THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY, AND CHILDREN

NATIONAL AIDS CONTROL PROGRAMME

NATIONAL GUIDELINES FOR THE MANAGEMENT OF HIV AND AIDS

7th Edition

APRIL 2019

List of Abbreviations

3TC	Lamivudine
AA	Adherence Assistant
AFB	Acid-Fast Bacilli
AIDS	Acquired Immune Deficiency Syndrome
ALAT	Alanine aminotransferase
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
ATV	Atazanavir
AZT	Zidovudine
BBP	Blood Borne Pathogen
BCG	Bacille Calmette-Guerin
BMI	Body Mass Index
BP	Blood Pressure
CBO	Community Based Organization
CBHS	Community Based HIV Services
CHMT	Council Health Management Team
CHTC	Couples HIV Testing and Counselling
CHW	Community Health Worker
CMV	Cytomegalovirus
CNS	Central Nervous System
CoC	Continuum of Care
CPT	Cotrimoxazole Preventive Therapy
CrAg	Criptococcal Antigen
CrAg LFA	Cryptococcal Antigen Lateral Flow Assay
CSF	Cerebrospinal Fluid
CTC	Care and Treatment Clinic
CTU	Care and Treatment Unit

DACC	District AIDS Control Coordinator
DBS	Dried Blood Spots
DMO	District Medical Officer
DOTS	Directly Observed Therapy, Short course
DRV	Darunavir
DTG	Dolutegravir
ECG	Electrocardiogram
EFV	Efavirenz
EIA	Enzyme Immunoassays
EID	Early Infant Diagnosis
EPI	Expanded Programme of Immunization
EPTB	Extra pulmonary Tuberculosis
ESR	Erythrocytes Sedimentation Rate
ETR	Etravirine
FBO	Faith Based Organization
FBP	Full Blood Picture
FDC	Fixed Dose Combination
FEFO	First to Expire, First Out
FP	Family Planning
GoT	Government of Tanzania
HAART	Highly Active Antiretroviral Therapy
HBA	Home Birth Attendant
HBC	Home Based Care
HBCT	Home Based HIV Counselling and Testing
HCP	Health Care Provider
HF	Health Facility
HIV	Human Immunodeficiency Virus
HIVRNA	Plasma Viral Load
HLD	High-Level Disinfectants
HSV	Herpes Simplex Virus

HTC	HIV Testing and Counselling
HIVST	HIV Self Testing
HVL	HIV Viral Load
IDU	Injection Drug Users
IEC	Information Education and Communication
LAM	Urine TB test called Lipoarabinomannan
ILS	Integrated Logistic System
IMAI	Integrated Management of Adolescence and Adults Illness
IMCI	Integrated Management of Childhood Illnesses
INH	Isoniazid
IPD	In-Patient Department
IPT	Isoniazid Preventive Therapy
IRIS	Immune Reconstitution Inflammatory Syndrome
ITN	Insecticide-Treated Bed nets
KS	Kaposi's Sarcoma
KVP	Key and Vulnerable Population
LFT	Liver Function Test
LIP	Lymphocytic Interstitial Pneumonitis
LPV	Lopinavir
LRTI	Lower Respiratory Tract Infection
M&E	Monitoring and Evaluation
MAC	Mycobacterium Avium Complex
MC	Male Circumcision
MCH	Maternal and Child Health
MDR	Multi Drug Resistant
MOHCDGEC	Ministry of Health, Community Development, Gender, Elderly, and Children
MSD	Medical Stores Department
MSM	Men who have Sex with Men
MTCT	Mother to Child Transmission
MUAC	Mid-Upper Arm Circumference

NACP	National AIDS Control Programme
NFV	Nelfinavir
NGO	Non-Governmental Organization
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
NRTI	Nucleoside Reverse Transcriptase Inhibitors
NSAID	Non Steroidal Anti Inflammatory Drugs
NTLP	National TB and Leprosy Programme
NVP	Nevirapine
OI	Opportunistic Infection
OPD	Out-Patient Department
ORS	Oral Rehydration Salts
OST	Opioid Substitution Therapy
PCP	Pneumocystis Jiroveci Pneumonia
PCR	Polymerase Chain Reaction
PPE	Papular Pruritic Eruption
PPE	Personal Protective Equipments
PEP	Post Exposure Prophylaxis
PrEPPre Exposure prophylaxis	
PGL	Persistent Generalized Lymphadenopathy
PHDP	Positive Health, Dignity and Prevention
PI	Protease Inhibitors
PITC	Provider Initiated Testing and Counselling
PLHIV	People Living with HIV
PMS	Patient Monitoring System
PMTCT	Prevention of Mother to Child Transmission
PPE	Personal Protective Equipment
QI	Quality Improvement
RAL	Raltegravir
RCH	Reproductive and Child Health
RFT	Renal Function Test

RHMT	Regional Health Management Team
RTV	Ritonavir
RUTF	Ready to Use Therapeutic Food
SOP	Standard Operating Procedures
SP	Sulfadoxine Pyrimethamine
STI	Sexually Transmitted Infection
SDM	Service Delivery Models
STGs	Standard Treatment Guidelines
TB	Tuberculosis
TDF	Tenofovir
TFDA	Tanzania Food and Drug Authority
THP	Traditional Health Practitioners
TLC	Total Lymphocyte Count
VCT	Voluntary Counselling and Testing
VIA	Visual Inspection with Acetic Acid
VL	Viral Load
VZV	Varicella Zoster Virus
WBC	White Blood Cells
WHO	World Health Organization

Foreword

In response to HIV epidemic and with the vision to achieve HIV epidemic control by 2030, Tanzania is implementing preventive, care, treatment and support interventions towards achieving the Global targets of 90-90-90 by 2020 and 95-95-95 by 2022 as per the Health Sector HIV/AIDS Strategic Plan IV (2017-2022). According to Tanzania HIV impact survey of 2016/2017, Tanzania has made a good progress towards attaining the 90 90 90 global targets by 2020 where as 60.6% of PLHIV are aware of their HIV-positive status, 93.6% of adults who are aware of their HIV-positive status are on ART and 87.0% of adults who are on ART have suppressed viral loads.

The Ministry of Health Community Development Gender Elderly and Children (MOHCDGEC) through the National NACP in collaboration with the implementing partners, has realized significant achievement as per 2018 progamme Annual report which shows that out of the total 1,500,000 estimated PLHIV; 1,126,366 (75%) were enrolled into HIV and AIDS care and treatment and out of those, 1,103,016 (98%) were currently on ART. Total of 893,559 clients on ART were tested for HIV viral load, amongst them 780,247 (87%) were virally suppressed. Moreover, the number of health facilities offering ART services has been increasing over time from the baseline of 96 in 2005 to 6,206 (2103 CTCs and 4103 Option B+ facilities) as of December 2018.

These recent recommendations, achievements and experiences in the field of HIV and AIDS in the country, have deemed it necessary the revision and updating of the National guidelines for Management of HIV and AIDS. The revision aims to sustain the attained achievements and to fast-track global and National targets.

This National Guidelines for Management of HIV and AIDS 7th Edition 2019 has adopted recommendations from scientific researches, informing polices and the supplements to the 2016 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (i.e., 2017 WHO guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy and 2018 WHO interim guidelines with updated recommendations on first-line and second-line antiretroviral regimens and optimization of pediatric ARVs.).

Since rapid changes will continue to take place in the field of HIV and AIDS, communication of new emerging evidence and science is highly encouraged so as the contributions from users of these guidelines. In turn they will be used to revise, improve and update the guidelines, so as to keep abreast with the scientific and technological changes that have taken place and thus improve the quality of health services provided.

Prof. Muhammad Bakari Kambi
Chief Medical Officer

Acknowledgment

The Ministry appreciates and acknowledges the valuable technical and financial assistance from all the involved stakeholders during the process of revision of the Guidelines. I would like to recognize and congratulate all staff of the National AIDS Control Programme who took on this task with great courage and passion. The strong leadership and guidance of Dr. Angela Ramadhani, the Programme Manager was critical in its success. It is difficult to mention all who played key roles in the revision of the Guidelines, hence I would like to appreciate the excellent coordination and support of Dr. Anath Rwebembera, Prof. Samwel Kalluvya, and the secretariat; Dr. Mohamed Mnyau and Dr. Yona Mwakabumbe who led the process of development of this guideline. Without your commitment and dedication, it would have been very difficult to complete the task on time.

The Ministry commends organizations under the US Government partners and UN family that worked hand in hand with the National AIDS Control Program in the revision of the Guidelines.

The Ministry commends all other institutions and organizations as per list in Annex I that worked hand in hand with National AIDS Control Programme, towards production of this document.

We thank all stakeholders, who have been using the sixth edition and provided suggestions for improvement and thus the development of this new edition.

Dr. Leonard Subi
Director of Preventive Services

EXECUTIVE SUMMARY

The National Guidelines for Management of HIV and AIDS 7th edition, 2019 covers key areas of adult, adolescent, and pediatric HIV and AIDS management; nutrition; mental health; management of opportunistic infections; community-based HIV services and the continuum of care; counselling Care; Counselling for HIV testing; management of advanced HIV disease as well as art adherence and disclosure. Other areas covered include, standard precautions in care settings and laboratory services, pre and post-exposure prophylaxis, and ARV logistics and dosages. There is also an emphasis on differentiated service delivery models (DSDMs) to support PLHIV.

The Guidelines, makes the following new recommendations in managing HIV and AIDS in the country across the HIV and AIDS services cascade;

- **HIV Testing Services (HTS):** Targeted testing complimented with the introduction and use of HTS screening tool to ensure smart testing and favourable yield of HIV positive clients; non-health trained and certified HIV testers (CHW CDOs, SWOs, VHWs, HIV HBC providers) in the community. HTS should be offered by trained and certified personnel at health facilities and community settings. For those who test negative, re-testing is recommended after 4 weeks and, thereafter, routine HIV testing should be offered annually. All HIV-positive should be re-tested using the same testing strategy and algorithm before enrolling into care and initiating ART.
- **Pre Exposure Prophylaxis (PrEP):** will be used by people who are at a substantial risk for HIV acquisition to lower their chances of getting HIV infection. Populations targeted for PrEP include Sex workers, Men who have sex with men, People who inject drugs, Vulnerable adolescent girls (15-19) and Young women (20-24) and Sero-discordant couples. The recommended PrEP regimen in Tanzania is: **Emtricitabine** (FTC) 200 mg**/Tenofovir Disoproxil Fumarate** (TDF) 300 mg **(Truvada)** PO Daily.
- **Post Exposure Prophylaxis** (PEP): The guidelines recommend the use of TLD (TDF+3TC/FTC+DTG) for adults and adolescents for.
- **Differentiated Service Delivery Models (DSDMs):** clients are categories as early presenters or late presenters with or without advanced disease at initiation of ART and stable or unstable after being on ART for six months. The guideline allows classification of clients on second line to be stable provided that they meet other criteria of being a stable client. Clients on TB Preventive Therapy (TPT) will be termed as unstable until completion of the preventive therapy (TPT).
- **ART Initiation:** within 7 days of a positive HIV test, unless there is a medical or psychosocial contraindication. Facility-led community ART initiation for KVP with a 1-month starter pack then to continue to receive care in the facility during the follow up visits.

- **Multi month prescription and dispensing:** Initially stable clients will be offered 6-month prescription with 3monthly dispensing for the first six months. Thereafter, the client who still meets criteria for stable client should be offered 6-month prescription and dispensing. Unstable clients will attend clinics on monthly basis.
- **Screen for serum Cryptococcal antigen:** all ART-naive adults and adolescents with CD4 cell count of <200 cells/mm^3 or WHO stage 3 or 4 if CD4 testing is not available. Pre-emptive therapy with fluconazole if Cryptococcal antigen screening test is positive (bloodstream disease) but no evidence of meningitis. The current guideline does not support the use of fluconazole monotherapy in the management of Cryptococcal Meningitis. Management of drug related toxicities during treatment of Cryptococcal and Cryptococcal IRIS have also been outlined.

- **Tuberculosis preventive therapy (TPT):** using Isoniazid (INH) tablets to eligible individuals in order to prevent progression to active TB disease. Other alternative short regimens recommended to be used when available are Rifapentine+INH (3HP) weekly for 3 months and Rifampicin+INH daily for 3 months.

- **TB diagnosis:** Lipoarabinomannan (LAM) testing is recommended for diagnosis of TB in HIV-positive patients with either a CD4 count of less than 200 cells/uL or who present with danger signs.

- **Dolutegravir (DTG)-based regimen** -TDF + 3TC + DTG (TLD) is recommended as the preferred default first-line regimen for adults living with HIV. TLE will remain as an alternative for clients who will not tolerate and Women at child bearing potential who will not opt to use DTG. A women-centered approach is adopted and women of child bearing potential including those who are using long term effective contraception will be given adequate information to enable them to make informed decision and informed choice consent to using DTG. The guidelines adopted recommendations for optimization of pediatric ARV, introducing the use of LPV/r granules and phasing out of NNRTI based regimes.
- **HVL Testing Algorithm for Adolescents and Adults;** In case the second HVL results after Enhanced Adherence Counselling is ≥1000copies /ml and ≥ 0.5log drop continue with the same regimen and repeat HVL after 3 months. If after the third HVL test HIV viral load is ≥ 1000copies /ml switch to subsequent line. Clients switched to subsequent line will test HVL six month after starting the new regimen and follow again the algorithm form above.

CHAPTER 1

OVERVIEW OF HIV AND AIDS

1.1 State of HIV Epidemic

Approximately 36.9 million people were living with HIV, globally by 2018[1]. In Tanzania by 2017 it was estimated that around 1.4 million people were infected with HIV in the country[2]. Tanzania mainland is experiencing a generalised HIV epidemic, with an HIV prevalence of 4.7% in general population. Heterosexual sex remains the commonest (attributing up to 80%) route for HIV transmission in Tanzania Mainland. HIV prevalence in Tanzania is characterized by significant heterogeneity across age, gender, socioeconomic status, and geographic location; implying differentials in the risk of transmission.

HIV prevalence is higher in sub-groups such as in people who inject drugs (PWID) (16-51%)[3] men who have sex with men (MSM) (22-42%)[4] and mobile populations and sex workers (14-35%)[5]. Women are disproportionally more affected, with an HIV prevalence of 6.3 % versus 3.9% among men. (THMIS 2011-12). The prevalence of HIV among young people aged 15-19 years was 1% (1.3% among girls, and 0.8% among boys). Furthermore, the percentage of women aged 20-24 infected with HIV is higher (4.4%) than that of men (1.7%) in the same age group.[6]

The UNAIDS and international community have set a goal to eliminate new HIV infections by 2030. In order to achieve this goal, an ambitious target of 90-90-90 has been set, that 90% of all people living with HIV (PLHIV) knowing their HIV status (diagnosed), 90% of those diagnosed to have HIV infection to be started on anti-retroviral therapy (ART), and 90% of those on ART achieving sustainable viral suppression by 2020. Attainment of these targets will lead to reduction of new HIV infections by 90% hence providing an opportunity for ending AIDS epidemic by 2030.

The government has strengthened efforts to scale up HIV prevention, care, treatment and support services including the recent adaption of Treat All (test and treat) strategy. These efforts have resulted into a drop of HIV incidence rates from the peak of 1.34% in 1992 to as low as 0.07% among 15-24 year-olds and 0.25% among adults (aged 15-64) in 2017.[2] The country's goal was to reduce the incidence in the general population to less than 0.16% by 2017.

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[1] UNAIDS Global AIDS Report 2018

[2] Tanzania Commission for AIDS (TACAIDS), Zanzibar AIDS Commission (ZAC). Tanzania HIV Impact Survey (THIS) 2016-2017: Final Report. Dar es Salaam, Tanzania. December 2018.

[3] The United Republic of Tanzania, Ministry of Health and Social Welfare; national aids control programme and Muhimbili university of Health and allied sciences, Dar es salaam. Integrated Bio-Behavioural Survey Among People Who Inject Drugs in Dar es Salaam. April 16, 2014

[4] Leshabari et al. A Prevalence of the Human Immunodeficiency Virus, other sexually transmitted infections, and health-related perceptions, reflections, experiences and practices among men having sex with men in Dar es Salaam,2013

[5] National AIDS Control Programme; A study of Female Sex Workers in seven Regions: Dar es Salaam, Iringa, Mbeya, Mwanza, Shinyanga, Tabora and Mara**.** A Report published in 2014 (ISBN 978-9987-650-83-5)

[6] National Bureau of Statistics, ICF International. *Tanzania HIV AND AIDS and Malaria Indicator Survey 2011-12.* Dar es Salaam, March 2013

1.2 Impact of HIV and AIDS

1.2.1 Health Impact

The HIV and AIDS pandemic causes/predisposes people to other infections such as Tuberculosis (TB), NCDs, which are among leading causes of morbidity and mortality among the PLHIV. TB and HIV co-infection has remained at rate of 35-36% for the last three years in 2015, 93% of all people diagnosed with TB infection were also tested for HIV, of whom 35% had co-infection with HIV.

In Tanzania Mainland, where human and financial resources for the health system are constrained, the implementation of additional care and management services for HIV infection has added to the overall health system challenges. Since HIV infection also affects health care personnel, an additional burden to the human resource crisis has been noted.

1.2.2 Economic Impact

There is a close relationship between HIV and AIDS and economic development. AIDS negatively affect economic growth, which makes it difficult for countries and individuals to initiate adequate and comprehensive responses to the epidemic, due to a weak economic base. Poverty is a powerful co-factor in the spread of HIV infection. The economically and socially disadvantaged segments of the population, including women, youth and other marginalized groups, are disproportionately affected by the epidemic. The health status and death due to AIDS are reported to have reduced the work force, productivity and disposable incomes in many communities.

1.2.3 Social Impact

HIV and AIDS related deaths among young and middle aged adults has resulted to thousands orphans. AIDS is widespread in both urban and rural communities and mostly affects persons at the peak of their sexual and productive lives. The death of a young adult often means loss of family's primary income earner. HIV and AIDS epidemic has caused break down of social networks in African societies. Stigma associated with HIV continues to prevail. Orphans are not only subjected to material, social and emotional deprivation, but lack of opportunities for education and health care. Widows and orphans are deprived of their inheritance rights.

Programmes to mitigate the impact of AIDS should include: strong and high-level political leadership, a national strategic plan and adequate funding for HIV and AIDS response; strong and sustained community involvement and initiatives; and supportive policies.

1.3 National Response to HIV Care and Treatment

The National response to HIV and AIDS includes interventions aimed at prevention, Care, Treatment and support. The Government, in collaboration with development and implementing partners, initiated a care and treatment programme under the NACP. The percentage of PLHIV receiving antiretroviral treatment in Tanzania Mainland have increased from 52 % in 2005 to 72% in 2018.

Over 6,000 health facilities are registered to deliver HIV care and treatment services, including provision of ART as of June 2018.[7] The country is implementing initiatives to increase HIV testing services through expansion of Client/Provider Initiated Testing and Counselling (C/PITC) and Community Based Testing and Counselling (CBTC). Moreover, rigorous strategies such as Index testing and self-testing are documented for reaching out the most at risk populations, including but not limited to men and adolescents.

Provision of Long life ART to pregnant and lactating mothers LLAPLA as part of PMTCT programs has contributed to the decrease the transmission of HIV infection from mother to child at six weeks from 8.7% in 2012 to 4.4% in 2015. RCH sites providing PMTCT services had increased to 5,361 out of 5,863 (i.e. about 91% of all RCH facilities) by 2014 and the percentage of pregnant and lactating women who are receiving ARVs had increased from 71% in 2012 to 90% in 2014.[8]

1.4 Basic Facts about HIV

1.4.1 Etiology of HIV

In Tanzania, HIV infection is caused by HIV-1 sub-types. The common HIV-1 sub-types (clades) in Tanzania are A, C, D, and their recombinants. There is no HIV-2 sub-type infection has been reported up to date.

1.4.2 HIV Transmission

HIV infection is acquired through unprotected sexual intercourse with an infected partner, exposure to infected blood and blood products, or transmission from an infected mother to the unborn child in the uterus during delivery or from breast milk. More than 90% of adults in sub-Saharan Africa acquire HIV infection through unprotected sexual intercourse with infected partners. Transmission of HIV through body fluids other than blood and genital secretions such as cerebrospinal fluid, pleural fluid and amniotic fluids are also possible. However, unless blood is visibly present, saliva, sputum, sweat, tears, faeces, nasal secretions, urine, and vomits carry a very low risk of transmission of HIV[2].

1.4.3 Pathophysiology of HIV infection

[7] Ministry of Health, Community Development, gender, Elderly and Children, The National AIDS Control Program (NACP). **HIV Data Handbook,** September 2018.

[8] MOH, Prevention of Mother to Child Transmission of HIV, Annual Report 2014

The virus through its envelope proteins attaches to the CD4 receptor and co-receptors found on the surface of T lymphocytes and macrophage to gain entry to the host cells. CD4 molecules are also found on the surface of Langerhans cells of the skin and the microglial cells of the brain.

Following entry of the HIV into a susceptible host cell using the enzyme reverse transcriptase, the viral genome copies itself from RNA to DNA genetic material. The viral DNA copy enters the nucleus of the host cell and becomes intimately incorporated into the host cell's own DNA using the enzyme integrase. The virus thus becomes a permanent part of an infected person's nuclear proteins. There follows a latent period during which the provirus in the infected nucleus waits for an external stimulus to start reproducing.

CD4+ T lymphocytes, when stimulated by new HIV, other infections and infestations which would normally result in the CD4+ T lymphocyte reproducing itself, now responds to these stimuli by manufacturing HIV. As more and more viruses are produced and leave the host cell, the cell membrane weakens leading eventually to the death of the infected CD4+ T lymphocytes.

Other factors, most of which are still unknown, lead to the rapid depletion of the CD4+ T lymphocytes. The decline in the CD4+ T lymphocytes count is a reflection of the declining cellular immunity, which manifests as the appearance of opportunistic infections. The infected CD4+ lymphocytes have a half-life of about two days, which is much shorter than that of uninfected CD4+ cells. Rates of CD4+ lymphocyte destruction correlate with plasma HIV level. Typically, during the initial or primary infection, HIV levels are highest ($>10^6$ copies/ml), and the CD4 cell count drops rapidly.

However, an immune response to HIV develops, that it restricts viral replication, resulting in a decrease in viral load and a return of CD4 T-cell numbers to near normal levels. Viral load remains relatively stable for a certain period (the "set point") and start rising again shortly before AIDS diagnosis.

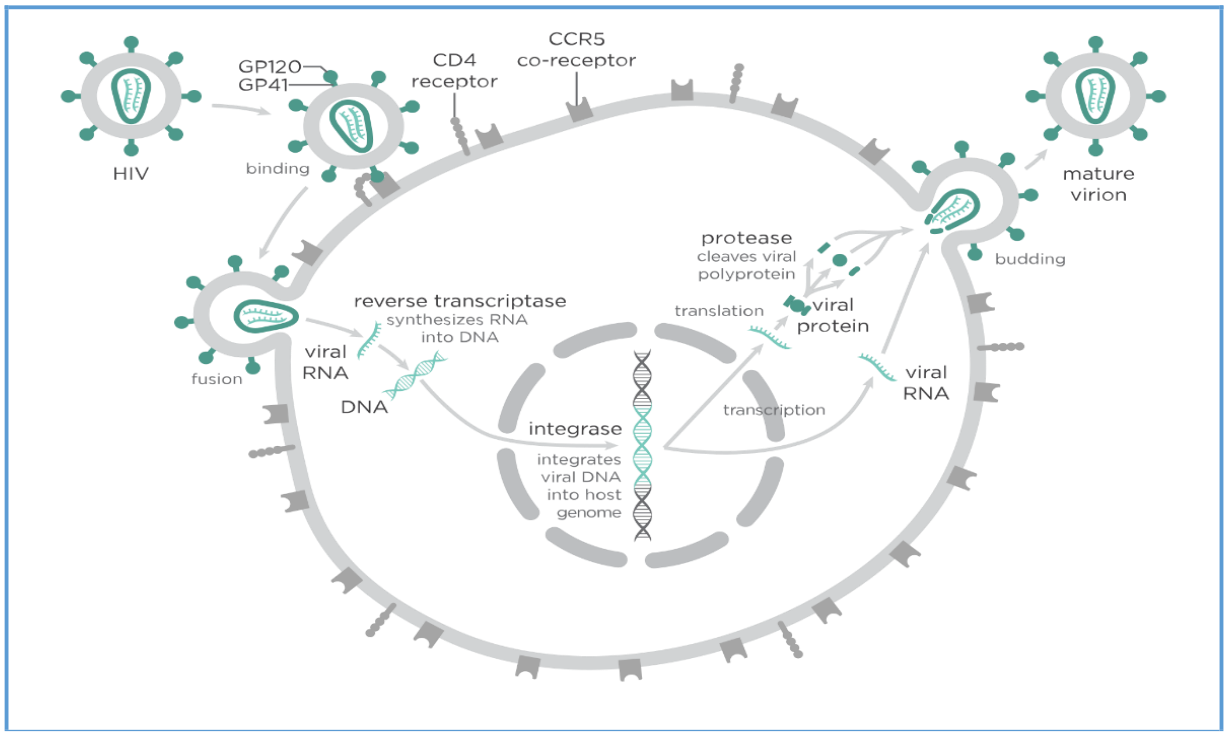
For ART-naive adults, a viral set point is reached after six weeks, and the median time to AIDS is 10 years. Paediatric patients, however, have *much* higher viral loads than adults; and a viral set point is reached after five years, and the median time to AIDS is one year.

Theoretically, the multiple steps in replication of HIV provide multiple opportunities for intervention. Therapeutic regimens may be directed at one or several of the following stages essential for viral replication: (1) attachment of HIV to the host cell; (2) reverse transcription of viral RNA to DNA; (3) integration of the pro-viral DNA into the host cells' DNA; or (4) expression of the viral gene after it has been integrated into host cell DNA, including the

transcription of more viral RNA and the translation of viral proteins.[9] (See Fig. 1.1). Because of rapid viral mutation, it is usual to recommend treatment that impacts the life of the virus at more than one site at any given time. As medications are developed, they may be co-formulated to make them easier for PLHIV to take more than one.

[9]Chan DC, Kim PS (1998). "HIV entry and its inhibition". *Cell*. **93** (5): 681–4.

Fig.1.1 Processing and Post-Translational Modification of Protein Products of the Virus



ARVs function by inhibiting HIV enzymes essential for HIV replication. These are such as reverse transcriptase, protease and fusion enzyme. Inhibition of enzymes finally results in reduction of viral replication and a consequent reduction or reversal of destruction of CD4+T lymphocytes.

1.5 Clinical Progression of HIV Infection

In the absence of ART, disease progression goes through the following clinical stages: (Also see WHO Clinical Staging Criteria in Annexes 2 and 3).

1.5.1 Primary Infection or becoming HIV Infected

Most primary infection, i.e. new infection with HIV, usually is not immediately noticed. It presents with short illnesses and flu-like symptoms such as fever, malaise, enlarged lymph nodes, sore throat, skin rash, and/or joint pain soon after being infected. It may last for a few weeks. This acute febrile illness is accompanied by widespread dissemination of the virus to different tissues, especially the lymphoid system. This is called sero-conversion illness.

1.5.2 Clinically Asymptomatic Stage

This stage is free of symptoms, except for the possibility of swollen glands: Persistent Generalized Lymphadenopathy (PGL). However, this is the stage where there is ongoing extensive immunologic fighting/changes and rapid viral replication begins. This may last for an average of eight to ten years. However, disease progression in children and elderly is faster due to high set point. This is WHO Stage 1.

1.5.3 Symptomatic HIV

Over time, the immune system loses the struggle to contain HIV, resulting in extensive destruction of CD4 cells. This is characterised by the occurrence of opportunistic infections (OIs), which is when symptoms develop. The most common symptoms include fever, respiratory infections, cough, TB tuberculosis, weight loss, skin diseases, viral infections, oral thrush, pain, and lymphadenopathy.

This is WHO Stage 2 or 3, depending on the particular OI seen. (See Annex 2 and 3 for reference.)

1.5.4 Acquired Immune Deficiency Syndrome (AIDS)

AIDS is defined as a point when a person with HIV develops severe immunosuppression, OIs, or malignancies/cancers. Such conditions are: severe weight loss, Kaposi's sarcoma, Cryptococcus meningitis, PCP, toxoplasmosis, CMV (Cytomegalovirus) retinitis, etc. This is WHO Stage 4.

Note: The risk of HIV transmission is higher in primary HIV infection and AIDS when the viral load is higher in the blood.

CHAPTER 2

HIV AND AIDS SERVICE DELIVERY

2.0 Introduction

This chapter describes the organization of HIV and AIDS services in Tanzania, specifically roles and responsibilities of care and treatment centre (CTC) staff, client registration, triage of clients, exit desk and accreditation of health facilities to provide HIV services. In addition, the chapter describes recommended differentiated service delivery models and quality of CTC services.

2.1. Organization of HIV Care and Treatment Services

Provision of quality HIV and AIDS services requires dedicated space in the outpatient department (OPD), availability of support services in and out of the clinic, and health care staff with well-defined roles and responsibilities.

2.1.1 Dedicated Space for the CTC

- Well-ventilated waiting area
- Registration area/desk
- Community-Based Health Services (CBHS) space/desk
- Data management room
- Phlebotomy room
- Record/file designated room/space
- Medicine dispensing room
- Consultation rooms
- Counselling rooms
- Exit space/desk

Note: Registration and recording of vital signs can be placed within the waiting area. Consultation and counselling rooms must be partitioned to maintain audio and visual privacy.

2.1.2 Support Services

These include:

- Laboratory
- Pharmacy
- Radiology

2.1.3 Staffing at CTC

The execution of CTC services depends on skills mix of health workers. The required staffs to run a CTC is composed of: Clinicians, Nurses, Laboratory Technologists, Pharmaceutical staff , Radiographers, and other support staff. The shortage of these staff limits accessibility for clients and negatively impacts health outcomes. To mitigate the acute shortage of health workers, these

guidelines recognise that Task Sharing practises and the NIMART approach can increase access to healthcare services. Roles and responsibilities of CTC staff are as stipulated in Annex 4

2.2 Types of services at Client Waiting Area, Registration, Triage and Exit

This section outlines the procedures starting with the client arrival until the time when she/he exits the health facility.

2.2.1 Waiting Area

This is an area where clients are expected to gather before receiving services. The healthcare provider at the waiting area will do the following:

1) Inform clients about services provided and whom they can expect to meet.
2) Inform clients on the clinic flow of services.
3) Provide group health education on the selected topics.

Triage

- Identify the seriously sick clients from the waiting area to fast-track for immediate service.
- Obtain brief history and assess the client needs.
- Link clients to relevant services according to their needs.

2.2.2 Registration

a) Initial visit

- Obtain a written referral form that confirms HIV positive test from the client.
- Perform retest for HIV verification for all clients with a prior positive antibody test regardless of the place where the initial test was performed (Refer to chapter 3 Section 3.3.7).
- Register all clients in an Appointment register and in Pre-ART Register for paper-based facilities.
- Elicit index contacts using elicitation form.
- Ensure availability of DTG consent form for women of child bearing potential age who are willing to start DTG based regimen.
- Fill in correctly and complete CTC1 and CTC2 cards.
- Give CTC1 card to the client and tell them to bring with them at every visit.
- Fill in correctly and completely the demographic data on TB screening tool.
- Ensure the HIV Exposed Infant Card (HEIC) is properly filled where applicable.
- Link the client to the relevant service.
- Keep and retain the file in the facility registration unit.
- Perform baseline laboratory investigations (CD4 count, Full Blood Picture (FBP), Liver Function Tests (LFT) and Renal Function Tests (RFT).
- Conduct first session of adherence counseling.

b) Follow-up visits

- Prepare client's files using either appointment book or existing CTC2 database one day before the clinic.
- Retrieve the client file number at every visit for all unscheduled clients.
- Up-date Client CTC1 and CTC2 card including index elicitation at each visit
- Record the clients in the appointment register.
- Check and ensure that CTC2 card, clinical forms, TB and STI screening questionnaire, client physical address, laboratory results, and nutritional assessment forms are in the file.
- Assess willingness and readiness to start ARVs and address any pending issues.
- If willing and ready, initiate ART within 7 days.
- Continue with adherence counseling.
- Direct the client to exit desk for next appointment.

2.2.3 Exit

- Countercheck if the client has been informed and given the date for the next appointment.
- Record in the client CTC1 card the date and time for the next clinic visit.
- Let the client mention the date and time for the next visit and advise to report back to the clinic as soon as she/he is not feeling well.
- Confirm contact details and willingness to be tracked.
- Record in the appointment register the date and time for the client's next clinic visit.
- Ensure the clients are linked to PLHIV support groups, CBHS, and other services as needed.

Note: Adolescents and youth require special consideration to ensure quality prevention, care, treatment, and support services.

Special consideration should focus on:

- Arranging youth clinics on special days and times.
- Establish clubs (pre-teen, teen, youth clubs)
- Involve peer educators in providing services.
- Fast-track registration and retrieval of their records.
- Guarantee privacy and confidentiality.
- Involve adolescents and youth in planning their services and in deciding on their treatment choices.
- Encourage adolescents to consult healthcare workers (HCWs) when they have concern with health-related issues, and ensure availability of equipment and supplies (e.g. condoms or other family planning methods, fliers, job aides, posters, etc.) at their clinics.

2.3 Establishing Care and Treatment Services at a Health Facility

For health facilities (HF) to qualify for the provision of HIV and AIDS Services to PLHIV the National HIV Programme developed a tool that is used to assess HF to provide care and treatment services (Refer Annex 5). The tool assesses adequacy of space, availability of support services, and minimum required staff to establish and maintain a CTC and PMTCT Option B+ HF.

Assessment of HF for provision of care and treatment services is done by the Council Health Management Teams (CHMTs) in collaboration with the Regional Health Management Teams (RHMTs).

If the HF meets the minimum criteria for establishment of a CTC, the District Medical Officer (DMO) should inform the Regional Medical Officer (RMO) who shall request an approval and provision of a CTC code number through NACP.

If the HF does not meet the minimum criteria for establishment of a CTC, the CHMT shall identify the areas for strengthening and plan for improvement to upgrade the HF.

Reassessment of the HF shall be conducted to ensure the improvement plan has been implemented.

Note:

For HF providing LLAPLa, i.e., a stand-alone PMTCT site, the HF must follow the same procedures. Upon approval, the assessed PMTCT HF will continue to use same PMTCT code numbers for running CTC services.

For an HF which does not meet the minimum criteria can be considered as either Outreach site or ART refill site.

2.4 Differentiated Service Delivery Models (DSDMs)

Differentiated HIV Care is a client-centred approach that simplifies and adapts HIV services across the treatment cascade. The aim is to reflect the preferences and expectations of various groups of people living with HIV (PLHIV) whilst reducing unnecessary burdens on the health system.

Differentiated Service Delivery Models are approaches that when applied result in delivery of HIV and AIDS services in a differentiated care perspective.

With the "Treat All" strategy, there are an increasing number of clients on ART. These clients will have a diverse range of needs challenging the capacity of health care system to manage all clients. Basing on this, differentiated service delivery models have been adopted to reach a diversity of clients, from those who present well, to those presenting with the advanced disease.

Three elements are considered in provision of client-centred care including:

1. **The clinical characteristics of the clients**: Based on clinical characteristics, clients are defined as Stable, Unstable, clients with early presentation and clients with late presentation (with or without advanced disease).

Table 2.1 Definitions of Different Categories of Clients for DSDMs At ART initiation
Clients with Early presentation: These are the clients who present with WHO clinical stage 1 or 2, **and** CD4 count > 350cell/ mm^3. These clients require additional and targeted adherence support in order to commit themselves to lifelong ART.
Clients with late presentation: These are the clients who present with WHO clinical stage 3 or 4, **or** CD4 count ≤ 350 cell/ mm^3.

Late Presenters are further subdivided into clients with Advanced HIV Disease or without Adavanced HIV Disease.

Clients with advanced disease: These are clients who present with low CD4 count <200 cells/mm^3 or WHO clinical stage 3 or 4 for adults and adolescents, and all children below five years who are HIV positive. This group of clients requires expedited clinical investigations, management and prophylaxis for opportunistic infections prior to initiation of ART in order to reduce ilhealth and prevent death.

After six months on ART a client can be categorized to stable or unstable client.

Stable Clients: These are clients who are on ART for at least six months and meet **ALL** of the following criteria:

- ✓ Age ≥5 years.
- ✓ Have no adverse drug reactions that require regular monitoring.
- ✓ No current illnesses (OIs and uncontrolled co-morbidities)
- ✓ Have good understanding of lifelong adherence of 95% and kept clinic visit appointments for the past six months.
- ✓ Undetectable viral load of less than 50 copies/ml.
- ✓ In the absence of HIV viral load monitoring, rising CD4 counts >350 cells/mm^3.
- ✓ On first or second line ART

This group represents the majority of people on ART. The clients on this group should be offered less frequent clinical visits and extended drug refills.

Unstable Clients: These are the clients who are on ART for at least six months and meet **ANY** of the following criteria:

- ✓ Age below 5 years
- ✓ Presence of an active OIs (including TB) or uncontrolled co-morbidities in the past six months.
- ✓ Poor or questionable adherence to scheduled clinic visits in the past six months.
- ✓ Recent detectable VL above 50 copies/ml,
- ✓ In absence of HIV viral load monitoring, decreasing CD4 cell count or CD4 ≤ 350 cell/mm^3
- ✓ People Who Inject Drugs (PWID).
- ✓ Pregnant and Breastfeeding Women.
- ✓ On TB Preventive Therapy (TPT).
- ✓ Clients on third line ART regimen.

These clients require additional clinical care, adherence support and timely switch to subsequent ART regimens in the case of treatment failure.

While these four groups have distinct needs, clients may change in between categories over the course of their lifetime in care.

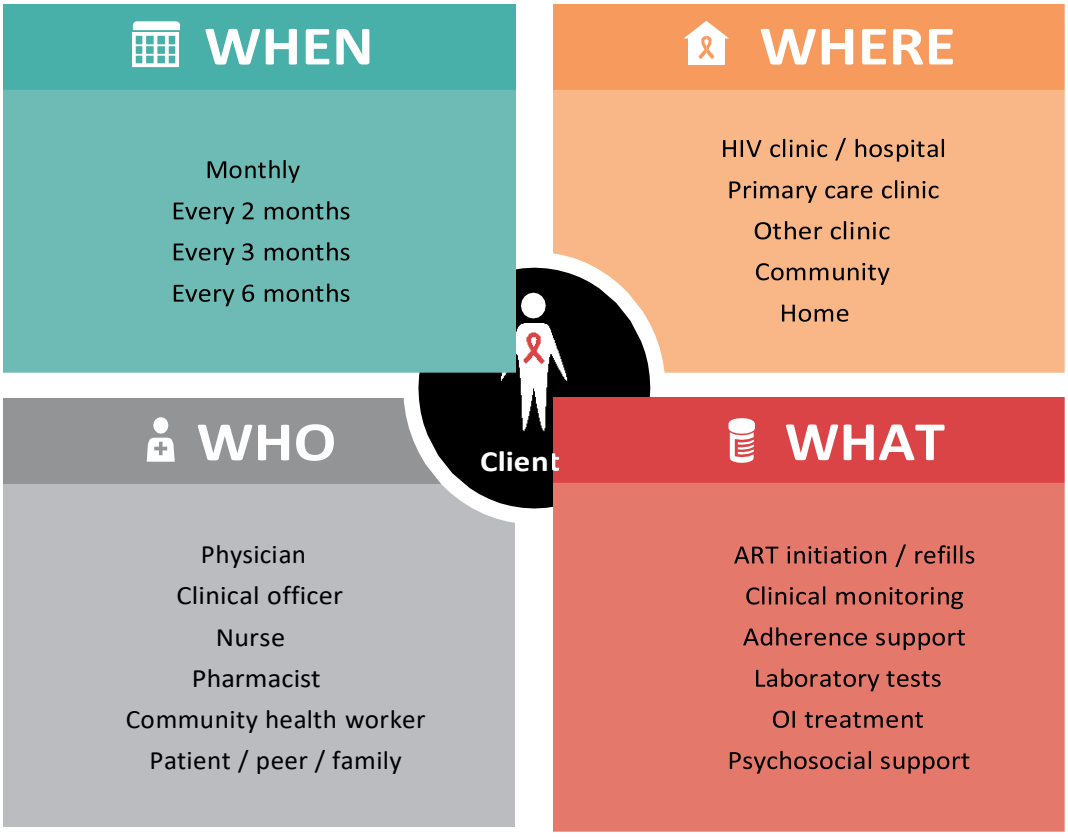
2. **The sub-population**: ART delivery should also be differentiated based on the challenges of different sub-populations such as adults, children, adolescents, pregnant and breastfeeding women, men, key and vulnerable populations.

3. **The context**: In order to maintain quality ART delivery, specific modifications are required when dealing with challenging settings such as conflict, urban/rural, high migration and low prevalence.

Differentiated Service Delivery Models are designed using the building blocks approach with four delivery components: (i) the types of services delivered; (ii) the location of service delivery; (iii) the provider of services; and (iv) the frequency of services. The four components are guided by the following key questions:

- ✓ When is care provided?
- ✓ Where is care provided?
- ✓ Who is providing care?
- ✓ What kind of care or services are provided?

Figure 2.1 The Building Blocks of Differentiated Service Delivery Models



Adapted from International AIDS Society (IAS). Differentiated Care for HIV: A decision framework for antiretroviral therapy delivery. July 2016. DSDMs should be designed and implemented as a direct response to specific challenges or barriers identified among clients and/or healthcare workers. To decide which models are appropriate in any given setting, an assessment of local data, healthcare worker and client experience needs to be made. The following tables (1-5) summarize the recommended service delivery models that are used in Tanzania.

Table 2.2 Differentiated HIV Testing Services			
When	Where	Who	What
General Population			
HTS should be available for 24 hours daily for facilities providing maternity and in-patient care. For other facilities HTS should be available in all facilities beyond official working hours depending on local needs.	Targeted testing (PITC/CITC) should be offered in all entry points of the health facilities. These include general OPD, IPD CTC, TB, STI, and RCH/PMTCT and in specialized clinics. Facility and community-based index client testing should be offered from all facilities. Targeted testing should also be offered as community-based outreach testing from all facilities.	Trained Peers should mobilise communities to access HTS. Trained and certified HCW to perform HTS. Capacitated non healthcare workers cadres (CHW,CDOs, SWOs, VHWs and CBHS providers) to conduct education and testing (including HIV self-testing) Every facility to ensure that there is always a HCW on duty who has been trained to perform HTS.	Index testing CITC HIV self-testing PITC Integrated approaches should be implemented in community testing strategies. This may include HIV testing, TB and STI screening, blood pressure, blood glucose checks, and nutrition assessments.
Special Considerations for Children and Adolescents			

Extended hours, weekends and public holidays	Targeted outreach testing to schools, colleges, street children and orphanages should be included in the outreach planning. PITC should be offered in all entry points of the health facilities including RMNCH, VMMC clinics adolescent-friendly settings, malnutrition and paediatric wards.	Trained peer adolescent should mobilise adolescents for testing. All cadres of existing health care workers should be trained to prepare DBS samples for EID testing. All facilities should ensure there is always a HCW on duty who has been certified to provide HTS and trained to prepare DBS samples for EID testing. Trained health care workers should perform HTS and EID DBS during mobile outreach activities.	Integrate EID DBS, HTS into outreach Health services e.g. EPI, TB, NCD and Family planning services
Special Considerations for Pregnant and Breastfeeding Women			
HTS should be available for 24 hours daily for facilities providing maternity care	Re-testing of HIV negative pregnant and breastfeeding women should be integrated in facility and outreach EPI and Family Planning activities.	Trained and certified Healthcare workers to provide HTS	Index testing PITC HIV retesting
Special Considerations for Key and Vulnerable Populations (KVP)			
Key and vulnerable populations should be consulted to determine the most appropriate time to offer community or facility-based HTS e.g. moonlight testing for female sex workers, long distance truck drivers and miners, peak	Districts should locate where specific KVP will access HTS and offer targeted outreach testing from the facility serving the defined location	Trained KVP peers should mobilise their communities to access HTS. Trained and certified Healthcare providers to provide HTS	KVP should be offered an integrated package of services with HTS as a core service e.g. for sex workers: HTS, Condom distribution, Family planning, STI screening and

seasons Fisher folks and farmers.			treatment, GBV services, Prevention services (PEP and PrEP).

Table 2.3 Linkage to Care
All HIV-positive clients identified at a facility should be guided (with their consent) to the CTC for enrolment into ART care. This should ideally be done by the HCW who has performed the test or other community health worker. All HIV-positive clients identified should be linked, with their consent, with a community health worker or other community-based services providers. A duplicated referral form should be completed for anyone testing positive in the community. A copy of the referral will remain with community-based HIV services providers for follow up of effective referral. The community-based providers should encourage the client to attend the facility of their choice. Any client who has tested HIV positive should be asked for their consent to be traced by a service provider. Any client who has not linked to care after one month should be traced. Tracing should initially be by phone followed by a home visit.

Table 2.4a Differentiated ART Initiation for Clients with Early presentation			
Eligibility Criteria for Early presentation: WHO clinical stage 1 or 2, and CD4 Count >350 cell/ mm^3			
When	Where	Who	What
General Population			
All clients should be assessed for the option of rapid initiation. This must include an assessment of both clinical and psychosocial readiness. Initiation should take place within 7 days of a positive HIV test, unless there is a medical or psychosocial contraindication. Adherence counselling should be done rapidly before ART initiation Following ART initiation, the client should be seen after 2 weeks and then monthly until the patient is stable. Additional visits may be needed to address any medical or psychosocial concerns	At all facility levels	Initiation may be performed by a trained healthcare worker (Clinician, NIMART trained nurse). Counselling including basic HIV and ART education and assessment for readiness to start ART (Nurse, doctor, AMO, clinical officer).	An assessment of both clinical (OI screening) and psychosocial readiness must be carried out before ART initiation. Counselling should include basic HIV and ART education and assessment for readiness to start ART. Management of any other conditions ART initiation

Table 2.4b Differentiated ART Delivery for Late presenters with Advanced Disease.			
Eligibility Criteria for Late presenters with Advanced Disease: All children below 5 years or Clients with WHO clinical stage 3 or 4, or CD4 Count < 200 cell/ mm^3			
When	Where	Who	What
Early initiation ofART will decrease risk of disease progression, including wasting and OIs Initiation should take place within 7 days of a positive HIV test, unless there is a medical contraindication or psychosocial contraindication. Following ART initiation, the client should be seen after 2 weeks and then monthly until the patient is stable. More frequent visits or	At all facility levels. Management of clients is done at any care and treatment centre/service delivery point. Referral to a higher-level facility when feasible if consultation is not adequate to stabilize the client.	Initiation may be performed by a trained healthcare worker (Clinician, NIMART trained nurse).	An assessment of both clinical and psychosocial readiness must be carried out before ART initiation. CD4 testing Assessment for Cryptococcal disease if CD4 <200 cell/mm^3 TB screening. TPT Cotrimoxazole

hospitalization may be required to stabilize acute medical conditions and address psychosocial and other concerns.			prophylaxis. STI screening. Counselling should include basic HIV and ART education and assessment of readiness to start ART. ART Initiation.

Table 2.5 Differentiated ART Delivery for Stable Clients

Eligibility for Stable Clients: Stable clients are defined as those who are five years of age and above, received ART for at least six months and have no adverse drug reactions that require regular monitoring, no current illnesses (OIs and controlled co-morbidities'), have good understanding of lifelong adherence of 95% and keeping clinic visit appointments for the past six months, on first or second line ARVs, recent undetectable Viral Load i.e. below 50 Copies/mls and in the absence of HIV viral load monitoring, rising CD4 counts and >350 cells/mm^3.

Note: A stable patient should meet all the above criteria.

- ✓ All clients on ART should have a booked appointment for their clinical and refill visits.
- ✓ All clients should be asked for their consent to be traced if they default.

