achieved by demonstrating the presence of cryptococcal antigen in cerebrospinal fluid. A lumbar puncture and CrAg test on CSF (CSF CrAg) is the recommended diagnostic approach for cryptococcal meningitis.

6.2.1.5 Treatment of Cryptococcal Meningitis

These include three phases:

- Induction phase
- Consolidation phase
- Maintenance phase

Table 32: Treatment of Cryptococcal Meningitis

<table>
<tr><th>Phase</th><th>Drug</th><th>Comments</th></tr>
<tr><td colspan="3">Newly Diagnosed Patient</td></tr>
<tr><td rowspan="2">Induction Phase (2 weeks)</td><td>Recommended:
Amphotericin B 0.7-1mg/kg/day + Flu cytosine (100mg/kg/day in four divided doses) for one week followed by High-dose fluconazole 1200mg / day (or 6-12mg/kg/day up to a max of 800 mg/day in children) for one week Or
Amphotericin B short course 5-7 days + high-dose fluconazole</td><td rowspan="2">Preventing Amphotericin toxicity:
To prevent nephrotoxicity and hypokalaemia, do the following;
▪ Pre-hydration with 1L Normal saline before starting the daily Amphotericin dose;
▪ Monitor Serum potassium and creatinine levels at initiation and at least twice weekly to detect changes in renal function;
▪ Routine administration of 40 mEq/day of potassium chloride can decrease the incidence of amphotericin-related hypokalaemia;
▪ Consider alternate day Amphotericin if creatinine is >3mg/dl;</td></tr>
<tr><td>Alternative:
Fluconazole 1200mg / day (or 6-12mg/kg/day in children) plus Flucytosine (100mg/kg/day in four divided doses) for two weeks</td></tr>
<tr><td>Consolidation phase (8 weeks</td><td>Amphotericin B is used in induction phase: Fluconazole 400-800mg/day (or 6-12 mg/kg/day in children and adolescent <19yr)</td><td>Initiate ART 4-6 weeks after starting CM treatment, and there is clinical response to antifungal therapy</td></tr>
<tr><td>Maintenance Phase (1 year)</td><td>Fluconazole 200mg/day (or 6 mg/kg/day up to 200mg in children and adolescent <19yr)</td><td>Criteria to stop after a minimum of 1 year of maintenance phase
Adults VL<1,000 copies/mm3 & CD4 ≥ 100 for 6 months or CD≥200 if viral load not available.
Children: If >25% or viral suppressed</td></tr>
<tr><td colspan="3">Relapse disease</td></tr>
<tr><td colspan="3">Present with a recurrence of symptoms of meningitis and have a positive cerebrospinal fluid culture following a prior confirmed diagnosis of cryptococcal meningitis
▪ Evaluate for drug resistance:
▪ Send CSF to the central public health laboratory (CPHRL) for Culture and sensitivity testing.
▪ If there are no drug resistance results, re-initiate the induction therapy for two weeks and complete other phases of treatment
▪ Other options for treatment are a combination of Flucytosine (100mg/kg/day in four divided doses) and fluconazole 800-1200mg daily. For patients on rifampicin Increase fluconazole dose by 50%.</td></tr>
<tr><td colspan="3">Adequate control of elevated CSF pressure</td></tr>
<tr><td colspan="3">Control of increased intracranial pressure improves survival by 25% in persons with cryptococcal meningitis.
▪ All patients with a CSF Pressure > 250 mm H2O will need a therapeutic LP the following day to reduce the CSF pressure to < 200 mm.
▪ In the absence of a manometer, one may use an IV giving set to create an improvised manometer measuring the height with a meter stick.</td></tr>
<tr><td colspan="3">Removing 20-30 mL of CSF (even in the absence of a manometer) may be adequate to decrease CSF pressure. Most patients will need 2-3 LPs during the induction phase.</td></tr>
</table>

If the CSF CrAg test is negative in a patient with positive serum CrAg, with or without signs of CNS disease, the patient has cryptococcal disease, but without CNS involvement and the patient should be started on pre-emptive therapy for cryptococcal disease.

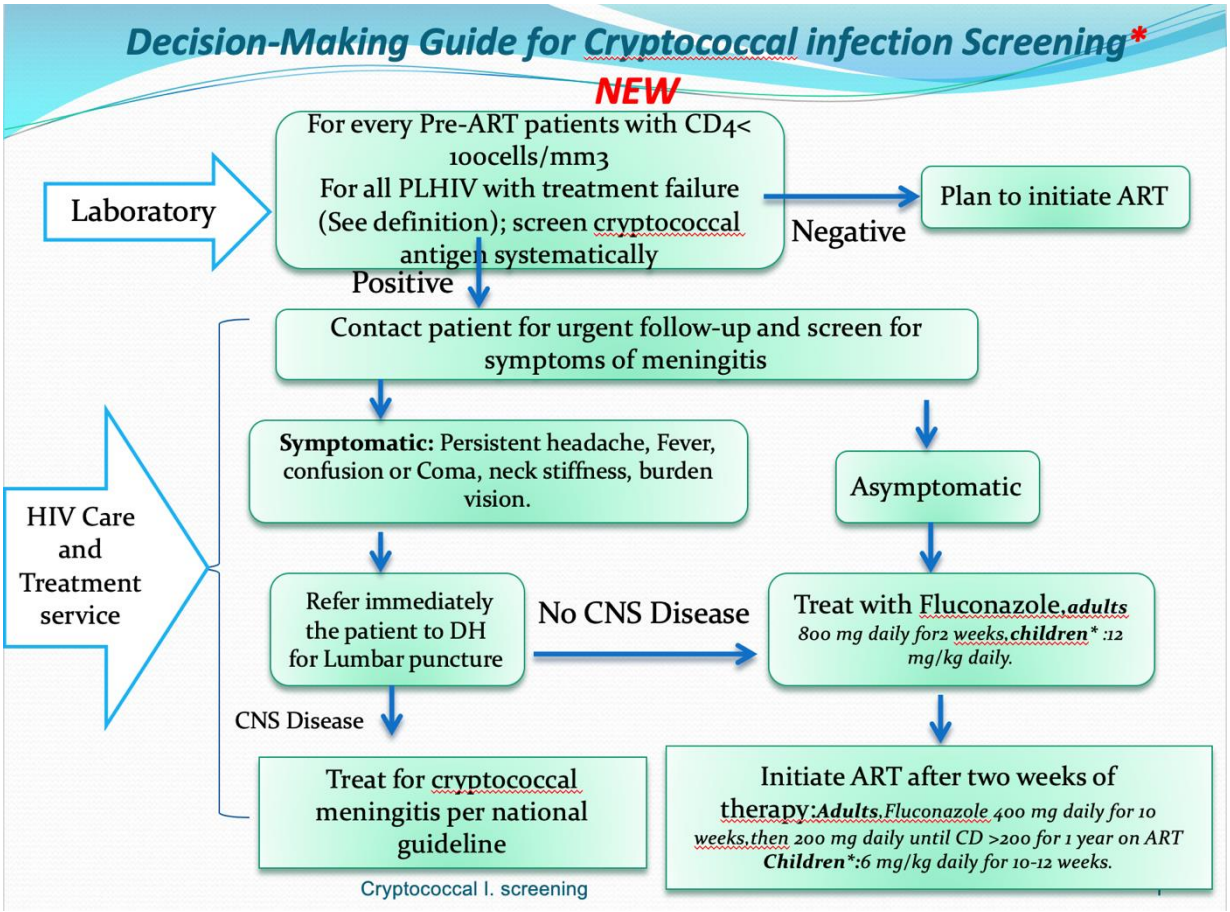
Induction Phase	Consolidation phase	Maintenance phase
Fluconazole 800mg/day for 2 weeks or 12 mg /kg/day for individuals below 19 years	Fluconazole 400 mg (or 6 mg/kg/day up to 400mg) for 8 weeks	Fluconazole 200 mg/day until CD4 is above 200.

For serum CrAg positive patients and site with no facility for lumbar puncture, CrAg-positive patients should be started on daily fluconazole 1200 mg, and referred to a site where LP can be done.

6.2.1.6 Considerations for drug interactions during treatment of Cryptococcal Disease

- Antifungals and Aminoglycosides, e.g. Gentamicin: Increased risk of nephrotoxicity
- Antifungals and Cardiac Glycosides, e.g. Digoxin: Increased risk of cardiac toxicity, especially in clients with Hypokalaemia
- Antifungals and Antiepileptic medicines: Antifungals may increase serum concentration of Carbamazepine, alprazolam, and other benzodiazepines
- Amphotericin B and non-potassium sparing diuretics: Increased risk of hypokalaemia
- Amphotericin B and Flucytosine: Amphotericin B can decrease renal clearance of 5-FC, and increase cellular uptake, which may increase the risk of 5-FC toxicity.
- Nevirapine use and Fluconazole: Fluconazole increases plasma concentration of Nevirapine and some Protease inhibitors
- TB medicines and Fluconazole: Rifampicin increases the metabolism of Fluconazole, thus increase the dose of Fluconazole by 50%.
- Pregnant and breastfeeding women: There is no data against the use of Amphotericin B in pregnancy. Because cryptococcal disease is life-threatening, amphotericin is the preferred treatment for pregnant women, especially those who are in the first trimester. 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 so fluconazole should be avoided if possible. Flucytosine is teratogenic in animals and should only be used when no alternative is available.
- In liver disease: Use with caution

Patients with negative serum CrAg with signs and symptoms of meningitis should be assessed for other causes of meningitis.



6.3 Pneumocystis Pneumonia (PCP)

PCP is a severe illness found in people with advanced HIV. PCP is caused by Pneumocystis jirovecii, a ubiquitous organism that is classified as a fungus but that also shares biological characteristics with protozoa. PCP is most common in patients whose CD4 cell count is <200. Diagnosis should be based on clinical presentation, oxygen saturation and chest X-ray.

6.3.1 Clinical presentation and diagnosis

- Sub-acute (days to weeks) progressive exertional breathlessness, fever, non-productive cough, and chest discomfort
- Findings on examination may include fever, tachypnea and inspiratory crackles, but physical examination of the chest is unremarkable in around 50% of patients.
- Oxygen saturation often very low and decreases further on exertion.

Imaging findings

- Chest radiographs are initially normal in up to a quarter of patients with PCP.
- Perihilar infiltrates in mild disease, and bilateral, symmetrical interstitial infiltrates emanating from the hila in a butterfly pattern in severe disease.
- Less frequently, PCP may present with unilateral or asymmetrical opacities.

- Pneumothorax can occur; consider PCP when an HIV patient presents with pneumothorax

6.3.2 Assessment of severity and management of PCP in adults

Table 33: Assessment of severity and management of PCP in adults

	Non-severe	Severe
Diagnosis		
Clinical features	Increasing exertional dyspnoea	Dyspnoea at rest, tachypnoea at rest, persistent fever, cough
O2	Normal oxygen saturation may desaturate on exercise	Hypoxia at rest (e.g. SaO2 <92%)
X-ray	Normal or minor Perihilar infiltrates	Extensive interstitial shadowing
Treatment		
High-dose Co-trimoxazole*	120mg/kg/day in 3-4 divided doses (see table 35)	If available: IV co-trimoxazole 120mg/kg/day IV in 3 divided doses; switch to equivalent oral dose after clinical improvement. If not available, 120mg/kg/day PO (see table 35)
Prednisolone	Not required	Days 1-5: 40mg PO BD Days 6-10: 40mg PO daily Days 11-21: 20mg PO daily
Duration	21 days, followed by ongoing prophylaxis (960mg orally OD)	21 days, followed by ongoing prophylaxis (960mg orally OD)
**** Renal impairment: use half normal dose if eGFR 15-30mL/minute and seek advice is eGFR<15mL/minute*** ***In the case of life-threatening cotrimoxazole intolerance, alternative adult treatment is Clindamycin 600-900mg IV 6-8hrly (300-450mg PO 6-8hrly) plus Primaquine 15-30mg PO OD for 21 days total***		

QUICK TIP – take the patient's weight in kg and divide it by 4. This will be the total number of 480mg tablets required per day in 2-4 divided doses. For example, a 48kg patient with PCP → 12 tablets per day → 4 tabs (1920mg) TDS. This is a higher dose than treating toxoplasmosis.

Dosing table for treatment dose co-trimoxazole for PCP; a standard dose of 960mg tabs OD should be used for prophylaxis. See toxoplasmosis guidelines for further guidance on management.)

Table 34: Co-trimoxazole Dosing for PCP

	Co-trimoxazole (Septrin) dosing for PCP – 120mg/kg/day			
Weight (kg)	**Total daily dose (mg)**	**Septrin solution 240mg = 5mL Total daily dose in mL**	**Septrin tablets 120mg Total daily number of 120mg tablets**	**Septrin tablets 480mg Total daily number of 480mg tablets**
2	240	5	2	-
3	360	7.5	3	-
4	480	10	4	-
5	600	12.5	5	-
6	720	15	6	-
7	840	17.5	7	-
8	960	20	8	-
9	1080	22.5	9	-
10	1200	25	10	-
12	1440	30	12	3
14	1680	35	14	3-4
16	1920	40	16	4
18	2160	45	18	4-5
20	2400	50	20	5
22	2640	55	22	5-6
24	2880	60	24	6
26	3120	65	26	6-7
28	3360	70	28	7
32	3840	-	-	8
36	4320	-	-	9
40	4800	-	-	10
44	5280	-	-	11
48	5760	-	-	12
52	6240	-	-	13
56	6720	-	-	14
60	7200	-	-	15
64	7680	-	-	16
68	8160	-	-	17
72	8640	-	-	18
76	9100	-	-	19
80	9600	-	-	20
84	10080	-	-	21
88	10560	-	-	22
92	11040	-	-	23
96	11520	-	-	24
100	12000	-	-	25

Care should be taken in renal impairment **–** *use half normal dose if eGFR 15-30mL/minute and seek advice is eGFR<15mL/minute. Note total dose should be given in 2-4 divided doses – for example, for a 64kg patient with PCP, 16 tablets should be given per day – this could be divided as 4 tablets QDS.*

Alternative therapy: Dapsone 100mg three times a day for 21 days
Pentamidine 4mg/kg/day for 21 days
Primaquine 30mg/day for 21 days.
Primaquine 30mg/day + Clindamycin 600mg QID for 21 days

Notes on treatment

- Start ART within the first 2 weeks of treatment; evaluate patients already on ART for treatment failure
- Patients usually improve slowly but with some improvement at 1 week. If patients are deteriorating on treatment, consider complications (e.g. pneumothorax) or alternative diagnoses (e.g. TB, pneumonia, pulmonary oedema)
- The most common reactions to co-trimoxazole are rash, diarrhoea, fever, nausea, bone marrow suppression (anaemia or leukopenia) and hepatotoxicity
- Where possible measure FBC and potassium at day 7 and 14 to monitor for drug-induced anaemia or hyperkalaemia
- Large volumes of fluid are required to give IV co-trimoxazole; monitor for pulmonary oedema

6.3.3 PCP in children

Presentation

- Fever, tachypnea, dyspnea, and cough.
- Severity varies and onset may be insidious or abrupt
- Non-specific symptoms include mild cough, poor feeding, diarrhoea, and weight loss.
- Most common in children under 12 months

Management

Empirical co-trimoxazole treatment should be considered for all HIV-exposed or -infected children under 12 months with severe pneumonia

- IV co-trimoxazole is the recommended treatment for PCP
- As children improve, those with mild-to-moderate disease can be transitioned to oral treatment with the same daily dose

Specific management in children

First-line	Oral or preferably IV co-trimoxazole 120mg/kg total daily dose in 2-4 divided doses
Second-line if co-trimoxazole is not tolerated	Pentamidine 4 mg/kg IV once daily x 21 days
Steroids should be added in severe disease	Days 1-5: 1mg/kg PO BD Days 6-10: 1mg/kg PO daily Days 11-21: 0.5mg/kg PO daily

Notes on treatment – *see the adult section above*

Prevention

Initiate all HIV-infected people on cotrimoxazole preventive therapy (CPT).