When	Where	Who	What
General population			

Clients should have a clinical review twice a year Initially stable clients should be offered 6-month prescription with 3 monthly dispensing. Thereafter, the client who still meets the stable client criteria should be offered 6-month prescription and dispensing. Clients should choose a "blocked appointment time (AM /PM)" as well as an appointment date. Clinics should provide extended opening hours for specific sub-populations (e.g. Adolescent and youth). Frequency of extended hours should be determined based on local demand.	ART refill should be done in all approved care and Treatment Clinics, Option B+ facilities and Facility led community Outreach or Mobile visit. Clients should receive ART at the health facility of their choice.	Follow up on ART may be performed by any trained healthcare Worker (Clinician, nurse).	Full clinical review should be done during clinical consultations. ART refills should be provided to clients according to Differentiated Service Delivery Model in use. 6-month prescription and dispensing
Recommended ART Refill models include: Facility based Individual fast-track from Health Facility pharmacy - clients are seen individually within health care facilities and are fast-tracked for collection of the ARVs. Community based individual ART delivery through facility led mobile outreach services/visit - clients are seen individually outside the healthcare facilities by HCW as part of routine mobile outreach visits. **Note:** *Provision of ART refill model in both settings should comply with Tanzania eligibility criteria for stable clients (Annex…)* Family member or treatment supporter refill - client nominates a family member or treatment supporter to collect their ART refill.			

Facility based healthcare worker managed group - clients are seen for a group counselling service e.g. teen clubs or youth clubs.
Special Considerations for Children and Adolescents
ART delivery should be provided outside school hours, during weekends or holidays. Stable Children and their guardians should be booked on the same day. Group counselling activities may be deployed for children and guardian and will be coordinated by the health care worker to facilitate disclosure, peer support and adherence. Adolescents and youth should be encouraged and offered a group counselling approach and peer support. They should be grouped according to age and consideration of disclosure status. Group counselling activities will be coordinated by the health care worker to facilitate disclosure, peer support and adherence. Children and adolescents attending boarding schools should be offered additional support while at school and follow up appointment during their school holidays.
Special Considerations for Pregnant and Breastfeeding Women
PMTCT and RCHS services should be integrated. Clients should receive PMTCT/SRH services in the same manner as HIV negative clients – i.e. a special room does not need to be dedicated for HIV positive clients. HIV positive pregnant women should be encouraged to join PLHIV groups for additional peer support. HIV positive breastfeeding women and their exposed infants should be seen on the same day “family approach”.
Special Considerations for Key and Vulnerable Populations
Facility-led community ART initiation for KVP with a 1-month starter pack and follow up at health facility of choice for refill. The second visit should be facility based. An integrated package of medical care should be offered tailored to the specific needs of the key and vulnerable population (e.g. should receive STI screening and treatment, condom distribution, GBV services, Hepatitis B vaccination and prevention services). Services for key and vulnerable populations should be friendly and integrated into existing services. Health care workers should provide the

integrated package of services in a non-judgemental manner. If feasible specific times of clinics for key and vulnerable populations may be allocated by individual sites. Peers should be trained to provide psychosocial support, adherence counselling and linkages. Clients who are stable should be offered the same refill options as the general population except for people who inject drug (PWID) Clients within a specific key and vulnerable population group may choose to form their own group for peer support.
Special Considerations for Mobile Populations
Mobile populations (clients working in other countries or cities from their CTC sites, nomadic pastoralists, truck drivers, fishermen) should be offered longer ART refills adapted to their travel plan. Clients in this sub-population should agree to attend for their annual review, which should be booked when they are in their area of residence or area of their ART facility.

Table 2.6 Differentiated ART Delivery for Unstable Clients			
These are the clients who are on ART for at least six months and meet any of the following criteria: ✓ Age below five years, ✓ Presence of an active OIs (including TB) or uncontrolled co-morbidities in the past 6 months ✓ Poor or questionable adherence to scheduled clinic visits in the past 6 months ✓ Recent detectable VL above 50 copies/ml ✓ In absence of HIV viral load monitoring decreasing CD4 cell count or CD4 ≤350 cell/mm^3 ✓ People Who Inject Drugs (PWID) ✓ On TB Preventive Therapy (TPT) ✓ Clients on third line ART regimen.			
When	Where	Who	What
General Population			
Every month. Additional visits as required to address any medical or psychosocial concerns	At all facility levels Management of the client is done at any ART service delivery point. Referral to a higher-level facility when feasible if consultation is not adequate to stabilize the client Third line initiation should be done as per guidelines (Section 10.7.3)	All levels of healthcare workers who have received training should be able to prepare a VL sample. Clinicians who have been trained to assess clients with treatment failure should be able to initiate process to switch clients to third line	Case management to address reason(s) for not meeting stable criteria Enhanced adherence counselling should be available both at facility and community levels Viral load monitoring according to the national algorithm. Appropriate switch to second or third line ART

2.5 Quality of CTC Services

Quality refers to the totality of features and characteristics of an entity that bears on its ability to satisfy a stated or implied need. It is associated with excellence, superiority, value, performance according to standards and compliance with requirements or specifications. Quality of CTC services in the country base on the following global principals: effective, safe, people-centred, timely, equitable, integrated and efficient.

Quality Management is responsible for the coordination and facilitation of these activities in an organization. Building a national HIV quality management program and ensuring quality services requires attention to specific process and activities that are driven by Quality Assurance (QA) and Quality Improvement (QI) approaches. These processes should be implemented across the health system from national, regional/partner down to health facility level.

Quality assurance measures are in place to ensure that services offered at CTC conform to the standards stipulated in the Health Sector Strategic Plan IV as well as in the Health Sector HIV and AIDS Strategic Plan IV.

2.5.1 Quality Assurance

Quality Assurance (QA): Quality Assurance can be done either internally or externally. QA involves planned, step-by-step activities that let one know that health service is being carried out correctly, results are accurate, and errors are found and corrected to avoid adverse outcomes.

Internal Quality Assurance

The facility and CTC in charge are responsible for planning regular check-ups to ensure quality of care. This includes establishing and facilitating the work improvement teams (WITs).

External Quality Assurance

National, regional and district QA team will visit CTC to conduct quality assurance supervision visits. During such visits, areas that might need to be strengthened will be identified and the supervising team will work with CTC staff to develop an implementation plan. This plan will be documented for future reference.

2.5.2 Quality Assurance for CTC Services

This is implemented by the Work Improvement Team (WIT) at the CTC. The health facility management has an obligation on ensuring that the CTC WIT remains functional throughout.

The WIT should conduct assessment of the health facility performance on all indicators that are monitored as per the M& E framework and guidelines. The WIT should document the assessed indicators' performance using the Standard Evaluation System (SES) forms and fulfil all the criteria of data management as described in the national guidelines on management of quality HIV and AIDS data.

2.5.3. Quality Improvement

Quality Improvement (QI) is a systematic process of assessing performance of a health system and its services, identifying gaps and causes, and introducing measures to improve procedures so as to obtain the desired outcome.

For the HIV and AIDS QI, the PDSA cycle model (i.e. a Plan, Do, Study and Act) has been selected as a reference QI model. In addition, the 5S and Improvement Collaborative approaches are deployed for improving the quality of the HIV and AIDS services.

At regional, district and Health Facility levels, QI Teams (QIT) and Work Improvement Team (WIT) should be formed and be active to carry out their roles and responsibilities as stipulated in the QI guidelines. The National Quality Improvement Framework (NQIF) also describes roles and responsibilities of QIT and WIT and should be referred to for these roles and responsibilities.

The initiatives for QI focus on nine dimensions and five principles of quality, hence a need for the QIT and WIT to have training on QI so as to be able to effectively apply the improvement science.

CHAPTER 3

HIV TESTING SERVICES

3.0 Introduction

HIV testing services (HTS) is the gateway to access HIV care, treatment, prevention, and support services. Provision of HTS in all settings should be voluntary and conducted ethically following 5 core HTS guiding principles which include Consent, Confidentiality, Counselling, Correct test results and Connecting clients to services, including care, treatment, prevention and support services. Key components of HTS package are Demand creation, pre-test session, HIV testing, post-test session, referral and linkage services. The main approaches for HTS include Provider Initiated Testing and Counselling (PITC), Client initiated Testing and Counselling (CITC) and HIV self-testing (HIVST). HIV self-testing (HIVST) has been recommended by WHO as an additional approach for delivering HIV testing services. The introduction of HIVST will be based on the recommendations from the ongoing 2018 Implementation Science on HIVST. In addition, there should be trained HTS provider CDOs, SWOs, Has, VHWs, HIV HBC providers, & members of health facility governing committee capable to offer testing services. Both are provided in facility or community.

3.1 HIV Testing Service Settings

HTS is the primary entry point for HIV diagnosis, counselling, prevention and management. The current recommendation on managing HIV requires early identification of PLHIV in order to link them to ART care. Therefore, HTS services should be provided with reflection to the preferences and expectations of various groups of people living with HIV (PLHIV) whilst reducing unnecessary burdens on the health system. By differentiating service delivery, HTS need to target and refocus resources to the most in need clients.

HTS delivery approaches shall extend beyond traditional provider-initiated HIV testing and counselling (PITC) and stand-alone client-initiated testing and counselling (CITC) sites. Thoughtful delivery points and approaches shall aim for co-location of services for key populations who were and reach them in their natural environments and therefore reducing access barriers. HTS shall also prioritize reaching key populations together with their sexual partners, where appropriate (For differentiated HTS services see Chapter 2 section 2.5).

3.1.1 Health Facility Based Testing

HTS should be recommended for all patients/clients including adults, adolescents, infants and children attending health facilities, regardless of whether they show signs or symptoms of HIV infection. Trained HTS providers shall provide HTS at every service delivery points but not limited to OPD, IPD, TB Clinic, Sexual and Reproductive Health (SRH), STI Clinic, VMMC, Laboratory, CTC and specialized clinics.

3.1.2 Community Based Testing

Community Based HTS is a service that is offered outside the health facility to all population groups. It is an important approach to reach first-time testers and people who seldom use clinical services, including people from key and vulnerable populations and their sexual partners, orphan and vulnerable children, index clients, adolescents, youth and men. Targeted Community-based HTS is useful for children and partners of index clients,

adolescents as well as for outreach HTS for key and vulnerable population. This also plays an important role in providing work place, mobile, home testing (door to door and index test), hot spots, campaign and National events.

Note: *Provision of HTS in both settings should comply with Tanzania National Guidelines for HIV Testing Services, 2019.*

3.2 Key Components of HTS Package

The HTS package recommended in Tanzania includes demand creation, pre-test information, HIV testing, post-test counselling, and successful linkages to prevention, treatment, care and support services for both HIV positive and HIV negative individuals.

3.2.1 Demand creation

This involves promotion of HIV testing services, mass and social media, information, education and communication materials (IEC material), signboards, combination, prevention, intervention, advocacy, sensitization and mobilization.

3.2.2: Pre-Test Session

Pre-test session is a dialogue between the client and HCW before HIV testing. This is done either through one to one (individual) or group sessions. These sessions can also be conducted through a short recorded pre-test video clips shown in waiting rooms or printed materials such as posters and brochures. For children and adolescents HTS information should be presented in an age-appropriate manner to ensure comprehension. HTS provider shall assess whether testing is in the best interest of a child and if it promotes the child's physical and emotional welfare.

3.2.3 HIV Testing Session

HIV testing is the central component of HTS and is conducted after the pre-test and client has to consent for the test. Rapid HIV Test kits are recommended for use in all HIV testing settings and results are established on the same day and do not require laboratories or specialized laboratory equipment. The HIV Rapid testing shall be conducted by Laboratory and non-laboratory healthcare workers, once they have been appropriately trained using the National training package and deemed competent. HIV rapid testing shall be performed in health facilities or community settings, using finger prick specimen collection. In special situations like External Quality Assurance (EQA) procedure and where multiple tests are performed, different types of specimens, such as dried tube specimen or venous blood samples may be used. (*Note: Venous blood collection for the multiple testing will be performed only by trained and authorized personnel*).

The National HIV Testing Algorithm and procedures shall be followed when performing the HIV test, as outlined in Figure 4.1 (Chapter 4). In order to provide accurate and reliable HIV

Test results, HTS providers shall adhere to good laboratory practices and quality assurance standards as stipulated in the National Guidelines for HIV Testing services, 2019.

3.2.4 Post-Test Session

All individuals who undertook an HIV test should be offered quality post-test counselling when being given their HIV test results. Post-test counselling shall be client-centred and focus on the specific risks and needs of the client or patient, based on their HIV test results, stated risk behaviours, and prior knowledge about HIV and AIDS.

Post-test counselling may be delivered to individuals, couples or families, depending on what they agreed to, during pre-testing counselling. However, couples shall be encouraged to receive post-test counselling together, when possible, to encourage mutual disclosure and to support couples' communication.

Post-Test Session for People Who Test HIV Positive

Post-test counselling should at a minimum, include five key messages that begin ART treatment preparation process for all PLHIV:

- ✓ Re-test of HIV Positive should be done for verification before enrolment to care and treatment.
- ✓ Treatment (ARV) is available and is recommended to all clients having HIV.
- ✓ Assess client readiness and willingness before initiation of ARV.
- ✓ Start treatment as soon as possible (preferably within 7 days after testing positive).
- ✓ ART should be taken as prescribed without missing a dose to allow long and productive life.

Retesting Messages for individuals who test HIV Negative

Scenario	When to repeat HIV test	When to do future HIV tests
A: GENERAL POPULATION		
General Population who test HIV Negative with no an ongoing risk	No "window" period retesting	Re-test annually
Inconclusive (Indeterminate test results) HIV status	Immediately repeat HIV test following the national HIV testing algorithm OR repeat test by another tester or laboratory practitioner	If still in inconclusive retest in 2 weeks. If still inconclusive take the sample for PCR or refer the client to a higher level facility/ laboratory
Have a spouse or partner who is HIV Negative (discordant couples)	4 weeks	Every 3 months until the HIV positive partner has confirmed viral suppression i.e. Viral Load less than 1000 copies/millilitre. Thereafter re-testing every 6 months.
Individuals on PrEP	4 weeks	Every visit
Have specific incident of HIV exposure past 3 months	4 weeks	With each new known exposure and if still negative, as for general population i.e. annually.
Have an ongoing risk of HIV infection (SW, IDU, MSM)	4 weeks	6 months
Has STIs/ RTIs	4 weeks	With each new STI, if still HIV Negative test annually
Survival of sexual violence or rape or experience occupational exposure	4 weeks	As per PEP guidelines
Adolescents and young people	4 weeks	Annually if sexually active
B: PMTCT SETTINGS		
Pregnant women and partners counselled and tested during first ANC visit	Third trimester, or during labour/delivery	Six months after delivery, if still negative test annually and with each new pregnancy

Pregnant women who had specific sexual risk behaviour in past 3 months.	4 weeks then third trimester, or during labor/delivery	Six months after delivery. If still negative test annually and with each new pregnancy.
Breastfeeding women who were tested during pregnancy, labour/delivery	6 months after last test	If still negative test annually and with each new pregnancy
Breastfeeding women with unknown HIV status: test at first postnatal contact.	6 months;	If still negative test annually and with each new pregnancy
HIV Exposed infants	PCR test at 6 weeks after birth.	Conduct Rapid antibody testing at 18 months for confirmation of HIV status. Repeat testing six weeks after cessation of breast feeding.
*High risk HIV exposed infants	DNA –PCR at birth, then at 6 weeks of age.	12 weeks after cessation of breastfeeding and a Final antibody (Ab) at 18 months.

3.2.3 Assessment of Other Health Related Conditions and Needs

The HTS provider should also assess other health related conditions and referred to appropriate services such as TB, STIs/RTIs, Cancer screening, Family planning, Gender based violence, VMMC, PMTCT, alcoholism, non-communicable diseases, and psychosocial issues.

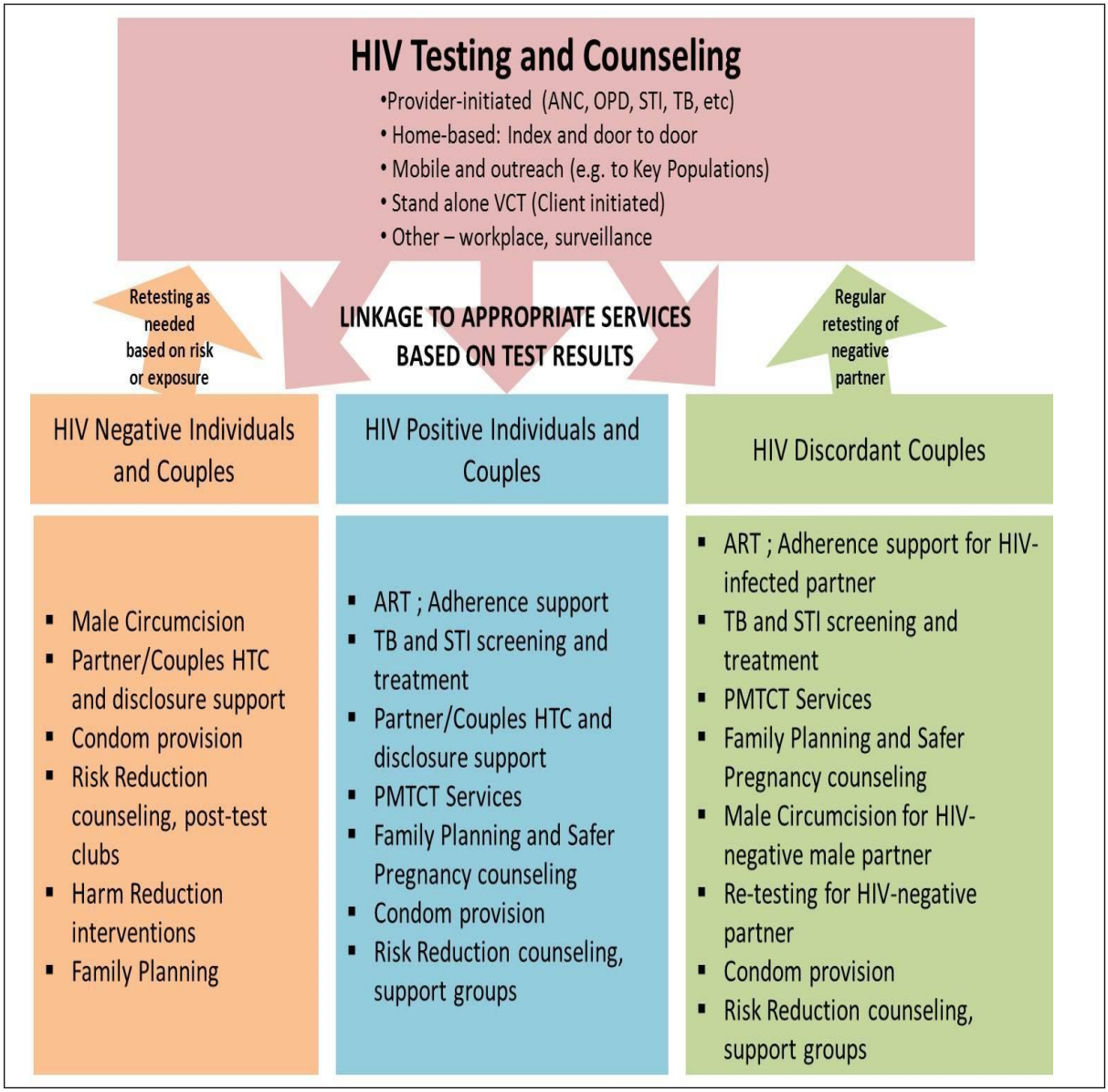
Effective Referral and Linkage

HTS providers have a crucial responsibility to ensure that all individuals with a confirmed reactive HIV test are immediately linked to care and treatment services for enrolment to ART and other supportive and preventive services

Also Link people who test HIV-negative with an ongoing HIV risk to appropriate prevention services.

Figure: HIV Post-test Linkages to Prevention, Care and Treatment Services

Figure 3.1 Post Test Linkages to Treatment Care and Support Services



3.3 HIV Testing Services for Different Populations

3.3.1 HIV-Exposed Infants (HEIs)

All infants born to mothers known to be HIV positive and on ARV should be offered routine HIV DNA PCR testing at 6 weeks after birth or at first contact thereafter. Infants with initial positive HIV DNA PCR result should be presumed to be HIV infected and started on ART. A second confirmatory HIV DNA PCR should be taken at the time of ART initiation. In case a High risk HIV exposed infants is identified, DNA PCR test should be offered at birth (see annex 12).

3.3.2 HIV Testing for Infants and Children Less than 18 Months

To establish an HIV exposure status of a child less than 18 months, conduct HIV antibody test to mother with unknown HIV status or previously tested negative during antenatal care.

The 6-week and six month immunization visit offers an excellent opportunity to establish the HIV exposure status of the child. Health care workers shall recommend HIV test for exposed infants during this visit.

3.3.3 HIV Testing for Children Older than 18 Months up to 17 Years

Conduct HIV testing by using HIV rapid test for all children with unknown HIV status. Parents or guardians must give their consent to have their children tested.

3.3.4 HIV Testing for Pregnant and Breastfeeding Women and their Partners

All pregnant women and their partners (unless known to be HIV positive) should be tested and counselled for HIV during their first ANC visit. For HIV negative pregnant women HIV test should be conducted during the third trimester or during labour or at delivery.

All breastfeeding mothers unless known to be HIV positive shall be encouraged to undertake HIV test during breastfeeding. For those who were tested during third trimester or at labour or delivery, a repeat HIV test should be offered at six months and thereafter as per general population.

3.3.5 HIV Testing for Key and Vulnerable Populations

Conduct HIV testing and counselling for key and vulnerable populations presenting at health facilities or community based testing; for key and vulnerable populations that test HIV negative, re-testing should be recommended four weeks and thereafter repeat after six months.

Prisoners shall be offered voluntary HTS as part of health service whether in prison or in any other setting.

3.3.6 HIV testing for Partners and Children of Index Clients

HIV testing and counselling should be encouraged (health facility or community based) for all partners and children of index clients and linkage to prevention, care and treatment services as appropriate. All PLHIV enrolled into HIV care should receive disclosure counselling and be supported to disclose their HIV status (assisted disclosure).

3.3.7 Re- testing to verify HIV – seropositive status prior to ART initiation

All individuals who have tested HIV positive should be re-tested to verify their HIV status prior to enrolling in care and starting ART.

Modalities of conducting re-testing for verifications

- The re-testing should be conducted by a different provider using different sample and the same testing algorithm.
- Re-testing should preferably be conducted at the site where the decision about ART initiation is made.
- If the HIV status is the same upon re-testing, the individual's HIV-positive status should be considered as verified.
- If the test status is not the same upon re-testing, the individual or their sample should be referred for additional testing at nearby higher level facility testing site.

3.4 Referral and Linkage Services

HTS providers have a crucial responsibility to ensure prompt linkage to care and treatment for people diagnosed with HIV infection. All clients undergoing HTS must either be connected to HIV prevention services if tested Negative, or referred and linked HIV care and Treatment services if positive. If available, use of mobile phones to verify that the person has been enrolled in care may be helpful. Collaboration and communication between HTS and ART providers is important to ensure effective referral support. This is important in the context of "treat all".

3.4.1 Strategies for Effective Referral and Linkage

- All people who test HIV-positive need immediate linkage to ART services.
- All people who test positive in community settings should be referred to the health facility for verification of HIV test results and assessment for ART.
- People who test HIV-negative with an ongoing HIV risk shall be linked to prevention services.
- Where possible, trained health care workers or peers and those who act as peer navigators, and Community Workers shall be used for effective linkage.
- Communication technologies, such as mobile phones and text messaging, may assist with disclosure, adherence and retention, particularly for adolescents and young people.
- Promotion of partner testing may increase rates of HIV testing and linkage to care. Male partners testing shall be encouraged in HTS including PMTCT settings.

3.4.2 Principles and Steps of Referral and Linkages

Regardless of whether a client is newly diagnosed with HIV infection, or has been previously diagnosed, or is HIV negative, the steps for making a referral and ensuring linkage to health services, risk-reduction, and/or other services follows the same basic process. The following are principles of referral; information will be available for referring and HIV care and treatment service provider, respect client willingness and readiness to be referred, preference on how the referral should take place, maintain confidentiality and obtained informed consent, The HTS provider should follow the following when making referral and linkages:-

Assess Referral Needs: Identify the factors that are most important in terms of their influence on a client's ability or willingness to engage in medical care or risk-reduction services;

Prioritize Referral Needs: There are often multiple factors that influence a client's ability or willingness to reduce risk that influences a client's health or that impact a client's ability or willingness to accept and access referral services;

Plan the Referral: Identify the strategies or methods you will use to facilitate a successful referral. Help the client to identify challenges that he or she may have in completing referrals (e.g. cost, lack of transportation). Identify strategies to overcome such challenges;

Facilitate Access to Services: Provide clients with both information and support necessary to access referrals. Information about the referral can, at minimum, include information about the referral agency (e.g. name, address, telephone number, contact name, hours of service, cost), eligibility, and the processes and timelines for making and getting appointments. As much as possible, linkage should be done on site care and treatment service through patient escort. When this is not possible (due to patient preference or service are not available) the testing facility should book the appointment with the receiving facility and follow up to ensure the patient is registered at the receiving facilities. Provide the patient with referral information, referral form and contact details of facility;

Follow Up and Confirm Linkage: Assess whether the client successfully completes a referral (i.e. has been linked to the service) and obtain client feedback, if possible. If the client was not successfully linked to services, attempt to determine the reasons for this and provide additional assistance, if appropriate. Where referrals are necessary such referrals should be coordinated (communication and documentation) between referring and receiving service delivery points;

Document Referral and Linkage Activities: Documentation is essential that referrals made and linkage completed be recorded in a client's file or chart. Uses of referral forms help staff follow up on referrals made and assess their completion. Monitoring referrals and linkage the main strategies for assessing client includes self-report and confirmation from referral providers through call phone, text message or completing referral forms and returns the form.

3.5 Documentation

HTS provider should make sure HTS information are accurate, correct and filled in the HTS register and HIV log book for tracking implementation of HT.

CHAPTER 4

LABORATORY TESTS FOR DIAGNOSIS AND MONITORING OF HIV AND AIDS

4.0 Introduction

Laboratory investigations are important for HIV and AIDS prevention, care, treatment and support services. Laboratory investigations provide important information on individual's HIV status and disease progression, detection of specific organ failure and toxicities. CD4 is used to determine immunological response while viral load is used to monitor the treatment. HIV Drug Resistance test is used to determine presence and pattern of resistance associated mutations (RAMs).

4.1 Tests for HIV Diagnosis

4.1.1 HIV Testing in Adults and Children over 18 Months

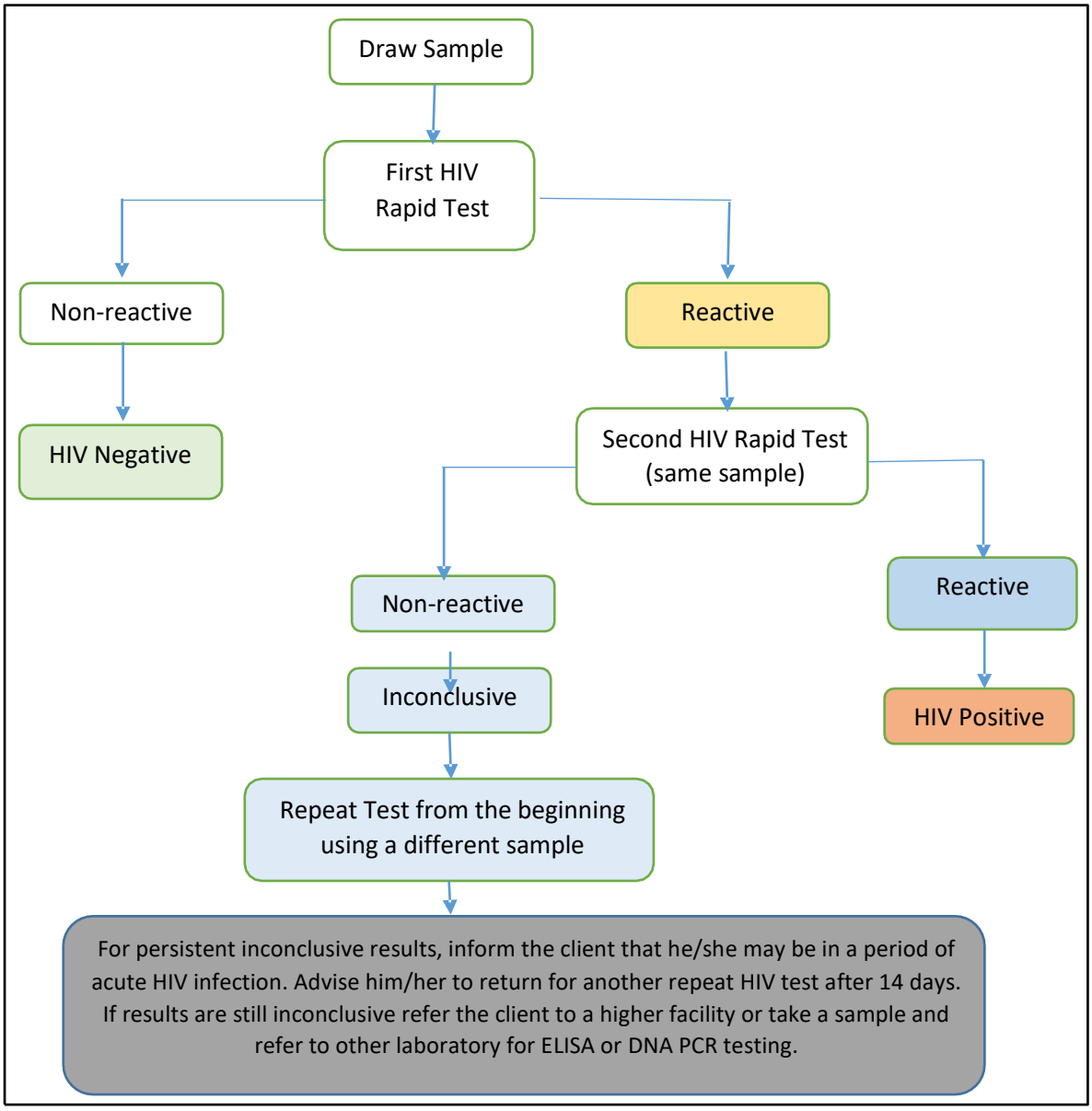
In adults and children older than 18 months, diagnosis of HIV infection is done by detection of antibodies using HIV rapid tests as indicated in the National HIV testing algorithms (See Figure 4.1 below).

HIV testing algorithm describes the number, type and order of tests that need to be performed. The first test to be conducted is *highly sensitive* (detects all true positive and a few false positive results), and the second test is *highly specific* (detects only true positive results). Inconclusive result repeat test from the beginning using a different sample.

The National HIV testing algorithm follows a 'serial' testing strategy. That is, blood sample is first tested using highly sensitive test, followed by a second highly specific test. A second test is only done when the first HIV test revealed an HIV- reactive result.

Although HIV rapid test is done using whole blood, serum or plasma samples, it is recommended to conduct HIV rapid test using a sample obtained from a finger prick. The HIV rapid testing can be performed in the laboratory or outside the laboratory setting by healthcare workers and non-healthcare workers trained and certified to perform HIV rapid tests.

Figure 4.1 Tanzania National HIV Rapid Testing Algorithm for Adults and Children over 18 Months



4.1.2 Verification of HIV results

Perform re-test for HIV verification before initiation of ART using the national approved HIV testing algorithm, to all HIV positive clients referred from any HIV testing points to CTC using different sample and the Test should be performed by a different HCW.

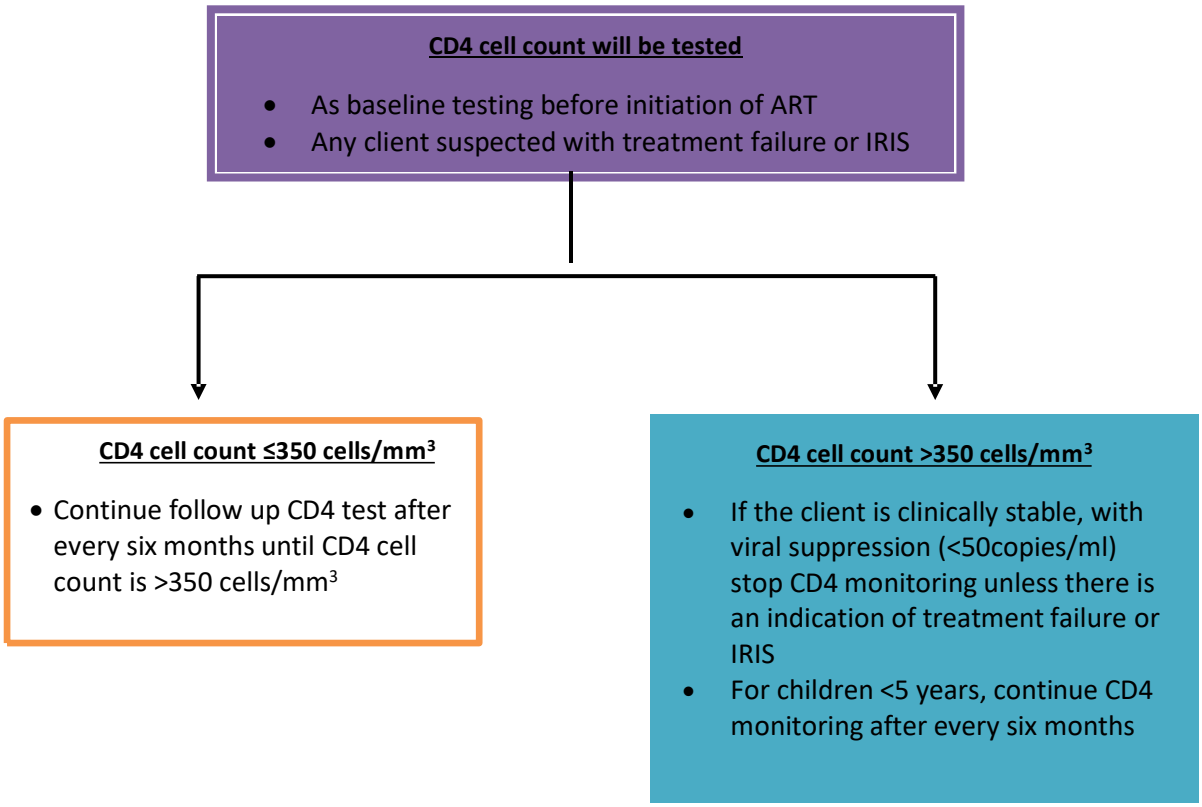
4.1.3 Diagnosing HIV infection in Children under 18 months

HIV DNA polymerase chain reaction (PCR) method is used to confirm HIV infection in infants and children ≤18 months of age. PCR can be used to diagnose HIV infection in most infected infants at the age of six weeks. Further details on diagnosis of HIV infections in children under 18 months, is outlined in Chapter 7 (Section 7.1.1).

4.2 Monitoring progression of HIV

CD4 cells progressively decrease as HIV advances and immune status deteriorates. Measurements of CD4 cells counts are important immunological markers of the disease progression. CD4 cells counts are reported in absolute numbers in clients five years and above while in children under five years, CD4 cells counts are reported in percentage (%). CD4 testing will be measured as a baseline test and for suspected treatment failure for those clients on ART (See Figure 4.2 below).

Figure 4.2 CD4 Testing Process for Adults, Adolescents, and Children ≥5 Years



4.3 Tests for Monitoring Responses to Anti-retroviral Treatment and Diagnosis of Treatment Failure

Clinical assessment and laboratory tests play a key role in assessing individuals before ART is initiated, monitoring treatment response and possible toxicity of ARV drugs. HIV Viral Load test is a preferred approach to monitor early treatment failure. Successful antiretroviral therapy result in decrease of HIV viral load, immune recovery and therefore increase in number of CD4 cells.

4.3.1 Cryptococcal Antigen (CrAg) Screening

Primary infection with *Cryptococcusneoformans* is typically asymptomatic. In HIV-infected patients with advanced HIV and AIDS and CD4 count below 200 cells/mm^3, the infection can be re-activated and spread through the blood stream.

Cryptococcal Antigen (CrAg), is a serological assay that detects the presence of C. neoformans capsular antigen in serum or CSF. Laboratory –based 'reflex' CrAg screening should be performed on every blood sample with CD4 <200 cells/mm^3.

Algorithm for Screening Cryptococcal meningitis in clients with Advanced HIV Disease.

4.3.2 HVL Testing Algorithm for Adolescents and Adults

Perform 1st HVL test at six months after initiation of ART. Repeat HVL test six months later if the initial HVL test result was less than 1000 copies/mL Then HVL test will be performed annually if two preceding HVL test results were less than 1000 copies/mL.

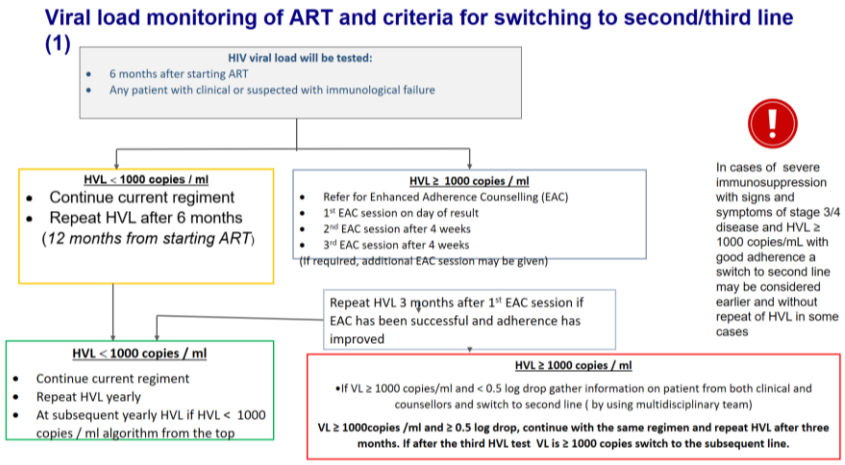
If the preceding HVL test result was more than 1000 copies/mL, perform HVL test after three months of enhanced adherence counselling.

For clients who have been on ART and immunological monitoring for more than six months without being tested for HVL test performed at any time of clients encounter.

NOTE: Thereafter, during subsequent HVL tests, if the results are greater than or equal to 1000cp/ml, the client should be subjected to Enhanced Adherence Counselling (EAC) and repeat the HVL test after three months from first EAC session.

Where HVL monitoring is unavailable, CD4 cell count monitoring are recommended.

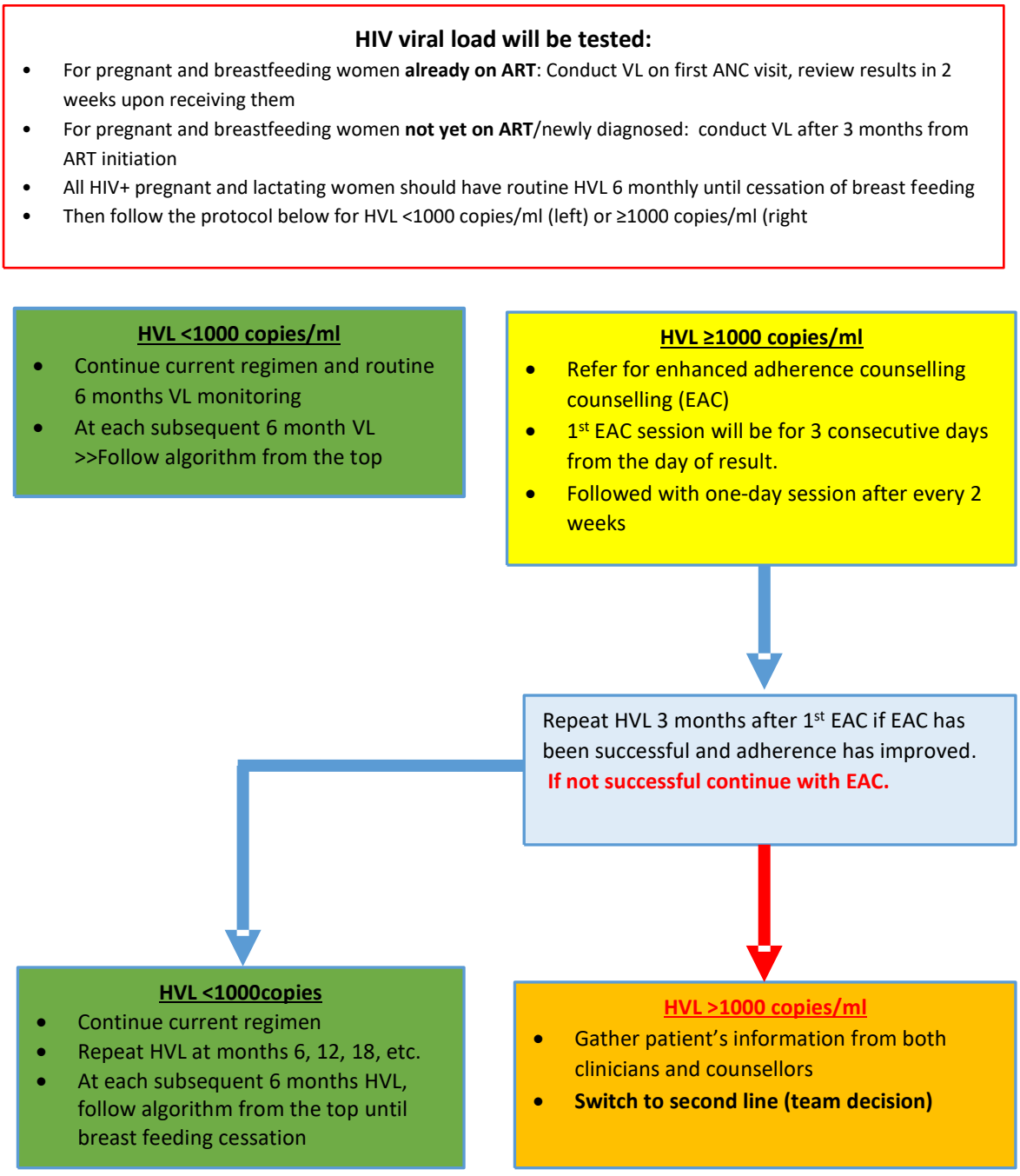
Figure 4.3 HVL Monitoring Algorithm for Adolescents and Adults



4.3.2 HVL Testing Algorithm during Pregnancy and Breastfeeding

Purpose: Early identification and management of adherence challenges and treatment failure. Minimize the risk of MTCT due to high maternal VL.

Figure 4.4: HVL Monitoring Algorithm for Pregnant and Breastfeeding Mothers



4.4 Tests for Monitoring Disease Progress and Treatment Safety

Table 4.1 Test for Monitoring Disease Progress and Treatment Safety

Phase of HIV management	Recommended
Baseline investigation	Retest for verification of HIV test results TB Screening CD4 count/percentages HbsAg Hematological test Biochemistry test (ALT, RFT) Cryptococcus antigen if CD4 count <200 cells/mm for Adults.Screening for sexual transmitted infections Urine for pregnant test (child bearing potential women)
During ART	Hb for AZT[1] Creatinine clearance for TDF[2] ALT Haematological test (FBP- Attn: Hemoglobin) Biochemistry test (Lipids, RFT) HVL
Suspected Treatment failure, IRIS & Adverse Effects	HVL CD4 Haematological test Biochemistry test HBsAg serology
Treatment Failure	HIV Drug Resistance where accessible

4.5 Tests for Monitoring Antiretroviral Treatment Safety (Toxicity)

Anti-retroviral drugs are known to produce short and long term side effects in some patients. Clinical follow up is supported by laboratory investigations. Capacity for testing haematology and clinical biochemistry will continue to be developed at all health facilities providing Care and Treatment in the country. The frequency of monitoring depends on the ART regimen used as summarized in table 10.4 in Chapter 10.

Furthermore, ART drug toxicity varies in severity which determines the clinical action to take. The following tables show the grading of adverse events as a result of ARV toxicity for adults and children.

Table 4.2 Grading Adverse Reactions in Adults

Abnormal Range of Laboratory Tests				
Item	Grade I Toxicity	Grade II Toxicity	Grade III Toxicity	Grade IV Toxicity
Haemoglobin	8.0-9.4 g/dl	7.0-7.9 g/dl	6.5-6.9 g/dl	<6.5 g/dl
Absolute Neutrophil Count	1-1.5 x 10^9/L	0.75–0.99 x10^9 /L	0.5-0.75 x 10^9/L	<0.5 x 10^9/L
ALT	1.25-2.5 IU/L upper normal limit	>2.5-5 IU/L upper normal limit	>5.0-10 IU/L upper normal limit	>10 IU/L upper normal limit
Triglycerides	3-4.51 mmol/L	4.52-8.48 mmol/L	8.49-13.56 mmol/L	>13.56 mmol/L
Cholesterol	>1.0-1.3 mmo/L upper normal limit	>1.3-1.6 mmol/L upper normal limit	>1.6-2.0 mmol/L upper normal limit	>2.0 mmol/L upper normal limit
Management	Continue ART Repeat test two weeks after the initial test and re-assess		Continue ART Repeat test one week after initial test and reassess If ALT still grade 3, consult expert about stopping ART	Consult expert immediately before stopping ART

Table 4.3 Grading Severity of Adverse Reactions in Children

Abnormal Range of Laboratory Tests				
ITEM	GRADE I TOXICITY	GRADE II TOXICITY	GRADE III TOXICITY	GRADE IV TOXICITY
Haemoglobin >3 months - < 2 yrs old	9.0-9.9 g/dl	7.0-8.9 g/dl	<7.0 g/dL	Cardiac failure secondary to anaemia
Haemoglobin ≥2 yrs old	10-10.9 g/dl	7.0-9.9 g/dL	<7.0 g/dL	Cardiac failure secondary to anaemia
Absolute Neutrophil Count	0.75-1.2 x 10^9/L	0.4-0.749 x 10^9/L	0.25-0.399 x 10^9/L	<0.25 x 10^9/L
ALT (SGPT)	1.1-4.9IU/L upper normal limit	5.0-9.9IU/L upper normal limit	10.0-15.0IU/L upper normal limit	>15IU/L upper normal limit
Triglycerides	-	1.54-8.46 mmol/L	8.47-13.55 mmol/L	>13.56 mmol//L
Cholesterol	-	4.43-12.92 mmol/L	12.93-19.4 mmol/L	>19.4 mmol/L

4.6 Laboratory Diagnosis for Opportunistic Infections

For laboratory diagnosis of common OIs such as TB, upper respiratory tract infections, Meningitis, Diarrheal and Septicaemia, diagnostic protocols and SOPs are available and should be used.

Teamwork between laboratory technicians and clinical staff at the CTC is required to optimize diagnostic capacities.

4.7 Laboratory Safety Precaution

Safety precautions in the laboratory should be adhered during all steps starting from specimen collection, storage, transportation, processing and disposal of biohazard wastes to minimize occupational risks. The risk of transmission of HIV, Hepatitis B virus (HBV) and other blood-borne disease agents are minimized if laboratory personnel observe safety precautions at all times. All specimens should carefully be handled as infectious.

4.7.1 Sample Storage and Disposal

All samples should be stored in tightly closed and well labelled tubes/ containers and kept in an upright position during storage. Temperature should be monitored and recorded in a temperature chart, which is provided in each equipment used for storage of specimens. All used or old specimens should be disposed immediately by autoclaving and incineration.

4.7.2 Sample Transportation

Laboratory protocols and SOPs should be followed when transporting samples from collection point to the hub and thereafter from the hub to the testing laboratory:

A specimen delivery checklist/ sample manifest form should be used to verify all transported samples.

Considering the SOPs, specimens should appropriately be packed and placed in proper and safe containers before transporting them.

Dispatch and receipt records of transported samples should be maintained.

4.8 Internal Quality Assurance

Laboratory Internal Quality Assurance (IQA) involves close monitoring and tracking processes and procedures done in the laboratory. It involves checking that all laboratory and testing equipment are in good working condition and perform accurately as expected; all tests done produce reliable results and documentation is properly done for all laboratory activities and outputs.

The bottom line for a functional laboratory internal quality control scheme is having well documented and archived laboratory activities (equipment performance and calibrations; testing results with appropriate controls; remedial actions for occurrences and safety practices).

IQA is mandatory for all tests that are done during monitoring of HIV clients, hence involving all areas that participate on testing and monitoring of HIV infected and AIDS clients (RCH, VCT, Laboratory, PITC etc.). All samples for IQA testing are treated as of client's samples. A well-

functioning internal control scheme culminates into good performance in External Quality Assessment

4.9 External Quality Assurance

External Quality Assurance (EQA) is a system used to objectively check the laboratory performance using an external agent or facility. Three methods are used to do EQA: Proficiency Testing (PT), Re-testing and on-site evaluation. The benefits of doing EQA include comparing performance among different testing sites, detection of the early warning signs for system problems, objective evidence of testing quality, areas that need improvement and training. EQA is mandatory for all tests done in monitoring of HIV clients, hence involving all areas that participate on testing and monitoring of HIV and AIDS infected clients (e.g. RCH, VCT, Laboratory, and PITC). All samples for EQA testing are treated as client's samples.

4.9.1 Proficient Testing

Proficient Testing Schemes (PTS) are inter-laboratory comparisons that are organized regularly to assess the performance of analytical laboratory and the competence of the analytical personnel.

4.9.2 Inter-Laboratory Comparison

Inter-Laboratory Comparison is a system whose sample testing is performed by one HF and then re-tested at the different HF or reference laboratory for comparison of results. The samples for interlaboratory comparison should be randomly selected.

4.9.3 On-Site Evaluation

On-site evaluation is done by an external supervisor who visits the facility to obtain a realistic picture of the laboratory practices and provides assistance on problematic areas. This will include re-testing of samples.

CHAPTER 5

HIV PREVENTION

5.0 Introduction

This chapter describes the Combination Prevention approach which includes: biomedical, behavioural and structural interventions to achieve maximum impact on reducing HIV transmission and acquisition. Particular emphasis is given on the Positive Health, Dignity and Prevention (PHDP) package. The chapter also includes a section on the key HIV prevention services for Key and Vulnerable Populations (KVP).

5.1 Positive Health, Dignity and Prevention (PHDP)

PHDP focuses on improving and maintaining health and well-being of PLHIV, which, in turn, contributes to the health and well-being of sexual partners, families and communities. Indirectly, PHDP is in contrast to previous approaches on 'positive prevention', which could be interpreted as treating people living with HIV as vectors of transmission. By focusing on the journey experienced by PLHIV from testing to support, care and treatment, ''Positive Health, Dignity and Prevention'' positions the health and social needs and experiences of PLHIV within a human rights framework. Promotion of high HIV risk behaviour reduction among PLHIV and non-infected individuals is important in controlling transmission and acquisition of HIV infection.

In order for PHDP programming to be successful, it must include a synergistic combination of interventions at three different levels.

Central Level Interventions

At this level, interventions mainly focus on changes in the policy and legal framework to alter the environment in ways that promote and support implementation of PHDP activities and services. To date, HIV prevention has largely focused on providing information, counselling and testing for those who are HIV-negative. While this is an important strategy, people living with HIV have often been left out of prevention. Recently, consensus has formed around the benefits of targeted HIV prevention among individuals who know that they are HIV-positive. The additional strategy of providing prevention recommendations and strategies to those who are already HIV-positive aim to prevent the spread of HIV to their sex partners and infants born to HIV-infected mothers, as well as to protect the health of HIV-infected individuals.

Health Facility Interventions

HIV care and treatment clinics provide an important setting for HIV infection prevention and control for several reasons. Firstly, CTC reaches a large number of PLHIV. Secondly, it integrates prevention strategies into care and treatment clinic ensuring comprehensive and consistent quality of care. Thirdly, it provides an opportunity in imparting prevention messages at every visit.

Components of a comprehensive package for HIV infection prevention and control in the clinical setting are:

- Condom distribution and promotion
- Messaging and counselling support for social and behavioural change including: sexual risk reduction, retention in care, adherence to medications, and partner HIV testing and counselling
- HIV testing and counselling
- ART as prevention
- Voluntary Medical Male Circumcision (VMMC)
- Screening and treatment of STIs and RTIs
- Prevention of Mother to Child Transmission (PMTCT)
- Safer pregnancy counselling and family planning services integration
- Identification of social needs, referral and linkage for community-based services

Cervical cancer screening with visual inspection using acetic acid (VIA)

Providers can impact the HIV epidemic in their communities by addressing it through offering prevention, care and treatment services to PLHIV,

Community Level Interventions

Community level interventions are in line with the national guidelines on Community Based HIV Services (CBHS). The following are the components of the minimum package of the CBHS:

Condom distribution and promotionMessaging and counselling support for health behaviours including: sexual risk reduction; retention in care, adherence to medications, and partner HIV testing and counselling

HIV testing and counselling

Screening of STI

Safer pregnancy and family planning counselling

Identification of needs for care, treatment, referral and linkage for health facility- based services

5.2 Condom promotion and distribution

Both male and female condoms are highly efficacious and cost effective in preventing sexual transmission of HIV and other STIs. Condom use will continue to be a key component of the HIV prevention package in Tanzania Mainland, with a focus of high-risk groups and the general population.

The key elements to successful condom programming include easy access to condoms for those who need them within the health care setting, provision of sufficient quantities of condoms to be used with every sexual encounter until the next visit, provision of education and demonstrations on consistent and proper condom use, choice options between male and female condoms, mass media marketing and promotion of condoms in order to increase availability, accessibility and utilization.

5.3 Social and Behaviour Change Communications (SBCC)

5.3.1 Comprehensive Knowledge on HIV and ART

Social and Behaviour Change Communication is the developmental practice of enabling individual and societal change through engaging communities to determine what changes are necessary to address their specific challenges and identifying localized strategies to facilitate the required change[10.]

Messages and behavioural drivers that contribute to social environment in which individuals grow and live and variously constitute barriers to health and wellness. Both structural and behavioural drivers collectively fuel the spread of the HIV and AIDS epidemic.

Table 5.1 Structural and Behavioural Drivers		
Migration and mobility Disempowerment through poverty Unemployment and economic inequality Gender inequality Social and cultural norms Weak policies, laws and law enforcement Barriers to accessing prevention and other services An absence of services	Stigma, discrimination, and lack of open communication around HIV and sex Multiple concurrent sexual partnerships Improper and inconsistent condom use Intergenerational and transactional sex Gender based violence Alcohol and drug abuse	

Source: Adapted from *Situation and Response Analysis Report on SBCC for HIV and AIDS, TB and STIs in SADC Member States.* Coxswain Social Investment Plus.

Communication is an essential element for HIV prevention and treatment and care efforts. It is the exchange of information, ideas or feelings. Communication is the core components of SBCC that enables interactive process of engagement between SBCC practitioners and communities. This engagement is aimed at empowering communities to change their behaviours.

SBCC interventions usually comprise a combination of advocacy, communication and social mobilization:

- Advocacy attempts to influence leaders at all levels from community right up to national and sometimes regional and international levels to promote enabling legislation and remove barriers to change.
- Communication can enable and promote behavioural change that often uses multiple channels including inter-personal (provider-client), TV, radio, print, drama, peer education, storytelling, etc.
- Social Mobilization to or within individuals, groups and communities can encourage grounds well support to address barriers of change.

Within the new scope of test and start, SBCC should play a lead role in raising awareness and appropriately communicate the "test and treat" approach, especially because this approach diverts from the previous messages on eligibility criteria for ART initiation.

Recent studies provide strong evidence for the prevention benefits of ART. PLHIV who are adherent to ART and successfully maintain low or undetectable viral load are far less likely to transmit HIV to their sexual partner(s). Therefore, early enrolment into care, retention, and adherence to ART is a key component of HIV prevention.

PLHIV who are recently infected and/or are not yet on ARVs, usually look healthy and clinically well, and continue with their normal lifestyle (including sexual behaviours). However, it is known that HIV-positive persons who are not on ARVs and having unprotected sex may have high viral loads and may be at a high risk of transmitting HIV to their sexual partners.

PLHIV once having being very ill but are now on ART, generally, enjoy better health and more active lives, which may lead to a renewed desire for sexual activity, and new partners. Thus, adherence to medication and retention in care is critical by ensuring that clients continue to receive life-saving medicines, and risk reduction message reinforcement.

Another important benefit of ART is that it leads to a viral load suppression to undetectable levels that decrease chances of transmitting HIV. However, it should be understood that, even if a client is on ARTs, there is a possibility of PLHIV transmitting HIV, including drug resistant strains. So, it is important for healthcare providers to help PLHIV understand that they can still transmit HIV and recommend that they take precautions, and adhere to prevention measures even when they are on treatment and HIV viral load is at undetectable level. Providers should inform clients that:-

The goal of ART is to suppress viral replication with the aim of reducing the patient's VL to undetectable levels.

Strict adherence will help maintain undetectable VL levels thereby preventing damage to the body's immune system and restoring and maintaining healthy living, as well as reducing the risk of sexual and vertical transmission of HIV.

ART is very effective in reducing onwards HIV transmission by infected individuals and helps to drastically reduce TB incidence.

5.3.2 Couple HIV Testing and Counselling

Healthcare providers should encourage PLHIV to bring in their partners for HIV testing and counselling. This provides an opportunity to counsel couple(s) together, and help to identify discordant couples.

For the discordant couple, healthcare providers should give prevention messages to help clients reduce the risk of transmission to HIV-negative sex partners. By encouraging partners in a discordant relationship to adopt safer sex behaviours, providers play an important role in helping discordant couples protect the negative sexual partner from becoming HIV-infected. Additionally, HIV-negative partners should get tested regularly. Recent evidence shows that, early initiation of ART to the infected sexual partner reduces the chances of infecting his/her partner.

In concordant relationships where both partners are HIV-positive, a potential consequence of unprotected sex to the HIV-infected sexual partner is that he or she may become "re-infected" with a different strain of HIV or STIs.

5.3.3 Reducing Risk Behaviours

Persons living with HIV remain sexually active and desire a healthy sex life. One of the first steps to providers taking a PHDP approach in clinical setting is to recognize that PLHIV have a right to sex as one of their human rights and needs, and need ongoing education and support from their healthcare providers on how to protect themselves and their sexual partners. PLHIV are receptive to various risk reduction advice given by HCWs. Specifically, risk reduction messages include reduction of concurrent sexual partners, consistent and proper condom use, disclosure and knowing your partner's status, and reduced alcohol consumption. *Include citation*.

5.4 Screening of Sexually Transmitted and Reproductive Tract Infections (STIs/RTIs)

Sexually Transmitted and Reproductive Tract Infections (STI/RTIs) remain a public health problem of major impact in many countries. Failure to diagnose and treat STIs/RTIs at an early stage may result into serious complications and consequences including infertility, foetal wastage, ectopic pregnancy, ano-genital cancer, premature delivery, as well as neonatal and infant infections. STIs are also known to enhance the spread of HIV infections in communities. On the other hand, there are other RTIs that are caused by organisms normally present in the reproductive tract, or are introduced during sexual contact or invasive medical procedures. These RTIs are wrongly labelled as STIs leading to unnecessary stigmatization of women and marital disharmony.

WHO estimates that over 357 million episodes of curable and many more incurable STIs occur each year worldwide. Non-sexually-transmitted RTIs are even more common. Tanzania is no exception to this state of affairs. In Tanzania, 10-20% of the sexually active population contract STIs each year. In 2011, the HIV and Syphilis surveillance among antenatal clinic attendees showed a 2.5% overall prevalence of Syphilis).[11] Also STIs/RTIs facilitate sexual acquisition and transmission of HIV infection as well as impacting the socio-economic status of the families. Furthermore, STIs/RTIs affect the success of other health programs. The control of STIs/RTIs is a public health priority. Therefore, a comprehensive STI/RTI control and prevention programme is vital.

Syndromic management of STIs is based on the diagnosis of defined symptoms and easily recognizable clinical signs.

Common symptoms of STIs/RTIs are painful micturation, abnormal vaginal/urethral discharge, genital ulcerations, genital itching, and swelling of inguinal lymph nodes, scrotal swellings, lower abdominal pain and pain during sexual act.

Each syndrome can be a result of a number of different causative agents. Table 5.1 below describes the advantages and disadvantages of different approaches in STIs/RTIs screening.

Table 5.1 Advantages and Disadvantages of Different Approaches in STI/RTI Screening

Aetiological/ Laboratory	Avoids overtreatment, saves drugs Conforms to traditional clinical training Satisfies clients who feel not properly attended without laboratory check up Can be extended as screening to identify clients with asymptomatic STIs/RTIs	Laboratory results are often not reliable due to lack of quality control Mixed infections are often overlooked Treatment delays, reluctance of clients to wait for laboratory results High costs Laboratory services not available at the majority of health facilities.
Aetiological/ Clinical	Saves time for clients No need for laboratory facilities	Mixed infections are often overlooked Similar clinical features can be

[11] ANC Surveillance 2012

		caused by a variety of causative agents Requires long term training Does not identify asymptomatic STI A typical presentation in HIV infection or mixed infections
Syndromic	Saves time for clients No need for laboratory facilities Provides adequate treatment, even for mixed infections Easy to teach and simple to apply Cost-effective Promotes integration of services	Entails frequent overtreatment of clients Requires special attention to microbial drug sensitivity monitoring on regular basis. Does not identify asymptomatic

Due to non-specificity of symptoms, stigma and social implications attached to STIs, healthcare workers should be careful not to mislabel RTIs as STIs. The latter should be diagnosed and treated promptly and adequately. Treatment to the sexual partners is strongly recommended, as well as periodic screening and presumptive treatment to sex workers, as per national STI guidelines.

5.4.1 Syphilis

Syphilis in both men and women is associated with high risk rate of HIV acquisition and with serious complications on pregnancy outcome. Co-infections of syphilis and HIV infections may alter the clinical presentation and treatment modalities of syphilis.

Indications and Opportunities for Screening

Screening for syphilis during pregnancy should be done at the first antenatal visit, or as early as possible. It can be repeated in the third trimester if resources permit, to detect infection acquired during the pregnancy.

Women who do not attend antenatal clinic should be tested at delivery. Although this will not prevent congenital syphilis, it permits early diagnosis and treatment of newborns.

Women who have had a spontaneous abortion (miscarriage) or stillbirth should also be screened for syphilis; in many areas, identification and treatment of syphilis remove a major cause of adverse pregnancy outcome.

Because of the serious complications of syphilis in pregnancy, the first priority should be to ensure universal antenatal screening.

Screening for syphilis should also be done in all women with history of abortion or preterm delivery.

Men and women with STI syndromes other than genital ulcer should be screened for syphilis. Screening is unnecessary for clients with ulcers who should be treated syndromically for both syphilis and Chancroid without testing.

Other opportunities for screening for syphilis include family planning, VMMC at any time, a speculum examination is performed; and in all male partners of female with STI/RTI and vice versa.

5.4.2 Overview of STI Syndromes

Although STIs are caused by many different organisms/agents, these organisms give rise to a limited number of syndromes. Table 5.2 below outlines the nine common STI syndromes and their etiologic agents.

Table 5.2 STI Syndromes and their Aetiological Agents

STI SYNDROME	SEX	COMMON AETIOLOGIC AGENT
Urethral Discharge Syndrome (UDS)	Males	*Chlamydia trachomatis* *Neisseria gonorrhoeae*
Painful Scrotal Swelling (PSS) (acute epididymoorchitis)	Males	*Chlamydia trachomatis* *Neisseria gonorrhoeae*
Vaginal Discharge Syndrome (VDS)[1]	Females	*Candida albicans* *Chlamydia trachomatis* *Gardnerella vaginali* *Neisseria genorrhoeae* *Trichomonas vaginalis*
Pelvic Inflammatory Disease (PID) (Lower Abdominal Pain)	Females	*Anaerobic bacteria* *Chlamydia trachomatis* *Neisseria gonorrhoeae*
Genital Ulcer Disease (GUD)	Males	*Chlamydia trachomatis*

	Females	*Haemophilus ducreyi* Herpes simplex virustype-2 *Treponema pallidum* *Klebsiella granulomatis*
Inguinal Bubos	Males Females	*Chlamydia trachomatis* *Haemophilus ducreyi*
Anorectal Syndrome	Males Females	*Neisseria gonorrhoeae* *Chlamydia trachomatis* *Herpes simplex* *Treponema pallidum* *Human papilloma virus*
Neo-natal Conjunctivitis (Opthalmia neonatorum)	Newborns Males and Females	*Neisseria gonorrhoeae* *Chlamydia trachomatis*
Oropharyngeal infection	Males and Females	*Treponema pallidum* *Neisseria gonorrhea* *Chlamydia trachomatis* *Klebsiella spp* *Human papiloma virus (HPV)*

Note: Cervical infections caused by Neisseria Gonorrhoea and Chlamydia trachomatis sometimes present with vaginal discharge.

For management of common syndromes, see Flow Chart for Syndromic Management of STI's/RTI's in the national STIs/RTIs guideline.

5.5 Cervical Cancer

Cervical cancer is the leading cause of cancer-related morbidity and mortality in Tanzanian women. One-tenth of the estimated 72,000 new cases and 56,000 cervical cancer deaths in Sub-Saharan countries in the year 2000 occurred in Tanzania.[12] Furthermore, 80% of patients diagnosed with cervical cancer die within five years of diagnosis. This low survival rate is mainly due to advanced stage of disease at presentation and limited access to cervical cancer screening, diagnosis and treatment services.

The problem is compounded by the HIV and AIDS epidemic. The association between HIV and invasive cervical cancer is complex with several studies now clearly demonstrating an increased risk of precancerous cervical lesions and more rapid progression to cancer among HIV-infected women. In Tanzania women with cervical cancer are twice as likely to be HIV-infected and HIV-positive women also develop cervical cancer 10 years earlier than HIV-negative women[13]. Although about 40–90% of women in developed countries are screened for cervical cancer, less than 5% of women in developing countries undergo cervical cancer screening.[14,15]

Researchers suggest that as women are living longer due to access to ART, they are at an increased risk of contracting cervical cancer. While access to antiretroviral therapy is beginning to reduce AIDS mortality worldwide, gynaecologic oncologists warn that women being treated for AIDS could end up dying of cervical cancer unless they have access to appropriate screening and treatment.

HIV-positive women require a more intensive screening schedule. It is recommended that annual cervical cancer screening using VIA as the primary screening method or rapid HPV testing be integrated into the national policy as part of routine care for HIV-positive women. Care and treatment clinic (CTC) sites should be closely linked with sites providing services for cervical cancer prevention, or ideally, provide the services themselves. In addition, amongst sexually active girls and women, cervical cancer screening should be done at HIV diagnosis and repeat annually regardless of previous results.

Women living with HIV are at a greater risk for developing cervical cancer because of higher rates of co-infection with HPV which is persistent in most cases. Characteristics of HPV related lesions

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[12] Parkin DM, Pisani P, Ferlay J: Estimates of the worldwide incidence of 25 major cancers in 1990. Int J Cancer 1999, 80:827-841.

[13] Kahesa C, Mwaiselage J, Wabinga HR, Ngoma T, Kalyango JN, Karamagi C (2008). Association between invasive cancer of the cervix and HIV-1 infection in Tanzania: the need for dual screening. BMC Public Health 8(1):262.

[14] Hakama M, Chamberlain J, Day NE, Miller AB, Prorok PC: Evaluation of screening programmes for gynaecological cancer. Br J Cancer 1985, 52(4):669-673

[15] Chirenje ZM, Rusakaniko S, Kirumbi L, Ngwalle EW, Makuta-Tlebere P, Kaggwa S, Mpanju-Shumbusho W, Makoae L: Situation analysis for cervical cancer diagnosis and treatment in east, central and southern African countries. Bull World Health Organ 2001, 79(2):127-132

in HIV positive women include larger precancerous lesions that are more difficult to treat, recurrence of precancerous lesions following treatment and rapidly progressive cervical cancer.

Cervical cancer screening should therefore be integrated as part of routine care for HIV-positive women. Annual screening using visual inspection with acetic acid (VIA) or rapid HPV testing is recommended. Screening should be initiated at HIV diagnosis, regardless of age, once sexually exposed. For women who have just delivered, screening can be initiated post puerperal. Refer to the Tanzania Service Delivery Guidelines for Cervical Cancer Prevention and Control for detailed information and guidance.

5.6 Family Planning and Safer Pregnancy Counselling Services

PLHIV have sexual desires and have the right to bear children, hence they need support from healthcare providers to safely plan for wanted pregnancies and to avoid unwanted pregnancies. Since many PLHIV attending CTCs do not make visits with their partners, provider assessment of fertility desires to both male and female CTC clients is essential. Typically, family planning and pregnancy services are directed toward women only, while within the partnership, men's fertility desires and expectations are equally important. HIV clinical care settings provide an opportunity to reach out to male members of the couples and emphasize shared decision-making and open communication about pregnancy and contraception.

One of the key strategies for ensuring that HIV positive couples have access to contraceptives and advice about pregnancy is to provide family planning (particularly dual protection i.e. barrier and non-barrier methods) and safer pregnancy counselling within the CTC following an integrated model of service provision. Another strategy is through prevention of mother to child transmission (PMTCT) services, where ART has proven to be the most efficacious treatment for prevention of transmission to the child. Women of child bearing potential who opt to use DTG should be counselled on the consistent use of reliable and long acting contraceptive and/or effective dual contraception with condoms (*Note: More details are available in the national SRHS/FP guidelines*).

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5.7 Biomedical Prevention of HIV

5.7.1 Infection Prevention and Control (IPC)

Exposure of the health service providers to the blood of those receiving care occurs mostly via accidental injuries, from sharps such as syringe needles, scalpels, lancets, broken glass or other objects contaminated with blood. Poor practices during patient care by HIV-infected medical staff may also expose the patient to infection. Also, when equipment (e.g. suction) is poorly sterilized, HIV may be passed from an HIV-infected individual to an uninfected patient within the healthcare setting.

Protecting HSPs from occupational exposure and ensuring that they know their status and receive HIV services is an important priority for the health sector. HIV and other Blood Borne Pathogens (BBPs) such as Hepatitis B and Hepatitis C may be transmitted in healthcare settings from patient to patient and patient to healthcare worker, or vice versa.

Accidental transmission can be prevented by implementing the following infection prevention and control measures:

- Adherence to standard precautions such as hand hygiene;
- Use of Personal Protective Equipment (PPE) such as gloves;
- Proper healthcare waste management
- Processing of instruments by decontamination
- Cleaning and sterilization using High-Level Disinfectants (HLDs)
- Observing safe work practices

For effective occupational health programme facilities, managers and providers should ensure:

- A good occupational health programme aiming to identify, eliminate and control exposure to hazards in the workplaces;
- Provision of training to health service providers in identifying and controlling hazards;
- Provision of immunization against Hepatitis B;
- Implementation of standard precautions;
- Provision of free access to post-exposure anti-retroviral prophylaxis for HIV;
- Promotion of reporting of incidents and quality control of services provided.

5.7.2 Post Exposure Prophylaxis (PEP)

Post Exposure Prophylaxis (PEP) is the immediate provision of preventive measures and medication following exposure to potentially infected blood or other bodily fluids in order to minimize the risk of acquiring infection. Several clinical studies have demonstrated that HIV transmission can be reduced by 81% following immediate administration of anti-retroviral agents.

Exposure prevention is the primary strategy for reducing occupational HIV transmission, that is, the chance of acquiring infection following exposure to blood and other bodily fluids (semen, vaginal secretions and breast milk) from an infected person. These bodily fluids should be considered as being infectious. Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water. In case of splash involving mucous membranes (e.g., eye) should be flushed with water immediately. Sexual exposure comprises an act of unprotected voluntary or forced sexual intercourse (rape/sexual assault), as well as in the case of slipped or torn condom during sex with discordant partner.

Effective post-exposure management entails the following elements:

- Management of exposure Site,
- Exposure reporting,

- Assessment of infection Risk,
- Appropriate treatment,
- Follow-up and counselling.

When an exposure occurs, the circumstances and post exposure management procedure applied should be recorded in the exposed person's confidential form for easy follow up and care.

Evaluation of the exposed Individuals

Individuals exposed to HIV should be evaluated within two hours rather than days and no later than 72 hours. A starter pack should be initiated within two hours after exposure and before testing the exposed person. Exposed healthcare workers should be counselled and tested for HIV at baseline in order to establish infection status at the time of exposure. PEP should be discontinued if an exposed healthcare worker refuses to test. To facilitate an effective choice of HIV PEP drugs, the evaluation should include information on the type of medication the exposed person might be taking and any current or underlying medical conditions or circumstances (such as pregnancy, breastfeeding, renal or hepatic disease) that might influence drug selection. Vaccination against Hepatitis B should be considered.

In addition, rape survivors should be offered counselling, crisis prevention and provision of on-going psychosocial support so as to reduce/minimize immediate rape trauma disorder and long-term post-traumatic stress disorder and referred to mental care, police and legal services, according to law and regulations.

Evaluation of the Source Person

Evaluation of the source person should be performed when the exposed individual agrees to take PEP. If the HIV, HBV and HCV status of the source person is unknown perform these tests after obtaining consent. The exposed healthcare worker should not be involved in obtaining consent from the source person. If the source person is unknown, evaluation will depend on other risk criteria. Do not test discarded needles or syringes for viral contamination.

Drugs for HIV PEP

Recommended PEP Regimen: TDF+3TC/FTC+DTG for adult and adolescents once a day for four weeks and for children (based on body weight) AZT + 3TC + LPV/r twice daily for four weeks. Children whose weight is more than 20kg DTG can be used instead of LPV/r and maintain AZT+3TC as backbone.

Note: If the source is using PI based regimen, then the PEP regimen should be PI based (similar to the source's regimen).

Follow-up of HIV Exposed Individuals

HIV antibody tests should be performed at least after 4-6 weeks' post-exposure (i.e. at 6 & 12 weeks). HIV testing should also be performed for any exposed person who has an illness that is compatible with an acute retroviral syndrome, irrespective of the interval since exposure.

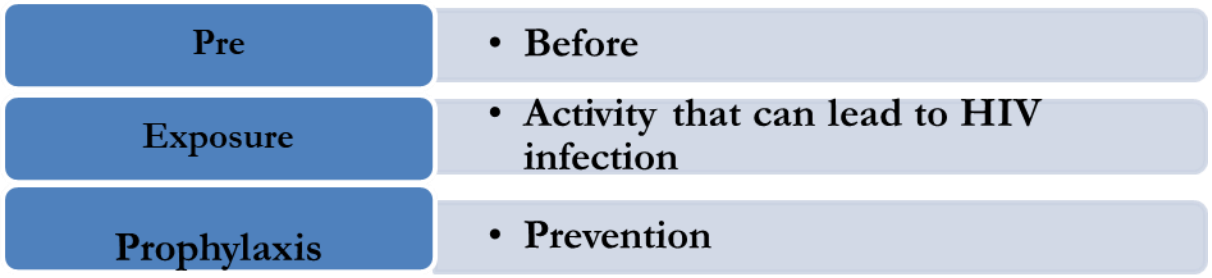
If PEP is administered, the exposed person should be monitored for drug toxicity at baseline and 2 weeks after starting PEP. Minimally, it should include a full blood picture (FBP), renal function test (RFT-Serum creatinine and urinalysis) and hepatic function tests (LFT- ALT).

Exposed persons should be re-evaluated within 72 hours, after additional information about the source of exposure including serologic status, viral load, current treatment, any resistance test results (if available) or information about factors that would modify recommendations, is obtained.

PEP should be administered for four weeks if tolerated. If not, manage symptoms accordingly and if intolerance persists, change to more tolerable PI based regimen. If the patient seroconvert and the exposed person becomes HIV infected, he/she should be referred to a CTC for proper care and treatment service.

5.7.3. Pre –Exposure Prophylaxis (PrEP)

Pre-Exposure **P**rophylaxis **(PrEP)** is the use of ARV drugs daily by HIV-uninfected persons to prevent the acquisition of HIV before the person becomes exposed to HIV. PrEP is used by people who are at a substantial risk for HIV acquisition to lower their chances of getting HIV infection.



5.7.3.1 PrEP targeted Populations for **PrEP**

Targeted population for PrEP include Sex workers (female, male and transgender adults (18 years of age and above), men who have sex with men, people who inject drugs, vulnerable adolescent girls (15-19), young women (20-24) and HIV negative partner of Sero-discordant couples when an HIV infected partner is not on ART or is on ART for less than six months or has not attained viral suppression less than 50copies/ml.

5.7.3.2 Eligible clients for PrEP

• Aged 15 years and older
• HIV sero negative
• At substantial risk* of HIV infection
• No suspicion of acute HIV infection
• Creatinine clearance >60ml/min**
• Willingness to consent for and use PrEP as prescribed

Substantial risk of HIV infection means:

a) vaginal or anal sex without a condom with more than one partner or,

b) history of a new sexually transmitted infection or,

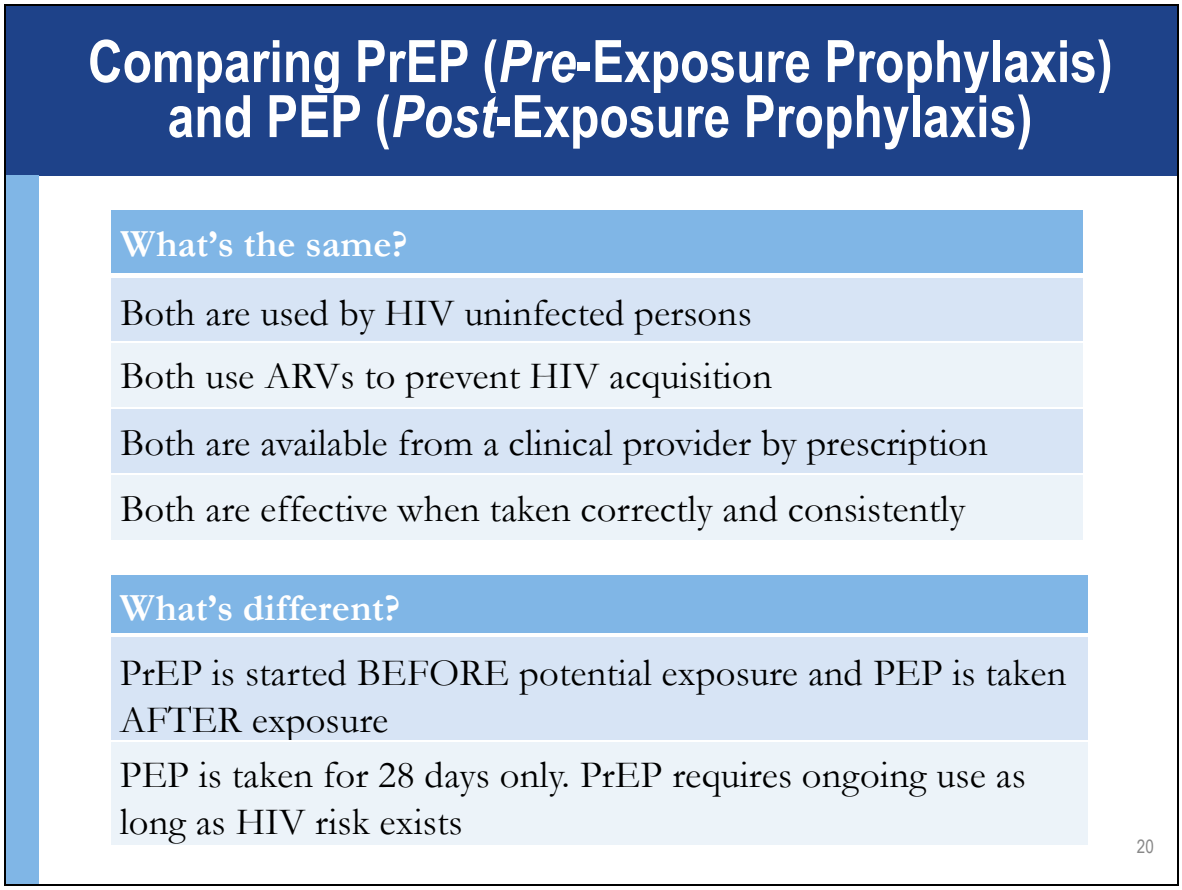
c) use of post exposure prophylaxis for sexual exposure or,

d) Has a known HIV positive sexual partner(s) who is not on ART/ on ART less than six months or refuses to report a risk category but still requests PrEP

5.7.3.3 Clients who are not eligible for PrEP include:

- Acute HIV Infection (AHI)
- Client with eGFR* <60ml/min
- Significantly mobile persons that will not be able to attend visits as prescribed. For example:
    - clients who will not be in a region where PrEP can be provided at the next visit
    - clients who do not have contact information
- Unwilling/unable to take daily medication
- Allergy or contraindication to any medication within PrEP regimen.

Comparing PrEP and PEP



Comparing PrEP and ART

- HIV treatment requires adherence to life-long therapy with consistent, fully-suppressive dosing.
- PrEP is needed during "periods" of high HIV risk.
- Both ART and PrEP require optimal adherence.
- Individuals taking PrEP require ongoing risk assessment and PrEP can be discontinued if they:
    - Acquire HIV infection.
    - Are no longer at substantial risk for HIV infection.
    - Decide to use other effective prevention methods.
- Motivation for adherence is different**:**
- ART is taken by HIV-infected persons, who may have symptoms, so as to remain healthy and prevent onward transmission of HIV.
- While PrEP is taken by HIV uninfected persons to prevent acquisition of infection.

ARVs Used for PrEP and Their Side Effects

The WHO recommends that oral PrEP regimens should contain tenofovir disoproxil fumarate (TDF).

The recommended PrEP regimen in Tanzania is: **Emtricitabine** (FTC) 200mg**/Tenofovir Disoproxil Fumarate** (TDF) 300mg **(Truvada)** PO Daily. For more information on minor and adverse effects of the drugs of the PrEP regimen refer Chapter 10, Table 10.5. .

5.7.3.4. Indications for PrEP discontinuation

Individuals taking PrEP require ongoing risk assessment and PrEP can be discontinued if individuals acquire HIV infection, are no longer at substantial risk for HIV infection or decide to use other effective prevention methods and poor adherence.

PrEP should be provided for at least 28 days after the last possible exposure to HIV. The client should return after completing the final prescription for an HIV test to confirm status. Refer the client to other relevant prevention services.

5.8 Voluntary Male Medical Circumcision (VMMC)

Voluntary Medical Male Circumcision (VMMC) has been implemented in different sub-Saharan countries in an effort to reduce the incidence of HIV infection amongst men. Three randomized controlled trials[16],[17] demonstrated that medical male circumcision is an effective protective factor against heterosexual HIV acquisition, reducing the risk of transmission from females to males by approximately 60%. Surgical removal of the foreskin reduces male's vulnerability to HIV in penile-vaginal intercourse. Therefore, VMMC is an important component of comprehensive HIV prevention in areas with a high prevalence of heterosexually-transmitted HIV infection.

In Tanzania, the national prevalence of male circumcision (medical and non-medical) is about 77.6% among male aged 15 years and older (THIS 16/17). The male circumcision rate is as low as 26% in non-circumcising communities. The coverage rate of VMMC amongst non-circumcising communities has risen up to between 14% to 38% following implementation of National Strategy for Scaling up Male Circumcision for HIV prevention.[18]

Early Infant Male Circumcision (EIMC) is another component in Tanzania's national HIV prevention strategy. There are significant benefits in performing EIMC in infancy (between one to 60 days of age). Procedures for EIMC are much easier to perform compared to that of adults/ adolescents. EIMC also has a lower rate of adverse events, faster healing and a lower unit cost than VMMC.

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[16]Bailey RC, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomized controlled trial. Lancet. 2007;369:643–656. [PubMed]

[17]Citation here—the famous three studies in Kenya and Uganda Gray RH, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. Lancet. 2007;369:657–666. [PubMed]

[18]United Republic of Tanzania MoHSW, National AIDS Control Programme,. National Strategy for Scaling Up Male Circumcision for HIV Prevention. 2010.

5.8.1 Minimum Package for VMMC Services

All HCW offering VMMC services should:

- Educate clients on the link between VMMC and HIV prevention
- Offer HIV testing and counselling so that clients know their HIV status and refer clients who test positive to a care and treatment clinic
- Refer clients who test HIV positive to care and treatment
- Screen for STIs and RTIs (and treatment, when indicated) since STIs increase a person's risk of acquiring or transmitting HIV
- Counsel on risk reduction
- Promote and distribute male and female condoms together with the promotion of their correct and consistent use
- Provide surgical care that is safe and of high quality, in settings that are adequately equipped and environmentally suitable for minor surgical procedures
- Provide appropriate postoperative care and care of any associated adverse events.

5.8.2 Minimum Package of Early Infant Male Circumcision (EIMC) Services

All HCW at facilities offering EIMC services for HIV prevention must:

- Provide information to parents or guardians on advantages and risks of EIMC.
- Offer of HIV testing and counselling to parents or guardians to ensure identification of HIV-exposed infants.
- Link HIV-positive parents to HIV care and treatment services.
- Counsel on the post-operative care of circumcised infants and identification of related complications, danger signs and where to go for follow-up care, if required.
- Provide surgical care that is safe and of high quality, in settings that are adequately equipped and environmentally suitable for minor surgical procedures.
- Provide appropriate postoperative care and care of any associated adverse events.
- Refer clients to appropriate services such as immunization, well baby care, and HIV care and treatment for HIV-exposed infants and/or those infants found to be HIV-positive through Early Infant Diagnosis (EID).

5.9 Blood Safety

Unsafe blood transfusion is a well-documented mode of transmission of HIV and other infections. Many recipients of blood and blood products are at risk of transfusion-transmissible infections, including HIV, as a result of poor blood donor recruitment and selection practices and the use of unscreened blood.

Access to safe blood transfusion is an essential part of quality health care. The MoHCDGEC has established National Blood Safety Program (NBSP) to ensure the availability of safe blood and blood products through a nationally coordinated blood transfusion service.

HCWs should ensure that clients in need of blood or blood products are transfused with safe blood which has been appropriately screened for all transfusable pathogens using WHO criteria at the zonal centre.

5.10 HIV Prevention Services for Key and Vulnerable Populations (KVP)

According to WHO, Key Populations (KPs): are defined groups of people who, due to specific higher-risk behaviours, are at increased risk of HIV irrespective of the epidemic type or local context. Also, they often have legal and social issues related to their behaviours that increase their vulnerability to HIV. WHO guidelines focus on five key populations: 1) men who have sex with men 2) people who inject drugs 3) people in prisons and other closed settings 4) sex workers and 5) transgender people. The key populations are important to the dynamics of HIV transmission. They are also essential partners in an effective response to the HIV epidemic.

Vulnerable populations (VPs): are groups of people who are particularly vulnerable to HIV infection in certain situations or contexts. Such groups are adolescents (particularly girls in sub-Saharan Africa), orphans, street children, people with disabilities, and migrant and mobile workers. These populations are not affected by HIV equally across all countries and epidemics.[19]

Key and vulnerable populations (KVP) are therefore important to the dynamics of HIV transmission and in an effective response to the epidemic. The groups include:

- Sex workers (SW) and their clients
- People who inject or use drugs – PWID/PWUD
- Men who have sex with men – MSM
- People in prisons and other closed settings
- Adolescent girls and young women (AGYW)
- Mobile populations (long distance truck drivers, fisher folks and fishing communities, miners and mining communities, construction and plantation workers)
- Disabled persons in all forms
- Street living or working children and displaced people.

[19]WHO Consolidated Guidelines on HIV prevention, diagnosis, treatment and care for key populations 2016

HSPs need to provide non-judgmental, non-discriminatory services to be able to identify and address the special needs of key and vulnerable populations within and beyond the healthcare setting. The following list summarizes the key services to be offered to KVP:

- Promote and provide male and female condoms
- Provide VMMC service
- Provide HTS
- Provide ART to HIV infected individuals
- Provide pre-exposure prophylaxis (PrEP)
- Screen and manage STIs, RTIs and cervical cancer
- Counsel and offer Reproductive Health Services (RHS) inclusive of family planning services and dual protection as well as counselling and PMTCT
- Link to facility providing medication-assisted treatment (MAT) and other drug dependence treatments (i.e. harm reduction)
- Provide behavioral change and communication service
- Screen for Hepatitis B and C and provide vaccination for Hepatitis B as appropriate
- Screen for Tuberculosis and manage accordingly
- Screen for sexual violence and provide PEP along with other interventions for gender-based violence (GBV)
- Link with psychosocial support services through targeted campaigns in identified key and vulnerable population settings, use community based outreach, mobile phone technologies, social networking and develop friendly key population services at health facilities; this will facilitate dissemination of behavioural messages, promote follow-up and referral to services, improve adherence to treatment, and increase client participation in their own health care.
- Sensitize and educate health service providers, community health workers, CBHS, peers, supportive staff and management on issues of specific key and vulnerable populations and on non-discriminatory practices and eliminating stigma, using pre-service and in-service training, job-aids, supportive supervision, and training follow up.
- Ensure confidentiality: Attention should be devoted to protecting privacy and confidentiality, e.g. closing the consultation room door or finding a private place to talk. Clients should be reassured of confidentiality.

- Proper Linkage and referral mechanisms to community support programmes (e.g. psychosocial support, income generating group, spiritual support and legal support etc.).

For further details on management of HIV for KVP, refer to the National Guidelines on Comprehensive HIV Interventions for Key and Vulnerable Populations, 2017 Edition.

CHAPTER 6

MANAGEMENT OF HIV OPPORTUNISTIC INFECTIONS AND CO-MORBIDITIES IN ADOLESCENTS AND ADULTS

6.0 Introduction

Anti-retroviral Therapy (ART) does not provide a cure for HIV, but has drastically reduced HIV related morbidity and mortality. This is due to the fact that ART reverses the HIV-induced immune depletion which is responsible for occurrence of different opportunistic Infections (OIs). Early ART initiation, whereby all HIV-infected clients are initiated anti-retroviral therapy regardless of CD4 cells count will prevent occurrence of OIs and other co-morbidities.

Effective use of ARVs among PLHIV has resulted into improved survival and quality of life. On the other hand, this has led to increased risk of age related diseases including NCDs. Raised blood levels of low density lipoprotein, total cholesterol (TC) and triglyceride, overweight/obesity, and abnormal waist circumference, are some of the risk factors of NCDs in PLHIV, also related to the side effects of some of ARVs[20] and HIV itself. Commonest NCDs in HIV include cardiovascular diseases, diabetes, chronic lung diseases and malignancies.[21,22] In Tanzania, the commonest NCDs reported among PLHIV are hypertension and diabetes mellitus.

This chapter highlights clinical features and treatment of the common symptoms encountered in persons infected with HIV, prevention, diagnosis and treatment of common opportunistic infections, and some of the co-morbidities commonly seen among adolescents and adults above 15 years. Provision of prophylaxis, prompt diagnosis and adequate treatment of OIs and screening, diagnosis and management of common NCDs in HIV care and treatment clinics are crucial in improving the quality of life in PLHIV.

6.1 Clinical Features Commonly Encountered in Patients with HIV and AIDS

6.1.1 Fever

Fever in a patient may be due to various causes. However, the associated clinical features may inform the diagnosis. If pointing features to a diagnosis are not present, as a minimum, the following investigations should be done:

- Rapid Diagnostic test (MRDT) for malaria followed by blood slide for malaria to quantify parasites / Blood slide (if MRDT is not available)
- Sputum for microscopy/AFB& gene Xpert/RIF

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[20]Nigatu, T., Integration of HIV and Noncommunicable Diseases in Health Care Delivery in Low- and Middle-Income Countries.Prev Chronic Dis, 2012.**9**.

[21]UNAIDS, Chronic care of HIV and non-communicable diseases. How to leverage the HIV experience? Joint United Nations Programme on HIV AND AIDS. 2011

[22]Kagaruki, G.B., et al., Magnitude and risk factors of non-communicable diseases among people living with HIV in Tanzania: a cross sectional study from Mbeya and Dar es Salaam regions.BMC Public Health, 2014.**14**(1): p. 904.

- Chest X-ray
- Urinalysis
- FBP& ESR

Where facilities are available, and if indicated, the following tests should also be done:

- Urine culture
- Sputum culture for MTB
- Blood culture for TB and other organisms
- Stool culture for salmonella species and other organisms

6.1.2. Cough and Shortness of Breath

Persistent cough and /or shortness of breath can usually be attributed to one of the following:

- Pulmonary TB
- Bacterial pneumonia
- Pneumocystis Jiroveci Pneumonia (PJP)
- Pulmonary Kaposi's sarcoma
- Viral pneumonia
- Disseminated pulmonary strongyloidosis
- Cardiac failure, commonly due to HIV associated cardiomyopathy
- Pleural or pericardial effusion, commonly due to TB
- Lymphocytic Interstitial Pneumonia (LIP)

Sometimes, it may be impossible to determine the underlying cause of cough and dyspnoea on clinical history and physical examination alone. At such times, laboratory tests may be of critical value. The recommended laboratory investigations include:

- Sputum for microscopy/AFB x 2 (can be done at all levels)
- Sputum for pyogenic culture and sensitivity
- Chest X-ray
- Bronchoscopy (consultant hospitals)
- Electrocardiogram (ECG) and Echocardiography (where available)
- FBP and ESR
- Oxygen saturation using pulse oximeter in PCP cases
- Stool analysis

6.1.3. Weight Loss

Weight loss in persons with HIV induced illnesses may be due to:

- Reduced food intake
- Difficult/painful swallowing
- Diminished gastrointestinal uptake (malabsorption, diarrhoea)
- TB (a frequent cause of rapid weight loss)
- Intestinal worms

Other concomitant debilitating conditions such as:

- Cancer
- Repeated vomiting
- HIV itself

Manage weight loss by treating the underlying cause. This includes provision of high calorie and protein foods treatment (for further reading see Chapter 13).

6.1.4. Diarrhoea

Diarrhoea in persons with HIV induced illnesses may have various causes including:

- Salmonella or Shigella (commonest)
- Amoebiasis
- Chronic malabsorption
- Cryptosporidiosis
- Mycobacterium Avium Complex (MAC) infection
- Isosporidiosis
- Clostridium difficile infection
- Cholera.

Investigations and Management:

Examine stools for microscopy and culture for treatable causes e.g. Salmonella, Shigella, V. cholerae, Amoeba, Mycobacterium Avium Complex (MAC) and Isospora.

Diarrhoea can be treated in the following ways:

- Rehydration with Oral Rehydration Salts (ORS) or Intravenous (IV) fluids
- Treatment of underlying causes
- Nutritional therapy (see details in Chapter 13)
- Anti-diarrhoea drugs such as Loperamide (in persistent diarrhoea among adults with no obvious treatable causes).

Note: Starting ART is often the best treatment for persistent/resistant diarrhoea (particularly cryptosporidiosis).

6.1.5. Persistent Generalized Lymphadenopathy (PGL)

Lymphadenopathy may be due to a number of causes including the following:

- HIV
- Mycobacterium tuberculosis infection
- Kaposi’s sarcoma
- Lymphomas
- Pyogenic bacterial infection with regional lymphadenitis
- Leukemia
- Juvenile Rheumatoid arthritis.

Investigations may include:

- Fine Needle Aspiration for Acid-Fast Bacilli (AFB)/Gram stain/cytology
- Lymph node biopsy for histological diagnosis
- Chest X-ray
- FBP and ESR

Treatment is mainly of the underlying cause.