6.4 Cerebral toxoplasmosis Management

Presentation

Usually, a subacute presentation (days to weeks) of focal neurological deficits, e.g. hemiparesis, speech difficulty, personality change, cranial nerve palsies etc. Raised intracranial pressure may cause headache, vomiting and decreased conscious level; seizures may occur. Rarer presentations include rapidly progressive encephalitis or transverse myelitis.

Diagnosis: CT brain with contrast if available. Consider CXR and Xpert sputum, as CNS TB is an important differential diagnosis. Consider empirical treatment for toxoplasmosis in all patients with HIV and a focal neurological deficit. Improvement in less than 2 weeks is characteristic so a trial of treatment may therefore be a good diagnostic test. If there is no improvement, consider differential diagnoses including CNS tuberculosis, lymphoma, other space-occupying lesions.

	INDUCTION PHASE	MAINTENANCE
Duration	6 weeks	Until asymptomatic and CD4 >200 on 2 occasions 6 months apart Then switch to standard co-trimoxazole prophylaxis
Adult treatment	First-line (if available): Pyrimethamine (loading dose 200mg PO then 50mg daily if <60kg and 75mg daily if >60kg) AND Folinic acid (15-30mg/day PO) AND Sulphadiazine (1-2g QDS PO) OR Clindamycin (600mg QDS PO/IV) Alternative regimen: Co-trimoxazole 60mg/kg/day in 2-4 divided doses IV/PO*	First-line (if available): Pyrimethamine (25mg daily PO) AND Folinic acid (15mg daily PO) AND Sulphadiazine (1-2g BD PO) OR Clindamycin (300mg QDS PO) Alternative regimen: Co-trimoxazole 30mg/kg/day in 2 divided doses PO

Paediatric treatment	First line (if available): Pyrimethamine (loading dose of 2mg/kg max 50mg PO daily for 3 days, then 1mg/kg max 25mg PO OD) AND Folinic acid (10-25mg/day PO) AND Sulphadiazine (25-50mg/kg QDS max 1-1.5g QDS PO) OR Clindamycin (600mg QDS PO/IV) Alternative: Co-trimoxazole 60mg/kg/day in 2-4 divided doses IV/PO	First-line (if available): Pyrimethamine (1mg/kg PO once daily, maximum 25mg/day) AND Folinic acid (5mg PO every 3 days) AND Sulphadiazine (25-50mg/kg BD max 1-1.5g BD PO) OR Clindamycin (7-10mg/kg QDS PO/IV) Alternative: Co-trimoxazole 30mg/kg/day in 2 divided doses PO
**** Renal impairment: use half normal dose if eGFR 15-30mL/min and seek advice if eGFR<15mL/min.***		

QUICK TIP for cotrimoxazole dosing – take the patient's weight in kg and divide it by 8. This will be the total number of 480mg tablets required per day in 2-4 divided doses. E.g., a 48kg patient with toxoplasmosis → 6 tablets per day → 2 tabs (960mg) TDS. This is a lower dose than treating PCP.

***Dosing table for treatment dose co-trimoxazole for Toxoplasmosis*: a standard dose of 960mg tabs OD should be used for prophylaxis. Note different doses are used for PCP – see relevant section)**

Table 35: Co-trimoxazole Dosing for Toxoplasmosis

	Co-trimoxazole (Septrin) dosing for toxoplasmosis – 60mg/kg/day			
Weight (kg)	Total daily dose (mg)	Septrin solution 240mg = 5mL Total daily dose in mL	Septrin tablets 120mg Total daily number of 120mg tablets	Septrin tablets 480mg Total daily number of 480mg tablets
2	120	2.5	1	-
3	180	3.75	1.5	-
4	240	5	2	-
5	300	6.25	2.5	-
6	360	7.5	3	-
7	420	8.75	3.5	-
8	480	10	4	-
9	540	11.25	4.5	-
10	600	12.5	5	-
12	720	15	6	-
14	840	17.5	7	-
16	960	20	8	2
18	1080	22.5	9	2
20	1200	25	10	2-3
22	1320	27.5	11	3
24	1440	30	12	3
26	1560	32.5	13	3
28	1680	35	14	3-4
32	1920	-	-	4
36	2160	-	-	4-5
40	2400	-	-	5
44	2640	-	-	5-6
48	2880	-	-	6
52	3120	-	-	6-7
56	3360	-	-	7
60	3600	-	-	7-8
64	3840	-	-	8
68	4080	-	-	8-9
72	4320	-	-	9
76	4560	-	-	9-10
80	4800	-	-	10
84	5040	-	-	10-11
88	5280	-	-	11
92	5520	-	-	11-12
96	5760	-	-	12
100	6000	-	-	12-13

Care should be taken in renal impairment – use half normal dose if eGFR 15-30mL/minute and seek advice is eGFR<15mL/minute.

Note total dose should be given in 2-4 divided doses – for example, for a 64kg patient with toxoplasmosis, 8 tablets should be given per day – this could be divided as 2 tablets QDS.

Notes about management

- Important or common side effects of cotrimoxazole include: rash, diarrhoea, bone marrow depression (anaemia, leucopenia), hyperkalaemia, hepatotoxicity; where possible measure FBC and potassium at day 7 and 14 to monitor for drug-induced anaemia or hyperkalaemia
- Steroids may be required if there is evidence of raised intracranial pressure or substantial mass effect; use a short course and stop as soon as possible
- Initiate ART when patient is stable and usually within 2 weeks[1]; if patients are already taking ART, evaluate for treatment failure

6.4.1 Cotrimoxazole Preventive Therapy (CPT)

Co-trimoxazole is a broad-spectrum antimicrobial agent that targets a range of aerobic gram-positive and gram-negative organisms, fungi and protozoa. Prophylactic co-trimoxazole administration to HIV-positive patients has shown to be helpful in improving the quality of life and reducing mortality among HIV infected patients.

Co-trimoxazole preventive therapy should be implemented as an integral component of a package of HIV-related services for prevention of Pneumocystis pneumonia, toxoplasmosis and bacterial infections, as well as benefits for malaria prophylaxis. Cotrimoxazole prophylaxis should be initiated immediately in all HIV infected adults and adolescents (including pregnant women at any stage of pregnancy and breastfeeding women) and from 6 weeks to all exposed infants and children living with HIV.

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

Recommended dose for Co-trimoxazole Prophylaxis

Adults: Co-trimoxazole 960mg daily (two single strength tablets) for life.
Children: Based on the WHO guidelines, the following recommendations for the use of co-trimoxazole prophylaxis have been developed for Sierra Leone:

- HIV exposed infants and children in Sierra Leone should receive co-trimoxazole prophylaxis starting from six weeks after birth and continued until six weeks after the cessation of breastfeeding and definitive exclusion of HIV in the infant.

[1] Not very much evidence for this recommendation, no direct studies – however very few reports of IRIS and evidence from study of people with non-TB OIs favours early initiation. BHIVA: “initiate as soon as patient is stable, usually within 2 weeks”

- All HIV infected infants (6 weeks old and above), children and adolescents in the country with confirmed HIV infection should be given co-trimoxazole prophylaxis irrespective of their CD4 count or their clinical stage.

Co-trimoxazole (Septrin) Dosing Guide for children and infants

Prophylactic dose of co-trimoxazole – note that treatment doses should follow weight-based guidance as above.

Age	Strength of tablet or oral liquid		
	Septrin Solution 200mg/40mg = 5ml	Septrin tablets 100mg/20mg = 120mg	Septrin tablets 400mg/80 mg = 480 mg
6 weeks to 6 months	2.5 ml	1 tablet	--
≥ 6 months to 5 years	5 ml	2 tablets	½ tablet
6 years to 15 years	10 ml	4 tablets	1 tablet
Post-pubertal Adolescents to Adults (≥ 25 kg)	--	--	2 tablets

Side Effects of Co-trimoxazole

- The most common reactions to co-trimoxazole are rash, fever, nausea, low white blood cells (leukopenia) and hepatotoxicity.
- Patients should see their health care provider if they experience a rash.
- If the rash is mild, then co-trimoxazole can be withheld for 2 weeks and then cautiously reintroduced or desensitisation considered. However, in the case of severe exfoliative rash, co-trimoxazole should be discontinued, as there is a risk of Stevens-Johnson syndrome, which may be fatal.

Co-trimoxazole Drug Interaction

- **Do not take Co-trimoxazole with sulphadoxine-pyrimethamine (Fansidar.)**
  Co-trimoxazole is equally effective for the prevention of malaria in pregnancy and should be used instead.

When to discontinue Co-trimoxazole Prophylaxis

- Occurrence of side effects
- Children testing HIV- negative (older than 18 months and no longer breastfeeding).

Guidance on how to manage Cotrimoxazole hypersensitivity

Table 36; Guidance on Management of Hypersensitivity

Severity	Description	Management
Mild	Dry; erythema +/- fine papules; itching; affecting < 50% of body surface area	Continue CTX; monitor closely; symptomatic treatment with antihistamines +/- topical steroids (NOT oral steroids)
Moderate	Dry; erythema +/- fine papules; Itching; affecting > 50% of body surface area	Stop CTX; symptomatic treatment with antihistamines +/- topical steroids (NOT oral steroids); trial of desensitization after symptoms completely resolved

Severe	Mucosal involvement; blistering; associated fever; any % of body surface area I (Steven Johnsons syndrome)	Stop CTX; admission to hospital for supportive management (IV fluids, wound care, pain control, infection control, monitoring for superinfection); patient should NEVER be re-challenged with CTX or other sulfa-containing drugs

Alternate drugs to use in case of hypersensitivity to cotrimoxazole

In patients with co-trimoxazole hypersensitivity, dapsone should be used. Dapsone provides protection against PJP/PCP. It does not have the other preventive benefits the CPT provides. Therefore, pregnant women receiving Dapsone should also receive IPT with SP.
Dose of Dapsone is 100mg daily.

6.5 Hepatitis B&C Co-Infection with HIV

Hepatitis B virus (HBV) is the leading cause of chronic liver disease among HIV patients. HCV-related liver disease progresses more rapidly in people co-infected with HIV.
Please refer to National Hepatitis B & C Treatment Guidelines

6.6 Malaria and HIV

- People living with HIV in malaria-endemic regions are at high risk of complications of malaria. Infants, children under five years of age, and pregnant women are at risk of severe and complicated malaria.
- Key malaria control interventions include early diagnosis, prompt and effective treatment with artemisinin-based combination therapies, use of insecticide-treated mosquito nets (ITNs), indoor residual spraying (IRS) to control the vector mosquitoes, and intermittent preventive treatment during pregnancy (IPT).
- PLHIV (as for the general population) should routinely use insecticide-treated bed nets or have access to indoor residual spraying to reduce their risk of exposure to malaria.
- Intermittent preventive treatment with Sulfadoxine-Pyrimethamine should not be given to pregnant women with HIV receiving cotrimoxazole prophylaxis.
- PLHIV who develop malaria should receive prompt and effective anti-malaria treatment using artemisinin-based combination therapies (ACTs)
- PLHIV receiving AZT or EFV should, if possible, avoid amodiaquine-containing artemisinin-based combination regimens because of the increased risk of neutropenia in when used with AZT and hepatotoxicity when used with EFV.

For treatment of both severe and uncomplicated malaria, please refer to the National Malaria Treatment Guidelines.

6.7 Screening and Management of Non-Communicable Diseases

Introduction

Due to the chronic inflammatory state of HIV infection, and also the side effects of ARVs, PLHIV have a higher risk of liver, kidney and cardiovascular diseases. As a result, patients should be routinely screened for diabetes, hypertension, and depression.

6.7.1 Diabetes Mellitus (DM)

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

Risk factors to diabetes mellitus in HIV-positive patients

In addition to the general risk factors to develop DM, there are a number of HIV-related risk factors, including:

- Fluctuating Viral load and CD4 cell count, which cause a chronic inflammatory state which may induce insulin resistance.
- Rapid weight gain after the sickness, co-infection with Hepatitis C, dyslipidaemia, and lipodystrophy.
- Anti-retroviral drugs are the major cause of the development of DM in PLHIV, e.g. Protease Inhibitors, e.g. lopinavir, and ritonavir causes insulin resistance by causing Lipodystrophy, Impaired Glucose Transporter Type 4 translocation, Reduced adipocyte differentiation, reduced insulin secretion, dyslipidaemia with lipotoxicity.

Note: Other ARVs like NNRTIs and Integrase Inhibitors can be used safely.

Screening and diagnosis

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

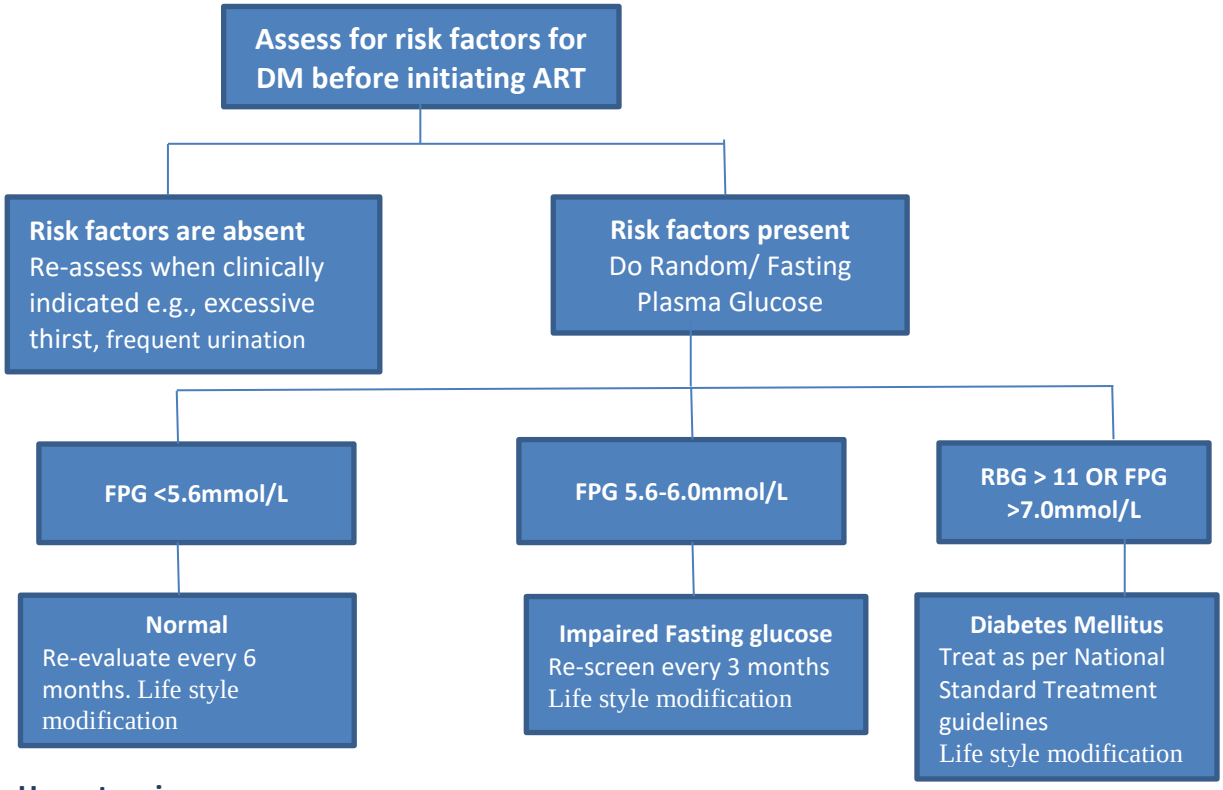
Treatment

HIV-positive patients with DM should be treated as per National Standard Treatment Guidelines. However, the following should be observed:

- Reinforce lifestyle interventions at every clinic visit.
- Metabolically neutral ARVs should be prescribed for patients at risk of developing DM. These include ABC, TDF, ATV/r, and DRV/r.
- DTG seems to be associated with weight gain and might be associated with increased risk of DM, but the benefit is generally felt to outweigh the risk
- DTG increases metformin levels; the latter should be used at the minimum dose needed to improve glucose values.