6.1.6 Altered Mental Status and Persistent Severe Headaches

The following are some of the possible causes for altered mental status and severe headaches:

- Infectious Conditions
- Bacterial Meningitis
- Cryptococcus meningitis
- Tuberculous meningitis
- Toxoplasma encephalitis
- Cerebral malaria
- Cytomegalovirus encephalitis (CMV)
- Metabolic Conditions
- Severe dehydration
- Hypoglycemia
- Electrolytes imbalance
- Renal insufficient
- Diabetic Ketoacidosis
- Mental Conditions
- HIV-dementia
- Depression
- Psychotic conditions
- HIV associated neuro cognitive disorders (HAND)

Recommended investigations include:

- Blood sugar
- Blood slide for malaria parasites
- Lumbar puncture for CSF examination
- Indian ink stain for cryptoccocal meningitis
- Salmonella and syphilis serology
- Blood cultures + sensitivity studies
- Serum Biochemistry where possible
- Serum Cryptococcus Antigen test (CrAg)
- CT brain scan/MRI brains scan (where available)

6.2. Management of Opportunistic Infections in Patients with HIV and AIDS

It is very important that all efforts are made to deal with such treatable conditions in people with HIV and AIDS, particularly because they are managed at various levels in the health care delivery system. Emphasis should be placed on early detection, treatment and proper referral where necessary. Table 6.1 shows recommendations on how to identify and handle treatable causes of morbidity as a result of selected opportunistic infections in HIV infected individuals.

Table 6.1 Management of Common Opportunistic Infections Among Adults and Adolescents		
Clinical Condition	Clinical Features and Investigations	Treatment
Skin conditions		
Scabies	Diagnosis of many skin conditions is usually made on clinical findings. Other diagnostic investigations include: Potassium hydroxide preparation microscopy, Skin scrapings microscopy Pus swab for culture & sensitivity Skin biopsy	Benzyl benzoate Emulsion 25% (twice a day applications after bath for 2-3 consecutive days) Crusted scabies use Ivermectin 20mcg/kg once then repeated in two weeks If secondarily infected CAmpiclox500mg TID for 5-7 days or Erythromycin 500mg TID for 5-7 days
Dermatomycoses		Whitefield's ointment Griseofulvin tablets 15-25mg/kg once daily for 6 weeks for Tinea Clotrimazole or Miconazole cream for Candidiasis Terbinafine 250mg od for at least 2 weeks Fluconazole 150mg or 200mg od for at least 2 weeks
Impetigo		Localized –use topical mupirocin ointment 2% BD for 5 days Extensive – Cloxacillin 250mg TID for 5-7 days Erythromycin 500mg TID for 5-7 days

Papular Pruritic Eruption (PPE)		Antihistamine, e.g., Cetirizine 10mg once daily for 3 days or Loratidine 10mg Topical steroids, e.g. hydrocortisone, Mometasone cream Antibiotics if there is a secondary bacterial infection, e.g. Cloxacillin or erythromycin

Seborrheic Dermatitis		Antifungal Ketoconazole 2% lotion 2-3 times/week for 4 weeks Systemic antifungal if severe Topical Steroids (careful if concomitant TB is suspected) 3% salicylic acid ointment

Molluscum Contagiosum		ART should be considered as the primary treatment of extensive and/or unusually distributed molluscum contagiosum in HIV-infected patients. Individual lesion may be treated by: Curettage Cryotherapy Electro cauterization
Kaposi's sarcoma (KS)	Cutaneous biopsies using punch biopsy Diagnosis based on clinical criteria and chest X-ray, abdominal USS in cases of systemic KS	This depends on the extent and severity and the options include: Anti-retroviral therapy (preferably PI-based, especially when extensive) Referral for chemotherapy and radiotherapy.

Viral infections		
Herpes simplex	Diagnosis is usually based on clinical history and physical findings. The classical presentation of primary HSV infection includes: Fever Lymph node enlargement Small painful vesicles Painful ulcers on the mucosa and skin Pain along gluteal and upper thigh muscles (Sacral radiculomyelitis) may occur with genital/rectal HSV Lesions that usually resolve within 10-21 days after primary infection. The HSV then becomes latent in trigeminal and sacral nuclei and may reactivate.	Acyclovir 400mg orally 8 hourly for 7 days for mild and moderate cases of HSV (e.g. cold sores) Acyclovir 800mg orally, five hourly for 5 days for severe and recurrent HSV(e.g. genital infection, gingivitis, pharengeal tonsilitis) Antibiotics such as Erythromycin should be used when there is secondary bacterial infection Analgesics when pain is severe
Herpes Zoster or Shingles	Early symptoms include pain (often severe and radicular) and fever followed by vesicular rash over involved dermatome(s) 2-4 days later. Primary varicella-zoster virus (VZV) infection usually results in chicken pox. Herpes zoster in HIV infected individuals may be more severe, with more recurrences and may involve more dermatomes. The diagnosis of herpes zoster is usually based on findings of characteristic of painful skin lesions at different stages of evolution (e.g. erythema, papule, vesicles, and crusts) in a dermatomal distribution.	Acyclovir 800mg 5 hourly for 7-10 days for mild and moderate cases IIV/oral Acyclovir 10 mg/kg/day 8 hourly for 7 days for disseminated VZV or ophthalmic nerve involvement Erythromycin or Cloxacillin 500mg 8 hourly for 7 days for bacterial super-infection Amitriptylin 25-50mg nocte for post-herpetic pain (neuralgia) or Carbamazepine start 100mg od Analgesics, e.g., Paracetamol, Aspirin, or Diclofenac to relieve pain Note: Use of steroids (prednisolone) in herpes zoster is not recommended.

Human Papilloma Virus Infection (HPV)	HPV is a family of viruses that cause genital warts in men and women. HPV is also known to cause cellular changes that can lead to cancer of the cervix in women and anal cancers especially in gay men. The association between HIV and invasive cervical cancer is complex, due to a more rapid progression of cancer amongst HIV-infected women.	Primary prevention of cervical cancer involves prevention of infection with HPV, therefore it can be achieved through behavioural change approaches and the use of biological mechanisms, including HPV vaccination and consistent condom use can reduce the risk of HPV transmission. Annual cervical cancer screening is recommended to all sexually active women under the age of 50 years done at Care and treatment centres (CTC) using VIA (visual inspection of the cervix with acetic acid). Treatment There is no cure for the virus (HPV) itself. There are treatments for the health problems that HPV can cause, such as genital warts, cervical changes, and cervical cancer. For more details for the treatment of genital warts, cervical changes and cervical cancer, refer to treatment guidelines.

Fungal Infections		
Oral, Oropharyngeal, Oesophageal, Trachea-Bronchial and Pulmonary Candidiasis	Patients with oropharyngeal and oesophageal candidiasis may complain of pain and/or difficulty in swallowing, which may be due to infection of the oesophagus with Candida. On examination white painless plaque ("curd like") on buccal or pharyngeal mucosa or tongue surface that can easily be scrapped off will be seen. Where available, barium swallow X-ray/oesophago-gastro duodenoscopy (OGD) can be performed. Symptoms for trachea-bronchial and pulmonary candidiasis may include fever, non-productive couch, dyspnoea, and tachypnea. Investigations include bronchio-alveolar lavage (BAL) for microscopy and biopsy using bronchoscopy.	For treatment, any of the following may be used: Fluconazole oral/IV 150mg/day or 200mg/day for 2-3 weeks (for oro-pharyngeal candidiasis and others) Miconazole oral gel 3-4 times/day after meals for 7 days Nystatin oral suspension 4-6mls 3-4 times/day continue for at least 2days after oral lesions have disappeared Gentian violet solution Note: Treatment should be continued until symptoms resolve.
Vaginal Candidiasis	This is one of the common illnesses presenting with itching and curd-like genital discharge.	Clotrimazole pessaries Miconazole pessaries Fluconazole taken orally (in case of pessaries failure)

Cryptococcal meningitis	Lumbar puncture-measurement of Cerebral Spinal Fluid (CSF) opening pressure and demonstration of positive CSF with Indian Ink preparation OR Rapid CSF cryptococcal antigen (CrAg) assay OR Rapid serum CrAg	The treatment should be done in 3 phases: Phase 1: Induction phase Amphotericin B 0.7-1mg/kg/day IV + 5 Flucytosine 100mg/kg/day administered orally for 7 days followed by 1 week of fluconazole (1200 mg/day for adults, 2 mg/kg/day for children and adolescents, up to a maximum dose of 800mg daily) In the absence of Flucytosine, alternative therapy should be: Amphotericin B 0.7-1mg/kg/day IV for 14 days (If liposomal amphotericin B is available give 3-6mg/kg iv for 10 days) and Fluconazole 1200mg IV/ORAL once daily for 14 days Phase 2: Consolidation phase Fluconazole 800mg/ day for 8 weeks or until CSF is sterile. Phase 3: Maintenance phase Give patient maintenance therapy with Fluconazole 200mg per day for 1 year. Discontinue Maintenance treatment if CD4 $\geq$ 100 with undetectable (<50 copies) viral load or CD4 $\geq$ 200 if viral load monitoring not available. Note: It is recommended to initiate ART 5 weeks after initiation of Cryptococcal meningitis treatment in ART naïve patient to prevent IRIS and reduce mortality.

Pneumocystic Jiroveci (PJP)	This condition is common in Tanzania especially among HIV infected children. Patients usually present with non-productive cough, fever, chest tightness and shortness of breath that has evolved over 2-4 weeks. A Chest x-ray may show increased diffuse and symmetrical interstitial markings or diffuse alveolar pattern with infiltrations characterized by asymmetry, nodularity, or cavitations. Normally there is a "bat's wing's appearance". Chest radiograph may appear normal in 10-30% of patients. Usually in clinical circumstances diagnosis is based on clinical presentation and exclusion of other common causes of severe dyspnoea.	Cotrimoxazole 1920 mg 8 hourly for 21 days and in severe cases give IV cotrimoxazole 15–20mgTMP/75-100mg SMX/kg/day IV, administered 6-8hourly, may switch to oral after clinical improvement. For those allergic to sulphur, and if available, give Trimethoprim 12-15mg/kg/day + Dapsone 100mg/day for 21 days as well as Clindamycin 450mg 4 times/day or 600mg three times daily + Primaquine 30mg once daily for 21 days Adjuvant therapy with steroids may also be beneficial in severe cases. Give Prednisolone 40mg twice daily for days 1 to 5, then 40mg once daily for days 6 to 10, and then 20mg once daily for days 11 to 21

Protozoal conditions		
Toxoplasmosis	Clinical features include: Focal paralysis or motor weakness depending on the brain area affected Neuro-psychiatric manifestations corresponding to the affected area in the brain Altered mental status (forgetfulness etc.) Diagnosis predominantly based on clinical findings after exclusion of other common causes of neurological deficit. If available, a CT scan or MRI with contrast is very useful for confirmation.	Acute infection Sulphadiazine tabs 1 gm 6 hourly + Pyrimethamine tabs 100mg loading dose, then 50mg /day + Folic acid tabs 10mg /day for 6 weeks. Clindamycin capsules 450mg -600mg 6 hourly + Pyrimethamine tabs 100mg loading dose, then 50mg /day for 6 weeks. After six weeks of treatment Give prophylaxis therapy with Sulphadiazine tabs 500mg 6 hourly + Pyrimethamine tabs 25-50mg /day + Folic acid tabs 10mg /day. For those allergic to sulphur replace Sulphadiazine tabs with Clindamycin capsules 450mg 6 hourly Discontinue maintenance therapy when CD4 count is >200 cells/ml, initial therapy is completed and the patient is asymptomatic. Primary prophylaxis therapy for toxoplasmosis can be accomplished with Trimethoprim–Sulphamethoxazole (TMP-SMX) tabs 160/800mg administered orally/day. For those allergic to sulphur, give Dapsone tabs 50mg/day + Pyrimethamine tabs 50mg per week + Folic Acid tabs 10mg 3 times a week.
Cryptosporidiosis	Cryptosporidiosis (*cryptosporidium parvum, cryptosporidium meleagridis and cryptosporidium hominis*) is the common cause of chronic diarrhoea. •Diagnosis can be made by microscopic examination of the oocytes in stool or tissue with acid-fast staining or direct immunoflourescence for better sensitivity.	Nitazoxanide is the recommended treatment 500mg-1000mg twice daily for 14 days + rehydration, electrolytes replacement and optimized ART. Alternatively Paromomycin 500mg PO QID for 14-21 days can be used.

6.3. Prophylactic Treatment of Common Opportunistic Infections in HIV and AIDS

Many opportunistic infections can be prevented by using cotrimoxazole prophylaxis, particularly in the case of:

- Bacterial infections e.g. pneumonia,
- Skin infection
- Sepsis
- Pneumocystis Jiroveci Pneumonia (PJP)
- Malaria
- Toxoplasmosis

6.3.1. Indication for Prophylactic Treatment Using Cotrimoxazole

Prophylactic treatment using Cotrimoxazole should be provided if any of the following criteria applies:

- Adults, adolescents, and pregnant women with CD4 cell count ≤350 cells/mm3
- Initiate CPT in all children <5 years of age regardless of CD4 and WHO clinical stage
- All HIV exposed uninfected infants (initiate in all starting 4-6 weeks after birth)
- All HIV-infected persons with active TB.

Note:

Caution should be taken when initiating Cotrimoxazole Preventive Treatment (CPT) during the first trimester of pregnancy in women who may not have access to good nutrition and anaemic patients, because Cotrimoxazole causes deficiency in folic acid.

Pregnant women who are receiving CPT do not need sulfadoxine pyrimethamine (SP), an additional medication to prevent malaria.

CPT will continue to be provided to virologically suppressed patients (<50 copies/mL) with low CD4 cell counts (immunological non-responders).

Dosage:

For adults: One double strength tablet (160/800mg) or two single strength tablets once a day on a daily basis. For those whose weight is <60kg, see ARV dosing chart under Cotrimoxazole dosing.

Criteria for stopping:

Occurrence of severe side effects such as severe cutaneous reactions or fixed drug reactions.

If ART is initiated and CD4 cell count is above 350 cells/ml in adults and adolescents and virological suppression (<50 copies/mL).

If the use of antiretroviral agents causes renal and/or hepatic insufficiency or severe haematological toxicity

Follow-up and monitoring:

Regular follow up is recommended, initially every month for the first three months, then every three months if the medication is well tolerated.

It is mandatory to monitor for side effects and adherence. Monitoring includes assessment of skin reactions, measurements of haemoglobin, and white blood counts every six months and when clinically indicated.

6.3.2. Tuberculosis Preventive Therapy against TB in PLHIV

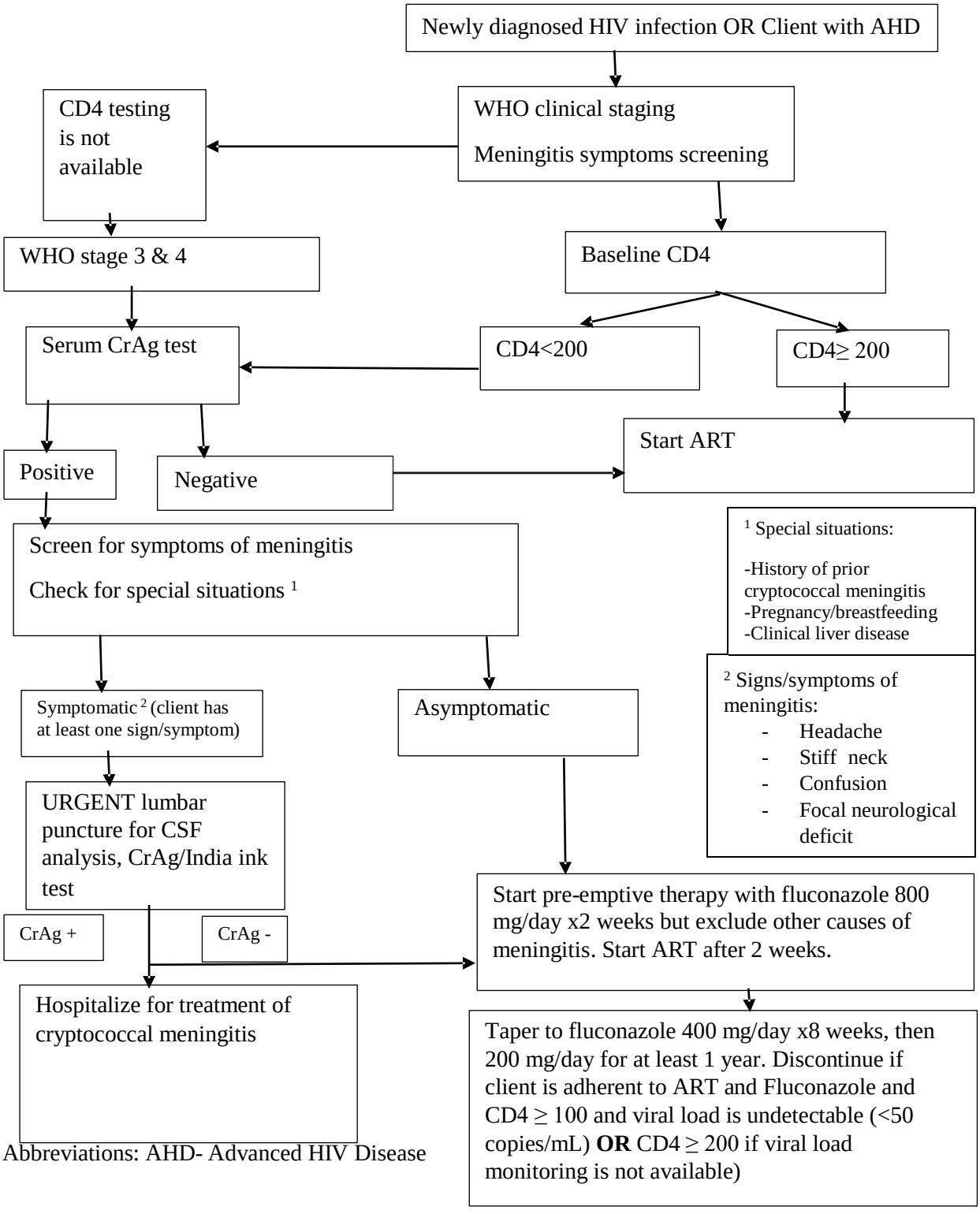
There is sufficient evidence on the benefits of Tuberculosis (INH) preventive therapy against Mycobacterium tuberculosis for HIV infected individuals in whom active TB has been excluded. In this category of HIV patients, Tuberculosis Preventive Therapy (TPT) can be offered at a dosage of 300 mg of INH daily for at least six months for adults and in children INH is given at a dose of 10mg / kg (Range 10-15mg/kg) daily for six months as well. IPT provides up to 18 months of protection against TB. Note that TB PT for both adults and children is given only once in lifetime (Further details on this are provided in Chapter 8).

6.3.3 Prevention of Cryptococcal Disease

Globally, cryptococcal meningitis is a leading cause of mortality among hospitalized adults living with HIV, but is less common among children living with HIV. Pre-emptive therapy for cryptococcal antigen–positive asymptomatic people is a key strategy to prevent cryptococcal meningitis related mortality.

6.3.3.1 Screening for CrAg

Algorithm for Screening Cryptococcal meningitis in clients with Advanced HIV Disease



Abbreviations: AHD- Advanced HIV Disease

Screen for serum Cryptococcal antigen for all ART-naive adults and adolescents with CD4 cell count of <200 cells/mm^3 or WHO stage 3 & 4 if CD4 testing is not available.

Through "reflex" testing, laboratory personnel should conduct Cryptococcal Antigen screening on any samples sent for CD4 count testing where CD4 is found to be <200 cells/mm^3.

If serum CrAg screening test is negative in ART-naïve clients, screen for other opportunistic infections and initiate ART. If screening test is positive (bloodstream disease) but there is no evidence of meningitis, give pre-emptive therapy with fluconazole 800mg once daily for 2 weeks (induction phase), followed by 400mg once daily for 8 weeks (consolidation phase) then 200mg once. Discontinue maintenance treatment if CD4 $\geq$ 100 cells/mm^3 with undetectable viral load (<50 copies/mL) /or CD4 $\geq$ 200 cells/mm^3 if viral load monitoring not available. Start ART two weeks after starting fluconazole pre-emptive therapy.

If screening test is positive with signs and symptoms of meningitis, perform Lumbar Puncture for CSF Cryptococcal Antigen. If CSF CrAg is negative give pre-emptive therapy as above and if the client is CSF CrAg positive give treatment as indicated in table 6.1 (management of Common Opportunistic Infections Among Adults and Adolescents) ART should be started after 5 weeks.

NOTE: The routine uses of antifungal primary prophylaxis for cryptococcal disease in HIV-infected adults, adolescents and children with a CD4 count less than 200 cells/mm^3 and who are CrAg-negative or where CrAg status is unknown is not recommended prior to ART initiation.

Summary of the diagnostic approach to cryptococcal meningitis.

	Lumbar puncture available	No lumbar puncture available or contraindicated
Rapid cryptococcal antigen test available	Perform CSF cryptococcal antigen	Perform serum, plasma or whole blood cryptococcal antigen. If CrAg-positive, treat immediately and refer for further investigation if indicated.
No rapid cryptococcal antigen test available	Perform CSF India ink	Prompt referral for further investigation

Common signs and symptoms of Cryptococcal Meningitis Symptoms

Symptoms

- Headache
- Nausea with or without vomiting
- Changes in vision or hearing (such as double vision, blindness or deafness)

Signs

- Change in mental status ranging from confusion to lethargy to coma
- Papilledema
- Seizures
- Cranial nerve palsies (such as movement problems, particularly cranial nerve VI)
- Other focal neurological nervous system deficits

Table 6.1 Management of Common Opportunistic Infections Among Adults and Adolescents

Cryptococcal meningitis	Lumbar puncture-measurement of Cerebral Spinal Fluid (CSF) opening pressure and demonstration of positive CSF with Indian ink preparation OR Rapid CSF cryptococcal antigen (CrAg) assay OR Rapid serum CrAg	The treatment should be done in 3 phases: Phase 1: Induction phase Amphotericin B 0.7-1mg/kg/day IV + 5-flucytosine 100mg/kg/day administered orally for 7 days followed by 1 week of fluconazole (1200 mg/day for adults, 2 mg/kg/day for children and adolescents, up to a maximum dose of 800mg daily) In the absence of 5-flucytosine, alternative therapy should be: Amphotericin B 0.7-1mg/kg/day IV for 14 days (If liposomal amphotericin B is available give 3-6mg/kg iv for 10 days) and fluconazole 1200mg IV/oral once daily for 14 days Phase 2: Consolidation phase

		Fluconazole 800mg/day for 8 weeks or until CSF is sterile. Phase 3: Maintenance phase Give patient maintenance therapy with fluconazole 200mg/day (discontinue maintenance treatment if CD4 ≥ 100 with undetectable [<50 copies/mL] viral load or CD4 ≥ 200 if viral load monitoring not available). Note: It is recommended to initiate ART 5 weeks after initiation of cryptococcal meningitis treatment in ART-naïve patient to prevent IRIS and reduce mortality.

Table 6.2 Amphotericin B toxicity prevention, monitoring and management

Pre-emptive hydration and electrolyte supplementation	
Adults and adolescents	One litre of normal saline solution with 20 mEq of potassium chloride (KCl) over two hours before each controlled infusion of amphotericin B and one to two 8-mEq KCl tablets orally twice daily. An additional 8-mEq KCl tablet twice daily may be added during the second week. If available, magnesium supplementation should also be provided (two 250-mg tablets of magnesium trisilicate or glycerophosphate twice daily, or magnesium chloride 4 mEq twice daily).
Monitoring (adults, adolescents and children)	
Serum potassium	Baseline and 2–3 times weekly (especially in the second week of amphotericin B administration)
Serum creatinine	Baseline and 2–3 times weekly (especially in the second week of amphotericin B administration)
Haemoglobin	Baseline and weekly
Management (adults, adolescents and children)	
Hypokalaemia	If hypokalaemia is significant (K <3.3 mol/l), increase potassium supplementation to 40 mEq KCl by intravenous infusion and/or one to two 8-mEq KCl tablets orally three times daily. Monitor potassium daily.

Elevated creatinine	If creatinine increases by ≥2 fold from the baseline value, increase pre-hydration to 1 L every eight hours and consider temporarily omitting a dose of amphotericin B. Once creatinine improves, restart amphotericin B at 0.7 mg/ kg/day and consider alternate-day amphotericin B. If creatinine continues to rise, consider discontinuing amphotericin B and continuing with fluconazole at 1200 mg/ day, especially if seven doses of amphotericin have been received. Consider fluconazole dose adjustment if significant renal impairment. Monitor creatinine daily.
Severe anaemia	Transfusion should be undertaken if possible, for severe amphotericin B–related anaemia (anaemia may also be a reason to discontinue amphotericin B prematurely in the second week of a planned two-week induction course of amphotericin B with fluconazole)

6.3.3.2 Special Situations

If a patient is already on ART and has a positive serum CrAg result, they should continue with ART. A history should be conducted to ascertain previous treatment. If the client has been previously treated then they may be experiencing persistent or recurrent symptoms.

Main causes of persistent and recurrent symptoms among people with Cryptococcal meningitis

Recurrent symptoms	**Persistent symptoms**
Raised intracranial pressure	Raised intracranial pressure
Treatment failure due to suboptimal induction, consolidation or maintenance treatment	Treatment failure caused by suboptimal induction treatment
Inadequate drug regimen, dose or duration	Inadequate drug regimen, dose or duration
Failure to prescribe or to adhere to fluconazole consolidation or maintenance treatment	Fluconazole drug resistance (rare)
Fluconazole drug resistance (rare)	Other concomitant illness (such as viral, bacterial, or tuberculous meningitis)
Cryptococcal immune reconstitution inflammatory syndrome (IRIS) following ART initiation	
Other concomitant illness (such as viral, bacterial or tuberculous meningitis)	

Rule out causes of recurrent or persistent symptoms (table above). Perform a lumbar puncture for CSF CrAg test and treat for cryptococcal meningitis if CSF is CrAg positive. If asymptomatic (or CSF cryptococcal antigen test is negative) then start pre-emptive fluconazole dose as for ART-naive patients.

If the client is presenting with cryptococcal meningitis relapse:

• Start or restart induction treatment according to the recommendations for induction treatment.

• Manage raised intracranial pressure with therapeutic lumbar puncture

• Reinforce adherence.

• If ART has not already started, initiate ART after 5 weeks of optimal antifungal therapy

After excluding other causes of symptoms among people who have started ART consider cryptococcal IRIS.

Management of Cryptococcal meningitis in pregnancy and Breastfeeding

Amphotericin B monotherapy (0.7-1mg/kg/day for 2 weeks) should be used to treat Cryptococcal meningitis in first trimester pregnancy. Fluconazole is considered category D and is associated with human fetal teratogenic risks. It should be avoided in first trimester of pregnancy. Clients presenting with these conditions should be referred to a specialist.

Fluconazole may be excreted in breast milk. If a Breastfeeding mother is required to use Fluconazole, she should be educated to make an informed choice to continue breast feeding since it is the best source of nutrients for the baby and supplementary feeding is too expensive or not affordable. Monitor the baby's Liver and renal Function Tests and refer to specialist if abnormal.

Clients with Immunological failure on ART

In patients who develop immunological failure while receiving ART and where the CD4+ T-lymphocyte count drops <200 cells/µl after secondary prophylaxis has been stopped, restart fluconazole at 200 mg daily and refer to the above section on maintenance-phase treatment for the duration of treatment.

Clients with clinical liver disease

If signs/symptoms of liver toxicity develop (e.g. abdominal pain), evaluate for liver dysfunction and refer client to specialist if abnormal.

6.3.3.3 Management of Patients on Cryptococcal Treatment

Management of Increased Intracranial pressure

Patients on Cryptococcal treatment should be regularly monitored for the signs and symptoms of increased intracranial pressure as highlighted above. For the initial two weeks of cryptococcal treatment, clinical response including recurrence or resolution of fever,

headache and other increased intra-cranial pressure should be assessed on daily basis and serial lumbar punctures performed if indicated.

CSF, Serum or Plasma cryptococcal antigen test is of little or no value in predicting treatment failure or relapse among PLHIV with cryptococcal meningitis.

Management of Drug toxicity;

Drug toxicity and side-effects from amphotericin B therapy, especially hypokalaemia, nephrotoxicity and anaemia, are barriers to optimal induction treatment, particularly in low- and middle-income countries.

Safe administration of amphotericin B should be given priority and may require referral to a centre with access to a minimum package of preventing, monitoring and managing toxicity. •

The routine uses of antifungal primary prophylaxis for Cryptococcal disease in HIV-infected adults, adolescents and children with a CD4 count less than 200 cells/mm^3 and who are CrAg negative or where CrAg status is unknown is not recommended prior to ART initiation.

Managing Cryptococcal IRIS

Even after successful treatment, living or dead yeast cells remain in CSF. With early initiation of ART and improved immunity, immune system can recognize these yeast components leading to marked inflammation and raised intracranial pressure.Very high intracranial pressure in response to ART and immune reconstitution may lead to death. Symptoms and signs for IRIS as explained in Chapter 10 should be elicited regularly for cryptococcal meningitis patients.

If a patient presents with Cryptococcal IRIS.

- Continue ART
- Promptly manage elevated intracranial pressure.
  Optimize antifungal therapy, restart induction therapy while waiting on culture results in case this might be relapsed disease.

Short-course of oral steroids (Prednisolone [PO] 1-2mg/kg daily for 5 - 7 days), although not recommended for routine use, may be considered if the patient experiences clinical deterioration and or and/or the development of life-threatening complications (such as intracranial space-occupying lesions with mass effect or extracranial disease impinging on vital structures) despite use of above measures.

1. Guidelines on the diagnosis, prevention and management of cryptococcal disease in HIV-infected adults, adolescents and children: supplement to the 2016 consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: World Health Organization; 2018. License: CC BY-NC-SA 3.0 IGO.

6.4 Common Non-Communicable Diseases among PLHIV

Prevention of NCDs is the mainstay of reducing the burden which can be achieved by lifestyle modification. Screening for hypertension, diabetes and dyslipidaemias for early identification and management of these diseases is of paramount importance in the HIV population.

In general lifestyle modifications include the following:

- Physical exercises- 30-60 minutes of aerobic exercises 4-5 times a week
- Maintain a healthy body weight (BMI 18.5-24.9kg/m2) and waist circumference <102cm in men and <88cm in women
- Smoking cessation
- Limit alcohol consumption (14 standard units per week for men and 9 times per week for women)
- Dietary changes- diet emphasis should be made on fruits, vegetables, low fat dairy products, reduce fatty foods, increase intake of whole grains and fish. Drink a minimum of 2 litres of water daily and restrict salt intake to <2g/day.

6.4.1 Screening, Diagnosis and Management of Hypertension

- Measurement of BP should be done and recorded during every visit to care and treatment clinic
- An elevated BP (defined as BP ≥140/90 mmHg on at least 3 different occasions) will require treatment as per Tanzania standard treatment guidelines and essential medicines list 2013 and lifestyle modifications.

Note: If there is persistent uncontrolled BP or development of Hypertension related complications, the patient should be referred to appropriate level for further evaluation and management.

6.4.2 Screening, Diagnosis and Management of Diabetes Mellitus

Baseline blood glucose (random/fasting) should be evaluated to all PLHIV during enrolment. If blood glucose is normal at baseline, annual evaluation is recommended. Symptoms such as polyuria, polydyspia, polyphagia and some risk factors such as family history of diabetes and BMI> 30kg/m2 warrant screening for diabetes. Blood glucose measurement can be categorized as:

- Normal fasting <6mmolL and random <11mmol/L
- Pre-diabetes fasting 6.1-6.9mmol/L and 2-hour post prandial 7.8-11.0mmol/L
- Diabetes fasting >7.0mmol/L and random >11.1mmol/L

Management

Regular monitoring of Fasting and Random blood sugar levels is essential where available, monitor HgA1c (glycated haemoglobin) every 3 months for patients with confirmed diagnosis of diabetes mellitus.

Patients should be encouraged to modify their lifestyle (such as weight loss, nutritional support (portion sizes and low glycaemic index foods to help with control of blood sugar)

If lifestyle change does not successfully control blood sugar levels, start treatment for diabetes as per the Standard Treatment Guidelines and Essential Medicines List 2013.

6.4.3 Screening, Diagnosis and Management of Dyslipidemias

Baseline screening of fasting lipid profile (total cholesterol, LDL and triglycerides) should be done at baseline for all PLHIV. Diagnosis of dyslipidemia is made when fasting total cholesterol is >5.2mmol/L, LDL>3.4mmol/L or triglycerides > 2.2mmol/L.

Management of dyslipidemias includes life style modifications for a minimum of 3 months. For patients on ARVs known to cause or exacerbate dyslipidemia such as LPV/r, then consider substitution to a more lipid friendly drug ATV/r before adding a lipid lowering drug. It is important to rule out ART failure before substitutions of LPV/r with ATV/r.

6.4.4 Screening for Chronic Kidney Disease

Diagnosis:

- Serum creatinine and urinalysis for protein are essential markers for kidney disease which can be evaluated at baseline.
- Abnormal results such as creatinine clearance <60ml/min or dipstick proteinuria ≥1 are indicatives of impaired kidney function. Repeated tests should be done to confirm diagnosis.

The estimation of the degree of kidney damage and staging is important to guide management and prevent further adverse outcomes of chronic kidney disease. Therefore, additional investigations and specialist consultation may be required.

For patients on TDF based regimen, substitution to another non TDF based regimen is recommended once chronic kidney disease is diagnosed.

Precaution should be taken to avoid nephrotoxic drugs and some ARV drugs may require dose adjustment for kidney impairment (all NRTIs except ABC). NNRTIs, PIs, and INSTIs do not require dose adjustments for impaired renal function.

6.5 Hepatitis B and C Co-infections

6.5.1 Hepatitis B Co-infection

Hepatitis B virus infection (HBV) shares the same routes of transmission as HIV but HBV is about 100 times more infectious. In endemic areas of both HBV and HIV, men who have sex with men (MSM) show higher rates of HBV and HIV co-infection than people who inject

drugs (PWIDs) or heterosexuals[23]. During acute HBV infection in HIV-infected individuals, there is an increased risk of developing chronic hepatitis infection, reducing the chances of spontaneous clearance and increased rate of HBV replication or reactivation. Such events increase the incidence of chronic liver disease, cirrhosis and hepatocellular carcinoma. Furthermore, HBV/HIV co-infection has been associated with a rapid HIV disease progression, poor ART outcomes and some complications of hepatotoxicity, drug interactions and hepatitis related immune reconstitution.

HBV screening

It is recommended that all HIV infected individuals are screened for HBV for the presence of Hepatitis B surface antigen (HBsAg). The presence of this antigen indicates that the patient is currently infected with HBV; its persistence for six months or longer indicates chronic infection. Patients testing positive for HBsAg should be tested for quantitative HBV DNA where available (giving the level of hepatitis DNA in blood).

Where available, other tests that can be done for further evaluation of HBV are:;

- Hepatitis B PCR (HBV DNA): polymerase chain reaction is a very sensitive method used to detect Hepatitis B DNA. It is either qualitative (giving positive or negative result) or quantitative (giving the level of Hepatitis B DNA in blood).
- Hepatitis B surface antibody (HepBsAb): If produced in large amounts (>100 IU) it usually indicates that the patient has cleared the virus (if they have been infected) and are now immune.
- Hepatitis B core antibody (HepBcAb): This is an antibody against Hepatitis B core antigen. Patients who have been infected with Hepatitis B virus produce antibodies to the core protein which is usually life-long (whether or not they clear the virus). Core antibodies do not confer immunity and are present in patients who still have active infection.
- Hepatitis B e antigen which is usually expressed when the virus is replicating at a high level. It is often found in individuals having abnormal liver function tests (LFTs) and chronic hepatitis. Presence of this e antigen indicates high infectivity.
- Hepatitis B e antibody (HepBeAb): this is the patient's antibody that is produced to Hepatitis B e antigen. When present, it sometimes indicates that the level of replication of the Hepatitis B virus is lower. In patients with abnormal LFTs and Hepatitis B e antibody present, a Hepatitis B PCR is indicated which will indicate the true level of ongoing replication. HepBeAb fall over time in patients who have cleared the virus and may eventually become undetectable.

[23]Konopnicki et al. Hepatitis B and HIV: prevalence, AIDS progression, response to highly active antiretroviral therapy and increased mortality in the EuroSIDA cohort. AIDS, 2005, 19:593–601.

HBV evaluation and treatment

The presence or absence of clinical evidence for cirrhosis might be the key issue in defining treatment strategy in HBV/HIV co infected patients. Physical examination should be performed to check for signs of liver disease such as jaundice, ascites, abnormal liver on palpation and other signs of cirrhosis. When there is evidence of chronic liver disease, close follow up is required to monitor for hepatotoxicity and referral to a consultant hospital may be warranted for additional evaluation and management. Laboratory measurement for liver enzyme ALT is required and if elevated, it may indicate an active liver disease but exclusion of other causes for elevation of ALT is important.

NOTE: *Because HBV positive patients are at higher risk of hepatotoxicity, closer monitoring of liver function (with ALT) is advised*.

Emtricitabine (FTC), Lamivudine (3TC), and tenofovir disoproxil fumarate (TDF) have activity against both HIV and HBV. Therefore, for patients co infected with HIV and HBV, ART should be initiated with the fixed dose combination of TDF/FTC or the individual drug combinations of TDF plus 3TC/FTC as the NRTI backbone of a fully suppressive ARV regimen.

The recommended ART regimen in HIV/HBV co-infection is TDF +FTC/3TC +EFV

NOTE:

TDF is indicated in HIV/HBV co-infection even with creatinine clearance <50ml/min, remember to avoid fixed dose combinations of ART to allow for renal dose adjustment**.**

Patients with impaired kidney function and the continuation of using TDF is importantly required, then management from a specialist in Internal Medicine or Nephrologists is required

Discontinuation of agents with anti-HBV activity may cause serious hepatocellular damage resulting from reactivation of HBV; patients should be advised against stopping these medications.

HBV prevention

HBV vaccination reduces the risk of new HBV infection in HIV-infected individuals. Also it reduces the risk of new infections progression to chronicity. Therefore, HIV-infected infants, children, adolescents and adults without evidence of hepatitis B infection (HBsAg negative) should be vaccinated against hepatitis B with the standard vaccination regimen.

6.5.2 Hepatitis C and HIV co-infection

Hepatitis C infection is low in the general population and among PLHIV but higher in HIV – infected people who inject drugs (PWID) due to the shared routes of transmission. Screening for HCV is by HCV serology testing offered to individuals at risk of HCV infection. For confirmation of chronic HCV, where available HCV RNA PCR is required and HCV genotype testing for selecting appropriate Direct Acting Antivirals (DDA) regimen. Liver

enzyme ALT, if elevated, may indicate an active liver disease but remember to exclude other causes of elevation of liver enzymes.

HCV is treated using direct acting antivirals (DAA) such as Daclatasvir (60 mg) + Sofosbuvir (400 mg) for genotypes 1, 2 and 3 for duration of 12 weeks.

References:

1. WHO, *Preventing and managing other comorbidities and chronic care for people living with HIV. World Health Organization 2013*

2. Rabkin M, N.S., *Scaling up chronic care systems: Leveraging HIV programs to support noncommunicable diseases services.* J Acquir Immune Defic Syndr, 2011. 57 (Suppl2): p. S87-S90.

3. Nigatu, T., *Integration of HIV and Noncommunicable Diseases in Health Care Delivery in Low- and Middle-Income Countries.* Prev Chronic Dis, 2012. 9.

4. UNAIDS, *Chronic care of HIV and non-communicable diseases. How to leverage the HIV experience. Joint United Nations Programme on HIV AND AIDS. 2011*

5. Kagaruki, G.B., et al., *Magnitude and risk factors of non-communicable diseases among people living with HIV in Tanzania: a cross sectional study from Mbeya and Dar es Salaam regions.* BMC Public Health, 2014. 14(1): p. 904.

CHAPTER 7

PAEDIATRIC AND ADOLESCENTS HIV AND AIDS-RELATED CONDITIONS

7.0 Introduction

Majority of HIV infection in children is acquired through mother to child transmission during pregnancy, delivery or breastfeeding. Exposure to HIV continues as long as a child of an HIV-infected mother is breastfed. HIV infected infants may not have any signs or symptoms soon after birth but usually develop the features in the early infancy period. These features may overlap with those of other common childhood diseases. The HIV infection progresses more rapidly in children than in adults.

7.1 Diagnosis of HIV Infection in Children

7.1.1 Diagnosis of HIV Infection in Children below 18 Months

Infants born to HIV-infected women have antibodies to HIV passively transferred from their mothers; these antibodies can persist until 9 to 18 months of age. Thus, a positive rapid HIV antibody tests in infant does not confirm nor exclude HIV infection. Therefore, DNA PCR is required in order to confirm HIV infection in children <18 months of age. PCR tests should be done at six weeks of age or at any time < or = 9 (months) as a first test. When the child of > 9 months is first seen by a healthcare worker, that child will be tested for HIV infection using antibody test. If the result is positive, then DNA- PCR should be used to confirm the HIV infection as per algorithm

Table 7.1 Summary of Diagnosis of HIV infection in children <18 Months who are being breastfed by a mother known to be HIV Positive
Do HIV DNA-PCR at 6 weeks of age; if positive, start ART immediately while waiting for second HIV DNA-PCR results. All children with negative results should have HIV test at 9 months of age using DNA PCR, and HIV antibody test at 12 weeks after complete cessation of breast feeding, and final rapid test at 18 months of age. If the result is positive then DNA PCR is used to confirm their status. If the child is being breastfed by an HIV infected mother, a negative antibody test does not exclude an HIV infection. On-going exposure to HIV through breastfeeding continues to put the child at risk of acquiring HIV infections. A single positive DNA- PCR test means the infant is presumably infected and should be initiated on ART. A second DNA PCR sample should be taken immediately after receiving a positive test result so as to confirm the first test result. NB: The second test should not delay ART initiation. For a child that was never breastfed: a single negative DNA PCR test after the age of 6 weeks excludes HIV infection.

For a child that has completely stopped breastfeeding for more than 3 months prior to virologic (DNA PCR) testing, a negative DNA PCR test excludes HIV infection.

Children at the age of 9 months should receive HIV test using DNA -PCR.

Note: Changes in transmission dynamics as well as in policy and practice have complicated RDT use for determining infection status at this age.

For High Risk HIV Exposed Infants Refer to Annex 11.

All positive tests should be confirmed with a DNA PCR test. However, if the child is symptomatic; *fulfilling WHO stage 3 or 4 criteria* and or a DNA PCR test is not available but HIV antibodies are present (rapid test is positive), a presumptive diagnosis should be made and ART started.

7.1.2 Diagnosis of HIV Infection in Children <18 Months where the Mother's HIV Status is Unknown

Testing of a mother is the best way to ascertain HIV exposure status of her infant. If the mother is HIV positive, testing of the infant should follow the steps for diagnosis of HIV infection in the HIV exposed infant or child <18 months. If the mother is not available, test the child for HIV infection using antibody test first. If the result is positive, then DNA- PCR should be used to confirm the HIV infection.

7.1.3 Diagnosis of HIV Infection in Children <18 Months where the Mother is Not Available

Since the mother's HIV status is unknown, the HIV exposure status of the baby needs to be established. The guardian or caretaker needs to be counselled for HIV testing of the child. If rapid test is positive take sample for DNA- PCR for confirmation, initiate ART while awaiting for the results, start the child on Cotrimoxazole prophylaxis; If DNA-PCR results turns negative then ART and Cotrimoxazole should be interrupted.

Table 7.2 Steps for diagnosis of HIV infection in children where the mother is not available
To children with > 9months and < 18months, Do rapid HIV antibody test immediately the child is seen at the HF to determine HIV exposure If HIV antibody test result is positive do HIV DNA PCR. If the result is negative, re- test if symptomatic, at 12 weeks after cessation BF or at 18 months of age (Ab test). If rapid HIV antibody test is positive and the child has stage THREE or FOUR symptoms (PRESUMPTIVE DIAGNOSIS), collect DBS for DNA PCR test and immediately initiate ART. If the child is younger than 18 months and is symptomatic, HIV DNA PCR should be taken even if the rapid antibody test is negative. All children with negative results should have a final rapid test at 18 months to confirm their status.

Note: Exposed children should be seen monthly for the first year of life and should be followed up as per recommendations for all children. A clinical examination to assess for signs and symptoms of HIV infection should be performed during all visits. Failure to thrive and neurodevelopmental delay might be signs of HIV infection.

Managing discordant results and treatment interruption in HIV Exposed Children

WHO has recommended initiating infants on ART after an initial positive Nucleic Acid Test (NAT) / DNA-PCR, while simultaneously collecting a confirmatory sample, if the second (confirmatory) NAT/DNA-PCR is negative; a third NAT/DNA-PCR should be performed before considering ART interruption

The following should be considered when assessing patients for ART interruption after discordant test results; positive then a negative result followed by a third test with a negative result:

1. The infant in question, is ought to have no clinical signs or symptoms suggestive of HIV infection
2. A follow-up plan should be agreed upon with family, caregiver(s) and health-care staff. There should active follow-up to ensure that a potentially infected infant is retained and re-initiated on treatment if virological rebound occurs;
3. Tracking information (phone, address, etc.) of the family/caregiver(s) should be collected and confirmed.
4. Infants who develop signs and symptoms indicative of HIV infection should undergo immediate testing

Note:
virological rebound in HIV-infected infants starting treatment early is expected to happen within 8 months of interruption in >99% of HIV-infected infants

Follow up of an Infant with ART interruption

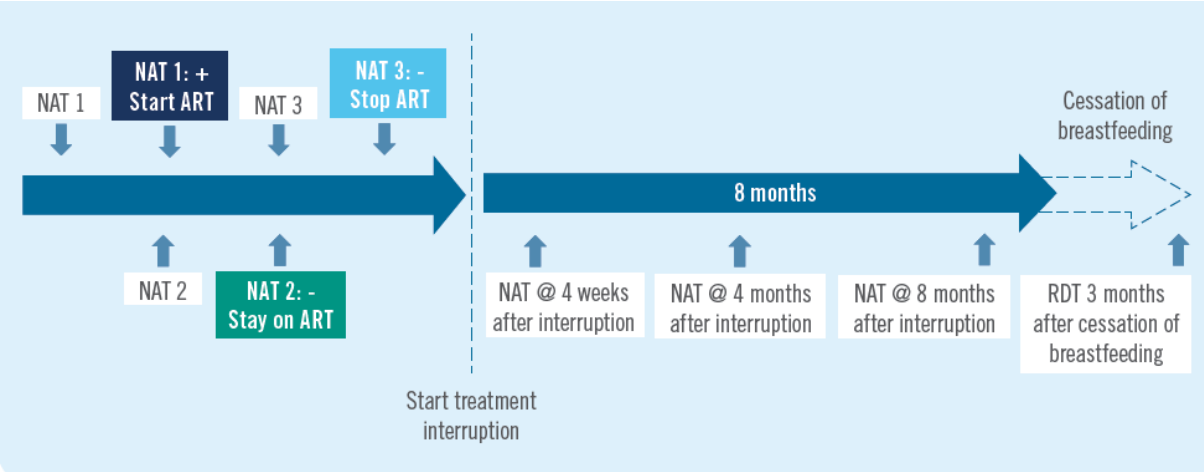
In settings were both EID (qualitative) and VL (quantitative) tests are available, tests should be performed at 4 weeks, 4 months and 8 months after treatment interruption

Infants who test positive on follow-up test should be re-initiated on treatment as per current guidelines and a confirmatory sample taken.

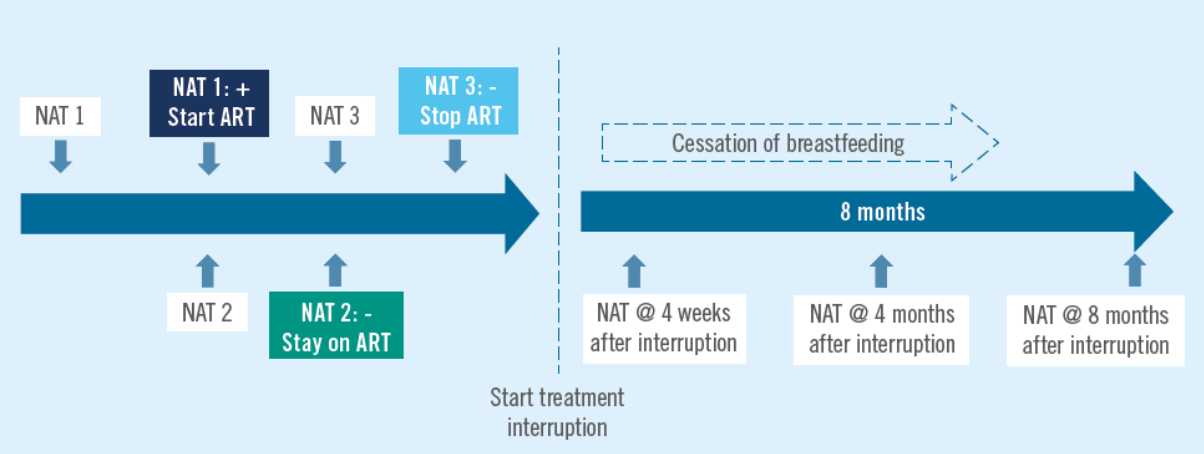
Follow up on ART interruption should consider the continuous risk of transmission resulting from breastfeeding and, once the intensive follow up is completed (that is 8 months after treatment interruption), the national infant testing schedule for HIV-exposed infants should be applied in order to ensure an appropriate final diagnosis. If breastfeeding has stopped prior to the end of the intensive follow up, final HIV status can be defined with NAT/DNA-PCR performed at least 6 weeks post cessation of breastfeeding, as summarised below in “Scenario a and or b” respectively.

EID and viral load at 4 weeks, 4 months, and 8 months after interruption

Scenario a: Cessation of breastfeeding occurs after completion of the follow up post ART interruption.



Scenario b: When cessation of breastfeeding occurs before completion of the follow up post ART interruption.



NB Initiate duo prophylaxis (AZT and Nevirapine) ePNP while waiting for NAT or PCR results

Fig 7.1: HIV Testing Algorithm for Infants and Young Children

Note: If the HIV PCR results are inconclusive, repeat HIV PCR and viral load at the earliest possible opportunity.

7.2 Manifestations of HIV Infection and AIDS in Children

Clinical signs and symptoms of HIV infections are useful parameters in making an HIV diagnosis. In children, these features sometimes overlap with those of other common childhood diseases. Children with severe or atypical clinical diseases are more likely to be HIV-infected.

Signs and Conditions Characteristic to HIV Infection:

- Pneumocystis pneumonia
- Oesophageal candidiasis
- Extrapulmonary cryptococcosis
- Lymphoid interstitial pneumonitis
- Herpes zoster (shingles) with multi-dermatomal involvement
- Kaposi's sarcoma
- Lymphoma
- Progressive multifocal encephalopathy
- Signs and Conditions Common in HIV-Infected Children
- Severe bacterial infections, particularly if recurrent
- Persistent or recurrent oral thrush
- Bilateral painless persistent parotid enlargement
- Generalized persistent non-inguinal lymphadenopathy
- Hepatosplenomegaly (in non-malaria endemic areas)
- Persistent and/or recurrent fever
- Neurologic dysfunction
- Herpes zoster (shingles), single dermatome
- Persistent generalized dermatitis unresponsive to treatment
- Signs and Conditions Common in both HIV-Infected and Non-Infected Children
- Chronic, recurrent otitis with ear discharge
- Persistent or recurrent diarrhoea
- Severe pneumonia
- Tuberculosis
- Failure to thrive
- Acute and chronic malnutrition

A presumptive diagnosis of severe HIV infection should be made if the child fulfils the criteria in Table 7.3.

<table>
<tr><td colspan="3">Table 7.3. Criteria for Presumptive Diagnosis of Severe HIV Infection in Infants and Children <18 Months</td></tr>
<tr><td colspan="3">A presumptive diagnosis of severe HIV should be made if:</td></tr>
<tr><td rowspan="3">A child has a positive rapid HIV antibody test result</td><td rowspan="3">AND</td><td>2a. The child is symptomatic with two or more of the following:
Oral thrush
Severe pneumonia
Severe sepsis</td></tr>
<tr><td>OR</td></tr>
<tr><td>2b. Any child who is fulfilling WHO stage 3 or 4 criteria

(criteria found in Annex 2, WHO Clinical Staging for Children)</td></tr>
<tr><td colspan="3">Other finding that support the diagnosis of severe HIV infection in an HIV-infected child include:
Recent HIV-related maternal death; or</td></tr>
<tr><td colspan="3">Start ART as soon as possible while waiting for DNA PCR results.
Confirm the diagnosis of HIV infection as soon as possible with DNA PCR.</td></tr>
</table>

Definition of Symptoms in Table 7.3 above.

Oral thrush: Creamy white-to-yellow soft small plaques on red or normally coloured mucosa which can often be scraped off (pseudomembranous), or red patches on the tongue, palate or lining of the mouth, usually painful or tender.

Severe pneumonia: Cough or difficult breathing in a child with chest in drawing, stridor or any of the IMCI general danger signs, i.e. lethargic or unconscious, not able to drink or breastfeed, vomiting, and presence or history of convulsions during current illness; responding to antibiotics.

Severe sepsis: Fever or low body temperature in young infant with any severe sign, e.g. fast breathing, chest in drawing, bulging fontanele, lethargy, reduced movement, not feeding or sucking breast milk, convulsions.

Note: The HIV status should be confirmed as soon as possible or at 18 months. Presumptive diagnosis should NOT be done in children older than 18 months of age. In these children, HIV infection must be confirmed or excluded using widely available antibody tests.

Diagnosis using the Integrated Management of Childhood Illnesses (IMCI).

IMCI guidelines are a useful tool at the first level health facility to screen children with possible HIV infection who need to be referred to HIV testing or that have the test performed and are referred to care and treatment if they test positive.

IMCI algorithm should not be used for initiation of ARVs in children rather it should be used to refer children to further HIV evaluation and management.

Any sick child, whether or not qualifying by IMCI algorithm, should as early as possible be offered HIV testing through PITC service to establish the infection status.

WHO Clinical Staging for Children with Confirmed HIV infection

(Refer to the Annex 2).

Clinical staging is useful for assessment at baseline (at diagnosis of HIV infection), entry into long-term HIV care and in the follow-up of clients in care and treatment programmes. The clinical stages have been shown to be related to survival, prognosis and progression of clinical disease without antiretroviral therapy in adults and children.

7.3 Care and Social Support of HIV Exposed and Infected Children

7.3.1 Management of HIV Exposed Children

HIV exposed child is defined as any child born to or who is being breast-fed by an HIV infected mother. The HIV exposure stops after complete cessation of breast-feeding. However, child's HIV infection can be excluded by an HIV DNA PCR test at six weeks and at nine months of age; or by rapid HIV antibody test three months after cessation of breast-feeding and a confirmatory test at 18 months of age.

The HIV-exposure status of all infants attending RCH services should routinely be established and documented. The counselling of parents on care of infants born by HIV positive mothers is an essential component of the management of HIV exposed children. Management strategies include:

- HIV diagnostic testing for the child
- Scheduled clinic visits for care.

Infants of HIV infected mothers should receive prophylactic treatment against PCP and other opportunistic infections using Cotrimoxazole from 6 weeks of age or at first encounter with the health care system and continued until HIV infection is excluded. This should be given orally as per required dosing (see annex 5 paediatric dosing chart).

Mothers should be counselled on the advantages of exclusive breast-feeding, with particular attention to the risk of mixed feeding. Infants should exclusively breast-feed for the first six months of life and then continue breast-feeding until 1 year. At six months of life, infants should begin taking complementary foods. Infants who are HIV positive should continue breast-feeding for at least two years.

Care for the mother of HIV-exposed children during follow up should always be addressed. These HIV infected mothers should receive appropriate care and treatment including psychosocial support.

7.3.2 Care of HIV infected children

All children should be assessed for symptoms related to HIV as well as the need for treatment and prophylaxis for opportunistic infections and other HIV related conditions.

A complete medical and immunization history should be obtained, with particular emphasis on the suspected mode of HIV transmission, history of ARV exposure (pre-, intra-, post-partum, and during breast-feeding) and timing of HIV diagnosis. HIV-infected children should receive routine paediatric care and be monitored for their HIV disease progression.

Baseline laboratory tests should be performed.

Children below the age of five (5) years are considered unstable and should be seen monthly.

Children above 5 years and adolescents should be considered stable if they meet the criteria for stable clients. At each visit, a complete physical examination should be done, focusing on assessment and management of intercurrent illness as well as assessment for development of new WHO stage 3 or 4 clinical conditions, which may indicate treatment failure.

Nutrition, growth and neurodevelopment assessment should be done every visit and documented in age appropriate monitoring tools.

Doses of prophylactic or treatment medications should be reviewed and adjusted on the basis of the current weight, compliance and tolerability at every visit.

Medication plans (OI prophylaxis and ARV therapy) need to be discussed intensively with parents or guardians. It is advisable that one single person in the household is identified as the consistent care provider responsible for dispensing treatment to the child.

HIV related care needs of parents or guardians themselves need to be discussed and appropriate referrals made accordingly.

Children using ARVs should be closely monitored at every visit for signs of toxicity (i.e. clinical or laboratory indications) and adverse events should be properly documented and reported to the Ministry of Health, Community Development, Gender, Elderly and Children through adverse drug reaction (ADR) forms.

Counselling and psychosocial support should include the children and be provided in an age appropriate fashion.

7.4 Prophylactic Treatment of Common Opportunistic Infections

7.4.1 Cotrimoxazole Prophylaxis for Infants, Children and Adolescents Living with HIV

All children younger than five years of age living with HIV should receive Cotrimoxazole prophylaxis regardless of symptoms or CD4 percentage and should continue until the age of five years when they can be reassessed.

After five years of age, initiation of Cotrimoxazole prophylaxis is recommended for symptomatic children (WHO clinical stages 2, 3 or 4) and children with a CD4 cell count of <350/ cells/mm^3.

In children older than five years of age, discontinuation can be considered for those with CD4 count above 500/ cells/mm^3 and adherent to ART.

Tuberculosis Preventative Therapy is an important component of TB prevention in children living with HIV. (For further details refer to Chapter 6, Section 6.3.2).

7.5 Clinical Manifestations of Paediatric HIV Infection

7.5.1 Respiratory Conditions in Children with HIV Infection

Pneumonia and chronic lung diseases contribute to the increased morbidity and mortality of HIV-infected children. The different pulmonary conditions are difficult to differentiate from each other but are common in immune suppressed children. The most common respiratory conditions include:

7.5.1.1 Bacterial pneumonia

The common causes of pneumonia include *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Staphylococcus aureus*, and gram negative bacteria such as *Klebsiella pneumonia.* Recurrent bacterial pneumonia suggests immunodeficiency. Further investigations should be done to exclude TB, LIP, and fungal infections.

Clinical Presentation

History of fever, cough and fast breathing (tachypnoea)

With or without signs of severe pneumonia (chest in drawing, cyanosis and lethargy)

On auscultation of the chest one hears unilateral or bilateral crepitation (crackles), decreased breath sounds or bronchial breathing

When pulse oximetry is available it may demonstrate hypoxia (0_2 saturations less than 90% at room air).

Diagnosis

- Diagnosis of pneumonia is mainly made by medical history and physical examination. Other laboratory investigations may be of assistance:
- Complete blood counts; raised white blood cells (WBC) with a neutrophilia suggest bacterial infection.
- A chest x-ray is not necessary for diagnosis of acute pneumonia but may be useful in ruling out complications or other pulmonary conditions
- Because symptoms of pneumonia and malaria may overlap, in malaria endemic areas remember to do a malarial smear and treat for malaria if indicated
- Blood cultures can assist in identifying the causative agent
- Sputum induction and nasopharyngeal aspirate may assist in the diagnosis of TB or PCP

Management of pneumonia at outpatient level

Management should follow national/ IMCI guidelines but include the following:

- Oral Amoxicillin 40mg/kg/dose BD for 5 days.
- For children above 5 years, atypical pneumonia should be considered (e.g. mycoplasma) give macrolides as drug of choice Azithromycin 10mg/kg orally OD 5 days or Erythromycin 12.5mg/kg orally QID for 5 days.
- Co-trimoxazole should not be used to treat pneumonia unless PCP is suspected. If PCP is suspected, then high dose Co-trimoxazole should be used.
- Give paracetamol for fever.
- Cough syrups have no added value and are not indicated

Management of severe pneumonia

Severe pneumonia should be managed in hospital and should include both supportive and specific therapy.

Supportive Care

- Pulse oximetry is critical for the assessment of 02 saturations and if below 90%, oxygen should be supplemented. If pulse oximetry is not available, children presenting with chest in drawing, cyanosis or hypoxia need supplemental oxygen.
- Ensure adequate hydration (either IV or oral depending on the severity) and monitor for signs of dehydration or over hydration.
- Remember to give paracetamol for fever and pain.
- Ensure adequate feeding, if necessary by naso-gastric tube.

Specific therapy:

- Give Ampicillin 50 mg/kg IV or IM every 6 h for at least 7 days and Gentamicin 7.5 mg/kg IV or IM once a day for at least 7 days.
- If the child does not show signs of improvement within 48 hours switch to ceftriaxone (80 mg/kg IV or IM once daily)
- Antibiotic therapy for HIV-infected children needs to be longer 7-14 days
- If an infant is HIV exposed or infected and suspected to have PCP add high dose Cotrimoxazole IV or Orally 8mg/kg of Trimethoprim and 40mg/kg of sulfamethoxazole every 8 hours for 21 days. Steroids can be prescribed in case of severe respiratory distress.
- Children treated for PCP should continue taking CPT prophylaxis until the diagnosis of HIV infection has been excluded and all HIV exposure has ended.
- If pneumonia is associated with typical Staphylococcal skin lesions, a positive blood culture for Staphylococcus aureus, and poor response to 1st line antibiotics, or if the child just had measles, consider staphylococcal pneumonia. A chest X-ray (if available) may show pneumatoceles (very small cavities). For such children, treatment should also include clindamycin or vancomycin.

7.5.1.2 Lymphocytic Interstitial Pneumonitis

Lymphocytic Interstitial Pneumonitis (LIP) usually occurs in children more than one year of age and is often mistaken for pulmonary TB. Diagnosis is usually by exclusion. The following are common clinical symptoms:

- Clinical signs and symptoms
- Chronic cough
- Cyanosis
- Digital/finger clubbing
- Difficulty in breathing
- May be associated with parotitis, generalised lymphadenopathy and hepatosplenomegaly
- Poor response to TB therapy.
- Radiological picture (Chest X-ray)
- Diffuse bilateral reticulonodular infiltrates may appear similar to miliary TB
- May develop consolidation, cystic lesions; bilateral hilar or mediastinal lymph node enlargement
- Particularly difficult to differentiate from TB.

Management

Management of children with LIP, after exclusion of TB, includes the following:

- Antiretroviral therapy as specific therapy
- Steroids are needed when children with LIP having respiratory distress
- Prednisone 2 mg/kg/day - initially for 2 weeks daily and then decrease the dose over 2 to 4 weeks, depending on the response to treatment. *When giving steroids, monitor closely for symptoms and signs of untreated TB as steroids can reactivate TB*
- Oxygen therapy during episodes of hypoxia
- Bronchodilators such as salbutamol where there is wheezing
- Antibiotics are needed during episodes of concurrent superinfection with pneumonia
- Chest physiotherapy and postural drainage if there is secondary bronchiectasis
- Supportive care includes correction of anaemia with iron supplementation
- Consult or refer to specialist care if the child shows poor response to treatment.

7.5.1.3 Pneumocystis Jiroveci Pneumonia

Pneumocystis Jiroveci Pneumonia (PCP) is the major cause of severe pneumonia and death in HIV infected infants. The incidence is highest during the first year of life and usually peaks at 3 to 6 months of age. Infants may be in a good nutritional state and may have no clinical features that indicate the presence of HIV.

Clinical features

- No or low grade fever
- Marked respiratory distress (chest in drawing, cyanosis, inability to drink)

- On auscultation clear chest or diffuse fine crepitating
- Poor response to standard antibiotic treatment
- Severe persistent cyanosis/hypoxia (SPO2< 90%)
- They may have other signs of HIV including hepatosplenomegaly, oral thrush, lymphadenopathy.

Investigations

The mainstay of PCP diagnosis in Tanzania is clinical therefore where there is a high index of suspicion, clinicians should promptly initiate therapy along with treatment for bacterial pneumonia.

- A chest x-ray may show hyperinflation, diffuse infiltrates or normal
- Sputum induction with nasopharyngeal aspirate stained with Giemsa or Silver or immunofluorescent stains
- Bronchoalveolar lavage where available can also be used to produce a specimen for staining.

Management of PCP

Management of PCP includes both specific and supportive treatment:

Specific:

- High dose cotrimoxazole (CTX) IV (or oral) 8mg/kg TMP-40mg/kg sulfamethoxazole given every 8 hours for 21 days
- Prednisone at 1- 2mg/kg/day for 7-14 day (taper if given for more than 7days)
- Secondary prophylaxis using cotrimoxazole after an acute episode of PCP

Supportive:

- Oxygen therapy
- Maintain and monitor hydration
- Antipyretic if there is fever
- Continue therapy for bacterial pneumonia
- Nutrition support

7.5.2. Tuberculosis in children

HIV-infected children should be evaluated for TB disease at the time of their HIV diagnosis and any time they present with symptoms suggestive of TB or have a history of a new contact to an adult with TB. There is a considerable overlap of clinical and radiological findings of PTB and other forms of HIV-related lung diseases and malnutrition. TB in children is discussed in detail in Section 8.5 of this guideline.

7.5.3 Diarrhoea

Diarrhoea is one of the most common causes of under -5 mortality. Diarrhoea illness is more frequent in HIV-infected children, it tends to be more severe and prolonged, and it is often associated with other co-morbid conditions, including severe acute malnutrition and pneumonia.

Causative organisms are similar to those in otherwise healthy children (i.e. Rotavirus, Enterobacter, E. coli, Salmonella species, etc). Persistent diarrhoea (≥14 days) is more common among children with more severe immune suppression.

Acute and chronic diarrhoea with or without dehydration should be managed according to IMCI guidelines as in all children. Rehydration with ORS is the first priority. Antibiotics should be used where indicated. Caregivers should be counselled about the management and hygiene (hand washing, safe water). In case of persistent diarrhoea other causes should be excluded.

A careful feeding history is essential in the management of a child with diarrhoea. Inquiries should also be made about: frequency of stools, number of days of diarrhoea, blood in stools, report of a cholera outbreak in the area, recent antibiotic or other drug treatment, and attacks of crying with pallor in an infant.

Note:

- Acute watery diarrhoea – non-bloody diarrhoea lasting <14 days
- Dysentery – diarrhoea with visible blood mixed in stools
- Persistent diarrhoea – diarrhoea lasting ≥14 days

Investigations

- Stool microscopy
- Stool culture/sensitivities if available
- May be particularly useful for persistent diarrhoea.

Management

- Management of diarrhoea in HIV-exposed and HIV-infected children should generally be the same as for HIV-uninfected children
- Dehydration status should be assessed and managed according to WHO/IMCI guidelines
- Elemental zinc supplementation is recommended for 10–14 days, with increased fluids and continued feeding, for all children with diarrhoea (10 mg per day for infants under six months of age, 20mg per day for infants and children over sixxx months).
- Emphasize continued or increased feeding during and after the diarrhoea episode
- Ciprofloxacin 15mg/kg BD for three days is recommended for treatment of bloody diarrhoea.
- Daily micronutrients and multivitamins are recommended for two weeks for all infants and children with persistent diarrhoea.

7.5.4 Oral candidiasis

Oral candidiasis or thrush is a very common presentation of HIV in children, and persistent or recurrent outside of the neonatal period is a WHO Clinical Stage III condition.

Management:

- 2% Miconazole oral gel 5mls BID for two weeks
- Nystatin suspension for minimum of two weeks
- Infants –100,000 units in every six hours
- Children – 400,000 – 600,000 units in every six hours

7.5.5 Esophageal candidiasis

Clinical features

- Usually associated with extensive oral thrush
- Infants and young children - present with refusal to feed and crying during feeds
- Older children – pain with swallowing
- Vomiting

Management

- Fluconazole 3-6 mg/kg orally once daily for 2 weeks

If the child is not responding to oral formulation or unable to tolerate oral medications or at risk of disseminated candidiasis, IV fluconazole (3-6mg/kg once daily) can be prescribed

Otitis media

Inflammatory condition of the middle ear cavity; if untreated can lead to hearing loss.

7.5.6 Acute otitis media

Purulent exudates in the middle ear cavity with or without ear discharge lasting less than 14 days.

Clinical features

- Otalgia (painful ear)
- Ear discharge
- Fever
- With an evidence of inflamed and bulging tympanic membrane on otoscopy

Investigation

If there is ear discharge: ear swab for gram stain, culture and sensitivity

Management

- Oral Amoxicilin 40mg/kg BD for 5 days or

- Oral Azithromycin 10mg/kg OD for three days and oral Paracetamol 15mg/kg TID for three days.

7.5.6 Suppurative (Chronic) otitis media (draining ears)

Recurrent/persistent suppurative (draining) ears are very common presentation of HIV-infection in children and should be an indication for HIV-testing in children with unknown status.

Clinical features

- Ear discharge
- With an evidence of perforated tympanic membrane.

Investigation

- Ear swab for gram stain culture and sensitivity.

Management

- Ear wicking
- Ciprofloxacin 0.3% ear drops three time a day —use immediately after wicking
- Keep ear upright for 15 minutes after drops
- Give oral cefalexin 12.5mg/kg (max dose 25mg/kg) BID for 10 days.

7.5.7 Skin manifestations

Rashes and other skin problems are a common manifestation of HIV in children. Examples include papular pruritic eruption (PPE), tinea corporis, warts and herpes zoster.

7.5.7.1 Herpes Zoster

Symptoms include pain and fever followed by vesicular rash over a dermatome. For more details, refer to Section 6.4.1.

Management

- Acyclovir 20mg/kg/dose po or IV 6 hourly per day for 7 days
- Apply Acyclovir cream 5% to the lesions every 6 hours or apply zinc oxide 5% 12 hourly
- Give gabapentine 5mg/kg orally 8 hourly for 2 weeks
- If infected add flucloxacillin po 25mg/kg/dose 6 hourly per day for 7 days.
- Paracetamol for pain.

7.5.7.2 Kaposi sarcoma (KS)

Though not as common as in adults, children do get Kaposi sarcoma. The presentation includes purple plaques on the skin and mucous membranes, especially the palate, nodular skin disease, lymphatic involvement with “woody” edema, and less commonly visceral and pulmonary presentations. However, children are also likely to present with enlargement of

lymph nodes and may have enlarged lymph nodes as their only presenting symptom of Kaposi sarcoma.

Management

- Children with KS should be referred to specialty centres for chemotherapy; the response tends to be good.
- ART should be given.

Note: KS patients can develop IRIS while on ART.

7.5.8 Malnutrition

Childhood acute malnutrition is high among HIV-infected children. Severe wasting is a common clinical presentation of HIV infection in children. Generally, despite of their HIV status, children with severe malnutrition are at risk for a number of life-threatening problems and require urgent and appropriate rehabilitation. HIV-infected children with severe malnutrition have a higher risk of mortality than uninfected children due to the frequency and severity of OIs including TB. After their recovery from the initial rehabilitation, HIV infected children need urgent initiation of ART. Children with an unknown HIV status, who present with severe malnutrition, should be tested for HIV and be screened for TB.

Clinical presentation of severe malnutrition

Severe malnutrition is characterized by the presence of any of the following: weight/height z score <-3, severe visible wasting or bilateral pitting edema. SAM is also defined by a MUAC of <11.5cm in children of 6-59 months of age, MUAC < 13.5 cm in children 5-9 years of age and <16.0 cm in children of 10-14 years of age.

Management of severe malnutrition

The treatment of severe malnutrition in HIV-infected children is the same as for uninfected children. Please refer to Guidelines for Integrated Management of Severe Acute Malnutrition and Community Based Management of Malnutrition for details.

In HIV-infected children, the initial period of stabilization may take longer due to direct effects of HIV on the gut, appetite suppression or presence of OIs, such as TB that may be hard to diagnose.

CHAPTER 8

TB AND HIV CO-INFECTION

8.0 Introduction

TB is the most common opportunistic infection and the major cause of deaths among HIV and AIDS patients. TB and HIV have been declared emergencies demanding global attention. HIV increases the risk of TB reactivation and progression from TB infection to active disease. The likelihood of developing TB in an individual who is HIV negative is 5-10%, while for those who are HIV positive the risk is higher at 20-30%[24]. On the other hand, TB increases the risk of progression from HIV to AIDS disease.

8.1 TB Management in HIV and AIDS Patients

8.1.1 Pattern of HIV-related TB

As HIV infection progresses, CD4+ T-Lymphocytes that play an important role in the body's defence against tubercle bacilli declines in number and function. Thus, the immune system fails to prevent the growth and local spread of *M. tuberculosis*. There are two types of TB: Pulmonary and Extra pulmonary TB (EPTB) whereby the most common type of TB in HIV is extra pulmonary TB.

8.1.2. Pulmonary TB

Pulmonary TB (PTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree. The suspected case can be diagnosed if one sputum examination is positive for acid-fast bacilli (AFB) by microscopy or gene X-pert.

AFB negative pulmonary tuberculosis is defined as the presence of at least two sputum specimens negative for AFB by gene X-pert or microscopy, but with clinical or radiological features consistent with active tuberculosis. Pulmonary TB can be detected by culture and sensitivity even if it has not been detected by Gene-Expert or Microscopy.

8.1.3. Extra-pulmonary tuberculosis (EPTB)

EPTB is defined as bacteriologically or clinically confirmed tuberculosis in organs other than the lungs proven by one specimen from an extra-pulmonary site: culture-positive for *Mycobacterium tuberculosis*, AFB positive by gene X-pert or microscopy, histological or strong clinical evidence consistent with active extra-pulmonary tuberculosis. The most common forms of EPTB are pleural effusion, lymphadenopathy, pericardial disease, milliary disease, meningitis, spinal TB (Pott's disease) and disseminated TB. Other sites of the body

[24] Manual for the Management of Tuberculosis and Leprosy, sixth edition, 2013

which may be affected by TB include bones other than spine, peripheral joints, adrenal glands, skin, genito-urinary tract, intestines, peritoneal membrane and upper respiratory tract.

8.1.4. Tuberculosis diagnostic approaches

There are two main approaches for TB diagnosis: Clinical and laboratory.

Clinical diagnosis

Clinical diagnosis involves history taking and physical examination.

History Taking

In clinical diagnosis of TB a careful and extensive history-taking is essential. The health provider should ask the patient about existing classical symptoms suggestive of TB disease among adults such as cough of any duration night sweats, fever and weight loss. If coughing, ask about sputum colour and quantity, history of TB disease and the outcome of treatment, the presence of other immune compromising medical conditions such as diabetes mellitus, treatment with immunosuppressants and history of TB contact(s).

The patient should also be asked about: tobacco-smoking, including frequency and duration of smoking, history of substance abuse (drugs and alcohol) and occupational history that may suggest exposure to silica dust, especially among miners.

Physical examination

Although no physical sign is sensitive or specific enough for TB, it is critical to assess patients for fever, look for anaemia, exclude lymphadenopathy, and confirm the presence or absence of chest and neurological abnormalities and hepato-splenomegaly in order to screen for co-morbidities and rule out EPTB in all patients, including those with suspected PTB. Furthermore, advanced HIV patients with TB may present with signs and symptoms of septicaemia.

Laboratory diagnosis

Early identification and effective treatment of TB cases is important in TB care and control. Diagnosis of PTB depends on the identification of tubercle bacilli either by sputum microscopy, or culture and identification of bacterial DNA using molecular techniques (Gene X-pert).

Sputum smear microscopy

Sputum smear examination is the cornerstone of TB diagnosis. The test is relatively quick, easy to perform, and inexpensive. The purpose of sputum microscopy is to:

- Diagnose people with active TB in the absence of Gene-Xpert.
- Monitor the progress of treatment.
- Confirm whether cure has been achieved.

Sputum culture

Culture is a more sensitive method for detecting Mycobacterium than AFB microscopy and can detect as low as 10 bacilli/ml of sputum. However, culture methods are slow and expensive.

Molecular tests

(i)GeneXpert® MTB/RIF Assay. This is a highly sensitive and specific rapid automated molecular test for the combined detection of TB and rifampicin resistance. WHO; recommends the use of GeneXpert test as the initial test for PLHIV. However, due to the limited number of GeneXpert machines and cartridges available in Tanzania it is an initial test in only health facilities where GeneXpert machines are available. In health facilities without GeneXpert machines, it is used as a follow-up test for smear-negative HIV-positive, TB suspects.

(ii) Polymerase chain reaction using strip technology in Line Probe Assay (LPA) for DST. LPA is used for rapid detection of Rifampicin and Isoniazid resistance, which can occur within two days, hence facilitating early initiation of correct treatment or appropriate measures to prevent transmission of MDR TB.

C) New technologies

Urine for TB Lateral Flow Lipoarabinomannan (LAM-Test)

The Lipoarabinomannan (LF-LAM) test is based on the detection component of the cell wall of mycobacterium in urine and has the potential to be a point-of-care test for TB. It is only sensitive to advanced HIV disease, and additional testing is needed for confirmation due to low sensitivity and specificity. Lipoarabinomannan testing is recommended for diagnosis of TB in HIV-positive patients with either a CD4 count of less than 200 cells/uL or who present with one of the four danger signs: respiratory rate greater than 30 breaths/minute, temperature exceeding 39°C, heart rate more than 120 beats/minute, and/or unable to walk unaided irrespective of CD4 count.

Drug Susceptibility Testing (DST)

Drug susceptibility testing (DST) is the laboratory technique used to determine whether the mycobacterium isolates from specimen (direct) or culture-based (indirect) are susceptible or resistant to a TB drug. In Tanzania, DST is done using rapid molecular testing on GeneXpert platforms (e.g. MTB/RIF, Ultra, and Omni); using first- and second-line LPA, polymerase chain reaction (PCR), TaqMan™ Array Cards,[25] and sequencer; or by culture using solid or liquid medium.

iii) Other relevant investigations for tuberculosis in adults

- Chest X-ray
- Histological examination.

Note: For more details on TB diagnosis please refer to the current NTLP Manual.

8.1.5 Presumptive TB treatment for severely ill patients

Presumptive TB case among PLHIV is defined as individuals suspected of having TB according to TB screening tool (Annex 7) or with any of the following danger signs: Respiratory Rate >30 per minute, Temperature >39 degree Celsius, Heart Rate >120 per minute and unable to walk unaided. Presumptive TB treatment is based on expert opinion where expedited diagnosis of TB is not possible or feasible due to patient or health system limitations, but TB investigations should be done even after presumptive TB diagnosis is made. Treatment should be stopped only upon having proof of a negative TB test or strong evidence of an alternative diagnosis.

8.1.6 Standard TB Treatment Regimens for adults

There are two phases of TB treatment: initial (intensive) and continual. During the intensive phase, there is a rapid killing of the TB bacilli. Most patients with smear-positive TB become non-infectious after about two weeks of effective treatment. During the continual phase, the drugs kill the remaining bacteria, and prevent relapse after completion of treatment.

All new or previously treated patients should receive a six-month regimen containing rifampicin: 2RHZE/4RH. The regimen requires daily observed treatment by a health care provider or other designated individual, which could include a family member or friend, throughout the six months.

Standard regimen for previously treated adults other than MDR-TB: All previously treated TB patients should provide a specimen for rapid molecular testing (GeneXpert MTB/RIF), where available, and culture and DST. All patients who are rifampicin resistant should receive MDR-TB treatment in a designated health facility.

Patients who are rifampicin susceptible should be treated with a first-line treatment regimen containing all four drugs (2RHZE/4RH) while waiting for DST results. In the sites with no GeneXpert, all previously treated patient specimens should be referred to the nearest facility

with GeneXpert. Culture and DST specimens should be submitted to the respective zonal facility/laboratory.

Previously treated patients who failed treatment (treatment failure) should provide specimen for Xpert MTB/RIF test and a sputum sample should be sent for culture and DST. In facilities where a GeneXpert machine is not available, patients should be initiated on first-line TB treatment while waiting for culture and DST results.

8.1.7 Tuberculosis associated Immune Reconstitution Syndrome

HIV positive patients may experience an occurrence of features of active TB or a temporary exacerbation of signs and symptoms of TB with or without an aggravated radiographic manifestation after the initiation of ART. This paradoxical reaction in HIV infected TB patients is a result of immune reconstitution. Signs and symptoms include fever, lymphadenopathy, central nervous system lesions and worsening of the chest X-ray appearance. This syndrome is known as the Immune Inflammatory Reconstitution Syndrome (IRIS).

In such cases, it is crucial that TB treatment failure is excluded before diagnosing IRIS. The management includes continuation of both ART and anti-TB therapies, and if severe, prednisone 1-2 mg/kg for 1-2 weeks can be given (thereafter gradually decreasing dosage).

8.2. Collaborative TB/HIV activities

The MoHCDGEC commits itself to the endeavour of dramatically reducing TB and HIV morbidity and mortality through comprehensive collaborative TB and HIV activities. The strategies adopted in these guidelines are in line with global efforts to combat dual TB and HIV epidemics recommended by the WHO. The strategies take into account the key values of effectiveness, efficiency, equity, equality, and timeliness of delivery.

The measures being implemented include: Strengthening the mechanisms of collaborations and joint management between HIV and TB-control programmers for delivering integrated TB and HIV services; reducing the burden of TB in PLHIV and initiate early Antiretroviral therapy (the Three I's for TB and HIV) and reduce the burden of HIV in patients with presumptive and diagnosed TB. The following collaborative TB and HIV activities are recommended to be implemented in the country by both HIV and TB programmes:

(i) Strengthen the mechanisms of collaborations and joint management between HIV and TB-control programmes for delivering integrated TB and HIV services:

- Set up and strengthen a coordinating body for collaborative TB and HIV activities, functional at all levels
- Determine HIV prevalence among TB patients
- Determine TB prevalence among PLHIV
- Carry out joint TB and HIV planning to integrate the delivery of TB and HIV services
- Engage NGOs and CBOs in implementation of TB and HIV activities

- Establish and integrate national M&E system for collaborative TB and HIV activities that informs both NTLP and NACP annual operational plans
- Address the need of Key populations for TB and HIV

ii) Reduce the burden of TB in PLHIV and initiate early ART (the Three I's for TB and HIV):

- Intensify TB case-finding implemented at all HIV care and treatment clinics and all other healthcare facility settings
- Provide high quality TB treatment for HIV infected TB patients
- Initiate TB Preventive Therapy (TPT) with Isoniazid for both adults and children.Other alternative short regimens (Rifapentine+INH, Rifampicin+INH) will be used when available in country.
- Initiate TB prevention through early initiation of ART as per national guidelines
- Ensure control of TB infection in health-care facilities and congregate settings.

iii) Reduce the burden of HIV in patients with presumptive and diagnosed TB:

- Provide HIV testing and counselling to patients with presumptive TB
- Provide HIV testing and counselling to patients diagnosed with drug-sensitive TB and drug resistant TB
- Provide HIV prevention interventions for patients with presumptive and diagnosed TB
- Provide co-trimoxazole preventive therapy for TB patients living with HIV (TB PLHIV)
- Ensure HIV prevention interventions, treatment and care for TB patients living with HIV
- Provide antiretroviral therapy to TB PLHIV irrespective of CD4 cell count as per national guidelines.

Since TB is the leading opportunistic infection in HIV, all PLHIV should: be screened for TB on every clinic visit in order to reduce morbidity and mortality; be provided with TPT to prevent them from developing active TB depending on eligibility criteria; and observe principles of TB infection control.

8.2.1 Intensified TB case-finding

Intensified TB case finding involves screening for symptoms and signs of TB in settings where HIV-infected people are concentrated using standardized TB screening tools (available for both children and adults) (Annex 7). TB screening promotes early identification of TB among PLHIV and thus increases access to TB treatment, improves survival and quality of life and reduces transmission of TB in the community. People with presumptive TB should undergo diagnostic follow up using the TB diagnostic algorithm.

Furthermore, the diagnosis of childhood TB may be done clinically in the absence of bacteriological confirmation by using the score chart (Annex 11).

8.2.2 TB Preventive Therapy (TPT)

TB Preventive Therapy (TPT) is an intervention that should be part of the package of care for PLHIV. Currently, TPT involves giving Isoniazid (INH) tablets to eligible individuals in order to prevent progression to active TB disease. Other alternative short regimens recommended to be used when available are Rifapentine+INH weekly for 3 months and Rifampicin+INH daily for 3 months.

Tuberculosis Preventive Therapy (TPT)

In individuals with HIV, IPT reduces the risk of developing tuberculosis for about 60% and prolongs survival[26].

Exclusion of active TB is critically important before this preventive therapy is started. Isoniazid is given daily for six to nine months and should be given only once in a life time. This therapy requires consideration of several steps, including identification of HIV-positive clients, screening in order to exclude active TB, assessing eligibility for IPT and monitoring of treatment adherence and side effects.

Eligibility for TPT among adults and adolescents

For patients with no history of TB treatment:

All HIV positive individuals who screen negative for active TB are eligible for TPT.

A tuberculin skin test should be performed to all HIV infected individuals wherever possible. However, tuberculin test may be negative in severely immunocompromised clients due to cutaneous anergy and should not be used as exclusion criteria for TPT.

For patients with history of TB treatment:

People living with HIV who successfully completed their TB treatment should immediately receive TPT for six months. It has been shown that PLHIV who receive TPT immediately after completion of TB treatment have less risk of TB recurrence and mortality.

Other exclusion criteria for TPT include:

- Alcohol abuse
- Non-adherence to long term treatment
- Current / past history of hepatitis
- Medical contra-indication to INH.

[26] Ayele HT, Mourik MSMv, Debray TPA, Bonten MJM (2015) Isoniazid Prophylactic Therapy for the Prevention of Tuberculosis in HIV Infected Adults: A Systematic Review and Meta-Analysis of Randomized Trials. PLoS ONE 10(11): e0142290. doi:10.1371/journal.pone.0142290

TPT should only be offered in the following situations:

- Where quality supportive counselling is available
- After effective screening for active TB
- Where there is capacity for follow-up and monitoring of patients to encourage adherence to preventive therapy.
- Where there is capacity to manage side effects and exclude active TB during IPT.

Dosage:

- Isoniazid: 300 mg daily for 6 months to complete one cycle of IPT
- IPT should only be given in one cycle in life time and no repeat cycle is needed.

Note: In case of neuropathy due to INH, Pyridoxine should be used for treatment of neuropathy.

TPT in pregnancy

The benefits of TB preventive therapy for eligible pregnant women outweigh the risks. Active TB during pregnancy is associated with spontaneous abortions, and adverse peri-natal outcomes. Ten percent of maternal deaths in Africa are due to TB/HIV co-infection. TB Preventive Therapy is not contraindicated in pregnancy and it can be given during any trimester. TB Preventive Therapy should be completed even if the woman becomes pregnant while on the medicine.

8.2.3 ART in HIV and TB Co-infected individuals

ART has been reported to reduce TB rates by up to 90% at the individual level, and 60% at the population level, and also reduces TB recurrence rates by 50%[27],[28],[29]. Initiation of ART for all those with HIV and TB co-infection, if accompanied by high levels of coverage and ART adherence, it reduces the number of TB cases, TB mortality rates and TB transmission at the population level.

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[27] Lawn SD, Myer L, Edwards D et al. Short-term and long-term risk of tuberculosis associated with CD4 cell recovery during antiretroviral therapy in South Africa. AIDS 2009; 23:1717–25. [PMC free article[PMC free article][PubMed][PMC free article][PubMed]

[28] Gupta A, Wood R, Kaplan R et al. Tuberculosis incidence rates during 8 years of follow-up of an antiretroviral treatment cohort in South Africa: comparison with rates in the community. PLoS One 2012; 7:e34156. [PMC free article[PMC free article] [PubMed][PMC free article] [PubMed]

[29] Van Rie A, Westreich D, Sanne I. Tuberculosis in patients receiving antiretroviral treatment: incidence, risk factors, and prevention strategies. J Acquir Immune Defic Syndr 2011; 56:349–55. [PMC free article[PMC free article][PubMed][PMC free article][PubMed]

For TBHIV co-infected individuals who are not on ART at TB diagnosis, TB treatment should be started first, followed by ART as soon as possible, within the first 2 weeks after starting TB treatment.

For PLHIV who are already on ART at TB diagnosis, TB treatment should be started immediately and ART continued as instructed below:

Rifampicin and Nevirapine should not be used concurrently due to drug interactions. PLHIV diagnosed with TB while on Nevirapine containing regimens should be switched to efavirenz based regimens

In individuals who need TB treatment and who require an ART regimen containing a boosted protease inhibitor (PI), it is recommended to use LPV/r double dose (i.e. LPV/r 800mg/200mg twice a day) or with an adjusted, super-boosted dose of RTV (i.e. LPV/r 400mg/ 400mg twice a day) but this is frequently associated with high levels of toxicity and requires clinical and laboratory monitoring.

NOTE:

Consideration 1: When TB is diagnosed in patients already receiving ART, TB treatment should be started immediately. There are two issues to consider in such cases: whether ART needs to be modified because of drug interactions to reduce the potential for overlapping toxicities, or the presentation of active TB in a patient on ART constitutes ART failure that requires a change on the ART regimen.

Consideration 2: When TB is diagnosed in PLHIV who are already on ART and Medically Assisted Therapy using Methadone, Rifampicin decreases Methadone level by 33% to 68% and hence the Methadone dose increase may be required[30].

8.3.4 TB Infection in health-care facilities and congregate settings

TB infection control should be implemented in health care facilities and congregate settings where people with TB and HIV are frequently confined. Measures to reduce TB transmission include administrative, environmental, and personal protection measures, which are generally aimed at reducing exposure to *M. tuberculosis* among healthcare workers, prison staff, police officers and their clients, and other persons in the congregate settings.

8.3.4.1 Administrative measures

Administrative measures should include early recognition, diagnosis, and treatment of TB patients, particularly those with pulmonary TB, and quarantine of suspected pulmonary TB

[30]HIV AND AIDS Treatment and Care for Injecting drug users. Clinical Protocol for WHO European Region 2007.

patients until a diagnosis is confirmed or excluded. Specifically, administrative measures include:

- Early identification of TB patients and reduction of TB transmission.
- All clients should be screened for TB as soon as they arrive at the facility to identify those with at least one TB symptom.
- In outpatient departments, coughing patients should wait in well-ventilated areas.
- TB suspects need to be examined in a well-ventilated room.
- Have patients turn their heads and cover their mouths when they cough.
- Avoid contact between TB and HIV positive patients by separating them.

Separation of TB patients from HIV patients can be done through one of the following modalities:

- If TB clinic is providing ART, channel PTB and HIV co-infected patients to the TB clinic where they should receive TB and HIV care, treatment (anti TB treatment/CPT/ART) and adherence counselling; refer them to CTC at the end the TB treatment to ensure continuum of care (general HIV care, CPT, ARV provision, HBC, etc)[4].
- If the TB clinic is not providing ART, evaluate PTB and HIV co-infected patients at CTC on separate days to avoid sharing the same waiting area with PLHIV.
- If volunteers living with HIV (e.g. peer educators) are working at the HF level (e.g. CTC), they should be informed about the risk of developing TB and they should avoid accompanying TB suspects/patients.[31]

Clinic operating procedure:

Patients who report at CTC for registration should be observed and be probed on coughing and if so they should immediately be sent to the laboratory for sputum sample and return back to CTC for registration and care.

TB infection control plan:

Every health facility needs to have TB infection plan which is to be reviewed at least once every year. TB infection control plan should contain information regarding TB control in the respective health facility. Moreover, every health facility needs to have TB infection focal person to oversee implementation of TB infection control measures.

8.3.4.2 Environmental control measures

Environmental protection should include maximizing natural ventilation and direct sunlight. This is the second line of defence for preventing the spread of TB in HIV care settings. If the

[31]Guidelines for Tuberculosis Infection Control in health care facilities, MOHSW Tanzania,2010

work practice controls are inadequate, environmental control will not eliminate the risk of TB spread. The common control measures include:

- Open doors and windows to allow cross air ventilation.
- Waiting places and examination rooms designed in a manner that they have maximum natural ventilation. Fans may also assist in the process of air circulation.
- Collection of sputum for TB should be done in an open environment and away from other people, not in small rooms or other enclosed places.

8.3.4.3 Personal protective measures

Personal protective measures protect healthcare workers, patients and family members in areas where the concentration of droplet nuclei cannot be adequately reduced by administrative and environmental control measures. These measures prevent the spread of TB infection and shield healthcare workers from possible exposure to TB infection.

Protection of healthcare workers:

- Respiratory protective equipment is an additional measure to protect HCWs from inhaling infectious droplet nuclei expelled out into the air by a patient with infectious TB disease.
- Personal protective measures should ONLY be used in situations where there is an increased risk of transmission.
- Respirators are among the equipment and interventions used to protect personnel who must work in environments with contaminated air. In Tanzania they are recommended to be used when providing care to infectious MDR-TB and XDR-TB patients or people suspected of having infectious smear positive MDR-TB or XDR-TB.
- The primary way to prevent transmission of TB to health workers and others at the health facility is for TB patients to take their medicines regularly. By doing so, they will become non-infectious in a week or two. Proper ventilation of the place where treatment is provided is also very important.

In addition:

All healthcare workers should be made aware of the increased risk of developing TB when they are HIV positive.

Those working in hospital departments where TB patients are admitted should be advised to test for HIV. If they test positive, they should avoid contact with presumptive TB and confirmed TB patients.

Normal masks do not protect medical staff against inhaling infected droplets and are therefore not recommended as preventive measures for healthcare workers.

8.4 HIV-related TB in Children

The natural history of TB in a child infected with HIV is similar to that of an adult as it depends on the stage of HIV disease, nutritional status and exposure to TB infections. During early stages of HIV infection when immunity is good, the signs and symptoms of TB are similar to those in a child without HIV infection. As HIV infection progresses and immunity declines, dissemination of TB becomes more common and TB meningitis, miliary TB, and widespread tuberculosis lymphadenopathy may occur.

8.3.1 Prevention of TB in children

i) BCG vaccination

In HIV positive neonates, BCG rarely causes disseminated infection of *M. bovis* and if it occurs it should be treated with 2{RH} E/4RH. The WHO recommends that in countries like Tanzania where there is a high prevalence of tuberculosis, BCG should be given to all neonates immediately after birth, regardless of HIV status. The possible benefits of BCG outweigh the possible disadvantages. However, BCG should not be given to children who present with clear signs and symptoms of HIV-disease or AIDS.

TPT in children

TPT in children is achieved by administering Isoniazid in order to prevent active TB, children should be considered for Isoniazid as follows:

- All new born without signs and symptoms of active TB disease that is born to mothers with active TB disease
- All under 12 months HIV-infected children without signs and symptoms of active TB disease and with a known TB contact
- All HIV-infected children who are 12 months or older with no signs and symptoms of active TB disease.

Explain to the child (if age appropriate) and parent/caregiver that treatment with the medicine Isoniazid is essential to prevent the child from becoming sick due to TB disease. Describe the potential side effects and that they should return to the clinic whenever any adverse reactions occur.

Emphasize to the parent/caregiver and/or child that:

The full duration of treatment is 6 months to complete one cycle of TPT (TPT should be given only once in a life time and no repeat cycle is needed). The child must adhere to and complete their treatment.

The child should return to clinic if they feel ill whilst on TPT, or if they develop TB symptoms such as cough, fever, and poor appetite.

The parent/caregiver does not need to limit the child's activities in any way.

Dosage:

Isoniazid: 10 mg/kg (10-15 mg/kg) daily for six months.

Note: IPT should be initiated only after TB disease has been ruled out. Neuropathy due to INH should be treated with pyridoxine.

8.4.2 Diagnosis of Tuberculosis in Children

The diagnosis of TB in children can be very difficult due to a wide range of symptoms. Sputum can hardly be obtained from children and is often negative even on culture. Signs and symptoms of TB in children are atypical. The diagnosis should therefore be based on at least one of the following: clinical findings especially when there is failure to thrive or weight loss; family history of TB contact; X-ray examination; tuberculin testing; culture results; and non-response to broad spectrum antibiotic treatment. A score chart can help to reach the diagnosis of tuberculosis. Older children who are able to cough up sputum should go through the same assessment as adults using Gene-Expert as the "gold standard" test.