- Exclude HIV-associated nephropathy before initiating metformin because lactic acidosis can occur.
- The gastrointestinal side effects of Metformin are increased in patients with HIV enteropathy. Metformin should, therefore, be started at a low dose and increased gradually.
- Avoid Lopinavir/r unless used with close monitoring.

Steps in diagnosis and management of diabetes



6.7.2 Hypertension

PLHIVs should be screened for risk factors of hypertension such as tobacco smoking, being overweight, physical inactivity and dietary habit. Persistently high resting BP >140/90mmHg at least two measurements five minutes apart with the patient seated should serve as a guide to advise that client modify lifestyle as described below:

Refer to National Standard Treatment Guidelines for Management of Hypertension

Lifestyle Modification to Prevent No communicable Diseases

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

Smoking cessation

HIV-infected persons who smoke should be encouraged to stop because none smoking reduces the risk of:

- Respiratory infections and chronic lung disease
- Cancers of the lung, oesophagus, and breast.
- Hypertension, diabetes, heart disease, and stroke

Exercise

Clients should be advised to exercises frequently as it has positive effects on blood pressure whether or not a person has hypertension. Exercise produces an average reduction of 4 mm Hg in systolic blood pressure and 3 mm Hg in diastolic blood pressure; therefore, health care workers should help patients find activities that they enjoy because this increases adherence.

Dietary changes/modifications

These should include;

- Eat a diet high in fruits and vegetables and low in fat. And limit processed and fast foods.
- Reducing sugar intake
- Reducing sodium intake to <1.5 g/day
- Reducing/ abstaining from alcohol **(See National Nutritional guidelines for TB/HIV)**

Weight reduction

HIV clients should be advised to maintain normal body weight by taking adequate exercise and reducing high-calorie food intake. Weight loss is an important lifestyle modification in reducing the risk of blood pressure and diabetes. A reduction of 4.5 kg can help reduce blood pressure or prevent hypertension. A reduction of approximately 9 kg may produce a reduction in systolic blood pressure of 5 to 20 mm Hg.

Assessment and Management of Depression

It is proven that people living with HIV are at risk of mental and neurological disorders. As a result, people living with HIV with depression are less likely to achieve optimal ART adherence which will result in poor treatment outcomes. Therefore assessment of depression should be an integral part of routine HIV care programs. It is particularly important to screen for depression during the following crisis points:

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

Tools for screening for depression

The patient health questionnaire (PHQ-2), a two-item instrument is recommended for use as the first- approach to detect depression symptoms at the point of enrolment into care. This tool is not to establish a diagnosis, but to improve case detection of depression. The PHQ tool score ranges between 0-6 and those with a score greater than three should be further evaluated using the longer version. ***Please refer to Annex for Tools***

Patient Heath questionnaire- Longer version (PHQ-9)

PHQ-9 can be used both as a screening and diagnostic instrument. It can also be used to monitor symptoms during treatment of depression. It is preferable that the PHQ-9 is used by a trained health care worker, and where necessary, a mental health care worker should be consulted to help the management of the patients. Below is the guide for diagnosis and management based on scores in the PHQ-9 tool. ***Please refer to Annex for Tool/Questionnaire***

6.7.2.1 Interactions between ARVs and Anti-depressants

ARV	Anti-depressant	Interaction	Management
Ritonavir	Amitriptyline	Increased Amitriptyline levels/effect	Monitor and adjust Amitriptyline dose as indicated
	Fluoxetine	Increased ritonavir effects	No dose adjustment required
Efavirenz	Bupropion	Decreased Bupropion effects	Monitor for signs and symptoms of Depression and titrate Bupropion dose to effect
Lopinavir/ritonavir	Bupropion	Decreased Bupropion effects	Monitor for signs and symptoms of Depression and titrate Bupropion dose to effect
	Trazodone	Increased Trazodone levels/effects	Use with caution; If benefits outweigh the risk, start with a low dose of Trazodone
Darunavir	Paroxetine	Decreased Paroxetine levels	Titrate Paroxetine dose to effect; Monitor for response
	Sertraline	Decreased Sertral ine effects	Titrate Paroxetine dose to effect; Monitor for response
	Trazodone	Increased Trazodone effects	Use with caution; If benefits outweigh the risk, start with a low dose of Trazodone

7. MONITORING RESPONSE TO ART

Introduction

Regular follow up, and monitoring of individuals receiving ART is important to ensure successful treatment. This section provides guidance on when and how to use clinical assessment and laboratory monitoring to monitor response to ART, ART side effects and toxicity. It also provides guidance on how to diagnose ART treatment failure. The aims of monitoring patients on ART include:

- Assessment of treatment response and diagnosis of treatment failure
- Identification of drug toxicity
- Screening for opportunistic infections (including TB screening at every visit) and other HIV-related complications
- Identification of comorbidities
- Identification of adherence problems and potential barriers to adherence

7.1 Clinical Monitoring

Clinical monitoring involves taking a medical history and doing a physical exam. In this section, we shall describe a comprehensive clinical assessment and as assessment for both patients who are well and unwell.

Components of a comprehensive clinical assessment of PLHIV

- Demographics (age, sex, etc.).
- Review of any symptoms or concerns
- Clinical staging of HIV disease
- Screen for signs and symptoms of OIs, e.g. TB cryptococcal meningitis, Hep B & C infection and other illness, e.g., malaria
- Screen for pregnancy (women of reproductive age)
- Screen & manage OIs
- Screen & managed co-morbidities
- Screen and manage STI's
- Screen for symptoms of depression.
- Previous history of ART.
- Previous history of chronic illnesses (hypertension, DM, COPD, Kidney disease)
- Current medication
- Establish family planning methods currently in use.
- Assess developmental, sexual awareness and behavioural issues in adolescents.
- School attendance (children of school-going age)
- Progress with disclosure if not done already
- Nutritional assessment-weight & height in all patients, plus Mid-upper arm circumference (MUAC) in children 6-59 months
- Growth & development assessment and monitoring in children under 5's
- Examination of vital signs, and general patient examination, e.g. Respiratory, nervous system

7.2 Laboratory monitoring for ART

Note
The availability of technical ability and resources will determine which tests are used. The inability to carry out these tests does not exclude the initiation of treatment.

Phase of management	Recommended tests	Desirable tests (only if feasible and available)
After HIV diagnosis, at start of ART	- TB clinical screening - Smear examination if TB clinical screening positive (Xpert MTB/RIF preferred if available) - Chest X-ray if XpertMTB/RIF/sputum examination negative - CD4 count - HBsAg - Any other depending on clinician's digression.	- Consider Cryptococcal antigen rapid test if CD4<100 - Screening for STIs - Pregnancy test to assess if ART initiation should be prioritized to prevent HIV transmission to the child - Hb if AZT considered - Serum creatinine and urine dipstick if TDF considered
During ART	- HIV viral load testing (see below) - TB clinical screening - Symptom-directed laboratory monitoring - CD4 cell count (see below)	- Consider Hb 1 month and 3 months after initiating AZT - Urine dipsticks, serum creatinine and estimated glomerular filtration rate (eGFR) for TDF - Liver function tests for NVP - Blood pressure measurement
Treatment failure	- CD4 count - HIV viral load - TB clinical screening - Symptom-directed laboratory monitoring	- HBV (HBsAg) serology (before switching ARV regimen if this testing was not done or if the result was negative at baseline)

Clients not receiving ARVs

Commencement of ART should be an informed choice of people who live with HIV. PLHIV who decline ART despite counselling should continue to be monitored clinically and immunologically (CD4) where possible to assess disease progression. They should be offered Cotrimoxazole and TB screening should be done at every visit. They should be counselled and their readiness to initiate ART reassessed at every visit.

7.3 Virological Monitoring

In Sierra Leone, viral load testing is now recommended as the preferred approach to monitoring ART success and diagnosing treatment failure, complementing clinical and immunological monitoring of people receiving ART. Viral load should be done at 6 months after initiating ART , at 12 month and if virally suppressed (VL <1000copies/ml), repeat every 12 months to detect treatment failure. Measuring viral load can also serve as a proxy for the risk of transmission at the population level.

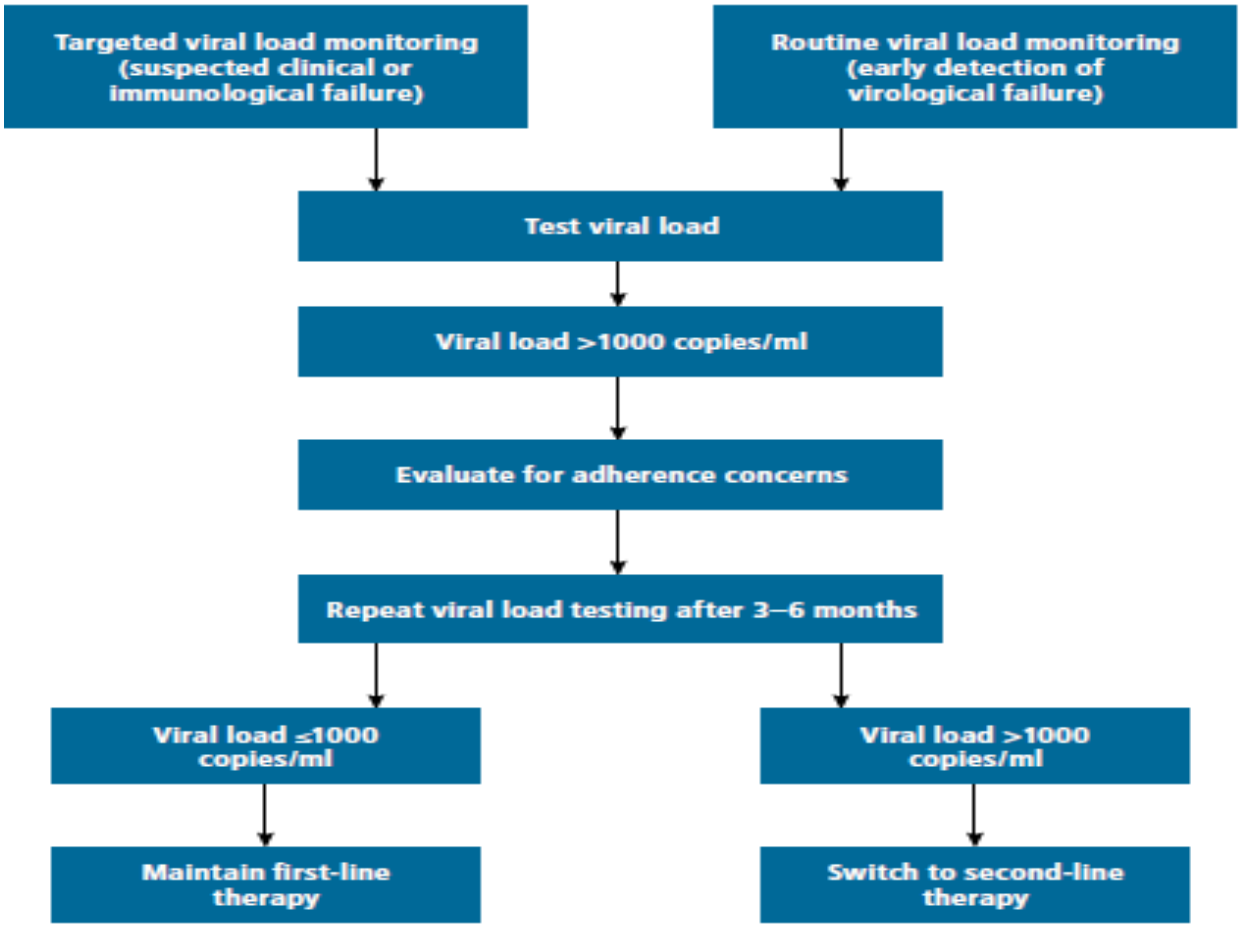


Figure 7: Viral Load Testing Protocol

Note: VL test should be preferably repeated after 3 months of intensive adherence counselling.

Frequency of Viral load

Adults

The First Viral load (VL) test should be done at six months after initiating ART, and then at 12 months thereafter, annually, if it is suppressed. If not suppressed, follow the protocol above.

Children and adolescents under 19 years of age

First VL test should be done at six months after initiating ART, and if it is suppressed, do VL every six months.

Pregnant women

- If newly initiating ART or already on ART, follow the standard protocol as of adults

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

For non-suppressed clients, repeat the VL test after 3 months of intensive adherence counselling after the last non-suppressed test. Within this period, the following should be done:

- Contact the patient to return to the facility within one week after the facility receives results
- The facility ART Team should hold a case discussion on patients with non-suppressed VLs to determine possible causes of non-suppression.
- Discuss results with the patient and assess barriers to adherence
- Conduct intensive adherence counselling support fortnightly or monthly for three months.
- Repeat VL test after completion of 3 months intensive adherence counselling session.
- If the repeat VL is suppressed, follow the standard protocol.

If repeat VL is not suppressed, and the ART team is confident that the client is adherent, then the client is failing on the current ARV regimen and should be switched according to the guidelines.

7.4 CD4 Count

Although CD4 count is no longer the standard for ART initiation, it can be used in the following circumstances:

- CD4 should be measured at HIV diagnosis and 6 monthly for the first year as it will help to screen for risk of opportunistic infections, e.g. in patients with CD4 less than 100 cell/mm, screening for cryptococcal infection is recommended.
- ART patients with VL >1000 with and/or WHO Clinical Stage 3 or 4 disease
- PLHIV who are on treatment or prophylaxis for Cryptococcal infection to inform a decision on when to stop fluconazole.
- CD4 should be measured every 6 monthly for patients with confirmed HIV-2 infection. This is because there are no commercially available assays that can be used to measure HIV-2 Viral loads in patients.