Treatment of TB in children

Treatment regimens for tuberculosis disease

Treatment of TB disease in children requires multidrug combination therapy. Anti-TB drugs have a synergistic effect on each other; their combined actions produce a greater effect than the sum of the individual medications.

In general, paediatric treatment regimens are comparable to adult regimens. Because TB in young children can rapidly disseminate with serious sequelae, prompt initiation of therapy is critical. Appropriate regimens, dosing, and duration are outlined in Table 8.1 and 8.2 below:

Table 8.1. Recommended treatment regimens for paediatric patients in Tanzania

TB disease category	Recommended regimen	
	Intensive phase	Continuation phase
All forms of pulmonary and extrapulmonary TB (except TB meningitis and TB of the spine/ bones/joints) and Previously treated bacteriologically confirmed TB cases (relapse, return after lost to follow-up and treatment failure, other previously treated)**	2 months of daily RHZE	4 months of daily RH
TB meningitis; miliary TB*; TB of the spine/bones/joints	2 months of daily RHZE	10 months of daily RH
MDR TB	See Annex 9.1 "Drug-resistant tuberculosis in children"	

E: Ethambutol; H: Isoniazid; R: Rifampicin; Z: Pyrazinamide.

*30 percent of children with a miliary picture on chest radiography have central nervous system involvement and should be treated with a 12-month regimen (see "Tuberculosis meningitis" on Section ...).

**All previously treated TB cases should be evaluated for MDR TB by sending samples for culture and drug susceptibility testing. Relapse cases are those who have been previously treated for TB, were declared cured or treatment completed at the end of the most recent treatment episode, and a new diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by re-infection).

Note: If an adolescent is pregnant, refer to the section in the adult guidelines on treatment of TB in pregnancy.

Adapted from: *Graham SM et al. Desk-Guide for Diagnosis and Management of TB in Children. Paris, France: International Union Against Tuberculosis and Lung Disease; 2010; and Definitions and reporting framework for tuberculosis – 2013 revision (updated December 2014), WHO/HTM/TB/2013.2.*

Medications and dosages

- To treat children with TB, calculate all anti-TB medicine doses by weight and use FDC tablets. It is important to weigh the child at each visit and adjust medication dosages as needed. Anti-TB medications, daily dose and range, maximum dose, and potential adverse reactions are provided in Table 8.2below.
- If available, give Pyridoxine supplementation to children receiving TB treatment at a prophylactic dosage of 1-2 mg/kg per day.

Table 8.2. Drug dosing and adverse reactions for the treatment of TB in children

Drug	Daily dose and range mg/kg	Maximum daily dose	Adverse reactions
Isoniazid	10 (7-15)	300 mg	Mild hepatic enzyme elevation, hepatitis, peripheral neuritis, hypersensitivity
Rifampicin	15 (10-20)	600 mg	Orange discoloration of secretions or urine, vomiting, hepatitis, influenza-like reaction, thrombocytopenia, pruritus
Pyrazinamide	35 (30-40)	-	Hepatotoxic effects, hyperuricemia, arthralgias, gastrointestinal tract upset
Ethambutol	20 (15-25)	-	Optic neuritis (usually reversible), decreased red-green colour discrimination, gastrointestinal tract disturbances, hypersensitivity

Adapted from *WHO, Stop TB Department. Rapid Advice: Treatment of Tuberculosis in Children. WHO/HTM/TB/2010.13; and WHO, 2014. Guidance for National TB Programmes on the Management of TB in Children, 2nd Edition.*

Fixed-dose combination tablets

Use FDC tablets whenever possible to facilitate adherence and simplify regimens. The FDCs available for use in children in Tanzania include Rifampicin, Isoniazid, and Pyrazinamide (R/H/Z, 75/50/150mg) and Rifampicin and Isoniazid (R/H, 75/50mg). Children below 25kg body weight will need to receive Ethambutol as a separate medication, but older children weighing 25kg and above can be treated using adult FDC tablets of Rifampicin, Isoniazid, Pyrazinamide, and Ethambutol (RHZE, 300/150/400/275mg). Table 8.3 lists the paediatric FDC dosage needed to achieve the correct dose by weight in children <25kg.

Guidelines for using TB dosing charts:

- If the child is less than 25kg: use paediatric FDC dosing chart (Table 3.3)
- If the child is ≥25kg: use adult FDC dosing chart (see NTLP Manual).

Table 8.3. Weight-based dosing of anti-TB drugs for children (0-24.9kg body weight)

	Intensive phase * (2 months)		Continuation phase (4 months)
Weight (kg)	RHZ (paediatric) 75/50/150mg	Ethambutol 100mg	RH (paediatric) 75/50mg
<4kg**	For infants below 4 kg, consult a paediatric specialist, DTLC, and RTLC for treatment advice		
4-7.9kg	1 tablet	1 tablet	1 tablet
8-11.9kg	2 tablets	2 tablets	2 tablets
12-15.9kg	3 tablets	3 tablets	3 tablets
16-24.9kg	4 tablets	4 tablets	4 tablets
≥25kg	use adult FDCs		

H: Isoniazid; R: Rifampicin; Z: Pyrazinamide.

*WHO recommends four-drug therapy during the intensive phase for all children.

**For children <4kg, recommend referral to paediatric specialist/DTLC/RTLC to assist with dosing and treatment in this high-risk group.

Note: For more details, refer to the National Guidelines for the Management of Tuberculosis in Children, 2018.

8.4.4 ART in HIV infected infants and children on TB treatment

For HIV infected infants and children below three years old, if on NVP- based regimen, continue NVP ensuring that dose is 200mg/m^2 (optimized dose), and if on LPV/r based regimen double the dose of LPV/r.

For HIV infected infants and children above three years old: It is recommended to give 2 NRTIs with EFV and if on LPV/r-based regimen double the dose of LPV/r.

8.5 Drug Resistant TB

This is a form of TB on which first-line anti-TB drugs have little or no effect. The diagnosis is confirmed through DST using molecular and/or phenotypic tests of *M. tuberculosis* strains.

All MTB detected as rifampicin-resistant cases should have specimen sent to a zonal TB laboratory for first- and second-line LPA, culture, and DST.

8.5.1 Identification of presumptive drug-resistant TB patients

The following patient groups are at high risk for DR-TB and should have their sputum specimen sent immediately for molecular testing, culture, and DST:

- Treatment failure after using first-line anti-TB medicines
- Close contact of a known DR-TB case
- Patients who remain sputum smear-positive after completion of Intensive Phase of first-line anti-TB drug regimen
- Relapse and return after loss to follow-up, without recent treatment failure
- HCWs presenting with TB symptoms
- Vulnerable groups in congregate settings (prisoners, urban poor, miners, people who use drugs)
- Patients who have a contact who died while on DOT for TB
- Residents or migrants from high MDR-TB burden settings who presents with TB symptoms.

Patients found to have RR-TB or MDR-TB at any point in time should be started on an adequate second-line drug regimen. The treatment of DR-TB involves standardised and individualised approaches consisting of intensive and continuation phases. For further details, refer to Chapter 9 in TB and Leprosy Manual 7th Edition, 2019.

CHAPTER 9: PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV

9.0 Introduction

The Prevention of Mother to Child Transmission of HIV (PMTCT) services have been implemented in the country since 2000. In 2012, Tanzania adopted the global plan for elimination of HIV infection among children born to HIV-infected mothers and keeping their mothers alive. The goal of the national elimination of Mother to Child Transmission of HIV (e-MTCT) plan was to reduce vertical transmission rate from 26% in 2010 to 4% by the end of 2015. To further expedite progress towards the set target, in 2013, Tanzania adopted the WHO recommendation of providing Life Long ART to pregnant and Lactating women living with HIV (LLAPLa), using a fixed dose combination regimen of one pill once per day (also known as Option B+). By December 2014, countrywide LLAPLa rollout was achieved. Ostensibly, the programme will contribute towards achieving the 90, 90, 90 goal by 2030.

Moreover, there has been emerging evidences resulting into various WHO recommendations that are geared to help programmes deliver services closer to people; integrate HIV treatment in RMNCAH, Tuberculosis and other services; and use a wide range of health workers to administer treatment and follow up care.

The programme is keen at adapting or adopting guidance that keep up with the latest scientific evidence and enables services to be delivered equitably and sustainably to all populations across the country.

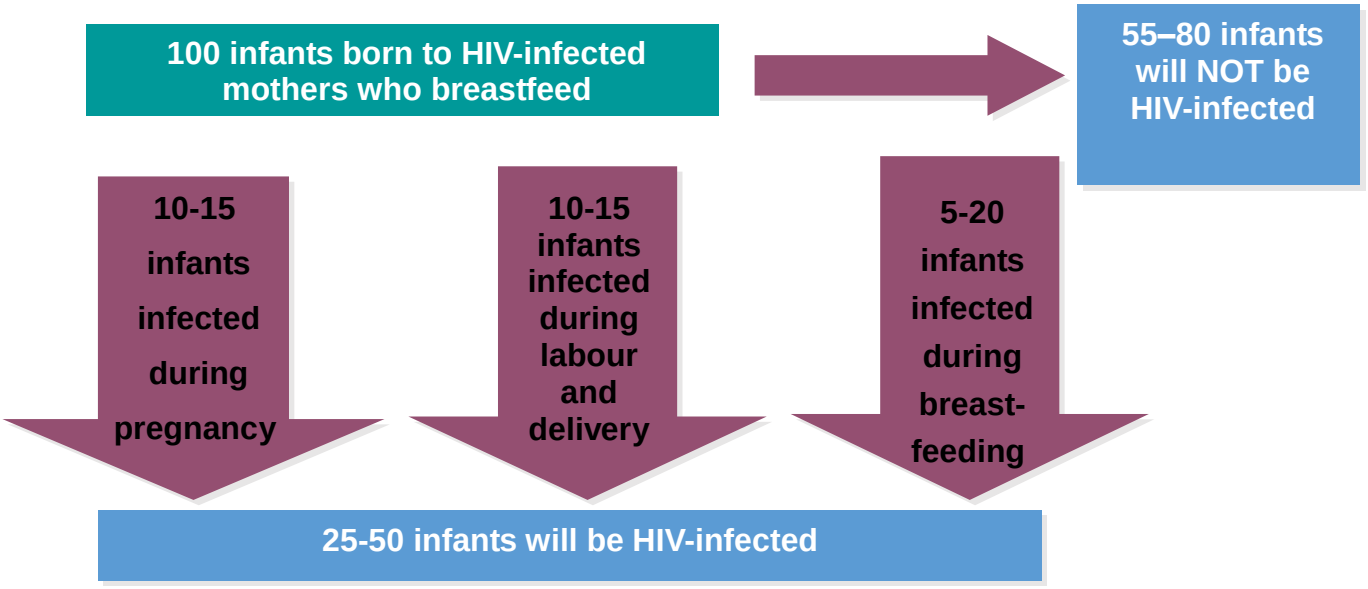
Tanzania has a policy of screening all pregnant women for HIV and syphilis at the first antenatal care visit. Of recent, WHO recommended the HIV/Syphilis Duo test for countries committed to eliminate mother to child transmission (e-MTCT) of HIV and Syphilis. The country is planning to start implementing Duo test in phases using the experience gained from a pilot carried out in Shinyanga region. The implementation will involve altering the National testing algorithm, procurement of kits revisions of the capacity building materials, and the feasibility assessment

In addition, the country plans to introduce gradually the PCR test at birth for HIV exposed infants who are identified as high risk. This will go hand in hand with the scale up of Point of Care (POC) testing technologies in order to expand HIV early testing within districts with high volume of HIV+ pregnant women and/or districts with logistical challenges for conventional HIV testing technologies. Health facilities with at least 30 HIV+ pregnant women in a year will be targeted and perform PCR at birth to HIV exposed infants who have identified as high risk. This is expected to capture more children who need ART much earlier and put them on care.

9.1 Basic facts about mother-to-child transmission of HIV

Mother-to-child transmission (MTCT) of HIV refers to the transmission of HIV infections from HIV-infected mothers to their infants. MTCT can occur during pregnancy, labour and delivery, and breast-feeding. Without intervention, the overall risk of MTCT is approximately 20% to 45%. Transmission of HIV from mother to her child accounts for over 90% (find current data) of all HIV infections in children aged below 15 years.

Figure 9.1: Estimated HIV outcomes for infants born to mothers living with HIV



There are multiple risk factors that increase the chance of a mother in transmitting HIV to her child:

- High maternal viral load and low CD4 cell count, which occurs in newly infected individuals, individuals with suboptimal HIV treatment adherence or response and in advanced stages of HIV disease (AIDS).
- Virulence of viral subtypes and strains impacts MTCT, rates are higher with HIV-1 than with HIV-2 infections.

Obstetric and neonatal risk factors, as outlined in Table 9.1 below:

Table 9.1: Viral factors, maternal conditions, and obstetric interventions that may increase the risk of HIV transmission

During Pregnancy	During Labour and delivery	When Breast-feeding

High maternal viral load and low CD4 cell count Viral, bacterial or parasitic placental infections (e.g. Malaria) Sexually transmitted Infections (STIs)	High maternal viral load and low CD4 cell count Chorioamnionitis (from untreated STIs or other infections) Rupture of membranes for more than 4 hours before delivery Prolonged labour	High maternal viral load and low CD4 cell count Oral disease in the infant (e.g. mouth sores) Breast abscesses, nipple fissures, and mastitis Duration of breast-feeding Mixed feeding (i.e. breast-feeding combined with other foods or fluids) before 6 months of age

9.2 Goal of Tanzania's PMTCT programme

The goal of the PMTCT programme is to attain virtual elimination of MTCT of HIV while improving care for infected parents and children, hence contributing towards the 90, 90, 90, Goal by 2030. The programme has the following objectives:

- Increase the proportion of pregnant women and breast-feeding mothers who know their HIV status
- Increase the proportion of HIV positive pregnant and breast-feeding women who receive ARVs
- Ensure access to care and treatment for mothers and babies living with HIV
- Improve child survival among HIV posed and infected children.

Note: Virtual elimination refers to 90% reduction in estimated number of new infections in infants; and an MTCT rate of <5%, which is associated with at least 90% of all the HIV exposed infants being alive and uninfected with the virus at the age of two years.

9.3 Four elements of a comprehensive approach to PMTCT

A comprehensive approach to PMTCT consists of four elements that guide interventions:

Four elements of a comprehensive approach
1. Primary prevention of HIV among women of childbearing age and their partners 2. Prevention of unintended pregnancies amongst women living with HIV 3. Prevention of vertical transmission of HIV from mothers to their infants 4. Provision of treatment, care and support to women living with HIV and their partners, infants, and families.

9.3.1. Primary prevention of HIV among women and their partners

Primary prevention is the most effective means to control the spread of HIV and minimize its impact on individuals, families, and communities. Preventing HIV infection in women of childbearing age is the best way to prevent MTCT.

Practice Points

1. Healthcare workers at RCH clinics should ensure that HIV testing and counselling is integrated and offered to all women of childbearing age, their partners, and children whose mothers are HIV positive or mothers with unknown status.
2. Sexually active women and men should be encouraged to use safer sex practices including barrier methods such as condom use, reduce the number of sexual partners, and stay faithful to their sexual partners.
3. All health care providers should emphasize early diagnosis and treatment of STIs in their practices.

Preventing and treating STIs is an important component in HIV prevention. Co-infection with an STI increases risk of HIV acquisition significantly. All healthcare providers should emphasize early diagnosis and treatment of STIs in their practices. Young people should be provided with information about and access to HIV prevention services and should be encouraged to abstain from sexual activity until they can make responsible decisions. Treating HIV-infected individuals with ARVs can also help prevent transmission of the virus to their partners or spouses.

Another basic effort in HIV prevention involves preventing the spread of HIV in health care settings. All facilities in Tanzania should use Standard Precautions to prevent transmission of HIV.

9.3.2. Prevention of unintended pregnancies among women infected with HIV

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 should be empowered to access and utilize effective contraceptive methods in order to avoid unplanned pregnancies. A woman's/couple's choice of contraceptive methods should be based on her health status and personal preference. The contraceptive option of her/their choice should be provided on site or through referral to the nearest facility when the method of choice is not available.

Dual protection is the simultaneous prevention of Sexual transmitted infections (including HIV) and unwanted pregnancy). For example, the use of condoms alone (male or female) or condom with any other method of contraception would provide dual protection.

9.3.3. Interventions to prevent HIV transmission from mothers to their Infants

The PMTCT program offers a range of services and interventions that can reduce the risk of MTCT. These include HIV education, testing and counselling for pregnant and breast-feeding women and their partners, antiretroviral treatment (ART) and prophylaxis to HIV exposed infants, safer delivery practices, and counselling on safer infant feeding and care of the HIV-exposed infant.

9.3.4. Treatment, care and support for HIV-infected women and their families

Providing HIV treatment, care and support is critical for enabling pregnant women living with HIV to address their health needs and ensure the well-being of their children and families. The PMTCT programme should strive to provide comprehensive HIV care and treatment services, and when this cannot be provided in RCH clinics it is important to strengthen coordinated referral systems to ensure that women and their families have access to comprehensive HIV care services at appropriate clinics.

In the context of treat all, lifelong ART is recommended for all pregnant women living with HIV and breast-feeding women regardless of their CD4 cell count or WHO clinical stage or gestational age. However, all women diagnosed with HIV infections should have their blood viral load, CD4 cell count checked and clinically evaluated to monitor their progress as they start ART. It is important that viral suppression is attained before delivery to ensure maximal reduction of MTCT; hence the need of frequent HVL monitoring. Care and treatment services to pregnant and breast-feeding women living with HIV should be provided in RCH settings or by referral when care and treatment services cannot be provided in RCH clinics. Infants born to mothers living with HIV will require close follow-up and monitoring of the following: growth and development, immunizations, prophylaxis against HIV infections and opportunistic infections (ARVs and CPT), early testing for HIV and nutritional counselling and support services. All HIV-infected infants should be provided with comprehensive paediatric HIV care and treatment services.

Table 9.2: Services that contribute to a comprehensive approach to PMTCT

PMTCT services	How these services contribute to a comprehensive approach
Routine HIV testing and counselling	• Identifies women/couples living with HIV so that they can receive PMTCT services and HIV care, treatment and support • Identifies women who are currently negative but at high risk for acquiring infections during pregnancy and or breast-feeding period. Women/couples should be encouraged to continue using protective interventions • Consider PrEP for HIV negative pregnant and breastfeeding women in case of discordant couples It should be given following the general guidelines. PrEP should continue until exposure of HIV to the baby ceases

Comprehensive antenatal care (ANC)	• Monitors pregnancy progress, early detection and treatment of pregnancy-related complications such as STIs and anaemia • Provides prevention of malaria and TB • Counsels mothers on optimal nutrition • Provides preventative methods such as (CPT) for PCP, IPT and malaria
Lifelong ART for HIV positive pregnant and breast-feeding women	• Improves maternal health, which in turn improves child's survival chances • Reduces maternal viral load, which in turn reduces infant exposure to the virus and risk of MTCT
ARV prophylaxis for HIV exposed infants	Reduces the chance of the HIV-exposed infant from getting infected with HIV from the mother during the postpartum period
Safer delivery practices	Reduces likelihood of labour and delivery complications and infant exposure to HIV during labour and delivery
Counselling for safer infant feeding practices	Promotes safer infant feeding options to improve child nutrition and survival and reduces infant exposure to the virus, hence reducing MTCT
Postpartum care for the mother	Supports mother's health and nutrition status and addresses woman's family planning needs
Early infant HIV diagnosis, and treatment	• Identifies infants infected with HIV and initiates them on ART to improve their survival • Monitors and manages signs and symptoms of infection in children exposed to HIV • Ensures HIV early infant diagnosis (HEID) and CPT for infants starting at six weeks of age • Ensures infant testing three months after cessation of breast-feeding and a confirmatory testing at 18 months of age • Facilitates early initiation of ART for HIV infected children
Partner and family involvement	• Identifies the partner who is HIV infected or who is at risk of being infected (discordant)

	• Identifies and facilitates children and other family members to receive HIV care, treatment and support
Family planning	Reduces risk of unintended pregnancy by giving proper contraception choice to both partners, preferably dual protection

9.4 Integrating PMTCT into routine Reproductive and Child Health Services

Integration of PMTCT into ANC services, will contribute to enable the National health care programs to improve care and pregnancy outcomes for all clients. The National policy for HIV testing requires all pregnant women to be tested for HIV once they start attending the ANC services. The service for women living with HIV includes the same basic services provided for all pregnant women. However, obstetric and medical care should be expanded to address the specific needs of women living with HIV.

Practice Point

- Pregnant women living with HIV should attend ANC clinic every month during pregnancy to be provided with adherence and medication support to ensure close follow-up and monitoring.
- Pregnant women should be advised to book early for ANC services, starting from ≤12 weeks of gestation.
- Adolescents and young mothers should be given special attention to address their needs during ANC.

Table 9.3 Essential package of Integrated ANC services for pregnant women living with HIV infection

Client and family history	Collect routine information as guided by the Tanzania obstetric record, including medical, surgical, obstetric, and family planning
Understanding Client's Context	Assess and help client identify special needs given their circumstance, e.g. psychosocial support, mental health needs, or tailored scheduling of visits
Disease Screening (History and Physical Examination)	Assess the current signs or symptoms of illnesses including HIV, TB, malaria, cervix cancer and STIs

Laboratory testing	Conduct routine tests and HIV-specific laboratory tests: • Syphilis • Confirmatory HIV testing (if indicated) • Urinalysis • Full Blood Picture (FBP)
HIV staging	• Conduct clinical and immunological staging according to the WHO clinical staging system
Treatment Readiness and support	• Assess readiness to start ART. Support client to formulate strategies for treatment adherence and support including disclosure • Plan for continuous treatment support.
Antiretroviral Treatment (ART)	• Provide life-long ART to all HIV positive pregnant women regardless of CD4 cell count, WHO clinical stage or gestational age
Tuberculosis (TB)	• Screen for signs and symptoms of TB disease at every visit. Evaluate for TB disease if symptomatic. • Initiate IPT for eligible pregnant and lactating women
Opportunistic infection (OI) prophylaxis	• Cotrimoxazole preventive therapy (CPT) should be provided to pregnant women with CD4 cell count ≤350 cells/mm^3
Malaria	• Support and monitor adherence to CPT. Women on CPT do not need Sulfadoxine - pyrimethamine prophylaxis for malaria • Identify acute cases of malaria; treat promptly according to the national guidelines
STI prevention and treatment	• Assess risk, diagnose and treat STIs according to the national guidelines. • Counsel on preventing STIs. Always recommend the use of condom throughout pregnancy and breastfeeding

Adherence to ART, CPT and TPT	• Provide counselling and education on healthy pregnancy, HIV care and treatment and PMTCT • Ensure knowledge and understanding of the rationale for ART and infant ARV prophylaxis and the risks of non-adherence to ART, CPT and TPT • Ensure accurate knowledge of maternal ART and infant
Nutrition	• Conduct nutritional and dietary assessment and provide counselling and supportive services. • Give iron, folic acid and multivitamin supplements according to national guidelines.
Planning Delivery	• Explain that interventions for PMTCT — including the provision of ARVs to the mother and infant — are critical during the labour and delivery period • Plan in advance with the client on the mode and place of delivery
Tetanus Toxoid	Administer immunization according to national guidelines.
Safe Motherhood	Instruct her to immediately return to the clinic/hospital if she experiences symptoms of pregnancy complications such as bleeding, fever, signs and symptoms of pre-eclampsia, severe pallor or abdominal pain.
HIV-exposed Infant	• Educate about infant ARV prophylaxis • Explain that infant prophylaxis is most effective when initiated as soon as possible (preferably within 6–12 hours) after delivery. Infants who have not received ARV prophylaxis soon after birth should receive prophylaxis immediately thereafter up to six weeks of age. For high risk HIV exposed infants ARV prophylaxis should be given for up to 12 weeks of age. • Inform about infant HIV testing and emphasize the importance of early diagnostic testing • All HIV exposed infant should be tested for HIV infection (see Section 4.1.3 Diagnosing HIV infection in children under 18 months) • Explain that all infants should initiate CPT at the age of 6 weeks. This should continue until HIV infection has been ruled out and the infant is no longer at risk (is no longer breast-feeding)

Infant feeding	• Support the mother to breast-feed exclusively for the first 6 months of life, followed by the introduction of complementary feeding with continued breast-feeding until 12 months of age • At 12 months of age, encourage cessation of breast-feeding over the course of about one month
Signs or symptoms related to HIV	Provide information and instructions on seeking healthcare for symptoms of HIV disease progression, such as frequent and recurrent illnesses, chronic persistent diarrhoea, oral and oesophageal candidiasis, fever, severe weight loss or signs of any opportunistic infection. Refer women to a CTC when appropriate.
Mental health, • Psychological and social support	Assess and address needs for mental health, psychological and social support • Refer for further mental healthcare if need be • Refer to community-based psychosocial support networks or organizations where available • Encourage partners to undergo testing and counsel them on disclosure • Assess need to test other children in the family, even if they are asymptomatic
Effective family planning and safer sex	• Counsel about consistent use of condoms during pregnancy, as well as throughout the breast-feeding period to avoid new HIV infection, re-infection and further transmission • Include long-term family planning with partner involvement when possible. Discuss dual protection (dual protection refers to the use of condoms in addition to the chosen method of contraception)

9.4.2 HIV Testing and Counselling for Pregnant and Breast-feeding women

All pregnant women and their partners (unless known to be HIV positive) should be counselled and tested for HIV during their first ANC visit. For those who are HIV negative, repeat test should be conducted during the third trimester (between 32 weeks and 36 weeks gestational age). A pregnant woman, who did not appear for testing at third trimester, will have an opportunity to test during labour and delivery. If testing at labour and delivery did not happen, then the test will be provided at six weeks immunization /postnatal visit. A second repeat test will be done at 6 months post-partum during Vitamin A supplementation and thereafter as per general population.

All breast-feeding mothers, unless known to be HIV positive, should be counselled and tested during breast-feeding. For those whom were tested during third trimester or at labour and delivery, a repeat HIV test should be offered at 6thmonth after the first test and thereafter as per general population.

9.4.3 Categories of status of PMTCT clients according to risk of vertical HIV transmission

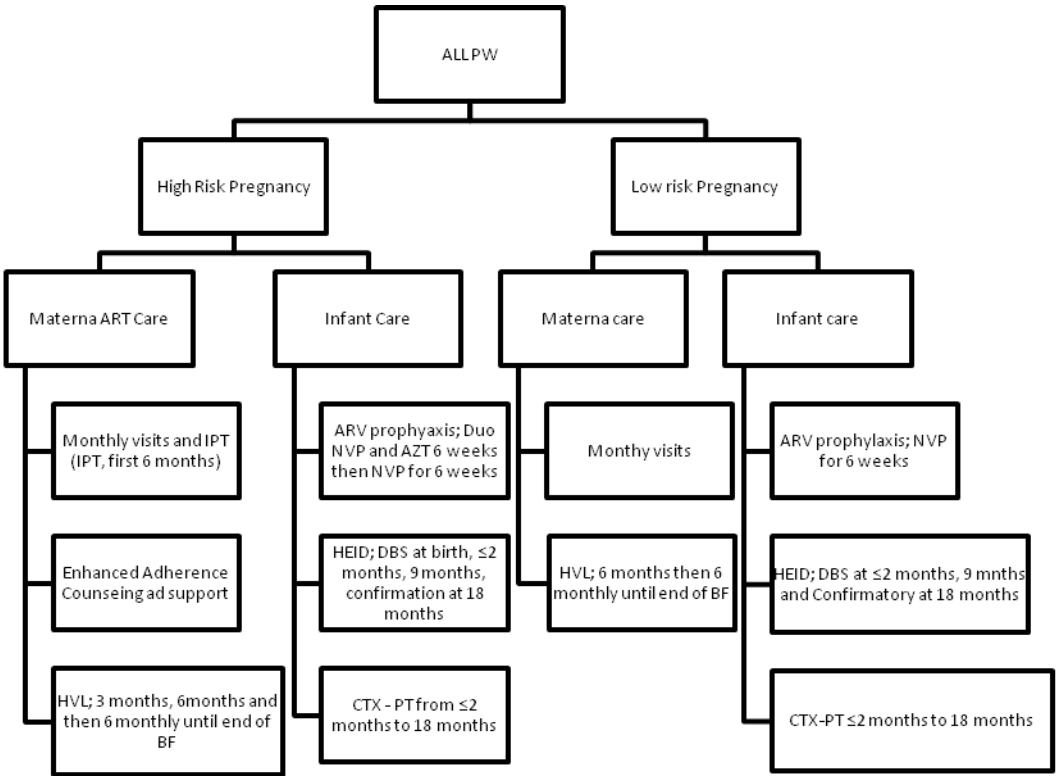
After HIV diagnosis, pregnant and lactating women living with HIV can be further categorized into two groups depending on the risk of vertical HIV transmission to their children.

High risk group: these are the ones with increased risk of transmission, it includes all women diagnosed to be living with HIV during pregnancy or breastfeeding period. Also, women known to be HIV positive but not yet on ART or already on ART but with high viral load (≥50/UL of blood).

Low risk group: these are the ones already on ART, and have achieved viral load of <50/UL according to VL results within three months diagnosis of pregnancy.

High risk is a fixed categorization throughout the follow-up of index mother-child pair, while low risk status can downgrade to high risk. Once downgrading occurs the high-risk status is maintained to the end of follow-up.

Summary of care tailored by risk category



9.4.3 Care of HIV-infected women during labour and delivery

All labour and delivery services should include interventions to prevent MTCT such as:

- HIV testing for women whose HIV status is unknown and women with initial negative tests that were not retested at third trimester (32 to 36 weeks of gestation)
- Administration of ART to HIV positive pregnant women and ARV prophylaxis to infants
- Implementation of safer obstetric practices
- Labour and delivery care

The Management of labour should follow obstetric best practices and all HCWs must use Standard Precautions during labour and delivery as outlined in Table 9.4 below:

Table 9.4 Safer obstetric practices to reduce MTCT

Safer Obstetrical Practice Description	
Use Standard Precautions (good infection prevention practices) for all patient's care	Use protective gear, safely use and dispose of sharps, use sterilized equipment and safe disposal of contaminated materials
Minimize vaginal examinations	Perform vaginal examinations only when necessary, using sterile technique

Avoid prolonged labour	• Use a partograph to monitor the progress of labour, and record all medications used during labour, including ART. • Consider use of oxytocic medications to shorten labour when appropriate • Use non-invasive foetal monitoring to assess need for early intervention
Avoid artificial rupture of membranes	Avoid early rupture of membranes (before 7cm dilation) unless necessitates
Avoid unnecessary trauma during delivery	• Avoid invasive procedures, including scalp electrodes or scalp sampling • Avoid routine episiotomy • Minimise the use of instrumental vaginal delivery such as forceps or vacuum delivery
Minimize the risk of postpartum haemorrhage	• Carefully manage all stages of labour to prevent infections and avoid prolonged labour • Actively manage the third stage of labour by using recommended uterotonic medicines and controlled cord traction • Perform uterine massage • Repair genital tract lacerations • Carefully remove all products of conception
Use safe transfusion practices	• Minimise the use of blood transfusions • Use only blood screened for blood borne infections such as HIV, hepatitis B and C also, when available, syphilis and malaria
Provide support and reassurance	Emotional support during labour is important particularly for women living with HIV. Whenever possible, women living with HIV should have a companion of their choice present during labour (preferably companions aware of their HIV status).

9.4.4 Special labour and delivery considerations

Obstetric care in the home delivery setting

Healthcare workers should strongly encourage all women to give birth at health facilities where skilled HCWs can address potential complications and provide specialized care to

reduce the risk of MTCT. In the interest of women who give birth at home, pregnant women and home birth attendants should have basic knowledge on PMTCT interventions. All pregnant women benefit when home birth attendants are knowledgeable about the signs and symptoms of complications during birth and know when and how to refer women to healthcare facilities. Home birth attendants should receive information on:

- How HIV is transmitted from mother to child
- Risk factors for MTCT
- Safer delivery practices to reduce the risk of MTCT
- Standard Precautions

Practice Point

All infants delivered at home should be brought to the health facility as soon as possible, preferably within 6 hours after delivery. HIV exposed infants should be provided with prophylaxis regimen.

9.4.5. Care after a spontaneous abortion (miscarriage)

Women living with HIV who are symptomatic may be at higher risk of spontaneous abortion

(miscarriage). In some cases, the HIV status of the woman may be unknown. For women who have a spontaneous abortion, HCWs should:

- Provide HIV testing and counselling, if not tested
- Assess for signs and symptoms of HIV infections
- Provide comprehensive post-abortion care
- Remove the conception products and uterine contents
- Use of uterotonics, such as misoprostol or oxytocin
- Provide post-abortion contraception counselling and support
- Provide the client with preferred method of the contraception options available for post abortion contraception

9.4.6. Immediate post-delivery care of HIV-exposed infants

Regardless of the mother's HIV status, all infants should be kept warm after birth and dried carefully. Infants should be handled with gloved hands until maternal blood and secretions have been washed off. In caring for new-borns, HCWs should observe standard precautions.

Prophylaxis for HIV Exposed Infants

- Administer NVP syrup immediately after birth to all HIV exposed infants and continue until six weeks of age
- In case a high-risk infant is identified, give enhanced postnatal prophylaxis (ePNP) for a total of 12 weeks as described in the table below.

Table xxxx : Enhanced postnatal prophylaxis (ePNP) for high risk HEI.

Dosage forms		
Fixed Dose Combination AZT/3TC/NVP (60/30/50 mg)	Dose 0-6 weeks ¼ tab twice daily	Dose 6-12 weeks NVP - once daily
If Fixed Dose Combination AZT/3TC/NVP is not available.	AZT + 3TC (60/30mg); ¼ tab twice daily and NVP syrup Once daily.	NVP - once daily

High-risk infants:

Are those who are: Born to women diagnosed to be living with HIV during pregnancy or breast-feeding period. Also, women known to be HIV positive but not yet on ART or already on ART but with high viral load (≥50/UL of blood).

Infant prophylaxis is most effective when given as soon as possible after birth, preferably within 6 to 12 hours

Infants identified beyond the age of four weeks should not be given ARV prophylaxis

Table 9.5 Infant NVP dosing

Infant NVP dosing recommendations	
Infant age	NVP daily dosing
Birth to 6 weeks Birth weight 2000–2499g Birth weight ≥2500g	 10mg once daily 15mg once daily

Based on the dosing required to sustain exposure in the infant of >100 ng/mL with the fewest dose changes

Low birth weight infants <2000g should receive mg/kg dosing; suggested starting dose is 2mg/kg once daily.

Practice Point

Infants who are diagnosed with HIV infection should be initiated on ART by a trained clinician or nurse at CTC or RCH.

- For High risk HIV exposed infants; Health care worker can use a fixed dose combination tablet to provide the prophylaxis as shown below:
- When administering the FDC tablet, remember to tell the mother that she should keep the remaining quarter of a tablet for the evening dose

Perinatal care for HIV-exposed infants should be geared to minimize trauma to the new-born and reduce the time that the new-born is exposed to the mother's blood and body Secretions.

9.4.7. Management of HIV-infected women and their infants in the immediate postpartum period

Immediate post-delivery care:

Healthcare workers should use Standard Precautions when assessing vaginal bleeding and should safely dispose the blood-stained linens and pads.

Practice Point

- Clamp the cord immediately after birth, and avoid milking the cord (avoid squeezing it towards the infant). Cover the cord with gloved hands or gauze before cutting to avoid splash of cord blood.
- Use suction only when the infant shows signs of distress or aspiration. Use either mechanical suction at less than 100mm Hg pressure or bulb suction, rather than mouth-operation suction.
- Place the infant immediately on the mother's breast if she is going to breast-feed; preferably within one hour after delivery. If she is using replacement feeding, place the infant on her body for skin-to-skin contact and provide help with the first feed
- Administer ARV prophylaxis as soon as possible following birth.
- Administer Bacillus Calmette-Guérin (BCG) and polio vaccines according to national guidelines.
- For non- breast-fed infants, administer vitamin A 50,000 IUs at birth or within 6 months.

Postpartum care for women with unknown HIV status
Women whose status is unknown and those with negative results from previous tests should strongly be encouraged to test for HIV and advised to breastfeed exclusively as per National recommendation. Partners and other siblings of HIV exposed infants should be encouraged to receive pre-test information, counselling and HIV testing.

HIV testing and counselling:

Women who received HIV testing during labour and delivery should receive additional HIV Post-test counselling postpartum. Women of unknown HIV status should receive pre-test information, counselling and HIV testing (unless they decline), so that their infants can receive ARV prophylaxis if needed. Partners and other siblings of HIV-infected women should be encouraged to receive pre-test information, counselling and HIV testing.

Counselling about safer infant feeding:

- All women, regardless of HIV status, should receive infant feeding counselling during postpartum care according to the guidelines
- Mothers should receive support to exclusively breastfeed

- Healthcare workers should encourage and provide counselling about exclusive breastfeeding or provide counselling on replacement feeding for women who choose to do so, before the women and their infants leave the facility or hospital
- Mothers should demonstrate chosen infant feeding method and HCWs should observe the mother implementing proper feeding technique before discharge
- Healthcare workers should discuss with the mother on how to cope with possible stigmatization if she chooses not to breastfeed and advise her on the suppression of lactation.

ARV treatment for mother and ARV prophylaxis for the infant:

All mothers living with HIV need to be informed on the importance of adherence and the correct way to take their ARVs and how to administer ARV prophylaxis to their infants.

Vitamin A supplementation:

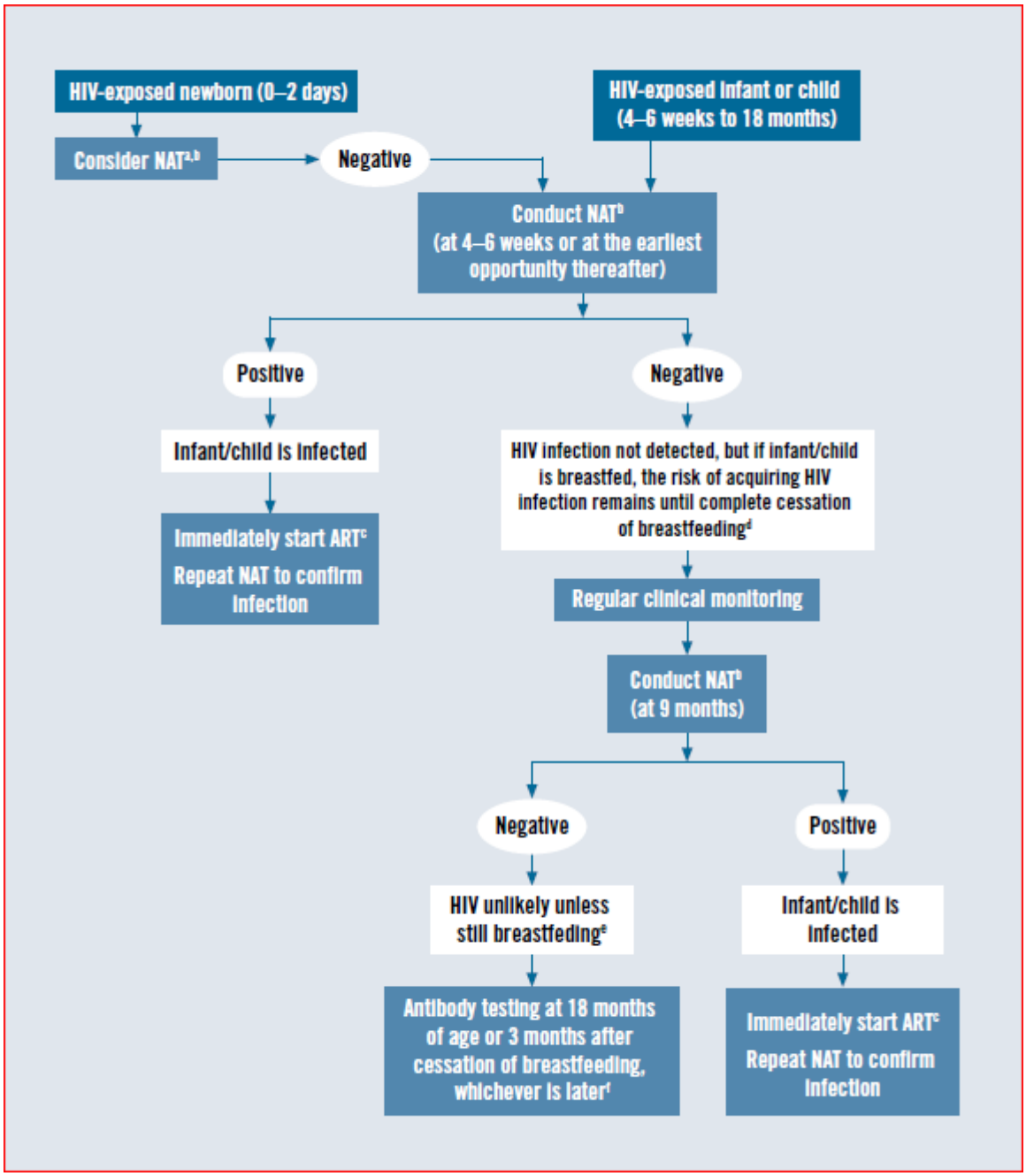
Before discharge, HCWs should administer vitamin A 200,000 IUs to the mother.

Counselling about infant HIV testing and CPT:

Women with HIV must be counselled on the importance of infant testing and be scheduled for testing prior to discharge. HIV-exposed infants should have an initial HIV test at the age of 6 weeks or as soon as possible thereafter. Infants who test HIV-negative will need a repeat HIV testing at 9 months using DNA PCR of age; 3 months after complete cessation of breastfeeding and a confirmation test at the age of 18 months using antibody test.

For HIV exposed infants who are identified as high risk, Nucleic Acid Test (NAT), DNA – PCR will be performed at birth. For infants who become HIV + at birth, initiate them on ART while taking another DBS for repeat HIV test using DNAPCR. For those who are HIV negative they should receive a second test at 6 weeks of age; at 9 months of age and 3 months after cessation of breastfeeding. A final test should be performed at the age of 18 months (Refer Infant testing algorithm)

In addition, all HIV-exposed infants should begin CPT at the age of six weeks.



Counselling about postpartum family planning:

Women living with HIV should receive counselling on preventing unintended pregnancies. Dual protection should be discussed in order to prevent HIV re-infection and pregnancy. In addition, all HIV-exposed infants should begin CPT at the age of six weeks.

Comprehensive care visits schedule for the mother and infant:

Mothers with HIV and their families will need uninterrupted HIV care, treatment and support services. Healthcare workers should prepare a follow up plan together with the client and ensure the mother knows the time, location, contact person and purpose of all follow-up appointments.

In case, the services required are not available at the health facility, healthcare worker should facilitate successful referrals and linkages to HIV treatment, care and support services

Practice Points

Standard of care, mother-child follow-up in RCH will continue until the child attains the age of 2 years.

- All postpartum follow-up appointments for the mother and the infant, including infant HIV testing and immunizations, should be scheduled before discharge.
- Women should be instructed on the amount, time, frequency and duration of their ART medication. They should receive information about the importance of adhering to ART. Women should receive information about the importance of observing time for infant HIV testing and adherence on ARV and CPT prophylaxis for their infants.
- Women living with HIV should return for postpartum care at seven, 28 and 42 days postpartum like other women in the general population.
- Where HIV care and treatment services are not available at the RCH clinic, they should immediately be referred to a nearby CTC.
- All infants should have their HIV exposure status recorded on their RCH cards/Booklet and should be followed monthly at Under-Five clinics until the child attains the age of 5 years. However, the PMTCT care and follow up will end at the age of 18 months after confirmation of the final HIV status
- When shifting the mother from PMTCT to CTC the HCWs should educate the mother/care giver on the importance of continuing protecting her child from HIV infection.

Postpartum assessment of healing and routine physical assessment

During the mother's postpartum visits, HCWs should conduct the following activities to monitor the mother:

- Measure blood pressure and temperature
- Monitor uterine involution (shrinking)
- Check healing of any repaired genital/perineal lacerations or episiotomy
- Examine the vulva and perineum for signs of infection, redness, tears, swelling or pus.
- Confirm cessation of postpartum bleeding (check sanitary pad for the amount of bleeding).
- Check for signs of infections
- Check for signs of anaemia (e.g. pallor) and ask about fatigue.

9.5. Use of antiretroviral (ARV) drugs during pregnancy and lactation

ARV drugs are used for pregnant and lactating mothers with HIV primarily for the mother's health and to prevent the exposed child from becoming infected. It may also offer benefits for preventing the sexual transmission of HIV.

9.5.1. Prevention of Mother to Child Transmission

The pregnant or breast-feeding women with HIV should be started on lifelong ART for their own health at the time of diagnosis. The recommended first line regimen is once a day fixed dose regimen of Tenofovir (TDF) +Lamivudine (3TC) + Dolutegravir (DTG), although Tenofovir (TDF)+Lamivudine (3TC) + Efavirenz (EFV) may be an option for use during the pre-conception period through the first eight weeks of pregnancy to avoid potential risk of neural tube defects. TLD should be continued postpartum and women should receive on-going counselling support to continuing HIV care and treatment in order to maintain good health and to reduce the risk of HIV transmission on others.

Practice point

Always

1. Discuss benefits of lifelong ART: health benefits, prevention of MTCT and prevention of onward HIV transmission to others
2. Discuss and make sure the client understands and comprehends all possible side effects of ARVs
3. Work with clients to find motivation to remain adherent to ART, and devise strategies to overcome threats against adherence (e.g. Multi months prescription, and longer interval between visits only when absolutely necessary)

For clients on 2nd and 3rd line ART regimens should continue with their current regimens.

The WHO guidelines released in July 2018 put forward a women-centred approach stating:

Key considerations:

- Women living with HIV receiving ART who present for pregnancy care should continue their ART during pregnancy, provided the regimen is tolerated & effective in suppressing viral replication
- The WHO guidelines highlight that DTG is safe in 2nd and 3rd trimester, and results from the DOLPHIN 2 study show a significantly greater proportion of women achieved undetectable viral load starting a DTG-based regimen late in pregnancy, compared with EFV.[1,2]
- Clinicians should assess the risks of changing treatment during pregnancy and decisions made according to the stage at which pregnancy is diagnosed, due to risks of viral load fluctuations when changing regimens.
- WHO recommends an EFV-based regimen as a safe and effective first line (1L) regimen that women of childbearing potential can use during the period of potential

risk for developing neural tube defects (at conception and up to eight weeks after conception)

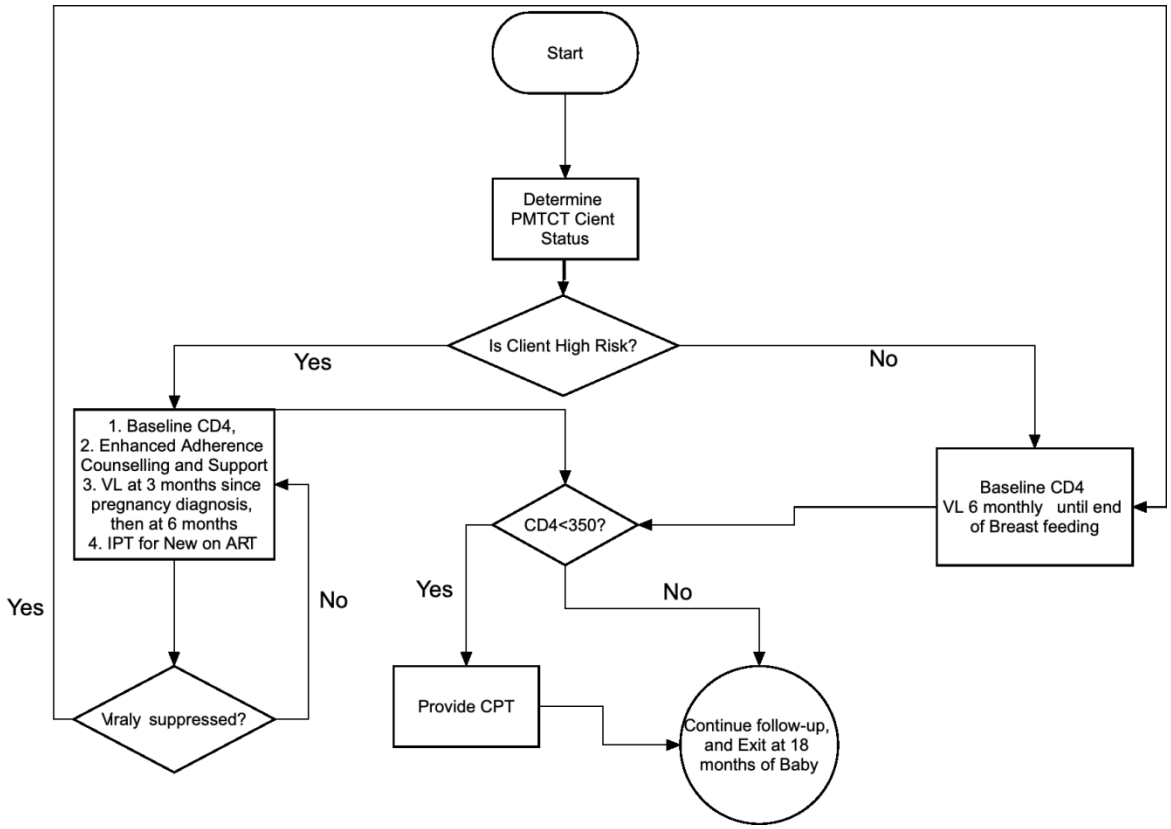
- Women of childbearing potential who do not currently want to become pregnant can receive DTG together with consistent & reliable contraception; hormonal contraception and DTG have no drug–drug interactions.
- A women-centred approach will be adopted and women of child bearing potential including those who are using long term effective contraception to be given adequate information to enable them make informed decision and informed choice consent to using DTG
- Women of child bearing potential who are not on long term effective contraception and choose to use DTG MUST sign a consent form
- Women who expect to become pregnant and choose not to take DTG should be given options to use TLE
- On spot Pregnancy testing using UPT
- All pregnant women should routinely receive high dose Folic acid (5mg) pre-conception and during pregnancy. Clients with DTG intolerance such as severe liver diseases should not be given DTG containing regimens.

NOTE: For women of child bearing potential they will be informed that while remaining on DTG, it is strongly recommended that they use an effective contraceptive method such as tubal-ligation, hormonal implant, Intra Uterine Device (IUD), injectable contraceptives, or oral contraceptive pills. Also, they will be informed that they can be given an alternative drug combination that is equally effective (TLE) if they don't opt for TLD. Even if they don't want to use contraceptive, they can still get TLD if she makes the informed decision to do so.

9.5.2. Monitoring PMTCT clients

Successful ART results in viral load decrease, immune recovery and therefore an increase in the number of CD4 cells/mm^3. This results into lower transmission risks, improved maternal survival and therefore improved HIV free survival for her baby.

In settings where routine HIV Viral Load monitoring is available, CD4 Tlymphocytes count should be done at baseline to determine immunological stage and establish need for CPT. For clients with CD4 count of <350 cell/mm^3, the test should be repeated every 6 months and when CD4 >350 cell/mm^3, stop CD4 monitoring and continue with HIV VL monitoring. Refer Chapter 4: Table 4. Viral Load Monitoring during Pregnancy and Breastfeeding



CHAPTER 10: ANTIRETROVIRAL THERAPY FOR ADOLESCENTS AND ADULTS

10.0 Introduction

- Antiretroviral therapy (ART) for the treatment of HIV infection has improved steadily since the advent of potent combination therapy. With advancement in treatment for HIV, there has been significant improvement in the safety and tolerability of regimens. ART has dramatically reduced HIV-associated morbidity and mortality and has transformed HIV disease into a chronic, manageable condition. The pill burden and dosing frequency for ARVs have been reduced and adverse events minimized; all of which have contributed to the success rates in initial treatment. In addition, treatment of HIV-infected individuals with ART is highly effective at preventing transmission to sexual partners.

These benefits are maximal when treatment is initiated soon after the HIV diagnosis is made and patients are virologically suppressed. Therefore, the lag time between an HIV diagnosis and treatment should be reduced drastically through early testing of asymptomatic individuals and early linkage to care and antiretroviral treatment. Antiretroviral drugs are effective and safe in suppressing viral replication when used in combination.

This chapter gives a general overview of ART and specific recommendations on managing adolescents and adults aged 15 years and above.

10.1 Types of Antiretroviral Drugs

- The recommended antiretroviral drugs to be used in these guidelines fall into the following five main categories:
- a) Nucleotide reverse transcriptase inhibitors (NtRTIs)
- b) Nucleoside reverse transcriptase inhibitors (NRTIs)
- c) Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
- d) Protease inhibitors (Pls)
- e) Integrase strand transfer inhibitors (INSTI)/ Integrase inhibitors
-
- Other antiretroviral drugs used elsewhere include:
- f) Fusion inhibitors e.g. Enfuvirtide (ENF)
- g) Chemokine receptor inhibitors/ CCR5 inhibitors e.g. Maraviroc

10.1.1 Nucleotide Reverse Transcriptase Inhibitors (NtRTIs)

Nucleotide analogues resemble nucleoside analogues (NRTI's). The mechanism of action involves selectively inhibiting viral reverse transcriptase enzyme. Examples of these antiretroviral drugs include:

- Tenofovir disoproxil fumarate (TDF)
- Tenofovir alafenamide (TAF)

10.1.2 Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

- This group of drugs is the mainstay of antiretroviral therapy in the country. The primary mechanism of action of this class is inhibition of viral RNA-dependent DNA polymerase (reverse transcriptase) enzyme. The drugs that are available in Tanzania for this class include:
  - Zidovudine (AZT)
  - Lamivudine (3TC)
  - Emtricitabine (FTC)
  - Abacavir (ABC)

10.1.3 Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

Similar to the NRTIs, NNRTIs also act by disrupting the reverse transcription of viral RNA into DNA that is then incorporated in the cell's nucleus. However, unlike the NRTIs, they are

not directly incorporated into the viral DNA; instead they inhibit replication directly by binding to the enzyme reverse transcriptase. Resistance to these drugs develops rapidly, especially when used alone due to low genetic barrier. There are two groups of NNRTIs, 1st and 2nd generation, the latter has an advantage of having a better resistance profile and a higher genetic barrier to the development of resistance. The 2nd generation of NNRTs may be effective after the failure of the first generation of NNRTI-based regimen due to resistance. Drugs under this class that are recommended in this guideline include:

a) 1st generation NNRTIs
    - Nevirapine (NVP)
    - Efavirenz (EFV)
b) 2nd generation NNRTIs
    - Etravirine (ETR)

10.1.4 Protease Inhibitors (PIs)

PIs competitively inhibit the HIV protease enzyme whose activity is critical for the terminal maturation of infectious virions. This inhibition prevents the maturation of virions capable of infecting other cells. Such drugs are usually boosted with a small dose of ritonavir (also a PI) to enhance therapeutic drug concentration and hence increase efficacy of the drug, reduce food restrictions, dose and frequency of administration. Boosted PIs have a high genetic barrier to resistance. The newer PIs such as Darunavir have an advantage of having a better resistance profile, a higher genetic barrier to the development of resistance and a broad spectrum of activity against PI resistant viruses. They are therefore effective after failure of a first generation PI-based regimen due to resistance. Drugs under this class that are recommended in this guideline include:

a) 1st generation currently available Protease Inhibitors (PIs)
    - Atazanavir (ATV).
    - Lopinavir (LPV),
    - Ritonavir (usually used as a booster with other PIs)
b) 2nd generation currently available Protease Inhibitors (PIs)
    - Darunavir (DRV)

10.1.5 Integrase Strand Transfer Inhibitors (INSTI)/ Integrase inhibitors

This group of drugs acts by inhibiting integrase enzyme which facilitates integration of viral pro-DNA into the host cell. Drugs under this class that are recommended in Tanzania include:

a) Dolutegravir (DTG)
b) Raltegravir (RAL)

10.2 Goals of Antiretroviral Therapy

The principal aim of antiretroviral therapy is to prevent morbidity and mortality in people with HIV and AIDS by durably suppressing viremia to undetectable levels, and thereby reconstituting and maintaining the immune capacity.

HIV and AIDS cannot be cured by using currently available ARV regimens because during the acute phase of HIV infection some viruses hide in some tissues (sanctuaries), where they stay dormant or with a very minimal replication for a life time. Early initiation of ART limits the number and reduces the size of sanctuaries, with subsequent reduction in the number of circulating viruses in the blood. The sanctuaries can last for a lifetime, therefore, once patients are initiated on ART, they need to be maintained on it indefinitely to prevent viral rebound.

The primary goals of combination antiretroviral therapy are:

1. Maximal and durable suppression of viral load to <50 copies/ml.
2. Restoration and/or preservation of immunologic function by attainment of CD4 recovery to normal thresholds ≥500 cells/mm³.
4. 3. Reduction of HIV-related morbidity and mortality. Improvement of survival and quality of life.

Secondary goals are to reduce:

- The pool of individuals who are virologically not suppressed, hence infectious and thus reduce the risk of HIV transmission in the community. The pool of pregnant and lactating mothers who are virologically not suppressed, hence infectious and thus reduce the risk of HIV transmission from mother to child and
- Transmission among discordant couples.

10.3 Rationale for early initiation of ART

Early initiation of combination antiretroviral treatment (ART) is associated with health benefits in terms of reduced morbidity and mortality in all age groups. In addition, ART is effective in prevention of HIV transmission and also helps to drastically reduce TB incidences.

Therefore, the Ministry of Health has adopted the Treat All approach where all individuals who are infected with HIV are started on ART regardless of CD4 cell count and clinical stage.

10.3.1 Evaluation to be done before initiating ART

From the moment a patient tests HIV-positive, he/she should be linked to the Care and Treatment Clinic (CTC). In health facilities where ART is being initiated at RCH and TB clinics, patients can be managed at those clinics. Mobile outreach clinics can also be used

where there are no nearby health facilities to provide ART services. For KVP ART can be initiated in the community (for ART services to KVP refer Chapter 2).

Before initiating any patient on ART, a complete assessment of the patient should be performed starting with in-depth medical history followed by a head-to-toe physical examination including WHO clinical staging. However, the WHO clinical staging should be used to provide baseline clinical information but it should not be used to determine eligibility for ART. In addition, the TB screening questionnaire should be administered. Patient data should be recorded in the CTC2 cards and in the patient file. For the baseline laboratory test before initiation of ART, refer to Table 4.1in Chapter 4. Treatment decisions should be based on HIV status, readiness of the patient and a solid adherence support plan.

10.3.2 When to start ART in Adolescents and adults

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A. Clients related Considerations

Before the client is initiated on ART, the following psychosocial conditions should be met:

i. They should be willing and ready to adhere to lifelong ART
ii. Commits him/herself to attend clinics as per schedule.
iii. The **clients** is not abusing alcohol and if he/she does is willing to stop it
iv. HIV infected PWID clients should be willing to attend medically assisted therapy e.g. methadone replacement therapy if services are available.

Note: The client should be encouraged to disclose his/her HIV sero-status to a treatment assistant and or a self-chosen family member.

B. Health Services Delivery Settings Considerations

i. The client, his/her treatment assistant and other family members (with clients' consent) should be educated on HIV and AIDS to ensure adequate ART literacy on the importance of optimal adherence, consequences of non-adherence, self-assessment of clinical red flags for seeking unscheduled clinic visits.
ii. Develop together with the client, his/her treatment assistant and other family members an adherence plan for his/her treatment.
iii. Provide general orientation to the client, his/her treatment assistant and other family members on the following:
    - whom to call and where to get refills,
    - whom to call and where to go when clinical problems arise,
    - whom to call/where to go for assistance on social, spiritual and legal problems and other community support services to ensure adherence, comprehensive service delivery and support services.
iv. Link the client to a PLHIV support group
v. Provide depression treatment and support for depressed clients
vi. Provide MAT for PWID and other support services
vii. Ensure friendly services for adolescents and young people.

10.4 First Line ART

10.4.1 Introduction

Antiretroviral therapy, both in naïve clients and those who have received treatment before, involves the use of a combination of antiretroviral drugs. Triple therapy consists of 2 NRTI + 1 INSTI or 2 NRTI + 1 NNRTI or 2 NRTI + 1 PI. It is important to remember that there is no single combination that is best for every client and/or that can be tolerated by all clients. It is stressed that for both initial and subsequent ART lines the aim is to attain undetectable viral load (<50 copies /ml) and regain CD4 cell count to normal thresholds (≥500 cells /mm^3). Prescriptions of ARV regimens should be recommended on the basis of a client's clinical condition, co-morbidities, co-administered drugs, age, pregnancy status, convenience, and ability to tolerate the regimen.

10.4.2 First line ARV combination regimens

ARVs should be used according to indications and contraindications that govern the use of ARVs to minimize side effects and drug-drug interactions. The following recommended ARV drug combinations are currently available as first line treatment for adults and adolescents:

a) DTG based regimens:

- TDF + 3TC + DTG (Default first Line regimen)
- ABC + 3TC+ DTG
- AZT+ 3TC+ DTG

b) EFV based regimens:

- TDF + 3TC + EFV600 or EFV400
- TDF+FTC+EFV600 or EFV400

c) NVP based regimens:

- AZT+3TC+NVP

The following 1st line ARV drug combinations will be systematically phased out when the new ARVs regimens are available:

- TDF+FTC+EFV600
- ABC/3TC+EFV600
- AZT /3TC+ EFV600
- AZT+3TC+NVP

Note: The following ARV drugs are in fixed drug combinations (FDC):

- TDF/3TC/DTG (TLD)
- ABC/3TC/DTG (ALD)
- TDF/3TC/EFV600 (TLE)
- TDF/3TC/EFV400 (TLE)
- TDF/FTC/EFV600 (ATRIPLA)

- TDF/3TC
- TDF/FTC (Truvada)
- ABC/3TC
- AZT/3TC/NVP (Duovir-N)
- AZT/3TC (Combivir)

Table 10.1 Recommended first line regimens for adults and adolescents

RECOMENDED FIRST LINE REGIMENS FOR ADULTS AND ADOLESCENTS		
Patient group	**Preferred (Default) Regimen**	**Alternative Regimen**
Adults and adolescents (≥15 years), Pregnant/lactating mothers	TDF +3TC +DTG (TLD)	ABC + 3TC+ DTG TDF + 3TC +EFV (TLE600 or TLE400) **Special situations:** AZT + 3TC + DTG
HIV and TB co-infections	TDF + 3TC +DTG (Double dosage of DTG)	TDF + 3TC +EFV (TLE600) ABC + 3TC+ DTG (Double dosage of DTG) **Special situations:** AZT + 3TC + DTG (Double dosage of DTG)
People who Inject Drugs (PWID)	TDF + 3TC +DTG	ABC + 3TC+ DTG TDF + FTC +ATV/r

NOTE:

- Clients with TB and HIV co-infection who cannot tolerate DTG and pregnant women who will opt not to use DTG will continue to use TLE (EFV600) until evidence to support use of TLE (EFV400) is available.
- For clients with TB and HIV co-infection consider using a PI based regimen if EFV600 is not available.
- The TDF+3TC+DTG combination is the default combination to be prescribed to all adult and adolescent clients if there is no any contraindication. The regimen can also be used in patients with TB and HIV, HIV and HBV co-infection and PWID.
- TLD is more efficacious compared to other available options with NRTI backbones, causing rapid decline in viral load of up to 50 RNA copies per milliliter in 12 weeks where as the optimal suppression occurs at 24 weeks when using Efavirenz containing formulations. Furthermore, TLD causes robust CD4 recovery in both early and

advanced disease; it is suitable for late presenters or those with advanced disease and more appropriate for pregnant women booking late at Antenatal Clinics.

- TLD has less side effects and few important drug-drug interactions hence well tolerated compared to previously use first line regimen. There are safety concerns for use of TLD in pregnant women but the pharmacokinetics studies do not show any difference between TLD and TLE.
- Higher genetic barrier of DTG means patients are less likely to develop resistance and do not shortly require switching to more expensive second-line treatment options.
- DTG does not interact with methadone; therefore it is a suitable drug for regimens in PWID.
- DTG dosing is 50mg OD but it should be administered at a dose of 50mg twice a day for patients on Rifampicin based treatment because Rifampicin reduces DTG drug levels in the blood.
- TLE600 should be used as an alternative first line to clients on anti TB Rifampicin to offset increased metabolism of EFV by Rifampicin
- TDF 300mg based regimens should not be initiated to patients with weight less than 30kg
- EFV600 should not be initiated for children aged <3 years or weighing <10kg.
- For pregnant women, TLE600 should be used as an alternative to TLE 400 due to increased volume of distribution during pregnancy.

Caution: ARV drugs have the potential to decrease the bioavailability in hormonal contraceptives especially with oral contraceptives. Dual contraception with condoms and injectable contraceptives is therefore recommended.

The major concern with Tenofovir (TDF) based treatment is renal toxicity. Tenofovir (TDF) associated nephrotoxicity is more common in patients with pre-existing renal dysfunction or those receiving other concomitant nephrotoxic medications cleared through the kidney, low birth weight, advanced age and lower CD4 cell counts. Otherwise, the overall rate of discontinuation for renal events is extremely low. TDF nephrotoxicity risk is also increased in patients with co–morbidities which may also be associated with renal dysfunction such as HIV Associated Nephropathy (HIVAN), hypertension and diabetes mellitus. It is recommended that for patients on TDF based regimens, routine renal toxicity monitoring by proteinuria and blood creatinine determination should be done at baseline and after every six months. Therefore, clients with high risk of nephrotoxicity or with pre-existing renal dysfunction should be kept on Abacavir based regimens.

10.4.3 ART in women of childbearing potential or pregnant women

The recommended first-line regimen for this patient subgroup is: TDF + 3TC + DTG. Alternative regimens for this group are the same as in adolescents and adults (see Table 10.1 above).

- Pregnant women, breastfeeding women and women of childbearing potential should be given adequate information to make informed choices about their treatment options.

- All women of child bearing potential should be tested urine for pregnancy (UPT) before ART initiation, especially if DTG is to be initiated.
- DTG can be used in pregnant and women of child bearing potential; however, there is a potential risk for neural tube defects for children born by mothers on DTG during conception and first trimester. All pregnant women and those who wish to conceive should be given Folic acid supplements.
- TLD (fixed-dose combination of TDF + 3TC + DTG) could be considered for pregnant women identified as receiving or starting ART later in the pregnancy (second and third trimester), although the switch to TLE (fixed-dose combination of TDF + 3TC (or FTC) + EFV) should be ensured after delivery in case the woman does not have access to reliable contraception.
- Pregnant women, who do not wish to use DTG, should be prescribed with TLE throughout the first trimester, and they will be switched to a DTG-based regimen thereafter.
- For women of child bearing potential who would not wish to conceive and use TLD, should be advised to use long acting contraceptive and/or effective dual contraception with condoms.
- For a woman of child bearing potential who wish to conceive should be advised to use TLE throughout the first trimester then be switched back to DTG thereafter.

NOTE: Effective contraception is defined as correct use of the following methods: Contraceptive intrauterine device (IUD) or intrauterine system (IUS); Subdermal contraceptive implant or Progestogen injections. Male or female condom use is recommended with all contraceptive methods for dual protection against pregnancy and to avoid transmission of HIV and other sexually transmitted infections.

Source; WHO July 2018 Interim Guidance on ARVs

10.4.4 Antiretroviral drugs for people who inject drugs (PWID) on medical assisted therapy

Drug use and addiction do not preclude successful ARV treatment. ART is as effective for HIV positive PWID as it is for other people with HIV and AIDS. Given appropriate support, former and active PWID can adhere just as well as others and should have equal access to ART. Special attention should be paid to the particular needs of former and active PWID when administering ART, including those related to substance dependence, co-morbidities and co-infections. ART services should be integrated into Medically Assisted Therapy (MAT) Clinics. For the ART naïve clients ART should be initiated when the client has been stabilised and his /her methadone dosage has been determined. This usually takes between 2-

3 months after starting MAT. The previously used NNRTIs, NVP and EFV and to a less extent Lopinavir and Ritonavir induce metabolism of methadone through cytochrome CYP 450 3A with a net effect of reducing serum concentration of Methadone. EFV for example, decreases methadone plasma concentration for up to 50% overtime. Use of combined TDF backbone with preferably DTG or alternatively use of ATV/r is recommended. These are not associated with significant decreases of methadone plasma concentration.

Thus the preferred regimen for PWID is TDF+ 3TC +DTG.

During the course of treatment, all treatment experienced PWID on regimens other than ATV/r or DTG should be switched to a DTG based regimens.

10.5 Second line ART

10.5.1 Second-line antiretroviral therapy in adults and adolescents

The second line NRTI choice for adults and adolescents depends on the first line regimen. For patients on TDF based regimens in first line, the preferred second line option is AZT plus 3TC combined with a ritonavir-boosted PI, preferably ATV/r because it is dosed once daily and has fewer metabolic complications and side effects. The same NRTIs, with exception of 3TC and FTC used in previous regimen should not be used in subsequent regimens during switching due to treatment failure. LPV/r can be used as an alternative to ATV/r in patients using anti-TB drugs (with ritonavir super boosting) and children below six years. Also, ATV/r (300/100mg) cannot be used in children below 30kg.

For patients who were on AZT and had never used TDF regimen, the default second line option will be TDF or ABC based regimen combined with a boosted PI (TDF+FTC+ATV/r).

For patients who were introduced to TDF in first line due to AZT toxicity, the default second line option is to use ABC plus 3TC combined with a ritonavir-boosted PI ATV/r or LPV/r. (ABC + 3TC + LPV/r or ATV/r). However, ABC may be rendered ineffective due to cross resistance with TDF associated resistance mutations. Doses for these drugs are shown in Annex 7.

Note that ATV/r, LPV/r, ABC/3TC and TDF/FTC are currently available as FDC formulations which simplify dosing and administration.

Table 10.2 Recommended second line regimens for adults and adolescents

RECOMMENDED SECOND LINE REGIMENS FOR ADULTS AND ADOLESCENTS		
Patient group	**Preferred (Default) Regimen**	**Alternative Regimen**
Adults, adolescents (≥15 years) and Pregnant women / breastfeeding mothers	AZT/3TC+ATV/r: if TDF was used in first-line TDF/FTC+ATV/r: if AZT was used in first-line	ABC/3TC+ATV/r ABC/3TC+LPV/r TDF/FTC+LPV/r AZT + 3TC + DTG (For patients who did not use DTG in the first-line)
HIV and TB co-infection	AZT/3TC+LPV/r	ABC/3TC+LPV/r[a] TDF/FTC+LPV/r [a] Note: double dosage of LPV/r to 800/200mg for Rifampicin based TB treatment
People Who Inject Drugs (PWID)	AZT/3TC + DTG	AZT + 3TC+ ATV/r ABC + 3TC +ATV/r

Note: Delayed diagnosis of treatment failure by using non-virological criteria results into accumulation of resistance associated mutations (RAMs). These RAMs compromise efficacy of drugs with similar resistance pattern (TDF and ABC) for future use. In case of previous AZT use, the accumulation of multiple Thymidine Associated Mutations (TAMs) compromise efficacy of all NRTIs and NtRTIs. AZT associated mutations limit future treatment options making future use of ABC and TDF ineffective.

10.6 Third-line Antiretroviral Therapy

Patients failing 2nd line regimens may have extensive NRTI and NNRTIs associated resistance mutations (RAMS) which limit their use in third line regimens. Therefore, 3rd line regimens, in order to have at least two or preferably three effective drugs, their regimens need to be constructed using other new classes of drugs or second generation formulations of previous drugs which have minimal resistance. These second generation drugs have a higher genetic barrier to resistance and their efficacy is not compromised by RAMs associated with the first generation formulations. For example, Darunavir (DRV) does not have cross resistance to PIs used in the second line.

ETR is a second generation NNRTI with minimal cross resistance to First generation NNRTIs (EFV and NVP) however, it has many drug-drug interactions and is contraindicated to use with many commonly used drugs such as Rifampin, Artemether/Lumefantrine, Carbamazepine, Prazquantel, fluconazole, amiodarone, digoxin etc.

Third-line regimens recommended in this guideline include:

a) Integrase Strand Transfer Inhibitors (INSTIs) or Integrase Inhibitors: Dolutegravir (DTG) and Raltegravir (RAL).

b) Second generation PI: Boosted Darunavir (DRV/r)

HIV Drug Resistance Testing and Third line ARV Regimens:

Before switching to third line ARV regimens, genotypic HIV drug resistance should be done to rule cross resistance between 1st and 2nd generation drugs and assist in the determination if treatment failure is due to HIV drug resistance. Genotyping will also inform on the possibility of recycling drugs used in previous regimens i.e. some drugs used in first or second regimens may still be effective in third line.

Table 10.3: Recommended third line regimens for adults and adolescents

RECOMMENDED THIRD LINE REGIMENS FOR ADULTS AND ADOLESCENTS		
Patient group	**Preferred (Default) Regimen**	**Alternative Regimen**
Adults, adolescents (≥15 years)	DTG+DRV/r+ AZT/3TC	RAL + DRV/r + AZT/3TC
Pregnant women/breastfeeding mothers	(DTG or RAL)+DRV/r+ AZT/3TC	DTG + DRV/r (AZT/3TC)
HIV and TB co-infection	DTG (BD) + LPV/r+ (AZT/3TC or TDF/FTC)	RAL+(AZT/3TC or TDF/FTC)+LPV/r
People Who Inject Drugs (PWID)	DTG+DRV/r+ AZT/3TC	DTG+ATV/r+ AZT/3TC
Note: (1) DTG in third line regimen should be given twice daily for clients who were previously exposed to INSTIs. (2) For TB and HIV co-infected patients on LPV/r should be switched to DRV/r after completion of TB treatment (3) For second and third line regimens which are non TDF based, in case of new Hepatitis B co - infection TDF with FTC should be added to the new regimen as treatment of Hepatitis B.		

10.7 Changing Antiretroviral Therapy

There are multiple reasons that may prompt the need to change antiretroviral therapy. These can be grouped into two major categories:

- Drug specific adverse events (toxicity)
- Treatment failure

When changing treatment, the following should be observed:

If changing due to toxicity

- Change only the drug suspected to be causing the problem.

If changing due to treatment failure

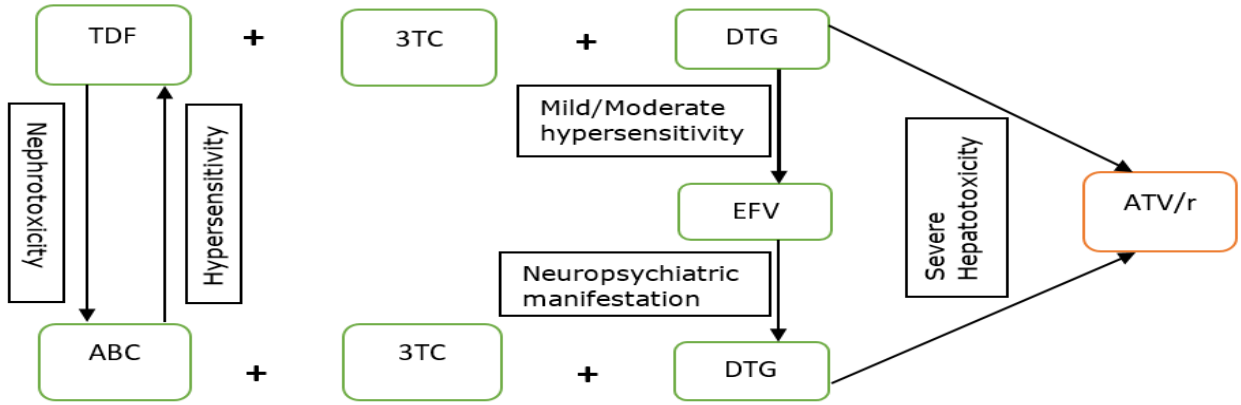
- Never change to monotherapy
- Change at least two drugs, preferably change all three drugs

- When selecting drugs, choose drugs that have not been used before, drugs which do not have cross-resistance/or no overlapping toxicities or drug-drug interactions
- Lamivudine has advantage of decreasing **viral fitness** and increasing susceptibility to AZT and therefore it may be retained when changing the failing regimen.

10.7.1 Changing antiretroviral therapy due to toxicity

From a clinical perspective, it is generally recommended that when changing a client`s regimen due to toxicity, only the toxic drug(s) should be replaced, wherever possible, by a drug without overlapping toxicities. Table 10.4 below shows types of toxicities and risk factors associated with first, second and third-line ARV drugs and suggested management

Figure 10.1: Substitution within First Line Antiretroviral Regimens



10.7.1.1 Severity of adverse events due to ARVs

All adverse events shall be recorded in the adverse effects forms (TFDA Yellow Form). Side effects or toxicities caused by ARVs can be classified into three broad categories:

First category: Symptoms are mild and transient and often require patient assurance that these symptoms are common and usually decrease over time. Symptomatic relief may be offered, such as paracetamol for headaches. ARV interruption is rarely indicated in this situation.

Second category: Symptoms are somewhat more severe and often respond to some medical intervention. They include more severe gastric upset with nausea and vomiting, more severe headaches and mild peripheral neuropathy that does not incapacitate or interfere with a patient's lifestyle. These symptoms can often be successfully treated with anti-emetics, anti-diarrhoea medicines, analgesics, neuroleptics (e.g. Amitriptyline) and other medicines. ARV interruption is usually not indicated in this situation and often symptomatic treatment is only temporary.

Third category: Symptoms are severe such that ARV drugs must be stopped and replaced by an alternative drug. These include anaemia (haemoglobin <7.5 gm/dl or a falling haemoglobin, that often drops by 2gm/dl) as can occur with the use of AZT. Severe symptoms noted in the first two categories can sometimes lead to the stopping of ARV due to severe toxicities such as nausea with severe discomfort and minimal intake for three or more days, vomiting all intakes in 24 hours or dehydration due to vomiting, severe headaches not

responsive to non-narcotic analgesics, or fatigue reducing activity by more than 50%. In such situations, one or more ARVs should be replaced by another drug.

10.7.1.2 ABC (Abacavir) hypersensitivity

ABC hypersensitivity is genetically predetermined with a marker HLA-B5701 allele. It occurs in between 3% to 5% of all people, being less common amongst individuals of African descent. It commonly occurs within the first six weeks of treatment; it rarely occurs after months of treatment. If clinical worsening occurs, after months of ABC treatment, other causes of clinical deterioration should be ruled out first. Hypersensitivity symptoms include: flu symptoms, shortness of breath, cough, fever, aches and pains, a general ill feeling, fatigue/tiredness, swelling, abdominal pain, diarrhoea, nausea, muscle or joint pains, numbness, sore throat or rash. ABC will be stopped immediately and not re-started if this occurs, because re-challenging can be fatal. Abacavir hypersensitivity should be suspected in case of clinical worsening during the course of treatment.

Table 10.4: Types of toxicities associated with First, Second and Third-line ARV drugs

ARV	Major types of toxicity	Risk factors	Suggested management
TDF	Tubular renal dysfunction, Fanconi syndrome	• Underlying renal disease • Older age • BMI <18.5 (or body weight <50kg) • Untreated diabetes mellitus • Untreated hypertension • Concomitant use of nephrotoxic drugs or a boosted PI	• If TDF is being used in first-line ART, substitute it with ABC • If TDF is being used in second-line ART, substitute it with AZT or ABC.
	Decreases in bone mineral density Lactic acidosis or severe hepatomegaly with steatosis	• History of osteomalacia and pathological fracture • Risk factors for osteoporosis or bone loss • Prolonged exposure to nucleoside analogues • Obesity	
	Exacerbation of hepatitis B (hepatic flares)	Discontinuation of TDF due to toxicity	No available alternative drug in the country for treatment of hepatitis B e.g. Entecavir
ABC	Hypersensitivity reaction	Genetic predisposition (HLA-B 5701 gene)	If ABC is being used in first or second-line ART, substitute with TDF or AZT
AZT	Anaemia, neutropaenia, myopathy, lipoatrophy or lipodystrophy	• Baseline anaemia or Neutropaenia • CD4 cell count ≤200 cells/mm^3	If AZT is being used in second-line ART, substitute it with ABC
	Lactic acidosis or severe hepatomegaly with steatosis	• BMI >25 (or body	

		weight >75 kg) • Prolonged exposure to nucleoside analogues	
EFV	Persistent central nervous system toxicity (such as dizziness, insomnia and abnormal dreams) or mental symptoms (anxiety, depression and mental confusion)	• Depression or other mental disorder (previous or at baseline) • Daytime dosing	For central nervous system symptoms, dosing at bedtime. Consider using EFV at a lower dose (400 mg/day or an integrase inhibitor (DTG) if EFV 400 mg is not effective in reducing symptoms.
	Convulsions	History of seizure	
	Hepatotoxicity	• Underlying hepatic disease • Coinfection with hepatitis B or C • Concomitant use of hepatotoxic drugs	For severe hepatotoxicity or hypersensitivity reactions, substitute with another therapeutic class (integrase inhibitors or boosted PIs).
	Severe skin and hypersensitivity reactions	Risk factors unknown	
	Gynaecomastia	Risk factors unknown	Substitute with another therapeutic class (integrase inhibitors or boosted PIs).
NVP	• Hepatotoxicity • Severe skin rash and Hypersensitivity reaction, including Stevens-Johnson syndrome	• Underlying hepatic disease • Coinfection with hepatitis B or C • Concomitant use of hepatotoxic drugs • High baseline CD4 cell count (CD4 count >250 cells/mm3 for women or >400 cells/mm3 for men)	• If hepatotoxicity is mild, consider substituting with EFV, including for children three years and older. • For severe hepatotoxicity and hypersensitivity, and for children younger than three years, substitute with another therapeutic class (integrase inhibitors or boosted PIs).
LPV/r	Hepatotoxicity	• Underlying hepatic disease • HBV and HCV co-infection • Concomitant use of hepatotoxic drugs	Replace it with ATV/r
	Pancreatitis	Advanced HIV disease	
	Lipoatrophy or metabolic syndrome dyslipidaemia,	Risk factors unknown	

	severe diarrhea and risk of prematurity		
ATV/r	Indirect hyperbilirubinaemia (clinical jaundice) Nephrolithiasis and risk of prematurity	• Underlying hepatic disease • HBV and HCV co-infection • Concomitant use of hepatotoxic drugs Risk factors unknown	Indirect hyperbilirunemia is usually transient and ATV/r can be continued, however, if severe jaundice develops and is associated with significantly raised transaminases, then ATV/r should be replaced with LPV/r Replace it with LPV/r
DTG	Increase in cholesterol levels; mild elevated liver enzymes; significant rises in creatinine levels; Insomnia and headache may also be experienced	History of dyslipidemia, diabetes, hypertension	• Monitor cholesterol levels; monitor Liver function especially in HBV and HCV. • Provide symptomatic treatment
ETR	Common: Skin rash, allergic reactions, Nausea, increased low density Lipids, Gastrointestinal disorders and Fatigue Rare: Severe skin rash, Peripheral neuropathy and renal failure	No known risk factors	• Monitor severity and occurrence of fever and other symptoms. • Provide symptomatic treatment
RAL	Increased Cholesterol levels, Glucose, Aspartate Amino Transferase (AST), Bilirubin. Rash, Cough, Fatigue, dizziness and insomnia	History of dyslipidemia, diabetes, hypertension	In case of severe adverse effects, switch to DTG if patient is >12 years old
DRV/r	Increased Cholesterol levels, triglycerides; Diarrhea, Headache, Rash, Abdominal pain and Nausea	History of dyslipidemia	• Monitor severity and occurrence of fever and other symptoms. • Provide symptomatic treatment

10.7.2 Changing antiretroviral therapy due to treatment failure

Monitoring individuals receiving ART is important to ensure successful treatment, identify adherence problems and determine whether and which ART regimens should be switched in case of treatment failure. Treatment failure can be virological, immunologic and/or clinical. It results from failure to suppress viral replication with the development of viral resistance. It is recommended that treatment failure diagnosis should be based on virological criteria because it is the earliest marker of treatment failure. The advantage of early diagnosis of treatment failure is that it is associated with less resistance associated mutations (RAMS) and hence preserves future treatment options. In contrast late diagnosis of treatment failure using

immunological (CD4) or clinical criteria is associated with accumulations of RAMS which reduce future treatment options.

Table 10.6: WHO definitions of treatment failure in chronological order of occurrence: virological, immunological and clinical failure for the decision to switch ART regimens.

Failure	Definition	Comments
Virological	Plasma viral load above 1000 copies/ml with a log drop <0.5 based on two consecutive viral load measurements after three months, with enhanced adherence support	An individual must be taking ART for at least six months before it can be determined that a regimen has failed.
Immunological	Fall of CD4 from the baseline or Persistent CD4 cell count levels below 100 cells/mm^3	Without concomitant or recent infection or steroid use to cause a transient decline in the CD4 cell count Immunological and clinical characteristics of treatment failure develop much later after virological failure. Immunological and clinical criteria of treatment failure may also misclassify treatment failure and lead to unnecessary ARV switch to subsequent (line of treatment) regimen
Clinical	New or recurrent clinical event indicating severe immunodeficiency (WHO clinical stage 4 conditions) after six months of effective treatment.	The condition must be differentiated from IRIS

Transient rises in viral load are called **viral blips** and are not due to treatment failure. A diagnosis of treatment failure requires two consecutive viral load levels after six months of treatment with HVL above 1000 copies/mL tested within an interval of three months after enhanced adherence counselling.

Treatment failure should be distinguished from IRIS in which case the viral load will be low and the CD4 cell count will be high.

10.7.3 Switching to third line ARV regimens

It is crucial that before a regimen is declared to have failed, a multidisplinary switch team is convened to rule out non-adherence which is the commonest cause of reduced CD4 cell count and a VL rise, but is often not associated with HIV drug resistance. This team will also plan for enhanced adherence and support, for a period of three months before a second VL test. In

case of non-adherence, these measures will lower the VL, increase CD4 cell count and avert a switch to a subsequent regimen.

Before switching to third line ARV regimens, genotypic HIV drug resistance is recommended to rule cross resistance between 1st and 2nd generation drugs and also assist in the determination of whether treatment failure is from non-adherence. Genotyping will also inform possibility of recycling drugs used in previous regimens i.e. some drugs used in first or second regimens may still be effective in third line.

10.7.3.1 Criteria for changing clients to Third-line ARV

10.7.3.1.1 Failing any Second-line regimen

Referral to specialist care is recommended where third-line regimen can be chosen according to genotype resistance testing and managed by an expert panel at tertiary care facilities.

The criteria for diagnosing second-line failure are the same as those used for diagnosing first-line failure. In the event of treatment failure, a comprehensive evaluation to ascertain the cause of failure should be conducted. Efforts must be made to assess and optimize adherence and rule out any significant drug interactions. When this has been done and there is still evidence of failure, patients should have a regimen change that will include at least two active agents.

Viral load testing should be the gold standard for diagnosing treatment failure and the resistance test should be used to determine the third-line regimen.

10.7.3.1.2 Eligibility for Third-Line Evaluation

All clients should have undergone an Enhanced Adherence Counselling

- Failing 2nd line regimens
- Documented virologic failure (VL >1000) on a PI regimen; except children below three years
- Steps to refer client to 3rd line review committee:
    1- Client suspected to have second-line failure from dispensary or health centre is referred to the hospital
    2- At the hospital, the client is reviewed by clinicians working in CTC, the checklist is completed and only the checklist is sent to the review committee at the tertiary care facility/zonal referral hospital
    3- At the zonal level, the review committee reviews the checklist and recommends which clients should be referred for evaluation including genotype resistance testing and decision
    4- Zonal level review committee communicates the decision back to the referring hospital within a month.

10.8 Monitoring Patients on ART

Monitoring of clients on ART is based on clinical and laboratory parameters.

Clinical Monitoring:

It is expected that, treatment success is associated with weight gain and reduced morbidity from opportunistic infections and improvement in the quality of life. At each clinic visit, thorough history and physical examination should be done and recorded in the patient file. Appearance of new or persisting opportunistic infections, or lack of weight gain, can indicate treatment failure, hence, it should require further evaluation to determine fulfilment of criteria for treatment failure. Switching to subsequent regimens should be based on virological

criteria; however, in settings where there is a limited access to HVL, immunological criteria should be used.

Laboratory Monitoring:
Initiation of ART is done irrespective of CD4 cell count levels. The CD4 cell count should nevertheless be determined from baseline to monitor immunological response. For patients with CD4 cell count less than 350 cell/mm^3 at baseline, the CD4+ T lymphocyte count should be repeated after six months, until the patient is stable (CD4+ T lymphocyte count more than 350cell/mm^3). However, in cases of suspected IRIS or treatment failure, CD4 can be tested at intervals less than six months. As HIV viral load testing is scaled up, then there will be less need to use CD4 levels for monitoring.

Viral load (VL) testing is the gold standard or most preferred monitoring approach to diagnose and confirm treatment failure. It provides an early and more accurate indication of treatment failure and the need to switch to subsequent ART line regimens, thereby reducing accumulation of drug resistance mutations. This improves clinical outcomes and preserves future ART line options. All health facilities should have access to viral load testing as per national HVL testing algorithm. Treatment should be considered successful if the viral load is <1000 copies/mL, but defined as "stable" with low risk of transmission at VL<50 copies/mL.

Discordant viral load and CD4 cell count response to ARV
Usually, concordant HIV viral load and CD4 response to ARV is when the client optimally suppressed HIV viral load (<50 copies/ml) and robust CD4 cell count gain. A discordant response occurs when there is optimal HIV viral load suppression without an associated robust CD4 cell count gain. This type of response is associated with increased morbidity and mortality. Risk factors for immuno-virological discordance response include: age more than 50 years at ART initiation, co-morbidities such as Hepatitis B, CMV, TB, high viral load at treatment initiation, low baseline CD4 cell count and late treatment initiation of WHO clinical stage 3 and 4. This also occurs more often in highly treatment-experienced patients with drug-resistant HIV.
In such scenario a HCW should first, make certain the patient is receiving appropriate prophylaxis for OIs; examine the patient's medication list for medications that can suppress bone marrow e.g consider switching from an AZT-containing regimen to a regimen that does not contain AZT; evaluate for any clinical manifestations, such as systemic symptoms or pancytopenia, which suggest a marrow infiltrative process and lastly continue ART, even if the patient has do not have a good CD4 cell count response.

10.8.1 Clinical and laboratory monitoring of clients on First and Second-line ART regimen

(i) Scheduled visits

The first six months of ART
Clients should attend the appropriate clinic (CTC, RCH, TB, MAT) monthly for the first six months for clinical and laboratory evaluation and drug refills.
Six months after starting ART

After six months of ART, if the client is clinically stable (*Refer Chapter 2*), with good adherence for at least six months to ART regimen, and no history of drug toxicity or recurrent OI, he/she may be given clinical appointment of six months and three months ARV refill based on client's preferred ARV refill model. . The client should be given two ARV prescriptions of three months each. During this period (before a clinical visit), the client will report to the health facility any clinical warning sign for earlier clinical review.

Six months prescription and dispensing

Clients who continued to be stable after receiving two consecutive three months prescriptions should receive six monthly prescriptions and dispensing of ARVs.

(ii) Unscheduled visits

Apart from scheduled visits, it is also important for the clients to present themselves to the clinic for clinical review if they develop any unexpected/warning symptoms and/or complications. Clinical review will determine the appropriate management required and the need for stability re-categorization.

(iii) In case of loss to follow up

Proactive follow-up is needed by clinic team members in collaboration with home based care providers to follow up patients who do not turn up for their scheduled visits. It is important to institute and maintain system triggers for this throughout follow-up. Use of reminders list, promised to come diaries, appointment blocks and patient healthcare provider ties which have shown to improve adherence. Also, the appointment and tracking registers should be used effectively to identify and track loss to follow up clients. A good referral mechanism with community service directory should therefore be established between the clinic and other levels of healthcare delivery.

Table 10.7: Summary of Laboratory Monitoring of Adolescent and adult on First and Second-Line ART Regimens

Regimens	Monitoring Tests	Frequency	Rationale
TDF+3TC+DTG ABC+3TC+DTG AZT+3TC+(EFV or NVP) TDF+FTC+(EFVor NVP)	HVL (All Clients)	For HVL monitoring, refer to HVL algorithm	ART monitoring
	CD4 (All clients)	Baseline (All) After every six months if CD4 is <350 cells/ml	ART monitoring
	FBP/Hb (All clients) If a client has Hb <8.5g/dl avoid AZT	Baseline, week 4, thereafter six monthly	Anaemia monitoring

	Serum Creatinine (For patients on TDF)	Baseline, and after every six months and whenever symptomatic	Screening for early renal toxicity
	ALT (For patients on DTG or NVP)	Baseline, one month, after every six months and whenever symptomatic	Liver toxicity
AZT/3TC+ATV/r TDF/FTC+ATV/r ABC/3TC+LPV/r or DTG	Bilirubin (For all clients on ATV/r)	Baseline, 6 months or whenever symptomatic	Indirect hyper-bilirubinemia

Note: - Frequent laboratory tests will determined by clinical evaluation outcome.

*-The frequency of CD4 and viral load monitoring may be less than six months when IRIS or treatment failure is suspected (*See Chapter 4 for more details on criteria and schedule of CD4 and HVL testing).

Laboratory Monitoring of Adolescent and adult on First and Second-Line ART Regimens

- FBC: at baseline, then monthly for three months, then after every six months with CD4 and viral load
- Fasting cholesterol and triglyceride: at baseline, six months and thereafter every 12 months
- Liver function tests (ALT): at baseline, six monthly
- Fasting glucose: every 12 months
- Urinalysis: at baseline and after every three months
- Serum creatinine: at baseline and once a year.

10.9 Immune Reconstitution Inflammatory Syndrome (IRIS)

IRIS is a phenomenon associated with the occurrence or worsening of opportunistic infections/malignancies which can occur early after initiation of ART or at later (several months to years) during the course of ART. There is an increased risk for occurrence of IRIS in the following situations:

- Treatment naïve patients
- Patients with advanced HIV disease with CD4 cell count <50 cells/mm^3
- Patients with undiagnosed and untreated opportunistic conditions

- Patients who have been introduced on ART before or shortly after initiation of treatment of opportunistic infection/malignancy
- In the advent of DTG use, there is increased likelihood for IRIS because of rapid HIV viral load suppression.

NB: *Any OI, malignancy and autoimmune diseases may present as IRIS*

For clients with TB, this syndrome has been reported to occur in as many as 30% of patients in the developed world. The syndrome is characterized by fever, lymphadenopathy, worsening pulmonary lesions and expanding central nervous system (CNS) lesions. These reactions are typically self-limiting although they may require the use of a brief course of corticosteroids to reduce inflammation for CNS or severe respiratory symptoms.

Initiation of ART can also unmask previously undiagnosed infections such as hepatitis B or C viral infections as it improves the inflammatory response while repairing the immune system.

In general, ART should not be stopped when immune reconstitution syndromes occur except in life threatening situations in which ART should be temporarily stopped. However, where there is doubt, the opinion of a senior HIV physician should be sought.

The criteria for making a diagnosis of IRIS are delineated in Table 10.8 below:

Table 10.8: Immune Reconstitution Inflammatory Syndrome

Diagnosis of IRIS would require: Both major (A plus B) criteria or Criterion A plus 2 minor criteria
Major criteria **A.** A typical presentation of "opportunistic infections or tumours" in patients responding to anti-retroviral therapy (ART) includes: • Localized disease e.g. lymph nodes, liver, spleen • Exaggerated inflammatory reaction e.g. severe fever, with exclusion of other causes of painful lesions • Atypical inflammatory response in affected tissues e.g. granulomas, suppuration, necrosis, perivascular lymphocytic inflammatory cell infiltrate • Progression of organ dysfunction or enlargement of pre-existing lesions after definite, clinical improvement with pathogen specific therapy prior to commencement of ART and exclusion of treatment toxicity and new diagnoses • Development or enlargement of cerebral space occupying lesions after treatment for cerebral Cryptococcus or toxoplasmosis • Progressive pneumonitis or the development of organizing pneumonia after treatment of pulmonary-TB or PCP • New onset or worsening of uveitis/vitritis after resolution of CMV retinitis • Fever and cytopenia after treatment for disseminated Mycobacterium avium complex (MAC) disease

- Enlargement of Kaposi's sarcoma lesions and subsequent resolution or partial regression without
- Commencement of radiotherapy, systemic chemotherapy or intralesional therapy

B. Decrease in plasma HIV-RNA level by >1 log base ten copies/ml (1 log drop = 9/10 of Baseline VL copies). This applies in settings where baseline VL is performed.