In patients who have been on ART for at least one year, who are stable on treatment and who have had two consecutive viral load measurements less than 1000 copies/ml, CD4 does not need to be measured as a routine monitoring test. If viral load is not routinely available, CD4 count and clinical monitoring should be used to diagnose treatment failure.

Follow-up lab tests and their clinical indication

Test	Indication
CRAG	(CD4<100cells/mm3)
Complete Blood Count (CBC)	Patients at risk of anaemic conditions, e.g. Patients on AZT, anti-cancer drugs, chronic renal disease, etc.
Serum Creatinine	Comorbidities', e.g. DM, Hypertension
ALT, AST	Compromised liver function, e.g. Hepatitis B and C infection, ART hepatotoxicity
Lipid profile & Blood glucose	comorbidities, e.g., Diabetes Mellitus, hypertension and lifestyle risk factors, patients on ART for more than five years, PLHIV ≥ 45 years

Follow-up schedules for PLHIV and monitoring components

Time	Clinical assessment	Laboratory tests
Before ART		
Baseline	Comprehensive clinical assessment (including TB symptom screen), prepare for ART, assess readiness for ART, provide CTX and provide FP if required	HIV test, CD 4, HBeAg, CrAg if CD4 <100 Do tests below if clinically indicated CBC (If the patient is at risk of anaemia), TB Tests (If TB is suspected), RFTs(For hypertensive and DM patients) LFTs (HBV or HCV infection, LipidProfile and Blood Glucose Cervical cancer screening (as per section 5.1.3)

Time	Clinical assessment	Laboratory tests
During on ART		
1 month	Comprehensive clinical assessment. Also, assess for; drug intolerance, side effects/toxicities, and IRIS Adherence assessment, monitoring, and support ART &CTX refill- In children adjust dose based on weight FP refill If the patient is clinically well, give one months' refill and appointment.	Do other lab tests if clinically indicated.
2 month	▪ Comprehensive clinical assessment (including TB symptom screen). ▪ Also, assess for; drug intolerance, side effects/toxicities, and IRIS ▪ Adherence assessment, monitoring, and support ▪ ART &CTX refill-In children adjust dose based on weight ▪ FP refill If patient is clinically well, give one month refill	Do other lab tests if clinically indicated
3 month	▪ Comprehensive clinical assessment (including TB symptoms screen) ▪ Also, assess for; drug intolerance, side effects/toxicities, and IRIS ▪ Adherence assessment, monitoring, and support ▪ ART &CTX refill-In children adjust dose based on weight ▪ FP refill If patient is clinically well, give three months' refill	Do other lab tests if clinically indicated
During ART		
6 month	▪ Comprehensive clinical assessment (including TB symptoms screen) ▪ Also, assess for; drug intolerance, side effects/toxicities, and IRIS ▪ Adherence assessment, monitoring, and support ▪ ART &CTX refill-In children adjust dose based on weight ▪ FP refill If patient is clinically well, give three months' refill	Do VL test If VL is not suppressed, call the patient back for intensive adherence counselling. Do other lab tests if clinically indicated Cervical cancer screening (as per section 5.1.3)
9 month	▪ Comprehensive clinical assessment ▪ Also, assess for; side effects/toxicities. ▪ Adherence assessment, monitoring, and support ▪ ART &CTX refill-In children adjust dose based on weight ▪ FP refill ▪ Determine eligibility and prepare for DSDM	For VL suppressed PLHIV, give VL results Do other lab tests if clinically indicated see

Time	Clinical assessment	Laboratory tests
12 month	▪ Comprehensive clinical assessment ▪ Also, assess for; side effects/toxicities ▪ Adherence assessment, monitoring, and support ▪ ART &CTX refill-In children adjust dose based on weight ▪ FP refill ▪ If patient is clinically well, give three months' ▪ refill	2nd VL Do other lab tests if clinically indicated Cervical cancer screening (as per section 5.1.3)
After 12 months on ART following DSDM		
3 monthly	▪ Adherence assessment, counselling, and support ▪ TB Screening ▪ ART and Cotrimoxazole refills ▪ Family planning refills ▪ Refer where clinically indicated	Do other lab tests if clinically indicated
6 monthly	▪ Comprehensive clinical assessment as at month one above ▪ Adherence assessment, counselling, and support ▪ TB Screening ▪ ART and Cotrimoxazole refills ▪ Family planning refills	Do other lab tests if clinically indicated
Annually	▪ Comprehensive clinical assessment as at month one above ▪ Adherence assessment, counselling, and support ▪ TB Screening ▪ ART and Cotrimoxazole refills ▪ Family planning refills	VL Cervical Cancer screening (as per section 5.1.3) Do other lab tests if clinically indicated

What to expect in the first month of ART

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

- Clinical and immunological improvement and viral suppression are expected when individuals adhere to ART, but

- Opportunistic infections (OIs) and immune reconstitution inflammatory syndrome (IRIS) may develop, as well as early adverse drug reactions, such as drug hypersensitivity, especially in the first three months of treatment.

- ART significantly decreases mortality overall, but death rates are also highest in the first three months of ART. These complications are most common when the people starting ART already have advanced HIV disease with severe immunodeficiency and existing coinfections and/or comorbidities, severely low haemoglobin, low body mass index, and very low CD4 cell counts or are severely malnourished.

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

7.5 Immune Reconstitution Inflammation Syndrome (IRIS)

For many opportunistic infections, including TB, there can be a transient worsening of infection 2-3 weeks after the initiation of ART. This is called Immune Reconstitution Syndrome. It may present in two different ways: paradoxical IRIS, when an opportunistic infection or tumour diagnosed before ART initially responds to treatment but then deteriorates after ART starts; or unmasking IRIS, in which initiating ART triggers disease that is not clinically apparent before ART. It 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 paradoxical IRIS are for TB, Cryptococcal disease, Kaposi 'sarcoma and herpes zoster. The most important steps to reduce the development of IRIS include:

- Earlier HIV diagnosis and initiation of ART before a decline to below 200 CD4 cells/mm3;
- Improved screening for opportunistic infections before ART, especially TB and Cryptococcal disease. In patients with CD4<100, CrAg screening should be offered if available, and fluconazole prophylaxis/treatment offered according to OI guidelines.
- Optimal management of opportunistic infections before initiating ART.

For those with TB, the syndrome is characterized by worsening/new onset of night sweat, fever, weight loss, lymphadenopathy, worsening pulmonary lesions, and expanding lesions of the central nervous system. These reactions are typically self-limiting, although they may require the use of corticosteroids to reduce the inflammation of the CNS or severe respiratory symptoms. The initiation of ART can also unmask previously undiagnosed infections by augmenting the inflammatory response.

In general, ART should not be interrupted if immune reconstitution syndrome occurs. However, ART initiation can be deferred in patients with serious opportunistic infections like Cryptococcal meningitis due to the high risk of immune reconstitution inflammatory syndrome (IRIS) with central nervous system disease, which may be life-threatening. In such situations, ART initiation should be deferred until there is evidence of a sustained clinical response to medical therapy (see OI guidelines for specific infections).

In Summary

- **IRIS is a spectrum of clinical signs and symptoms thought to be associated with immune recovery brought about by a response to ART.**
- **It is a widely recognized phenomenon that occurs among 10–30% of the people initiating ART, usually within the first 4–8 weeks after initiating therapy.**
- **IRIS should be considered only when the presentation cannot be explained by a new infection, the expected course of a known infection or drug toxicity.**
- **The most serious and life-threatening forms of IRIS are for TB, cryptococcosis, Kaposi's sarcoma and herpes zoster. BCG vaccine–associated IRIS (localized and systemic) may occur in infants infected with HIV in settings where BCG immunization is routine.**

Risk factors for IRIS include

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

7.5.1 Managing IRIS

- IRIS is generally self-limiting, and interruption of ART is rarely indicated.
- Treat the infection
- If the symptoms are protracted, reassure the patient and treat the symptoms to prevent discontinuation of or poor adherence to ART.
- Consider administrating steroids (based on the severity of IRIS, hence case-by-case basis)

Steps to reduce the development of IRIS

- Diagnose HIV early and initiate ART before CD4 declines to below 200 CD4 cells/mm3
- Screen and optimally manage opportunistic infections before initiating ART, especially TB and Cryptococcus.

The timing of ART in people with opportunistic infections requires balancing a greater risk of IRIS after early initiation against continuing high mortality if ART is delayed.

7.6 ARV Drug Toxicity

Toxicity refers to the inability to tolerate the side effects of medication and to the significant organ dysfunction that may result. Antiretroviral drugs can cause a wide range of toxicities, from low-grade intolerance that may be self-limiting to life-threatening side effects. Differentiating between ART toxicity (also known as adverse reactions) and complications of HIV disease is sometimes difficult. Observed toxicity could be due to a concurrent infectious process or due to a reaction to medications other than ARVs, e.g. Isoniazid – induced hepatitis in a child on treatment for TB or a rash induced by cotrimoxazole. This can be monitored clinically on the basis of patient reporting and physical examination, and may also be detected on laboratory tests.

Mild drug side effects are common with ART. It is important to counsel patients about side effects, to reassure them and to reinforce the need for adherence. Many will settle with simple measures such as anti-emetics, and reduce with time. Patients and health care workers should be aware that switching to a different regimen does not always make side effects better, and if side effects are mild, it may be best to persist with the first-line regimen where possible. However, when toxicity is severe or on-going (intolerable side effects which frequently compromise adherence despite simple measures), it may be necessary to change medications.

For example, TDF can be used in place of AZT due to AZT-related symptoms of anaemia. For other toxicities, for which a specific agent cannot be identified as causal, and/ or low grade but intolerable side effects which frequently compromise adherence, a complete regimen switch to the second-line

drugs is recommended. If an interruption in therapy is indicated to permit resolution of toxicity, the entire regimen should be temporarily interrupted in order to prevent the emergence of drug resistance.

7.6.1 Drug Substitution

Table 37: Drug Substitution due to toxicity of first-line ARVs

ARV Drug	Common associated Toxicity	Suggested management
ABC	Hypersensitivity reaction	Substitute with AZT or TDF
AZT	Severe anaemia or neutropenia Severe GI intolerance not responding to simple measures Lactic acidosis, hepatic steatosis, lipodystrophy, myopathy	Substitute with TDF or ABC
TDF	Renal toxicity , lactic acidosis, hepatic steatosis	Substitute with AZT or ABC
EFV	Persistent & severe CNS toxicity Hepatotoxicity Severe skin and hypersensitivity reactions	For CNS symptoms, dose at night-time. use boosted LPV/r or DTG
NVP	Hepatotoxicity Severe skin rash and hypersensitivity reaction, including Stevens-Johnson syndrome	Substitute with EFV. If the person cannot tolerate either NNRTI, use boosted LPV/r or DTG (for weight above 30kg)
ATV/r	Indirect hyperbilirubinemia (clinical jaundice) Nephrolithiasis	Note that clinical jaundice is benign but potentially stigmatising. Counsel patients and substitute only if adherence is compromised. Substitute with LPV/r if required.
LPV/r	Hepatotoxicity, pancreatitis, arrhythmias, dyslipidaemia, diarrhoea	If LPV/r is used in second-line ART for adults, use ATV/r or DTG If LPV/r is used in first-line ART for children, use (EFV or DTG depending on the weight for children 3 years and older).

7.6.2 Management of ARV Drug Toxicity

Healthcare workers should assess patients on ART for ARV side effects and toxicities at every clinic visit. If the patient has side effects or toxicity, the following should be done:

1. Determine the seriousness of the toxicity.
2. Evaluate concurrent medications and establish whether the toxicity maybe attributable to an ARV, or to a non-ARV medication taken at the same time.
3. Consider other disease processes. Not all problems that arise during treatment are caused by ARV drugs.

4. Manage the side effects and toxicities according to severity, as shown in Table 39 below.
5. Report the event using the Pharmacy Board of Sierra Leone (PBSL) adverse drug reaction reporting form.

Table 38: Management of ARV Drug Toxicity

Category	Action
Severe Life-Threatening Reactions	Immediately discontinue all ARV drugs, manage the medical event, substitute the offending drug when the patient is stable and report using the adverse drug reaction reporting form
Severe Reactions	Substitute the offending drug without stopping the ART and report using the adverse drug reaction reporting form
Moderate Reactions	Substitute with a drug in the same ARV class but with a different toxicity profile, or with a drug in a different class Do not discontinuation ART. Continuation of ART as long as feasible. If the patient does not improve on symptomatic therapy, consider single –drug Substitution.
Mild Reactions	Do not discontinue or substitute ART. Reassure the patient or caregiver that while the reaction may be bothersome, it does not require a change in therapy; provide support to mitigate the adverse reactions as well as counselling about the events.

7.6.3 Toxicities/side effects of commonly used ARVs and recommended substitutions

Table 39: Recommended ARV substitutions for side effects

Age category	Regimen	Major toxicity events	Responsible ARV	Suggested management
Adults, adolescents, pregnant and lactating women	TDF+3TC+EFV	Persistent central nervous system toxicity (such as dizziness, insomnia, abnormal dreams)or mental symptoms(anxiety, depression, mental confusion)	EFV	Re-assure, lower the dose of EFV to 400mg. If persists substitute with DTG Use regimen TDF+3TC+DTG
		Convulsions		Substitute with DTG Use regimen TDF+3TC+DTG
		Hepatotoxicity		
		Severe skin and hypersensitivity reactions	TDF	Substitute with ABC Use regimen ABC+3TC+EFV or ABC+3TC+DTG
		Chronic Kidney Disease Acute kidney injury and Fanconi syndrome		

		Decreased bone mineral density		
		Lactic acidosis or severe hepatomegaly with steatosis		
	TDF+3TC+DTG	Gynecomastia	TDF	Substitute with ABC Use regimen ABC+3TC+DTG
		Chronic Kidney Disease Acute kidney injury and Fanconi syndrome		
		Decreased bone mineral density		
		Lactic acidosis or severe hepatomegaly with steatosis		
		Hepatotoxicity	DTG	Substitute with EFV Give TDF+3TC+EFV If EFV is contraindicated Use TDF+3TC+ATV/r or TDF+3TC+LPV/r
		Hypersensitivity reactions		
		Gynecomastia		
		Weight gain		
	ABC+3TC+DTG	Hypersensitivity reaction	ABC	Stop and substitute with TDF Use regimen: TDF+3TC+DTG If TDF is contraindicated Use AZT+3TC+DTG
		Hepatotoxicity	DTG	Substitute with EFV Give TDF+3TC+EFV If EFV is contraindicate Use TDF+3TC+ATV/r or TDF+3TC+LPV/r
		Hypersensitivity reactions		
	AZT+3TC+NVP	Severe anaemia, neutropenia	AZT	Substitute with TDF Use regimen: TDF+3TC+DTG If TDF is contraindicated Substitute with ABC Use regimen: ABC+3TC+DTG
		Lactic acidosis or severe hepatomegaly with steatosis Lipoatrophy, Lipodystrophy, Myopathy		
		Severe vomiting		
		Acute symptomatic hepatitis	NVP	Substitute with DTG Use regimen: TDF+3TC+DTG
		Severe skin rash		
		Hypersensitivity reaction, Steven Johnson Syndrome (Severe or life-threatening rash)		
		Electrocardiographic abnormalities (PR and		Use with caution in people with pre-existing

	ATV/r Based regimen	QRS interval prolongation)	ATV/r	conduction disease or who are on concomitant drugs that may prolong the PR or QRS intervals.
		Indirect hyperbilirubinemia (clinical jaundice)		This phenomenon is clinically benign but potentially stigmatizing. Substitute with LPV/r only if adherence is compromised.
		History of nephrolithiasis		Substitute with LPV/r. If boosted PIs are contraindicated, and NNRTIs have failed in first-line ART, consider using TDF+3TC+DTG
Children 0-9.9 years	**ABC+3TC+EFV**	Hypersensitivity reaction	ABC	Stop and substitute with AZT Use regimen AZT+3TC+EFV
		Persistent central nervous system toxicity (such as dizziness, insomnia, abnormal dreams) or mental symptoms(anxiety, depression, mental confusion)	EFV	Reassure; If fails to tolerate substitute with NVP Use regimen ABC+3TC+DTG
		Convulsions		Substitute with Use regimen- ABC+3TC+DTG or ABC+3TC+LPV/r
		Gynecomastia		
		Hepatotoxicity		Substitute with LPV/r Use regimen ABC+3TC+LPV/r
		Severe skin and hypersensitivity reactions		
	ABC + 3TC+NVP	Hypersensitivity reaction	ABC	Stop and substitute with AZT Use regimen AZT+3TC+EFV
		Acute symptomatic hepatitis	NVP	Mild Hepatotoxicity Substitute with EFV Use regimen: ABC+3TC+EFV Severe Hepatotoxicity Substitute with LPV/r Use regimen: ABC+3TC+LPV/r
		Severe skin rash		Substitute with LPV/r

		Hypersensitivity reaction, Steven Johnson Syndrome (Severe or life-threatening rash)		Use regimen: ABC+3TC+LPV/r According to weigh ABC+3TC+DTG can be used
	ABC+3TC+LPV/r	Hypersensitivity	ABC	Stop and substitute with AZT Use regimen AZT+3TC+LPV/r
		Electrocardiographic abnormalities (PR and QRS interval prolongation, torsade's de pointes)	LPV/r	Stop and substitute with EFV Use regimen: ABC/3TC/EFV According to the weight ABC+3TC+DTG can be used
		Hepatotoxicity		
		Pancreatitis		
		Dyslipidaemia		
		Diarrhoea Unable to tolerate the taste		
	AZT+3TC+NVP	Severe anaemia, neutropenia	AZT	Substitute with ABC Use regimen ABC+3TC+NVP
		Lactic acidosis or severe hepatomegaly with steatosis Lipoatrophy, Lipodystrophy, Myopathy		
		Severe vomiting		
		Acute symptomatic hepatitis	NVP	Mild Hepatotoxicity Substitute with EFV Use regimen: ABC+3TC+EFV Severe Hepatotoxicity Substitute with LPV/r Use regimen: ABC+3TC+LPV/r
		Severe skin rash		Substitute with LPV/r Use regimen: ABC+3TC+LPV/r Or ABC+3TC+GTG(if >20kg)
		Hypersensitivity reaction, Steven Johnson Syndrome (Severe or life-threatening rash)		

Drug Substitution for Virologically Suppressed Children 3years and 10 years

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

When children on LPV/r based first-line regimen turns 3 years of age, a viral load should be done, and if they are viral suppressed, LPV/r should be substituted with EFV.

Benefits

This will harmonize their treatment with the recommended regimen for that age group and simplify forecasting and quantification. Also, EFV is cheaper than LPV/r, and study has shown that EFV provides similar virologic suppression and improved immunologic response and lipid profile outcomes as those who continue on LPV/r.

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

When children on ABC based first-line regimen are 10 years of age and weight 35kg, a viral load should be done, and if they are viral suppressed, ABC should be substituted with TDF
The children who are not virally suppressed should be investigated for treatment failure and managed accordingly.

7.7 Drug Interaction

Table 40: Drug Interaction

Drug Family	ARV Drug	Interaction	Action
Anti-TB Medicines	NVP	Rifampicin decreases NVP concentrations in blood They could cause liver toxicity	Do not co-administer NVP and rifampicin. See Table 27 and Table 28 for TB/ARV Co-management
	DTG	Rifampicin lowers DTG levels	Adjust DTG dose to twice daily
	ATV/r, LPV/r, DRV and RTV	Rifampicin boosts metabolism of PI's	If given together with LPV/r- increase the dose of RTV to achieve 1:1 ratio.
Combined Oral Contraceptive Pills, Implants (Etonogestrel)	EFV or ATV/r, LPV/r, DRV and RTV	Risk of contraceptive failure due to increased metabolism of contraceptives	Use an additional barrier method OR Use Depo-Provera or IUDs
Anxiolytics, e.g.	ATV/r, LPV/r,	Risk of respiratory	Reduce the dose of Midazolam

Drug Family	ARV Drug	Interaction	Action
Midazolam, Diazepam	DRV and RTV	depression (Midazolam) Increased sedation (Diazepam)	or Diazepam
Antifungals, e.g. Ketoconazole	NVP	Risk of Hepatotoxicity	Use Fluconazole
Simvastatin, Rosuvastatin, Atorvastatin	ATV/r, LPV/r, DRV and RTV	Inhibition of CYP450 3A4 (Reduced metabolism of Statins)	Use Atorvastatin with lowered dose and monitor for side effects like muscle pains
Anti-epileptics, e.g. Carbamazepine, phenobarbital, and phenytoin	EFV, DTG, Etravirine,	Carbamazepine decreases DTG Levels by 30-70%	Use Valproic Acid
Drugs for acid reflux or ulcers, e.g. Omeprazole, Esomeprazole, Lansoprazole, Pantoprazole	ATV/r	Reduced concentrations of Atazanavir	Use alternatives like Ranitidine, Cimetidine, etc.
Polyvalent Cation products containing Mg, Al, Fe, Ca, Zn (e.g. vitamin supplements and antacids)	DTG	Reduce DTG levels	Use DTG 2 hrs before or 6 hrs after the product to avoid the interaction.
Antimalarial Artemether/lumefantrine Halofantrine	LPV/r, Nevirapine, Efv	Possibility of delaying blood elimination Artemether/ lumefantrine	

8. DIFFERENTIATED SERVICE DELIVERY

Introduction

Differentiated service delivery (DSD) is an approach to service delivery centred on people living with HIV, that simplifies and adapts HIV services across the cascade of care, to reflect the preferences and expectations of various groups of people living with HIV, while reducing unnecessary burdens on the health system.

The approach involves assessing individuals to determine the level of care they need and matching them to appropriate services. Differentiated service delivery is applicable across the HIV care continuum, including HIV prevention, testing, linkage, ART initiation, and ART delivery.
This section of the guidelines outlines the recommended approaches to DSD for PLHIV. The National DSD Operation Toolkit, 2020, provides structured guidance on the implementation of the DSD models.

8.1 Differentiated ART Services

The core principle for DSD is to provide ART in a way that acknowledges specific barriers to access to ART identified by clients and empower them to manage their disease with support from the existing health system. Differentiated care and treatment will involve modifications of existing patient flow, appointment schedules and location of services with the aim of improving access, coverage, and quality of HIV services.

8.1.1 DSD Approach to PLHIV Newly Diagnosed with HIV

All patients enrolling into HIV care should have a complete medical history taken, a thorough physical examination and appropriate laboratory investigations. Findings from this initial evaluation should be documented legibly in a retrievable health record management format (electronic or paper-based) to facilitate long-term follow-up of the patient. Additional history should be obtained, and physical examination performed when clinically indicated.

Following the initial patient evaluation, patients should be categorized into those who are **well** and those who present with **advanced disease**. Patients who present well are those with a WHO stage I or II, and CD4 > 200 cells/mm3 whereas those with advanced HIV disease are those patients with a WHO stage III or IV, or CD4 ≤ 200 cells/mm3 and all children ≤ 5 years of age. Patients who present with advanced disease may require a different level of care than those who present while still clinically well.

The DSD framework for clients who are **well** at diagnosis of HIV and those who present with **advanced disease** is outlined in the subsequent Table 42 and Table 43.

PLHIV Presenting Well

Table 41: Differentiated Service Delivery Approach to PLHIV

Patients who Present Well: WHO Stage 1 or 2, and CD4 count > 200 cell/mm^3	
Package of Care	Standard Package of Care that includes same-day or rapid ART initiation
Service Location	Management at any ART service delivery point and at all facility levels
Service Intensity	Immediate ART initiation to maintain good health and active life, decrease the risk of developing opportunistic infections as well as reduce the risk of transmitting HIV to others
Service Frequency	• Weekly follow-up until ART initiation • After ART initiation, follow-up visit at week 2 and week 4 and then monthly thereafter until viral suppression is confirmed • Additional visits can be scheduled as required to address any medical or psychosocial concerns
Service Provider	Initial management and ART initiation to be conducted by a trained and experienced HCW

PLHIV with Advanced HIV Disease

Table 42: Differentiated Service Delivery Approach to PLHIV with advance HIV disease

Patients who Present with Advanced HIV Disease: WHO Stage 3 or 4, or CD4 count ≤ 200 cell/mm3 and all children ≤ 5 years of age	
Package of Care	• Standard Package of Care • Priority for identification, management and prevention of OIs and management of malnutrition • Priority for ART initiation with caution if there is suspected or confirmed TB, TB meningitis, or cryptococcal meningitis • Close monitoring for development of immune reconstitution inflammatory syndrome
Service Location	Management at any ART service delivery point; all facility levels; home visits may be required if unable to come to facility
Service Intensity	Immediate ART initiation, unless contra-indicated, to maintain good health and active life, decrease the risk of developing opportunistic infections as well as reduce the risk of transmitting HIV to others
Service Frequency	• Weekly follow-up until ART initiation • After ART initiation, follow-up visit at week 2 and week 4 and then monthly until viral suppression is confirmed • More frequent visits or hospitalization may be required to stabilize acute medical conditions and address psychosocial and other concerns
Service Provider	• Initial management and ART initiation to be conducted by a trained and experienced HCW • Case consultation with the multi-disciplinary teams, mentors, and senior clinicians as needed • Referral to a higher-level facility when feasible if consultation is not adequate to stabilize the patient

8.1.1.2 Follow-up of newly diagnosed PLHIV during the initial 12 months on ART

In order to initiate all PLHIV on ART within the shortest time possible, newly enrolled patients should be seen in clinic every week until ART is initiated.

The follow-up of patients on ART includes scheduled clinical appointments, unscheduled clinical assessments for patients with concerns/complaints, and routine and as-needed laboratory monitoring. After ART initiation, patients need close monitoring to assess for development of adverse events, identify and address barriers to adherence, and assess for development of IRIS (particularly for those who initiate ART with advanced HIV disease).

A reasonable follow-up schedule for most patients is: 2 weeks and 4 weeks after ART initiation, then monthly until viral suppression is confirmed—[Refer to the section on routine viral load monitoring]. Clinical follow-up can be spaced further apart once the patient has been on ART for a year or more and meets the criteria as "stable" or "unstable".

8.1.2 DSD Approach to PLHIV on ART for at least 12 months

After the first year of ART, most patients will have developed good adherence habits, have adequate coping mechanisms and support systems in place, and will have achieved virologic suppression. With their improved self-care, these "stable patients" require less intensive facility follow-up and monitoring, with up to three months between clinic appointments, allowing facility resources to be focused on patients who have not achieved these milestones. Less intensive follow-up for stable patients may also decongest health facilities, reduce patient costs and inconvenience, and improve quality of care by allowing more time for sick and/or unstable patients.

Unstable patients require more intensive follow-up to address the issues that are leading them to be categorized as unstable.

8.1.2.1Stable PLHIV

Table 43: Differentiated Service Delivery Approach to Stable PLHIV

Stable Patient: **A patient is considered stable if they meet all the following criteria:** • **On their current ART regimen for ≥ 12 Months** • **No active OIs (including TB) in the previous 6 months** • **Adherent for the previous 6 months** • **Most recent VL < 1,000 copies/ml** • **BMI ≥ 18.5** • **Age ≥ 20 years** • **Healthcare team does not have concerns about providing longer follow-up intervals for the patient**	
Package of Care	• Standard Package of Care • Viral load monitoring (and any other routine investigations) timed to coincide with patient appointments (e.g. the annual VL can be drawn 2-4

	weeks before the patient's clinical follow-up visit so that the results are ready for discussion and decision-making during the visit) • Re-assessment of criteria as a stable patient at every visit (and move to "unstable" category if any criterion is not met)
Service Location	• Clinical review and ART from any ART service delivery point using either facility-based or community-based models • Multi-month dispensing of ART up to 3 months to cover the period between clinical appointments preferred
Service Intensity	Adherence to ART to maintain good health and active life, decrease the risk of developing opportunistic infections as well as reduce the risk of transmitting HIV to others
Service Frequency	• Maximum of 3-month intervals between clinical reviews • ART can be distributed through multi-month dispensing method for up to 3 months through facility or community ART distribution models • Patients on injectable contraception should be provided with FP through a fast-track process between clinical follow-up visits, while those on oral contraceptives and condoms should receive their choice of family planning method through their ART distribution model together with their ART • Additional visits as required to address any medical or psychosocial concerns • Closer follow-up can be considered based on patient preference
Service Provider	Clinical review to be conducted by a trained and experienced HCW at 3-month intervals

ART should only be dispensed for up to 3 months at a time, to control for national and facility supply chains, safe drug storage and conditions that may reduce the expiration period. During the three-monthly clinical assessments ART, CPT and condoms and any other medications, such as oral contraceptive pills should be dispensed for 3 months.

The health facility is responsible for ART prescription, dispensing, and distribution for all patients enrolled in care. ART distribution for stable patients can take place at the health facility or through a community distribution system, depending on patient preference and health facility systems and resources.

Dispensing of ART through community models must be dispensed pre-packed for individual patients by a healthcare professional, and documented in the pre-requisite pharmacy dispensing tool, accompanied by the completion of the community ART distribution documentation with this information being submitted to the health facility on a regular basis.

8.1.2.2 Unstable PLHIV

Differentiated Service Delivery Approach to Unstable PLHIV

Table 44: Differentiated Service Delivery Approach to unstable PLHIV

Unstable Patient: **A patient is considered unstable if they have any of the following:** • **On their current ART regimen for < 12 months** • **Any active OIs (including TB) in the previous 6 months** • **Poor or questionable adherence in the previous 6 months** • **Most recent VL > 1,000 copies/ml** • **Pregnant or breastfeeding** • **BMI < 18.5** • **Age < 20 years** • **Healthcare team has concerns about providing longer follow-up intervals for the patient**	
Package of Care *	• Standard Package of Care • Case management to address reason/s for not meeting stable eligibility criteria
Service Location	Management at any ART service delivery point and all facility levels
Service Intensity	• ART is the most important treatment to improve health and return to an active life • Targeted counselling to address reason/s they have not met stable eligibility criteria
Service Frequency	• Every 1-3 months, based on clinical judgment and the specific reason/s they have not met stable eligibility criteria • Additional visits as required to address any medical or psychosocial concerns
Service Provider	• Case consultation with the multi-disciplinary teams, mentors, and senior clinicians as needed • Referral to a higher-level facility if consultation is not adequate to stabilize the patient

8.1.3 DSD Approach for special populations

This section outlines the recommendations for DSD for children, adolescents, pregnant and breastfeeding women, men and the working class / VIP clients.

Children, adolescents and pregnant and breastfeeding women should not be excluded from DSD but should be closely evaluated to ascertain clients who qualify for less intensive follow-up against those who may benefit from closer follow-up.

Men form a unique group of clients who are likely to benefit from targeted and structured approaches that are considered acceptable to men within the context that they live in. likewise, there is an emerging group of working-class clients who will be better served through client-centric approaches that cater to their busy schedule.

8.1.4 Child and Family Centered approach to DSD

Caregivers and parents of children living with HIV (CLHIV) who are enrolled may be stable clients and their children who also meet the “stable” patient criteria (other than the age criteria) outlined in Table 46 can be considered eligible for less intensive models of DSD.

This should follow a family-centred approach in which the family is given synchronized clinical appointments with multi-month dispensing of up to 3 months.

A case-management approach should be used for children and their caregivers and parents and appointment spacing must be determined based on the specific needs and situation of the child. Anticipated weight-based dose adjustments, viremia, ARV optimization plans and any concern on the well-being of the child should prompt the HCW to allow for shorter clinical appointments.

Children require close monitoring of growth and developmental milestones, and weight-based dose adjustments of their ART and CPT (although this becomes less frequent beyond the second year of age. If a child is enrolled into a stable family care model with less frequent appointments accompanied by multi-month dispensing of ARV, weight monitoring and dose adjustments should be incorporated in both the facility and community models (e.g. by using portable weighing scales).

Table 45: Child and Family-Centered DSD Approach

Caregiver and Child who are virally suppressed	
Package of Care	Standard Package of Care with synchronized clinical appointments
Service Location	Management at any ART service delivery point and all facility levels
Service Intensity	• ART as the most important treatment to improve health • Caregiver training and support
Service Frequency	• Reduced frequency of clinic visits to every 3 months while providing multi-month prescribing and dispensing up to 3 months • Additional visits as required to address any medical or psychosocial concerns
Service Provider	• Clinical review to be conducted by a trained and experienced HCW at 3-month intervals • Case consultation with the multi-disciplinary teams, mentors, and senior clinicians as needed
Caregiver virally suppressed and Child NOT virally suppressed	
Package of Care	• Standard Package of Care with synchronized clinical appointments • Case management to address reason/s for child instability
Service Location	Management at any ART service delivery point and all facility levels
Service Intensity	• ART as the most important treatment to improve health and return to an active life • Targeted counselling to address reason/s stable criteria is not met • Caregiver training and support • Review for possible treatment failure and if confirmed, effect regimen switch to the next level of ARV

Service Frequency	• Frequent clinic visits at least monthly based on clinical judgment and the specific reason/s they have not met stable eligibility criteria • Additional visits as required to address any medical or psychosocial concerns
Service Provider	• Clinical review to be conducted by a trained and experienced HCW • Case consultation with the multi-disciplinary teams, mentors, and senior clinicians as needed • Referral to a higher-level facility if consultation is not adequate to stabilize the child
Caregiver NOT virally suppressed, and Child virally suppressed	
Package of Care	• Standard Package of Care with synchronized clinical appointments • Case management to address reason/s for caregiver instability
Service Location	Management at any ART service delivery point and all facility levels
Service Intensity	• ART as the most important treatment to improve health and return to an active life • Targeted counselling to address reason/s stable criteria is not met • Caregiver training and support • Family psychosocial support • Social worker evaluation through home visits • Daily observed treatment • Review for possible treatment failure and if confirmed, effect regimen switch to the next level of ARV
Service Frequency	• Increase frequency of visits to at least monthly • Additional visits as required to address any medical or psychosocial concerns
Service Provider	• Clinical review to be conducted by a trained and experienced HCW • Case consultation with the multi-disciplinary teams, mentors, and senior clinicians as needed • Referral to a higher-level facility if consultation is not adequate to stabilize the caregiver
Caregiver and child and NOT virally suppressed	
Package of Care	• Standard Package of Care with synchronized clinical appointments • Case management to address reason/s for caregiver and child instability
Service Location	Management at any ART service delivery point and all facility levels
Service Intensity	• ART as the most important treatment to improve health and return to an active life • Targeted counselling to address reason/s stable criteria is not met • Caregiver training and support • Family psychosocial support • Social worker evaluation through home visits • Daily observed treatment • Review for possible treatment failure and if confirmed, effect regimen switch to the next level of ARV
Service	• Increase frequency of visits to at least monthly

Frequency	• Additional visits as required to address any medical or psychosocial concerns
Service Provider	• Clinical review to be conducted by a trained and experienced HCW • Case consultation with the multi-disciplinary teams, mentors, and senior clinicians as needed • Referral to a higher-level facility if consultation is not adequate to stabilize the caregiver and child

8.1.5 Adolescents

Adolescents have unique challenges with adherence related to their psychological development and social support systems. In addition, adolescents may need their clinical reviews and ART refills harmonized with school holidays.

Adolescents who meet the stable patient criteria in Table 44 will need less frequent appointments. In addition, psychosocial support and ongoing adherence assessments and counselling should be aligned with clinic visits and community follow-up.

8.1.6 Pregnant and Breastfeeding Women

Pregnant and breastfeeding women may be clinically stable as outlined in Table 44 nonetheless it is recommended that their HIV clinic appointments should be integrated with their focused antenatal care visits that is integrated with the follow-up of the HIV-exposed infant (HEI).

8.1.7 Men

Given the lower viral load suppression among men, compared to women, the establishment of structured male adherence clubs is recommended. These clubs should be self-forming and led by male peers in order to empower the men in these clubs to adhere to treatment and to manage their health with a goal of attaining and sustaining viral suppression.

Additional services strengthened within these clubs include HIV testing for spouse and children, up to date viral load testing, reduction of stigma and discrimination, adherence to ART and clinical appointments as well as household economic strengthening and Income generation.

8.1.7 VIP/ Working Class Clients

Stable PLHIV (see Table 44) with busy working schedules will be eligible for a VIP ART distribution model.

Table 46: DSD Approach to stable VIP/Working class PLHIV

Stable Patient: **A patient is considered stable if they meet all the following criteria:** • **On their current ART regimen for ≥ 12 Months** • **No active OIs (including TB) in the previous 6 months** • **Adherent for the previous 6 months** • **Most recent VL < 1,000 copies/ml** • **BMI ≥ 18.5** • **Age ≥ 20 years** • **Healthcare team does not have concerns about providing longer follow-up intervals for the patient**	
Package of Care	• Standard Package of Care • Viral load monitoring (and any other routine investigations) timed to coincide with patient appointments (e.g. the annual VL can be drawn 2-4 weeks before the patient's clinical follow-up visit so that the results are ready for discussion and decision-making during the visit) • Re-assessment of criteria as a stable patient at every visit (and move to the "unstable" category if any criterion is not met)
Service Location	• Clinical review and ART delivery to preferred ART service delivery point • Multi-month dispensing of ART up to 3 months to cover the period between clinical appointments preferred
Service Intensity	Adherence to ART to maintain good health and active life, decrease the risk of developing opportunistic infections as well as reduce the risk of transmitting HIV to others
Service Frequency	• Maximum of 3-month intervals between clinical reviews • ART can be distributed through multi-month dispensing method for up to 3 months through preferred ART service delivery model • Patients on injectable contraception should be provided with FP through a fast-track process between clinical follow-up visits, while those on oral contraceptives and condoms should receive their choice of family planning method through their ART distribution model together with their ART • Facility visits as required to address any medical or psychosocial concerns
Service Provider	Clinical review to be conducted by a trained and experienced HCW or lay health worker at 3-month intervals

9. INTEGRATING CONTINUOUS QUALITY IMPROVEMENT (CQI)

Introduction

Continuous quality improvement (CQI) is recommended as a means to ensure the provision of high-quality health services and attainment of the 90-90-90 HIV target. CQI is an approach to improvement of service systems and processes through the routine use of health and program data to meet patient, and program needs. The basis of CQI is a continuous measurement of the actual performance against the desired outcome as per set national standards. The National AIDS Control Programme will adopt methodologies to implement quality improvement.

9.1 Steps use in addressing HIV service deliveries

CQI embraces five principles of client focus, teamwork, review of processes and systems, use of data to make decisions and effective communication. Below is a description of the steps involved in using CQI to address HIV service delivery gaps.

Table 47: CQI Steps to improve HIV service delivery gap

Step	Description
1. Establish the health facility QI team	▪ The team should have a leader. ▪ They will supervise the HIV work improvement teams (WIT) for different care processes.
2. Set up HIV work improvement teams (WIT)	▪ WIT should be set up for the different care processes along the HIV continuum of care. ▪ They will dedicate time to understanding their current process for providing HIV care services, identify gaps and bottlenecks. ▪ They will implement the CQI approach by applying the principles of an interactive cycle of improvement (Plan, Do, Study, Act (PDSA) Cycle).
3. Identify gaps	▪ WIT should regularly review performance HIV QI indicators ▪ Analyse the data and identify performance gaps by comparing performance Vs set targets
4. Prioritizing improvement gaps	▪ Use a prioritization matrix to list and score the gaps using set criteria. ▪ Based on the ranking the WIT should select the gaps to address in a specified time
5. Developing improvement projects using the documentation journal	▪ WIT will develop improvement aims from the prioritized gaps. ▪ Listing all the activities in a particular process targeted for improvement. ▪ Use the activities to develop a flow chart for the process. ▪ Use the flow chart to identify the individuals who perform the different activities and include them in the WIT for the process. ▪ Develop an improvement objective from the prioritized performance gap with the aid of the HIV QI indicator manual. ▪ Using QI tools such as brainstorming, flowcharting, five whys, or cause and effect analysis or driver diagrams, the team should identify the root causes of the performance gaps.

	▪ Brainstorming possible changes that the team will test to address the identified root causes using a PDSA cycle. ▪ Documenting the data from the data review process in the graph template of the DJ. ▪ Developing an action plan indicating the changes that the team as agreed to test or redesigning the service delivery model.

10. PROCUREMENT AND SUPPLY CHAIN MANAGEMENT SYSTEM

Introduction

This section describes the supply chain management components that support the scale-up of HIV prevention, care and treatment services for the attainment of the 90-90-90 goal in Sierra Leone.

10.1 Selection of HIV Products at Facilities

ART health facility staffs are expected to select antiretroviral drugs and related commodities for both existing and new patients in line with these treatment guidelines.

- Only health facilities designated as ART or PMTCT sites should request for antiretroviral and other HIV-related commodities, which include; (ARVs, medicines for opportunistic infections, Isoniazid, HIV test kits, condoms, and other laboratory diagnostics).

10.2 Product Quantification/Ordering and Reporting

Health facilities staff are required to complete the RR&IV form at the end of every month and submit to the District Pharmacist. The RR&IV document contains a report section on commodities and request section for HIV commodities required. The completion of both sections is mandatory.

10.3 Ordering of HIV commodities

- Reporting and ordering of medicines at health facilities is a multi-disciplinary task that should involve facility In-Charges, Pharmacists, clinicians, Laboratory Officer, M&E officer, and store managers.
- Ordering process should be coordinated and led by a pharmacist or a person designated to manage supplies of medicines in the health facility.
- Health facilities are to use the RR&IV for reporting and requesting ARVs and HIV related commodities.

10.4 Source of ARVs

ARVs should be accessed and obtained from the National warehouse, district hospital pharmacies, district medicals stores, and ART accredited health facility.

10.5 Preparing the RR&IV

Health facilities should use the following information to complete the RR&IV:

- Consumption data obtained from the daily dispensing register.
- Stock on hand of commodities from a recently conducted physical count.
- Information on commodities about to expire

- Any additional information can be included as a comment in the RRIV

Please refer to the Job Aid for Completing the RRIV

Submitting the RR&IV

- MCHPs, CHPs and CHCs should submit the paper-based RR&IV to the District Pharmacist in their respective districts by the 5th day of every month.
- Hospitals should report electronically through the RR&IV in the DHIS2/Sierra Leone Pharmaceutical dashboard by the 5th day of every month

10.6 Rational Use of Medicines

This is to ensure 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.

Principles

The following principles should be followed in prescribing medications:

- Prescription of medications must follow the national guidelines.
- .
- Counsel the patients on how to take the medicines.
- Counsel patient whenever substituting or switching treatment regimens.
-
- Offer further explanation/counselling to patients on multiple medicines because of other co-morbidities. Information on possible drug interactions and adverse effects should be included.

10.7 Guidance for Stock management at Health facilities

- Medicines and medical supplies should be received at the facility store according to the Standard Operating procedure of the MoHS.
- The person receiving the supplies should update the facility Inventory Control cards, and store them under recommended storage conditions.
- Inventory Control cards should be updated whenever stock is issued from the health facility store.
- Monthly physical counts should be done.
- Expired and damaged commodities should be removed from the current stock and reported for appropriate disposal.

10.8 Commodities distribution in Sierra Leone

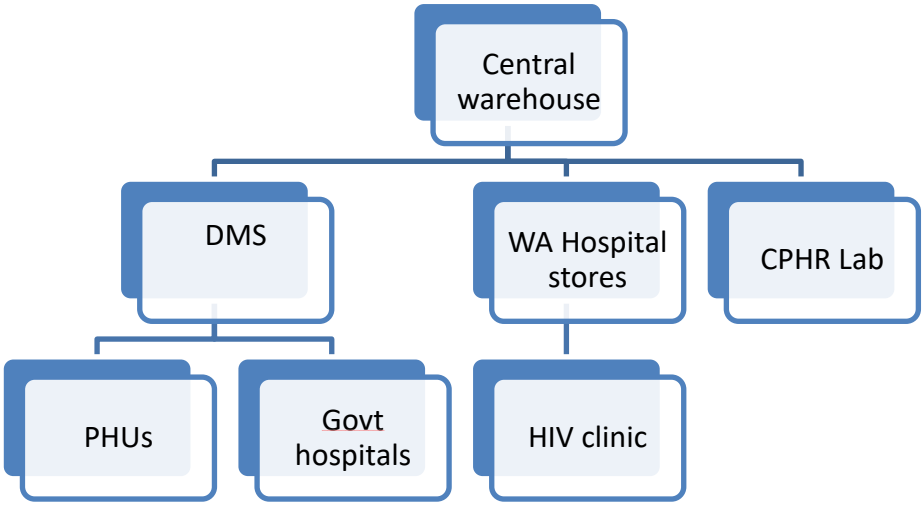


Figure 8: Commodity Distribution in Sierra Leone

10.9 Pharmacovigilance

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (WHO definition)

Reactions to ARVs are common, and many patients are taking multiple medicines at once.

- It is important for patients to report any adverse drug effects on the health care worker. Side effects are difficult to predict in individual patients; a good history taking is important.
- Side effects may be a major reason for poor compliance to prescribed regimens and a major cause for treatment failure.

Existing Notification System:

- The Pharmacy Board of Sierra Leone hosts the National Pharmacovigilance centre which is responsible for providing technical expertise on medicines and vaccines safety issues in Sierra Leone
- All serious suspected and serious unexpected adverse drug reactions should be reported within 7 calendar days to the PBSL; all other adverse drug reactions should be reported to the PBSL within 28 calendar days.
- Reporting forms are available in all healthcare facilities and can be submitted through the PBSL regional offices, directly to the headquarter office or submitted online through the website www.pharmacyboard.gov.sl

Adverse reaction report/notification

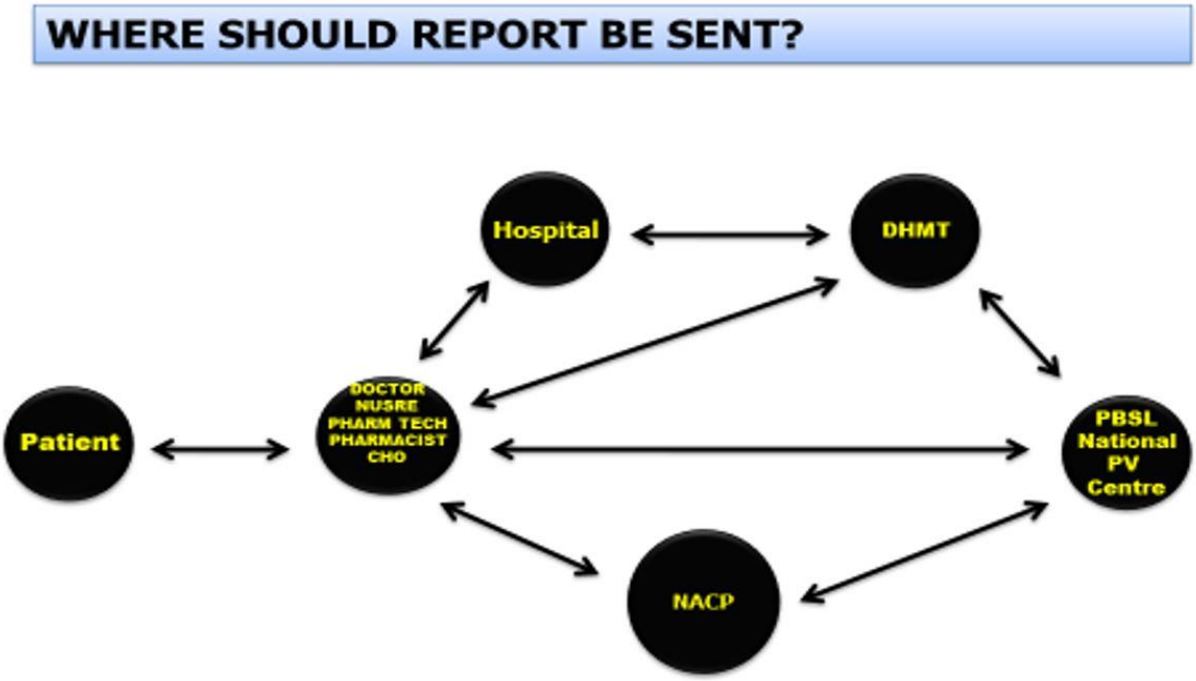


Figure 9: Adverse Reaction Report/Notification

11 MONITORING AND EVALUATION

Introduction

A robust and functional monitoring and evaluation (M&E) system is essential for effective and efficient HIV prevention and treatment using ART.

This section provides guidance on how to monitor the implementation of the revised guidelines, program performance and to provide a framework for assessing the impact of the guidelines. It is aligned with the guidance contained in the National HIV/AIDS Strategic Plan and National HIV/AIDS Monitoring and Evaluation Plan 2016 - 2020.

11.1 Overview of Clients Monitoring System

Currently, ART Client monitoring is paper-based at health facilities. However, NACP/MoHS, NAS and partners have adopted an electronic client monitoring system (Patient Tracker) in the DHIS2. A unique identifier will be assigned to each client to facilitate linking and tracking patients across different facilities, service areas, and databases. The system has been piloted at a high client volume facility and will be rolled out gradually.

The Monitoring and Evaluation system will include:

- Clearly defined indicators.
- Standard reporting tools.
- Data sources and collection methods.
- Clear guidelines, protocols and standard operating procedures.

11.2 Monitoring and Evaluation Tools

Healthcare workers providing ART services will use the following standard tools for the recording of services:

- HIV Testing Registers
- Linkage Register
- ART Registers
- Viral load Registers
- EID register
- Monthly summary forms
- Patient's HIV care/ART card
- Patient's Appointment card
- Patient's referral forms.

11.3 Data Collection

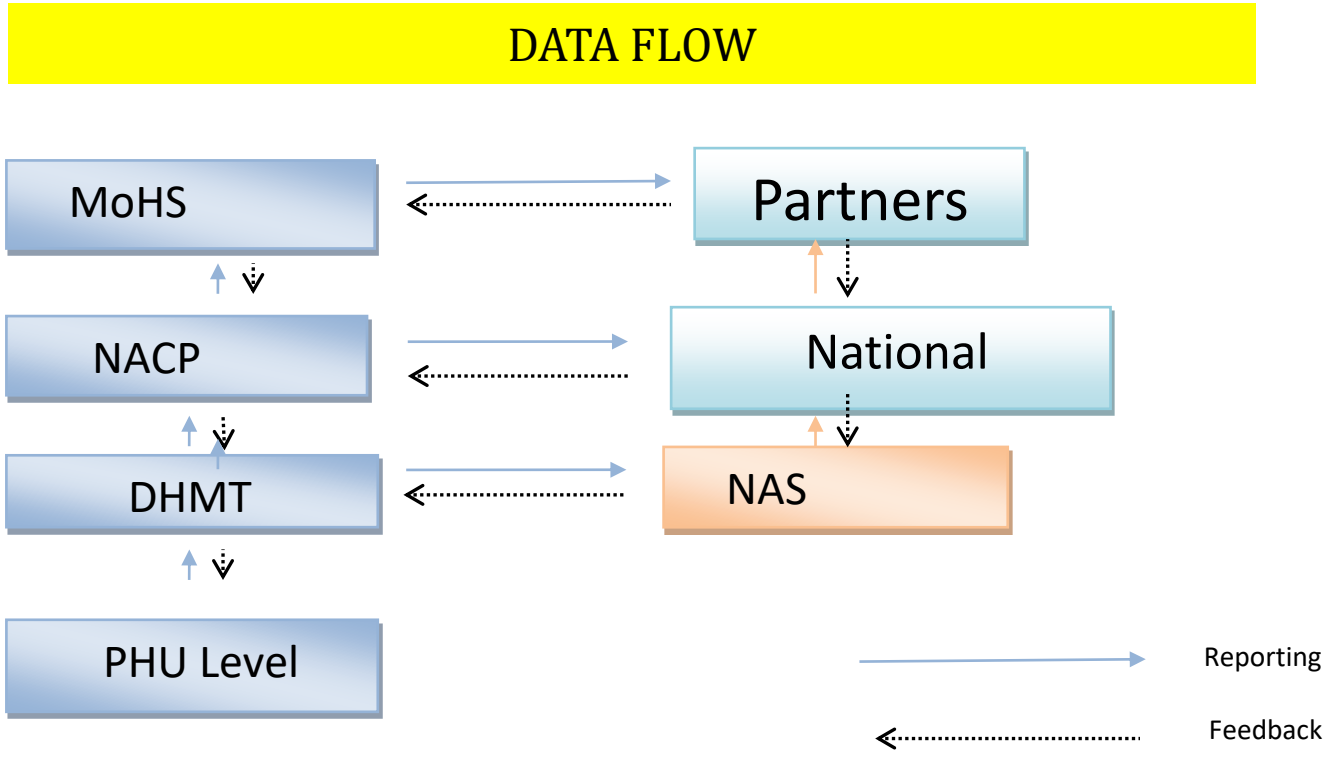
Data should be collected on the following information areas:

- Number of patients including age, sex and different population (such as adults, adolescents, children, pregnant and breastfeeding women and key populations) accessing HIV services.
- The indicators for the different thematic areas (HTS, PMTCT, EID, ART, VL and PSM) will be collected in line with the national M&E.

Monthly summary reports for Programme management and reporting

District HIV Focal Persons in collaboration with District Monitoring and Evaluation Officers should collate and compute HIV data as part of the overall district health information system. The data collected should be reviewed by the District Health Management Team (DHMT) before entering into the national Health Management Information System (HMIS). At the District level, the information should be used to identify bottlenecks and find solutions.
It is also important to provide feedback to PHU staff on a regular basis.

11.4 Data Flow



Health facilities should submit timely, aggregated client data on a monthly basis. The monthly reports shall be entered into DHIS-2.

11.5 Other Data Source

The following sources complement the data generated from the HMIS:

- Surveillance data from the AIDS Indicator Survey, HIV/AIDS Sero-behavioural Survey, ANC sentinel surveillance, HIV case-based surveillance.
- Longitudinal and evaluation studies.
- HIV estimates from modelling.

11.6 Indicators for Routine Monitoring

Routine monitoring indicators are based on the National HIV and AIDS Monitoring and Evaluation Plan, 2016 – 2020.

11.7 New Considerations for Routine Monitoring

Indicators from programmatic areas identified in the revised guidelines should be incorporated into the M&E framework and monitoring and reporting tools.

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

11.8 HIV Drug Resistance Monitoring

Early warning indicators on HIV drug resistance should be integrated into the routine data collection and monthly reporting for program monitoring in the near feature.

11.9 Routine Data Quality Auditing and Supportive Supervision

In order to ensure adherence to standards and data quality, routine supportive supervision and routine data quality assessments (RDQAs) should be conducted on a monthly basis.

11.10 Data Use

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

11.11 Research and Evaluation

NAS, NACP and Partners will continue to conduct the undermentioned research studies to inform the disease burden and evaluate the impact of programs:

- HIV Seroprevalence Survey
- AIDS Indicator Survey and HIV/AIDS Sero-behavioural Survey
- ANC sentinel surveillance
- HIV case-based surveillance
- Modes of transmission study
- Research on treatment failures.
- Assessment of drug stock-outs in a given period.
- Survival – This is to understand the impact of ART through increased survival and extended life-years of people living with HIV receiving ART.
- Retention – To monitor the number of people who are initiated on ART and continue for a given period of time.

Programs and academia should conduct operational and scientific research in the area of differentiated service delivery and other relevant areas. The research should be conducted in line with the National HIV and AIDS Monitoring and Evaluation Plan with the full involvement of the NACP and NAS.

ANNEX 1 Patient Health Questionnaire (PHQ)

PATIENT HEALTH QUESTIONNAIRE-2 (PHQ-2) Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute				
Over the last two weeks, how often have you been bothered by any of the following problems? (Use "X" to indicate your answer)				
	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9) Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.				
Over the last two weeks, how often have you been bothered by any of the following problems? (Use "X" to indicate your answer)				
Question	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3
Trouble falling or staying asleep, or sleeping too much	0	1	2	3
Feeling tired or having little energy	0	1	2	3
Poor appetite or overeating	0	1	2	3
Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
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				
(Grand Total) Add totals together =				

10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult ☐

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

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

TABLE 1 The HEEADSSS psychosocial interview for adolescents

	Potential first-line questions	*Questions if time permits or if situation warrants exploration*
Home	Who lives with you? Where do you live? What are relationships like at home? Can you talk to anyone at home about stress? (Who?) Is there anyone new at home? Has someone left recently? Do you have a smart phone or computer at home? In your room? What do you use it for? (May ask this in the activities section.)	Have you moved recently? Have you ever had to live away from home? (Why?) Have you ever run away? (Why?) Is there any physical violence at home?
Education and employment	Tell me about school. Is your school a safe place? (Why?) Have you been bullied at school? Do you feel connected to your school? Do you feel as if you belong? Are there adults at school you feel you could talk to about something important? (Who?) Do you have any failing grades? Any recent changes? What are your future education/employment plans/goals? Are you working? Where? How much?	How many days have you missed from school this month/quarter/semester? Have you changed schools in the past few years? Tell me about your friends at school. Have you ever had to repeat a class/grade? Have you ever been suspended? Expelled? Have you ever considered dropping out? How well do you get along with the people at school? Work? Have your responsibilities at work increased? What are your favorite subjects at school? Your least favorite subjects?
Eating	Does your weight or body shape cause you any stress? If so, tell me about it. Have there been any recent changes in your weight? Have you dieted in the last year? How? How often?	What do you like and not like about your body? Have you done anything else to try to manage your weight? Tell me about your exercise routine. What do you think would be a healthy diet? How does that compare to your current eating patterns? What would it be like if you gained (lost) 10 lb? Does it ever seem as though your eating is out of control? Have you ever taken diet pills?
Activities	What do you do for fun? How do you spend time with friends? Family? (With whom, where, when?) Some teenagers tell me that they spend much of their free time online. What types of things do you use the Internet for? How many hours do you spend on any given day in front of a screen, such as a computer, TV, or phone? Do you wish you spent less time on these things?	Do you participate in any sports? Do you regularly attend religious or spiritual activities? Have you messaged photos or texts that you have later regretted? Can you think of a friend who was harmed by spending time online? How often do you view pornography (or nude images or videos) online? What types of books do you read for fun? How do you feel after playing video games? What music do you like to listen to?
Drugs	Do any of your friends or family members use tobacco? Alcohol? Other drugs? Do you use tobacco or electronic cigarettes? Alcohol? Other drugs, energy drinks, steroids, or medications not prescribed to you?	Is there any history of alcohol or drug problems in your family? Does anyone at home use tobacco? Do you ever drink or use drugs when you're alone? (Assess frequency, intensity, patterns of use or abuse, and how patient obtains or pays for drugs, alcohol, or tobacco.) (Ask the CRAFFT questions in Table 5, page 25.)

	Potential first-line questions	Questions if time permits or if situation warrants exploration
Sexuality	Have you ever been in a romantic relationship? Tell me about the people that you've dated. Have any of your relationships ever been sexual relationships (such as involving kissing or touching)? Are you attracted to anyone now? OR: Tell me about your sexual life. Are you interested in boys? Girls? Both? Not yet sure?	Are your sexual activities enjoyable? Have any of your relationships been violent? What does the term "safer sex" mean to you? Have you ever sent unclothed pictures of yourself on e-mail or the Internet? Have you ever been forced or pressured into doing something sexual that you didn't want to do? Have you ever been touched sexually in a way that you didn't want? Have you ever been raped, on a date or any other time? How many sexual partners have you had altogether? (Girls) Have you ever been pregnant or worried that you may be pregnant? (Boys) Have you ever gotten someone pregnant or worried that might have happened? What are you using for birth control? Are you satisfied with your method? Do you use condoms every time you have intercourse? What gets in the way? Have you ever had a sexually transmitted infection or worried that you had an infection?
Suicide/ depression	Do you feel "stressed" or anxious more than usual (or more than you prefer to feel)? Do you feel sad or down more than usual? Are you "bored" much of the time? Are you having trouble getting to sleep? Have you thought a lot about hurting yourself or someone else? Tell me about a time when someone picked on you or made you feel uncomfortable online. (Consider the PHQ-2 screening tool [Table 6, page 26] to supplement.)	Tell me about a time when you felt sad while using social media sites like Facebook. Does it seem that you've lost interest in things that you used to really enjoy? Do you find yourself spending less time with friends? Would you rather just be by yourself most of the time? Have you ever tried to kill yourself? Have you ever had to hurt yourself (by cutting yourself, for example) to calm down or feel better? Have you started using alcohol or drugs to help you relax, calm down, or feel better?
Safety	Have you ever been seriously injured? (How?) How about anyone else you know? Do you always wear a seatbelt in the car? Have you ever met in person (or plan to meet) with anyone whom you first encountered online? When was the last time you sent a text message while driving? Tell me about a time when you have ridden with a driver who was drunk or high. When? How often? Is there a lot of violence at your home or school? In your neighborhood? Among your friends?	Do you use safety equipment for sports and/or other physical activities (for example, helmets for biking or skateboarding)? Have you ever been in a car or motorcycle accident? (What happened?) Have you ever been picked on or bullied? Is that still a problem? Have you gotten into physical fights in school or your neighborhood? Are you still getting into fights? Have you ever felt that you had to carry a knife, gun, or other weapon to protect yourself? Do you still feel that way? Have you ever been incarcerated?

Abbreviations: CRAFFT, Car, Relax, Alone, Forget, Friends, Trouble; HEEADSSS, Home, Education and employment, Eating, Activities, Drugs, Sexuality, Suicide/depression, Safety; PHQ-2, Patient Health Questionnaire 2.

Adapted from Goldenring JM, et al[1]; Goldenring JM, et al.[2]

ANNEX 2 WHO staging for children and adults

WHO Clinical Stage 1	WHO Clinical Stage II	WHO Clinical Stage III	WHO Clinical Stage IV
For Adults and Children • Asymptomatic • Persistent generalized lymphadenopathy	For Adults • Moderate unexplained weight loss (under 10% of presumed or measured body weight) • Angular cheilitis For Adults and Children • Papular itchy skin eruptions • Recurrent oral ulcerations (2 or more episodes in 6 months) • Herpes zoster • Recurrent or chronic respiratory tract infections (sinusitis, otorrhea, tonsillitis, otitis media) • Fungal nail infections Additional for Children • Unexplained persistent hepatomegaly & splenomegaly • Extensive wart virus infection • Extensive molluscum contagiosum • Unexplained persistent parotid gland enlargement • Lineal gingival erythema	For Adults • Unintentional weight loss >10% of body weight in absence of other illness For Adults and Children • Oral candidiasis (after first 6 weeks of life) • Oral hairy leukoplakia • Persistent diarrhea (>1 month in adults, > 14 days in children) • Unexplained anemia (<8g/dl), neutropenia ($1000/mm^3$), or thrombocytopenia ($<50,000/mm^3$) • Pulmonary TB • Acute necrotizing ulcerative gingivitis/periodontitis • Unexplained fever (above 37.5°C, intermittent or consistent, for > 4 weeks) Additional for Children • Unexplained moderate malnutrition not adequately responding to standard therapy((For children younger than 5 years, moderate malnutrition is defined as weight-for-height <–2 z-score or mid-upper arm circumference ≥115 mm to <125 mm) • lymph node TB • Severe recurrent bacterial pneumonia • Symptomatic lymphoid interstitial pneumonia • Chronic HIV-associated lung disease	For Adults and Children • HIV wasting syndrome • Pneumocystis pneumonia • Chronic herpes simplex infection (orolabial or cutaneous >1 month, any organ) • Extrapulmonary TB • Kaposi sarcoma • Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ with onset at age > 1 month • Cryptococcus (including meningitis) • Central nervous system toxoplasmosis (after neonatal period) • Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiomycosis) • Cryptosporidiosis with diarrhea > 1month • Isosporiasis with diarrhea > 1 month • Progressive multifocal leukoencephaly • Candidiasis of oesophagus, trachea, bronchus • Atypical mycobacterium (MAC) • Lymphoma • HIV encephalopathy • HIV-associated cardiomyopathy or nephropathy Additional for Children • Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy • Recurrent severe bacterial infections (empyema, sepsis, meningitis, pyomyositis, bone or joint infections) or bacteremia • Extrapulmonary TB, (excluding TB lymphadenopathy)

ANNEX 3 Recommended summary actions for the maintenance of Antiretroviral Therapy

Timeframe	Recommended action
1 month after initiating therapy	Conduct a general examination
	Conduct laboratory monitoring as available
	Monitor drug toxicity
	Reinforce adherence issues
	Reinforce patient's role in decision-making and treatment success
	Switch regimen only if necessary
	Reinforce adherence issues
Every month thereafter	Conduct a general examination
	Conduct laboratory monitoring as needed, including viral load at 6 months after starting treatment
	Monitor drug toxicity
	Switch regimen only if necessary
	Reinforce adherence issues
	Reinforce patient's role in decision-making and treatment success
	If the patient's results remain stable, schedule the next visit every 3 months

ANNEX 4 Nevirapine Dose Adjustment Table

Weight (kg)		AZT/3TC/NVP (Duovir-N)			Additional NVP dose (Form. 10mg/ml)	
From	To	Form. (Tablets)	AM	PM	AM	PM
3	3.9	60/30/50	1	1	No additional NVP	
4	4.9	60/30/50	1	1	No additional NVP	
5	5.9	60/30/50	1	1	½ ml	½ ml
6	6.9	60/30/50	1.5	1.5	No additional NVP	
7	7.9	60/30/50	1.5	1.5	No additional NVP	
8	8.9	60/30/50	1.5	1.5	½ ml	½ ml
9	9.9	60/30/50	1.5	1.5	1 ml	1 ml
10	29.9	Switch to AZT/3TC + EFV			-----	
30	60				-----	

NEVIRAPINE Dose Adjustment Table (when child is also on TB treatment with Rifampicin)

ANNEX 5 Paediatric ART Dosing Table

Table 1. Simplified dosing of child-friendly fixed-dose solid formulations for twice-daily dosing for infants and children 4 weeks of age and older

Drug	Strength of dosage form (mg)	Number of tablets or ml by weight-band morning (AM) and evening (PM)										Strength of adult tablet (mg)	Number of tablets by weight band	
		3.0-5.9 kg		6.0-9.9 kg		10.0-13.9 kg		14.0-19.9 kg		20.0-24.9 kg			25.0-34.9 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
SOLID FORMULATIONS														
AZT/3TC	Tablet (dispersible) 60mg/30mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300mg/150mg	1	1
AZT/3TC/ NVP	Tablet (dispersible) 60mg/30mg /50mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300mg/150mg/ 200mg	1	1
ABC/3TC	Tab (dispersible) 60mg/30mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	600mg/300mg	1	1

For infants younger than 4 weeks of age, see Table 4 for more accurate dosing, which is reduced because of the decreased ability to excrete and metabolize medication. For infants who are at least 4 weeks of age but less than 3 kg, the immaturity of renal and hepatic pathways of elimination is less of a concern, but uncertainty still exists on the appropriate dosing of ARV drugs for preterm and low-birthweight infants.

Table 2. Simplified dosing of child-friendly solid and oral liquid formulations for once-daily dosing for infants and children 4 weeks of age and older

Drug	Strength of dosage form (mg)	Number of tablets or capsules by weight-band once daily					Strength of adult tablet (mg)	Number of tablets or capsules by weight band once daily
		3.0-5.9kg	6.0-9.9kg	10.0-13.9 kg	14.0-19.9kg	20.0-24.9 kg		25.0-34.9kg
EFV	Tablet (scored) 200mg	-	-	1	1.5	1.5	200mg	2
ABC/3TC	Tablet (dispersible) 60mg/30mg	2	3	4	5	6	600mg/300mg	1
ATV	Capsules 100mg	-	-	1	2	2	300mg	2 (100mg) 0r 1 (300 mg)
TDF	Oral powder scoops 40 mg/scoop	-	-	3	-	-	300mg	2 (100mg) 0r 1 (300 mg)
	Tablets 150 mg or 200 mg	-	-	-	1 (150mg)	1 (200mg)		

a. *EFV is not recommended for children younger than 3 years and weighing less than 10 kg.*
b. *ATV is only approved for use for children 3 months and older. ATV single-strength capsules should be administered with RTV 100 mg for all weight bands. The ATV powder formulation enables administration of ATV to infants and children as young as 3 months. Infants and children weighing 5–10 kg should be administered 200 mg of ATV powder (4 packets, 50 mg per packet) with 80 mg of RTV oral solution (5 ml).*
c. *TDF is only approved for use for children 2 years and older. Target dose: 8 mg/kg or 200 mg/m2 (maximum 300 mg).*

Table 3. Simplified dosing of child-friendly solid and oral liquid formulations for twice-daily dosing for infants and children 4 weeks of age and older a

Drug	Strength of dosage form (mg)	Number of tablets or ml by weight-band morning (AM) and evening (PM)										Strength of adult tablet (mg)	Number of tablets by weight band	
		3.0-5.9 kg		6.0-9.9 kg		10.0-13.9 kg		14.0-19.9 kg		20.0-24.9 kg			25.0-34.9 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
SOLID FORMULATIONS														
AZT	Tab (dispersible) 60mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300mg	1	1
ABC	Tab (dispersible) 60mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300mg	1	1
NVP	Tab (dispersible) 50mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	200mg	1	1
LPV/r	Tab 100/25mg	-	-	-	-	2	1	2	2	2	2	100mg/25mg	3	3
	Pellets 40mg/10mg	2	2	3	3	4	4	5	5	6	6	100mg/25mg	3	3
DRV	Tab 75mg	-	-	-	-	3	3	5	5	5	5			
RAL	Chew Tab 25mg	-	-	-	-	3	3	4	4	6	6	400mg	1	1
	Chewable tablets 100 m	-	-	-	-	-	-	1	1	1.5	1.5	400mg	1	1
	Granules (100 mg/sachet	0.25	0.25	0.5	0.5	-	--	-	-	-		-	-	-
LIQUID FORMULATIONS														
AZT	10mg/ml	6 ml	6 ml	9 ml	9 ml	12 ml	12 ml	-	-	-	-	-	-	-
ABC	20mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	-	-	-	-	-	-	-
3TC	10mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	-	-	-	-	-	-	-
NVP	10mg/ml	5 ml	5 ml	8 ml	8 ml	10 ml	10 ml	-	-	-	-	-	-	-
LPV/r	80/20mg/ml	1 ml	1 ml	1.5 ml	1.5 ml	2 ml	2 ml	2.5 ml	2.5 ml	3 ml	3 ml	-	-	-
DRV	100mg/ml	-	-	-	-	2 ml	2 ml	3.5 ml	3.5 ml	-	-l	-	-	-

a. For infants younger than 4 weeks of age, see Table 4 for more accurate dosing, which is reduced because of the decreased ability to excrete and metabolize medication. For infants who are at least 4 weeks of age but less than 3 kg, the immaturity of renal and hepatic pathways of elimination is less of a concern, but uncertainty still exists on the dosing of ARV drugs for preterm and low-birth-weight infants.

b. *NVP dose escalation with half dose for 2 weeks when initiating ART is still recommended to avoid toxicity from high initial NVP levels.*
c. *LPV/r liquid requires a cold chain during transport and storage. The LPV/r heat-stable tablet formulation must be swallowed whole and should not be split, chewed, dissolved or crushed. d The adult, 200/50 ml tablet, could be used for children 14.0–24.9 kg (1 tablet in the morning and 1 tablet in the evening) and for children 25.0–34.9 kg (2 tablets in the morning and 1 tablet in the evening) e The LPV/r pellets formulation should not be used for infants younger than 3 months.*
d. *DRV must be administered with 0.5 ml of RTV 80 mg/mL oral suspension if the child weighs less than 15 kg and with RTV 50 mg solid formulation for children weighing 15–30 kg.*
e. *RAL granules are approved for use for children as young as 4 weeks, but the feasibility and acceptability of such formulations have not been widely investigated, and concerns have been raised regarding administration in resource-limited settings.*

Drug dosing of liquid formulations for twice-daily dosing for infants younger than 4 weeks of age

Drug	Strength of oral liquid (mg/ml)	2-3 kg	3-4 kg	4-5 kg
AZT	10mg/ml	1ml	1.5ml	2ml
NVP	10mg/ml	1.5ml	2ml	3ml
ABC/3TC	10mg/ml	0.5ml	0.8ml	1ml
LPV/r	80mg/20mg/ml	0.6ml	0.8ml	1ml

a. *LPV/r solution should not be given in preterm infants until they have reached 42 weeks of gestational age. This guidance will be updated when more evidence is available from ongoing trials.*
b. *Do not use LPV/r solution for infants <2 weeks of age. LPV/r pellets should not be used for infants younger than 3 months.*

RITONAVIR DOSE TO BE ADDED WHEN CHILD IS ALSO ON TB TREATMENT WITH RIFAMPICN

Weight (kg)		Lopinavir/Ritonavir (Kaletra)			Additional Ritonavir (100mg Tab)	
		Form.	Dose		Dose	
From	To	(ml or tab)	AM	PM	AM	PM
3	3.9	80/20 mg/ml	1 ml	1 ml	½	½
4	9.9	80/20 mg/ml	1.5 ml	1.5 ml	1	1
10	10.9	80/20 mg/ml	2 ml	2 ml	1	1
		100/25 mg tab	2	1	1.5	1
11	13.9	80/20 mg/ml	2 ml	2 ml	1	1
		100/25 mg tab	2	1	1.5	1
14	19.9	80/20 mg/ml	2.5 ml	2.5 ml	1.5	1.5
		100/25 mg tab	2	2	1.5	1.5
		200/50 mg tab	1	1	1.5	1.5
20	24.9	80/20 mg/ml	3 ml	3 ml	1.5	1.5
		100/25 mg tab	2	2	1.5	1.5
		200/50 mg tab	1	1	1.5	1.5
25	29.9	80/20 mg/ml	3.5 ml	3.5 ml	2	2
		100/25 mg tab	3	3	2	2
		200/50 mg tab	2	1	3	1.5
30	34.9	80/20 mg/ml	4 ml	4 ml	2	2
		100/25 mg tab	3	3	2	2
		200/50 mg tab	2	1	3	1.5
35	39.9	80/20 mg/ml	5 ml	5 ml	3	3
		100/25 mg tab	4	4	3	3
		200/50 mg tab	2	2	3	3
40	60	80/20 mg/ml	5 ml	5 ml	3	3
		100/25 mg tab	4	4	3	3
		200/50 mg tab	2	2	3	3

DOSE OF NEVIRAPINE PROPHYLAXIS FOR INFANTS

Infant Age	Infant weight	**NVP ONCE daily dosing** (10 mg/ml)
Birth** to 6 weeks	Low birth weight **<2 kg** and older than 35 weeks gestational age	Use weight-based dosing – **2mg/kg once daily**
	Birth weight **2 kg - 2.4 kg**	**1 ml syrup**
	Birth weight **≥ 2.5 kg**	**1.5 ml syrup**
≥ 6 weeks to 12 weeks		**2 ml syrup**

*Nevirapine prophylaxis should be initiated within **72 hours** after delivery.*

- If it is known that the mother has initiated triple ART greater than 4 weeks before delivery - **6 weeks** of infant prophylaxis with once-daily NVP
- If it is known that the mother has initiated triple ART less than 4 weeks before delivery - **12 weeks** of infant prophylaxis with once-daily NVP