Minor criteria

- Increased blood CD4+ cell count after initiation of ART
- Increase in immune response specific to the relevant pathogen e.g. delayed type hypersensitivity to mycobacterial antigens (PPD conversion)
- Spontaneous resolution of disease without specific antimicrobial therapy or tumour chemotherapy with continuation of anti-retroviral therapy.

Management of IRIS

Mild to moderate forms:

- Reassure the patient
- Do not stop ART
- Provide specific treatment for the opportunistic infections/malignancies or other diseases

Severe life threatening IRIS

- Reassure the patient
- Stop ART temporarily
- Provide high doses of Prednisolone 1mg/kg for 4 weeks then taper down the dose. In case of severe cryptococcal meningitis IRIS, short course of Steroid may be prescribed (Refer cryptococcal meningitismanagement, on Chapter 6).

NOTE: When using high dose steroids, it is important to rule out *Strogyloides stecolaris* infection to avoid disseminated strongylodiasis.

- Provide other appropriate supportive measures such as management of fever, oxygen therapy, i.e. fluids
- Restart ART when the patient stabilizes

CHAPTER 11:

ANTIRETROVIRAL THERAPY IN CHILDREN AND ADOLESCENTS LIVING WITH HIV

11.0 Introduction

ART in children and adolescents has been proven to increase survival and decrease HIV-related morbidity and mortality. Children and adolescents should be started on ART as soon they are diagnosed including those with presumptive diagnosis. This chapter discusses ART for children and adolescents living with HIV and AIDS (C/ALHIV) below 15 years of age.

11.1 Goals of Antiretroviral Therapy in Children and Adolescents

The goals of antiretroviral therapy for children and adolescents are to suppress HIV replication and therefore prevent disease progression, preserve, enhance, or reconstitute the immune system and therefore reduce opportunistic infections, reduce morbidity, promote optimal growth and development and long life prolong the survival of C/ALHIV and improve their quality of life. In most children, viral load decline is followed by rising CD4 cell counts after ART initiation. Generally, CD4 cell count increases over the course of the first year of treatment reaches a plateau and then continues to rise further over the second year. However, in some children, severe immunosuppression may persist. The lower the CD4 cell counts at the start of ART the slower the recovery. Persistent failure of CD4 cell count response should alert the clinician to potential adherence problems or non-response to ART. Undetectable viral loads of <50 copies/ml should be achieved and sustained.

In order to achieve these goals, the following strategies should be used:

- Identify barriers (e.g. Non-disclosure, suboptimal dosage, adherence to frequency of drug prescribed) to adherence and implement supportive strategies for caregivers and clients to maximize adherence to the antiretroviral regimens
- Adequate counseling of the parent/caregiver and of children an age appropriate way
- Rational sequencing of drugs for the preservation of future treatment options
- Monitoring of drug resistance
- Monitoring of toxicities and adverse drug reactions.

11.2 When to start ART in children and adolescents under 15 years

It is important that prescribers are clear about when to start antiretroviral drugs. They also need to know which drugs to use, in which order, when to change therapy, and which alternative drugs to use when changing therapy.

11.2.1 Initiation of ART for children and adolescents under 15 years

Among children and adolescents under 15 years, there are three groups for eligibility to begin treatment:

All children and adolescents <15 years of age who have a confirmed diagnosis of HIV, regardless of WHO clinical stage or CD4 cell count

Children <18 months of age with a positive DNA /RNA PCR test who should start ART and repeat the DNA /RNA PCR test for confirmation

Presumptive HIV infection: HIV exposed children below 18 months with a presumptive HIV infection without a DNA /RNA PCR test result, (see criteria for presumptive diagnosis of severe HIV infection in infants and children <18 months in Chapter 7) should start ART and do a confirmatory DNA /RNA PCR test as soon as possible.

Table 11.1: When to start ART in children and adolescents under 15 years

Age	When you start
Children 0-15 years	Treat all of them regardless of WHO clinical stage or CD4 cell count
Children below 18 months old who qualify for presumptive diagnosis	Start ART while are waiting for DNA-PCR confirmation test results.
Children <18 months of age with a positive DNA/RNA PCR test	Start ART while waiting for the second DNA/RNAPCR test result

11.2.2 First-Line ARV Regimens in Infants and Children under 15 years

The first-line regimen for children under 15 years is as shown in Table 11.2 below:

Table 11.2 Summary of first line ART Regimen for children under 15 years old

Patient group	Preferred 1st Line Regimen	Justification	Alternatives	Comments
Infants and Children weighing <20kg	ABC/3TC+LPV/r	Higher genetic resistance barrier Avoids NNRTI transmitted resistance from mother during PMTCT Potential for malaria prevention Spares AZT	AZT/3TC+LPV/r AZT/3TC+DTG (25mg or 10mg DTG if available)	LPV/r is available in three formulations (syrup, granules and tablets) -LPV/r oral solutions for younger infants until they are able to take granules -LPV/r granules for infants and younger children

		for second-line		-LPV/r 100mg/25mg heat stable tablets for children 10kg and above and able to swallow whole tablets
Children and adolescents weighing ≥20kg	ABC + 3TC + DTG	-Lowers HIV viral load very fast -Has high genetic barriers to resistance compared to both PIs and NNRTIs -Spares AZT for second-line	ABC+3TC+LPV/r	ABC/3TC Dispensable Tablet 120/60 mg plus DTG tablet 50mg
Children and Adolescents weighing ≥30 kg	TDF + 3TC + DTG	Higher genetic resistance barrier Avoids NNRTI transmitted resistance from mother during PMTCT Possibility of malaria prevention Spares AZT for second-line	ABC+3TC+DTG TDF+3TC+EFV600 or EFV400	TLD Fixed Dose Combination
For TB and HIV co-infected children already on LPV/r based	ABC/3TC+LPV/r	Continue with ABC/3TC+LPV/r but the dose of LPV/r should be doubled due to		ABC/3TC+LPV/r in the morning and onlyLPV/r in the evening

regimen		the interaction between ritonavir and rifampicin		
For TB and HIV co-infected children already on DTG based regimen	ABC/3TC+DTG	For children 20-25 kg who get TB/HIV co-infection it is advisable to give them ABC/3TC/EFV for the time of the TB treatment then revert to ABC/3TC/DTG after completion of TB Treatment For children > 25 kg Continue with ABC/3TC+DTG but the dose of DTG should be doubled due to the interaction between ritonavir and rifampicin		ABC/3TC+DTG in the morning and only DTG in the evening
For TB and HIV co-infected on TLD	TDF+3TC+DTG	For children 20-25 kg who get TB/HIV co-infection it is advisable to give them TDF/3TC/EFV for the time of the TB treatment then revert to TDF/3TC/DT		TLD in the morning and only DTG (50mg) in the evening

		G after completion of TB Treatment For children > 25 kg Continue with the same regimen, Double dose of DTG		

For dosing of ARV regimens see Annex 8, Paediatric Antiretroviral Dosing

NOTE: Children with weight above 30kg can use 300mg TDF as a fixed dose combination with 3TC.

Special Considerations for LPV/r syrup, granules and tablets:

LPV/r (80mg/20mg/mL) oral solution for infants with HIV infection who are unable to safely swallow LPV/r pellets or granules. Infants will typically use oral solution until 3-6 months of age (typical upper weight limit of 6 kg), before transitioning to pellets or granules.

The LPV/r syrup requires a cold chain during storage at the facility only. After dispensing, the syrup is stable at room temperature for one month so patients should be given a maximum of one month supply.

LPV/r granules: to be used for CLHIV who are able to safely swallow LPV/r granules but who are unable to swallow LPV/r tablets whole. LPV/r granules are appropriate for many infants who weigh 3-5.9kg, all infants 6-9.9kg, and some children in the 10-13.9 kg weight band who cannot yet swallow small tablets whole

LPV/r tablet is heat stable but must be swallowed whole and should not be split or crushed as it loses effectiveness and LPV/r has shown protection benefit against malaria[32].

LPV/r 100mg/25mg tablets for CLHIV who are able to swallow tablet whole without splitting or crushing. Transition to LPV/r tablets should occur as early and as safely as possible. This will require a proactive approach to teaching young children how to swallow tablets whole. These tablets are smaller and easier to swallow than LPV/r 200mg/50mg used in older children and adults. This formulation is appropriate for some children in the 10-13.9

[32]Achan J et al. antiretroviral agents and prevention of malaria in HIV infected Ugandan Children. New England Journal of Medicine 2012, 367:2110-2118.

kg band and most children in the 14 kg-19.9 kg weight band. Transitioning younger children from pellets or granules to tablets is better for patients and caregivers as it greatly simplifies administration.

11.3 Changing ARV Therapy in children and adolescents under 15 years

11.3.1 Drug toxicity

The principles for changing ARVs and the managing drug toxicity in children and adolescents are similar to those applied to adults. When toxicity is related to an identifiable drug in the regimen, the offending drug should be replaced with another drug that does not have the same side effects.

11.3.2 Treatment failure

11.3.2.1 Virological treatment failure

Viral load is the most reliable method to detect early treatment failure. Virological treatment failure is recognized if the child or the adolescent is adherent to the current ART regimen, for six months or more and has two consecutive viral load measurements over 1000 copies/ml at three months apart. For more details on routine HVL see Chapter 4, Section 4.4.

Changing a child or an adolescent from first to second-line ARV is a decision that should only be undertaken after consultation with an expert. Second-line treatment is generally used following treatment failure, as reflected by a HVL greater than 1000 copies/ml despite good adherence. General considerations prior to defining treatment failure:

- Allow reasonable trial on therapy with good adherence (at least 12 – 24 weeks) before concluding that a regimen is failing. (Calculate HVL drop from previous measurement using 0.5 log thresholds for children above 2 years and 0.7 log for children below 2 years)
- Monitor closely the adherence during this time
- Always attempt to improve adherence before switching regimens, as poor adherence to treatment is the most common cause of virological failure.

11.3.2.2 Immunological treatment failure

If adherence is good, immunological criteria indicating that a change to second-line therapy is warranted where/when HVL test is not available includes the following:

Table 11.3: CD4 criteria suggesting immunological failure [a]
Immunological failure is recognized as developing or returning to the following age-related immunological thresholds after at least six months on ART, in a treatment-adherent child:

<5 years of age	CD4 count of <200 cells/mm^3 or CD4 <10%
≥5 years of age	CD4 count of <100 cells/mm^3

[a] Preferably, at least two CD4 measurements should be available

Use of percentage CD4 in children <5 years and absolute CD4 cell counts in those ≥5 years of age is preferred.

If serial CD4 values are available, the rate of CD4 cell count declines from the peak, CD4 cell count reached should be taken into consideration.

Note: CD4 cell percentage should not be measured during an inter-current infection but can be determined when the child has recovered.

If there is a modest decline in CD4 cell count or percentage (<5%); and if there is no failure to thrive do not change medication, instead maintain close monitoring.

11.3.3 Clinical treatment failure

Clinical treatment failure is a new or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 and 4 with exception TB) after six months of effective treatment.

Clinical conditions indicating that a change to second-line therapy is warranted include:

Poor growth (failure to gain weight, declining or stagnant weight) over a six-month period, after excluding other causes, such as TB, feeding problems and food insecurity, no improvement of neuro-developmental milestones, development of HIV encephalopathy, recurrent infections, such as oral candidiasis, persistent diarrhoea, recurrent severe bacterial pneumonia and advancement from one clinical stage to another or new evidence of new WHO stage 3 or 4 disease (see Paediatric WHO Clinical Staging).

Note:

- Short inter-current episodes of pneumonia, LRTI and gastroenteritis should not be regarded as clinical failure.
- Pulmonary or lymph node TB, which are clinical stage 3 conditions, are not indications of treatment failure, and thus may not require consideration of second-line therapy
- The response to TB therapy should be used to evaluate the need for switching therapy
- Before an ARV regimen is thought to be failing based on clinical criteria, the child and the adolescent should have received the regimen for at least six months.
- The condition must be differentiated from immune reconstitution inflammatory syndrome.

11.4 Laboratory parameters for monitoring children and adolescents under 15 years at baseline, before and during ART

Table 11.4: Laboratory parameters for monitoring infants and children under 15 years at

baseline, before and during ART

Laboratory tests for diagnosis and monitoring	Baseline (at entry into care)	At initiation of first-line or second-line ART regimen	Every six months	As required or symptom-directed
HIV diagnostic testing	√			
Haemoglobin	√	√		√
WBC and differential count	√			√
%CD4+ or absolute CD4 cell count	√		√[b]	√
Pregnancy testing in adolescent girls		√		√
Full chemistry (including, but not restricted to, liver enzymes, renal function, glucose, lipids, amylase, lipase and serum electrolytes)[e]		√	√e	√
HIV VL measurement			√[d]	√
OI screening (where possible)	√	√	√	√

a. HIV re-testing for verification before ART initiation, re-testing is not indicated when switching to 2nd or 3rd line

b. For children of <5years continue CD4 monitoring every six months

c. CD4 cell count should be taken on emergence of WHO stage 3 or 4 disease

d. Viral load monitoring is done annually if the first two VL results 6th month apart are ≤1000 copies/mL

e. Regular monitoring (every six months) of full chemistry, particularly lipid levels, liver enzymes and renal functions, should be considered for infants and children on ART.

11.5 Assessment of infants and children receiving ARV therapy

Important clinical signs of response to ARV therapy in children include improvement in growth and development and decreased frequency of infections (bacterial infections, oral thrush, and/or other opportunistic infections). Clinical monitoring of ARV treatment in children should consist of feeding practice and nutritional status, growth monitoring: weight, height, MUAC (mid-upper arm circumference), head circumference should be monitored in children under 3 years old, neurologic symptoms and developmental milestones, cotrimoxazole prophylaxis taken daily, adjustment of ARV dose based on weight, WHO

disease clinical staging, immunization status, other medical conditions, screening for malaria and TB and drugs side effects

11.6 Recommended Second-Line ARV Therapy for Infants and Children under 15 years

Optimized NRTIs backbone should be used: AZT following TDF or ABC failure and vice versa.

For children and adolescents less than 20kgs whose first-line regimen was EFV or NVP based, then switched to LPV/r based regimen and maintain PIs. Measures to improve adherence should be taken, (since PIs have high genetic barrier for mutation) for improvement of virological suppression.

For children and adolescents whose 1st regimen was EFV or NVP based, then switched to DTG based regimen and were not previously exposed to PIs, their preferred 2nd line regimen is PIs based. However, DTG can be re-cycled in the second line due to its high genetic barrier.

Note: Infants and children take longer time to attain adequate viral suppression. Before confirming treatment failure, calculate drop in VL (using 0.5 log for two years and above, 0.7 log below two years - for further details on how to convert VL into numbers see Annex 06).

Table 11.5: Recommended second-line ART regimens for children and adolescents under 15 years

Patient group	If is on the following first line	Preferred 2L	Comments
Children and adolescents <20kg whose 1st regimen was EFV or NVP based, then transitioned to LPV/r based regimen	ABC+3TC+LPV/r AZT+3TC+LPV/r	Maintain PI AZT+3TC+LPV/r	-Higher genetic resistance barrier -Spare INSTI for third-line
Children and adolescents ≥20kg whose 1st regimen was EFV or NVP based, then transitioned to DTG based regimen	ABC+3TC+DTG AZT+3TC+DTG	AZT+3TC+ATV/r AZT/3TC+DTG ABC+3TC+DTG (for those who cannot tolerate AZT)	Maintain DTG in the 2L due to higher genetic barrier than PIs.

Children and adolescents weighing ≥30kg	TDF+3TC+DTG	AZT+3TC+ATV/r ABC+3TC+ATV/r	

For dosing of ARV regimens see Annex 8, Paediatric Antiretroviral Dosing

Note:

- ATV/r can be used as an alternative to LPV/r in children above six years old if pediatric formulation is available but adolescents >30kg can take adult formulation.

11.7 Third Line ARV regimens in children and adolscents under 15 years

With the roll out of routine HIV viral load monitoring in the programme, early and accurate confirmation of treatment failure will be determined. This will prevent accumulation of drug resistant mutants and thereby improving clinical outcomes. Similarly, improvement in diagnosis of second line ART failure will go hand in hand with the scale up of HIV viral load monitoring.

Clients failing 2nd line regimen have extensive NRTI and NNRTIs associated resistance mutations which minimise their use in third line regimens. Third line regimen is constructed using new classes of drugs or second generation formulations, in order to have at least two or three effective drugs. For examples, Darunavir (DRV) is a second generation PI without cross resistance to Lopinavir/r used in the previous regimens. New classes of drugs include Integrase Strand Transfer Inhibitors (INSTIs) or Integrase Inhibitors such as Dolutegravir (DTG) and Raltegravir (RAL). The other groups include Fusion Inhibitors such as Enfuvirtide (ENF) and Chemokine Inhibitors (CCR5 Inhibitors) such as Maraviroc. The disadvantages of the last two groups are the currently available fusion inhibitor requires parenteral administration while the CCR5 Inhibitor Maraviroc requires prior determination of HIV tropism, a test which is not yet available in Tanzania.

Therefore, this guideline recommends the use of Integrase Inhibitors DTG and RAL, Second generation PIs (DRV/r) as third line

11.7.1 Criteria for Change to Third-line

Failing any 2nd line regimen

The criteria for diagnosing second-line failure are the same as those used for diagnosing first-line failure. In the event of treatment failure, a comprehensive evaluation to ascertain the cause of failure should be conducted. Efforts must be made to assess and optimize adherence and rule out any significant drug interactions. When this has been done and there is still evidence of failure, patients should have a regimen change that will include at least two active agents.

Viral load testing should be the gold standard for diagnosing treatment failure and the resistance test should be used to determine the third line regimen. Referral to specialist care is recommended where third line regimen can be chosen according to genotype resistance testing and managed by an expert panel at tertiary care facilities.

Eligibility for Third Line Evaluation:

All clients Failing 2nd line regimens who have undergone an Enhanced Adherence Counselling and documented HIV virologic failure (VL >1000) on a PI regimen; except children below 3 years.

Steps to refer client to 3rd line review committee

1. Client suspected to have second line failure from dispensary or health centre is referred to the hospital
2. At the hospital, the client is reviewed by clinicians working in CTC, the checklist is completed and only the checklist is sent to the review committee at the tertiary care facility/zonal referral hospital.

At the zonal level, the review committee reviews the checklist and recommends which clients should be referred for evaluation including genotype resistance testing and decision.

Zonal level review committee communicates the decision back to the referring hospital within a month.

Selection of third-line regimen should consider genotype resistance test results as well as treatment history.

Table 11.6. **Third-line regimens paediatrics and adolescents**

Patient group	3L Options	Justification
Children <20kg	RAL + DRV/r + AZT/3TC	DRV/r -High genetic barrier, Effective for patients with resistance to LPVr and ATVr, cannot be used in children <3 years of age RAL-Can be used for children <20 kg DTG-Can be used for children ≥20 kg
Children ≥20kg and above	DTG + DRV/r + AZT/3TC	

11.8 Adverse reactions in children and adolescents

Drug-related adverse reactions while on ART can occur immediately (soon after a drug has been administered), early (within the first days or weeks of treatment) or late (after months of treatment).

Adverse reactions can vary in severity from mild to severe to life-threatening and may be specific to the drug or general to the class of drugs in use.

Table 11.7 Major Types of ARV Toxicity in Children and adolescents

ABC	ABC is associated with hypersensitivity reactions. Patients may have severe skin rashes or other non-specific symptoms such as fever, arthralgias and lymphnode enlargement
AZT	AZT is associated with risk of haematological toxicity which can include anemia neutropenia and thrombocytopenia. Measuring hemoglobin is recommended before initiating ART among children and adolescents with low body weight, low CD4 cell counts and advanced HIV disease. Patients with severe anemia at baseline (haemoglobin <7.5 g/dL) should avoid AZT as first line therapy
TDF	TDF is associated with nephrotoxicity. Nephrotoxicity is more common in elderly patients but it also occurs in children and adolescents, especially if co-administered with PI based therapy. Monitoring of creatinine clearance is recommended.
EFV	EFV's main type of toxicity is central nervous system side effects, which typically resolve after a few weeks. However, in some cases, they can persist for months or never resolve at all.
NVP	NVP's major toxicities include severe skin rash and hypersensitivity reaction (Steven's Johnson syndrome) and hepatotoxicity. Because of the risk of potentially life-threatening hepatotoxicity associated with NVP, hepatic dysfunction of any aetiology in a child and an adolescent on NVP requires careful consideration of whether NVP should be continued.
LPV/r	LPV/r's major toxicity includes hepatotoxicity, pancreatitis, diarrhoea and lipoatrophy. The risk of hepatotoxicity is increased in patients with underlying hepatic disease and the risk of pancreatitis is increased in patients with advanced HIV disease. Electro-cardiac abnormalities are also possible; patients with pre-existing conduction system disease are at an increased risk

ATV/r	Toxicities of ATV/r are similar to those of LPV/r. ATV/r can cause jaundice (indirect hyperbilirubinemia). Jaundice (indirect hyperbilirubinemia) is usually transient and ATV/r can be continued. If severe jaundice develops and there are significantly raised transaminases, then ATV/r should be replaced with LPV/r
DRV/r	DRV/r's major toxicity is hepatotoxicity. Patients with underlying hepatic disease, hepatitis B or C co-infection or who are taking other hepatotoxic drugs are at a higher risk. The other side effect is severe skin and hypersensitivity reactions. Patients with sulfonamide allergy are at a higher risk
RAL	RAL's potential toxicity includes rhabdomyolysis, myopathy and myalgias as well as hepatitis and hepatic failure and severe skin rash and hypersensitivity reactions.
DTG	DTG major toxicity is hepatotoxicity and hypersensitivity reactions. Patients with underlying liver disease or hepatitis B or C co-infection are at a higher risk.

Principles in the management of ARV drug toxicity:

- Determine the seriousness of the toxicity
- Evaluate concurrent medications and establish whether the toxicity is attributable to ARV drug or non-ARV medication taken at the same time
- Consider other disease processes (e.g. viral hepatitis in a child (or an adolescent) on ARV drugs who develops jaundice). Not all problems that arise during treatment are caused by ARV drugs.
- Manage the adverse reactions according to its severity.

In general:

Severe life-threatening reactions: Immediately discontinue all ARV drugs, manage the medical event (i.e. provide symptomatic and supportive therapy) and reintroduce ARV drugs using a modified regimen (i.e. with an ARV substitution for the offending drug) when the patient is stabilized.

Severe reactions: Substitute the offending drug without stopping ART.

Moderate reactions: Consider continuation of ART as long as it is feasible. If the patient does not improve on symptomatic therapy, consider single-drug substitution.

Mild reactions: Reassure a child (or an adolescent) and the caregiver that while the reaction may be bothersome, it does not require a change in therapy; provide counselling and support to mitigate adverse reactions.

Emphasize on the maintenance of adherence despite mild and moderate reactions.

Table 11.8: Severe toxicities of ARVs in infants and children, and potential drug substitutions

Toxicity events	Responsible ARV	Suggested first-line ARV drug substitution
Acute symptomatic hepatitis Severe or life-threatening rash (Stevens-Johnson syndrome)	NVP	EFV If the patient cannot tolerate either NNRTI, use boosted PI boosted PI
Hypersensitivity reaction	ABC	AZT
Lipoatrophy/metabolic syndrome	LPV/r	If LPV/r is used in first line ART for children and adolescents, use an age appropriate NNRTI (NVP for children below 3 years and EFV for children and adolescents with 3 years and above) ATV/r can be used for children and adolescents above 6 years
Severe anaemia or neutropenia Severe gastrointestinal intolerance	AZT	Substitute with ABC if < 35 kg Substitute with TDF if > 35 kg
Persistent and severe central nervous system toxicity	EFV	NVP
Tubular renal dysfunction	TDF	If TDF is being used in first line ART, substitute with AZT or ABC If TDF is being used in second line ART, substitute with ABC

Patients on third-line ARV regimen who develop toxicities should be managed by a specialist.

CHAPTER 12:

ADHERENCE TO ART AND RETENTION ACROSS CONTINUUM OF CARE

12.0 Introduction

Adherence means sticking firmly to treatment regimen by taking the right medicine, with the right dose, at the right time, in the right frequency, in the right way every day and exactly as agreed between healthcare providers, clients and care givers. High level of sustainable adherence is crucial for achieving viral suppression needed for attainment of ART benefits which include immune restoration, prolonged survival, reduced resistance, improved quality of life and treatment as prevention. This chapter explains factors and strategies that influence adherence counselling and monitoring among children, adolescents, youth and adults.

12.1 Factors and Strategies that Influence Adherence to ART

Adherence level of >95% is needed to maximize the benefits of ART. However, achieving such high rates over a long period of time is a challenge. Therefore, to improve adherence, different approaches should be sought and tailored to the patient's lifestyle through proper counselling and health education.

12.1.1 Factors that Influence Adherence

The following are predictors of good adherence to ART:

- Client's self-commitment
- Availability of emotional and practical life support
- Clients' ability to fit the medications into their daily routine
- Uninterrupted availability of ARVs
- Accessibility to CTC services
- Good tolerability of ARVs.

12.1.2 Factors that Enhance Adherence

Factors that enhance adherence are categorized as follows:

(i) Client related factors

- Disclosure of HIV status
- Readiness to be on life-long medication
- The understanding that the first-line ART regimen has the best chance of long-term success
- The understanding on the advantages and disadvantages of adhering to ARVs
- Involvement of a treatment supporter/family member
- Readiness to participate in Couple/Family counselling.

(ii) Health service providers related factors include:

- Agreement between a client and HSPs on the treatment plan
- Building a trusting relationship with the clients
- Supportive, non-judgmental attitudes and behaviours of the HSPs
- Health education to clients at every clinical encounter with emphasis on adherence and possible side effects associated with ART
- Linkages to community support services
- Teamwork approach by HSPs.

(iii) Regimen-related factors

- Use of fixed drug combinations to reduce pill burden
- Minimise Drug interactions and side effects through rational drug selection
- Observe ARVs medication requirements (e.g. with food, without food, etc.).

Adherence Counselling for Treatment in Adults in the context of ‘‘Treat All’’

For achieving optimal and sustained adherence in the context of ‘‘Treat All’’, clients should be educated on, the benefits of early treatment regardless of CD4 cell count or clinical stage. These benefits include much prolonged survival, better clinical outcomes, early restoration of immunity, community prevention of TB and new HIV infections.

12.2.1 Sessions on Adherence Counselling for Adults

i) First session of adherence counselling

Review:

- CTC 1 card and ensure client’s information filled out is complete and accurate
- CTC 2 card to understand client’s socio-demographic data
- Use the checklist for counselling session I and document the information in CTC2 card, provide enough time for questions and respond accordingly
- Review client’s basic knowledge on HIV infection, AIDS progression and correct any misconceptions
- Provide information on early lifelong treatment of ARVs
- Discuss with the client on how ARVs inhibit HIV replication
- Discuss with the client on importance of treatment adherence and the consequences of failing to take ARV as prescribed
- Provide information on the role of CD4 cell count and viral load in monitoring treatment outcome
- Discuss potential barriers and lifestyles that might influence adherence to ART and assist the client to make a plan to overcome the barriers (See Table 12.2 below)
- Discuss with the client on Positive Health, Dignity and Prevention (PHDP)

- Refer the client for treatment and prophylaxis in case of any OIs
- Discuss and link to community based health services Assess client's willingness and readiness to start ART
- Schedule the client on early appointment for the 2nd counselling session if the client is not willing and ready to start ART.

(ii) Second Session of Adherence Counselling for Adults

- Review the previous counselling session and answer client's questions appropriately
- Use counselling session II checklist and document the information in CTC2 card, provide enough time for questions and respond accordingly
- Discuss potential barriers and lifestyles that might influence ARVs adherence and assist the client to make a plan to overcome the barriers (See Table 12.2)
- Assess client's willingness and readiness to start ART. Schedule the client on early appointment for the 3rd counselling session if s/he is not willing and ready to start ART.

(iii) Third Session of Adherence Counselling for Adults

- Confirm the client's readiness to start ART and initiate treatment
- Use counselling session III checklist and document the information in CTC2 card, provide enough time for questions and respond accordingly
- Assess barriers to adherence and address them
- Involve the client to change (if needed) treatment plan
- Review adherence to risk reduction behaviours, lifestyles, and use of traditional herbs
- Document successes and revisions in plans
- Let the client paraphrase instruction on how to take ARVs
- Encourage the client to return to the clinic as early as possible when he/she experiences side effects before deciding to stop ARV
- Identify appropriate adherence helpers such as alarm clocks, cell phone alarms, pill boxes and dose schedule cards and advise the client accordingly
- Encourage the client to have two or more adherence helpers
- Provide time for questions, respond and refer the client accordingly
- Emphasize on the importance of adherence to care and on ART
- Schedule the client for the next appointment
- Remind the client to bring the remaining pills when attending the scheduled visit.
- Follow-up Visits after Initiating ART
- Use the checklist and document follow–up visits after ARV drug initiation

Review with the client on the following:

- Proposed treatment adherence plan
- Understanding of the prescribed treatment regimen
- Assess client's understanding on the importance of correct use of prescribed ARVs
- Assess adherence from self-report and pills' count and explore about missed doses since the last visit
- If adherence is <95% with or without viral, immunological or clinical failure, then re-educate the client. If adherence is >95%, encourage the client to adhere to treatment
- Discuss the current (positive as well as negative) experiences about medications
- Discuss the strategies to minimize side effects
- Explore the factors that might prevent correct use of drugs
- Discuss about storage of drugs at home
- Discuss on how to ensure adequate supply of drugs in the event of unexpected travel
- Schedule with the client on the next appointment.

12.2.2 Monitoring Adherence

Optimal adherence requires full participation by the healthcare team as every client's interaction represents an opportunity for reinforcement. It is also important to have close linkages between CTC based and community based HIV services to ensure a strong client tracking system that will help to understand and mitigate any reasons for missed visits and loss to follow up for both clients on ARV drugs. The following are important considerations for care and treatment team members:

- All care and treatment team members shall provide continual monitoring for adherence and timely response to adverse events or interim illnesses
- Adherence support must be intensified when some negative changes are noted, by investigating barriers, scheduling appropriate visits, linking with home-based services and assessing support of family/friends
- All team members should provide consistent messages related to adherence to clients and their adherence assistants
- Clients and/or treatment assistants or care providers should be reminded to bring their drug stocks with them at every visit
- Pharmacy staff should monitor adherence using self-reporting
- Specific training regarding ART and adherence should be offered and updated periodically for all healthcare team members
- Systems shall be in place to adequately document indicators for levels of ARV drug adherence for individual clients as well as using collected information to assess performance at site level.

Note: Clients who take <80% of their pill doses are unlikely to have any durable viral suppression. When available, HIV viral load measurement should be used to determine whether clients are targeted for enhanced adherence counselling.

Formula for Calculating % Adherence:

$$\% \text{ of pills missed} = \frac{\text{No. of pills remaining} \times 100}{\text{Total No. of pills prescribed}}$$

$$\% \text{ adherence} = 100 - \% \text{ of pills missed}$$

Table 12.2: Barriers to Adult Treatment Adherence and How to alleviate them

Key Barrier to adherence	Suggestions to Alleviate
Social economic problems e.g. transportation, food insecurity	• Refer /Link to support groups for assistance • Refer to organizations for economic support e.g. Income Generating Activities (IGA) • Identify nearby CTC sites • Involve other family members
No disclosure	• Counsel on benefits of disclosure
Travels frequently	• Carry pills • Collect pills in advance for longer period • Walk with your CTC 1 card • Visit any nearby health facility for required services
Behavioural barriers e.g. Drinking alcohol regularly, not planning refill for travels or not having a reminder	• Counsel to stop or reduce alcohol intake • Involve other family members for support • Plan for drug refill • Address the use of reminders
Emotional barriers e.g. Depression or Mental illness	• Counsel for psychosocial support • Refer to clinician for treatment • Involve other family members for support
ARVs issues e.g. side effects, pill burden	• Discuss effectiveness and safety of drugs

	• Discuss issues of misconception • Discuss drugs side effects and resistance • Carry pills to hospital
Unexpected hospital admissions	• Inform healthcare staff that you are on ARV treatment
Stigma and Discrimination	• Link patients with support groups • Create awareness in the communities • Refer to CBHS • Provide health education on HIV and AIDS
Cultural Beliefs	• Provide Health Education on HIV and AIDS • Create awareness in the communities including religious leaders and traditional healers
Gender Based Violence	• Provide couple and family counselling • Link clients to Human Rights and Legal issues organizations for support
Communication Problems	• Use colours, symbols and pictures for elaboration • Usage of sign language • Use simple language • Use treatment supporter • Have adequate preparation before treatment initiation

12.3 Adherence Counselling in Children and Adolescents

12.3.1 Factors that Influence Adherence in Children

The HSPs should inquire to find out the factors that affect child's adherence:

Child related factors

Child related factors include the child's living environment, age, the complexity of the drug regimen, HIV disclosure status and the health status. Include other medications the child is also taking.

Family/ caregiver related factors

They include reliability, education and socioeconomic status of the caregiver, family cultural beliefs and practices, the HIV status of the parents and caregivers and the relationship between the caregiver and the child and ability of parents/caregiver to disclose.

System related factors

These include the relationship between the caregiver and the clinician, stock outs of medications and contradicting information from HSPs regarding medication regimen.

12.3.2 How to Prepare for Adherence in Children

The health service provider should:

- Identify a primary committed parent/ caretaker and counsel them fully
- Discuss with parent/ caretaker on disclosure of HIV status of a child/ adolescent
- Confirm availability of support services
- Assess for stability of family environment
- Assess caregiver and child's readiness to start ARV
- Have an agreement with a caregiver/ child that medicines should be taken as prescribed
- Address the key barriers to adherence and suggest how to alleviate them
- Disclose child's status and need for lifelong treatment to parents/ caregiver
- Support parent/caregiver to disclose HIV status to the child
- Identify responsible person for daily drug administration
- Family centred approach is recommended
- Conduct demonstration sessions on drug dosages and administration
- Ensure access to primary care for nutrition counseling and support.

12.3.3 Considerations for Readiness to Start Treatment for Children

Before starting medications, the HSPs should consider the following:

- Parent/caregiver understands the importance of clinic visits and maintaining CTC 1 card
- Understand roles of different household members in drug administration
- If the caregiver is ready to start ART to the child, initiate it on the same clinic day.

12.3.4 Strategies for Successful Adherence among Children

- Assess for readiness to treatment
- Identify and address all potential barriers to treatment
- For adherence, focus on strategies that are household or family oriented

Adherence counselling is an ongoing process and it takes time and commitment

- Ensure the use of relevant checklist and SOPs
- Address on adherence at every client's visit
- review regularly, the strategies to meet the changing needs of the growing child
- HSPs should work as a team – doctors, nurses, pharmacists, counsellors to reinforce adherence
- Identify one household caregiver who gives medication to the child and attends to the clinic with the child.

Table 12.3. Common Challenges and Strategies to Improve Adherence in Children

CHALLENGE	STRATEGIES
Child not taking medications	• Obtain a detailed history aimed at identification of the specific causes of his/her broad complaint • Explore with the parent/caregiver on ways to convince the child to take the medications • Teach the parent/caregiver on the importance of adherence for the child's survival • Simplify adherence information to ensure the parent/caregiver understands the treatment regimen
2. Medicines make a child sick e.g. nausea and vomiting	• Administer medications with food • Administer medications with liquid to help reduce gastric irritation • Reassure the caregiver/parent that most nausea and vomiting will resolve • If symptoms are severe, seek expert advice on regimen change and timing of medication.

3. Fear of ART harming the child e.g. the child is clinically deteriorating despite good adherence	• Ensure that the child is taking the correct dose • Examine the child for other opportunistic infections • Examine the child for side effects of the regimen • Encourage the caregiver/parent to continue the regimen unless the child has severe side effects, in which case seek an expert advice about changing the regimen • Utilize visiting nurses/HBC providers to assist with adherence assessments and follow up home visits.
4. Regimen dosing confusing to a caregiver/parent	• Provide the caregiver/parent with a written schedule/ illustration of medications • A written calendar could include symbols for the times of the day to aid with understanding, or utilize colour-coded labels to match with drug regimen colour- coded calendar • Where possible, elicit additional support from another family member or other community resource person.
Parent/caregiver is ill or absent and other family members cannot give medications to the child	• Treat the ill parent/caregiver • Probe and promote disclosure • Identify another treatment supporter • Address stigma and discrimination; provide health education to dispel myths on HIV and AIDS. Refer to CBHS.
Complexity of measuring pediatric formulations e.g. LPV/r syrup	• Provide the parent/caregiver with a written schedule/illustration of medication • Demonstrate procedures; if possible seek additional support from other family members or other community resource persons.

12.3.6 Consequences of Poor Adherence in Children

Consequences of poor adherence to ART in children include treatment failure, HIV drug resistance, increased morbidity and mortality as well as growth and developmental faltering.

12.4 Adherence among Adolescents and Youths

Adolescents and youths living with HIV are subject to stigma related with chronic illness, challenges of parental authority and therefore, they may wish to have their own friendly services. Adolescents and youths are susceptible to default a regimen if they encounter any difficulties.

Favourable circumstances for adherence:

- Dedicated adolescents and youth friendly services/clinics
- Adequate support from caregiver, family, and friends
- Stability in one's life so that they are able to obtain basic needs as well as play and attend school like other children
- Beneficial and early disclosure leading to increased participation in their treatment
- Change in health status or laboratory parameters, encourages continuation of treatment
- Familiarity with people responding well to similar therapies encourages the adolescent to adhere to treatment. It is essential that they get a chance to share experiences with peers having similar experiences
- Familiarity with someone who is sick or who may have recently died due to non-drug adherence encourages the adolescent to avoid a similar fate, so s/he will adhere to the regimen
- Access to a supportive clinician may also provide discussing options. Adolescents are curious and should be given as much information by the HCP.
- Supportive community that do not stigmatize HIV clients
- Adequate support during transition from paediatric/adolescent to adult clinics.

Factors affecting drug adherence among adolescents:

- Unstable living conditions where s/he moves from one guardian to another or if living in the streets
- Lack of support from guardian, family, friends and school teachers
- Lack of readiness and refusal to initiate/continue ART
- Limited access to adolescent friendly services
- Depression and other mental issues
- Substance use makes it difficult for individuals to adhere to treatment
- Alcoholism increases the risk of ARV drug toxicity
- Suicidal ideation

Strategies for enhancing ARV drug adherence among adolescents:

- Consider practicing drug adherence with vitamin pills, IPT and Cotrimoxazole-prophylaxis
- Involve the adolescent when discussing treatment options

- Explore with the adolescents challenges they experience in taking the drugs and work out strategies to address them. Family members and teachers may assist in the adherence plans
- Provide adolescent friendly services
- The members of the testing and counselling team with the best relation to the adolescent should take the lead in the counselling and support of the adolescent
- Regimens should fit into the adolescent's life as much as possible. Remind the adolescents that they need to continue taking the drugs even when they are feeling unwell or feeling well.
- Use of simplified regimens, preferably ARV taken once daily
- Positive approach to treatment that nurtures the adolescent's belief in their success, this task should be taken by the adolescents themselves as well as their family, friends and the care providers
- Information should be given proactively, in appropriate simple and understandable language and in writing
- Use real life examples to illustrate issues as adolescents often think in concrete terms
- Explain to adolescents what to expect while on therapy and how to manage potential positive and negative side effects and adherence problems
- Adolescents should be encouraged to discuss and disclose their problems with their care providers or person whom they trust.

How to help the adolescents develop an individual strategy for drug adherence:

- Encourage the adolescent to establish a schedule for taking drugs
- Keep the drugs where they can see them in the morning and evening
- Take the ARV drugs at the fixed time every morning and evening
- Write notes and stickers to remind them to take the drugs. If they have an alarm or phone, they can put it on as a reminder
- Keep a diary of how they are taking their drugs and to review it with the care provider. The diary will also help them to see the changes in health as well as any diverse changes in the body
- Plan ahead to carry ART with them when they are away from home
- Plan for sudden events that may change their normal schedule, and therefore always they should have a few tablets with them
- Identify a treatment supporter – this strategy has been found to be very successful in adults. Adolescents who are living alone may find it difficult to find a treatment supporter
- Provide a dedicated adolescent and youth friendly services.

12.5 Adherence Issues among Pregnant and Breastfeeding Women

Pregnancy and lactation periods present significant biological, social and economic challenges that may affect treatment adherence. It is estimated that around a quarter of pregnant women have inadequate ART adherence, and this is higher during the lactation period. Pregnancy-related conditions such as nausea and vomiting may negatively affect

treatment adherence. Other individual factors include suboptimal understanding of HIV, ART and PMTCT, lack of partner disclosure and support, and fear of stigma and discrimination. Service delivery barriers include poor-quality clinical practices, gaps in provider knowledge and training, poor access to services and health worker attitudes.

All these should be taken into consideration when counselling pregnant and lactating women to avoid vertical transmission.

12.6 Adherence among Key and Vulnerable Populations

In many settings, key vulnerable populations face multiple challenges related to stigma and discrimination that can affect access to health services, all of which may impact negatively on adherence.

Key factors to consider when providing services to key and vulnerable populations:

Assuring access: Create demand for HIV testing and counselling and prevention services through targeted campaigns in identified key and vulnerable population settings, use community-based outreach, mobile phone technologies, social networking and develop friendly key population services at health facilities; this will facilitate dissemination of behavioural messages, promote follow-up and referral to services, improve adherence to treatment, and increase client participation in their own healthcare.

Sensitize and educate health service providers, community health workers, CBHS, peers, supportive staff and management on issues of specific key and vulnerable populations and on non-discriminatory practices and eliminating stigma, using pre-service and in-service training, job-aids, supportive supervision, and training follow up.

Ensure confidentiality: Attention should be devoted to protecting privacy and confidentiality, e.g. closing the consultation room door or finding a private place to talk. Clients should be reassured of confidentiality.

12.7 Management of ART Experienced Clients

The CTC team should review treatment of clients who have been previously exposed to antiretroviral therapy.

Those who stopped for reasons other than treatment failure and for whom failure is not suspected should restart the original regimen.

Those known or suspected to have failed the previous regimen should be given an enhanced adherence counselling and later be started on drugs they have not been exposed to before as appropriate.

12.8 Adherence Counselling Follow-up

Evidence shows that adherence to preventive therapies such as IPT, CPT and balanced diet, TB treatment and ART is an important factor to ensure better health outcome of clients on long term therapy.

During a visit to the CTC, each client will be screened for TB and be provided with relevant prophylaxis if s/he deserves. In addition, adherence probing through a checklist will be used to identify possible lapses of adherence and reinforce key practices related to optimal management.

Patients also receive information and counselling on various PHDP elements such transmission risk reduction, nutritional and family planning advice, and adverse event management. Other psychosocial needs such as social or legal support, disclosure of HIV status, mental health, referrals to home based care services and facilitation for joining PLHIV support groups will also be addressed.

Note: Adherence assessment checklist is described in specific codes within the CTC2 card.

12.9 Enhanced Adherence Counselling (EAC)

Treatment failure should be suspected whenever a patient has been on ART for at last six months and has an HIV viral load more than 1000 copies/ml, declining in CD4 cell count, or developing a stage 3 or 4 disease condition. Poor adherence is often the most important factor in developing treatment failure, though there can be other causes.

Enhanced Adherence Counselling (EAC) is recommended when treatment failure is suspected. EAC is usually conducted in three sessions within eight weeks. An intensive counselling session is provided to overcome factors contributing to treatment failure. It is recorded into log form in which the sessions are documented. After the third session, another HVL test is done. When the results come back and the HVL is above 1000 copies, treatment failure is confirmed and the treatment regimen should be changed to a second or third-line. If it is below 1000 copies/ml, the client is regarded as adherent and continues with the same regimen.

12.9.1 Assessment of adherence

As soon as treatment failure is suspected, it should be discussed by the facility multi-disciplinary team and thereafter develop a plan for assessing barriers to adherence (including scheduling a home visit) and assessing other potential causes of treatment failure (e.g. inadequate dosing/dose adjustment, drug-drug interactions, impaired absorption drug food interactions). All clients who are confirmed to have treatment failure should have thorough assessment of potential barriers to adherence.

12.9.2 The goal of enhanced adherence counselling

The goal of EAC is to assess possible barriers to adherence in a non-judgmental way and help the client construct an adherence plan with concrete objectives. It is important not to focus solely on knowledge of HIV and ART but also to review psychological, emotional and socio-economic factors that may contribute to poor adherence. In addition, exploring the client's motivation for taking medication often highlights the reasons for poor adherence.

A minimum of three sessions are recommended for enhanced adherence counselling. If the adherence is adequately evaluated, a repeat HIV viral load should be done after three months of good adherence and another enhanced adherence counselling is conducted to discuss the HIV viral load results. It is preferable to have the patient go through all adherence

counselling sessions with the same counsellor in order to provide continuity and adequately document it to ensure follow-up of all issues identified.

Table 12.3 Components of Sessions for Enhance Adherence Counselling

Enhanced Adherence Counselling Sessions: Overview	
Session 1	Review understanding of viral load (VL) and discuss why the patient's VL is high Review cognitive, behavioural, emotional and socio-economic barriers to adherence: Treatment literacy Medications: dosage, timing, storage Side effects Discuss risk reduction (e.g. for substance abuse) Motivation
Session 2	Review adherence plan from the first session and discuss any challenges Identify other possible gaps and emerging issues Referrals and networking Assist patient to modify the adherence plan to address the identified issues
Session 3	Review adherence plan from the first and second session and discuss any challenges Identify other possible gaps and emerging issues Assist the patient to modify the adherence plan to address the identified issues Decision on repeat VL based on current adherence: If the adherence is good: plan repeat VL testing after three months of good adherence and explain possible ways forward, emphasizing the role of the patient and the health facility If adherence challenges persist: plan for further Enhanced Adherence Counselling sessions before repeating the HVL.
Session to Discuss Repeat Viral Load	Discuss the result of the second HVL test Plan the way forward: If HVL now is <1,000 copies/ml: continue with the current regimen with enhanced adherence, repeat VL after six months If HVL ≥1,000 copies/ml: prepare the patient for the change of regimen.

CHAPTER 13:

MENTAL HEALTH CONDITIONS IN HIV AND AIDS

13.0 Introduction

Mental health conditions are more common in HIV infected than in non-infected people. In some instances, this is due to (i) mental conditions existing prior to the HIV infection (ii) mental health condition as a psychological consequence of chronic HIV infection (iii) presence of the HIV virus in the brain. It is important to be aware that HIV individuals have an increased risk for developing mood, anxiety, and cognitive disorders.

The common groups of mental health conditions among people living with HIV are:

- Organic Disorders (Delirium and Dementia)
- Mood Disorders (i.e. Depression and Mania) mania, adjustment disorders, post-traumatic stress disorders
- Anxiety Disorders (i.e. adjustment disorders, panic disorders, generalized anxiety disorders, post-traumatic stress disorders, HIV and AIDS related phobia)
- Psychotic Disorders (i.e. schizophrenia, schizoaffective disorders)
- Alcohol and other substance use disorder (i.e. cannabis, heroin and cocaine)
- Social difficulties faced as a result of stigma and discrimination
- Exacerbation of a pre-existing mental disorders, depression, mania anxiety disorders and substance abuse may be related to the stress of living with HIV and AIDS.

Other mental disorders may be secondary to neurological complications of HIV, opportunistic infections or side effects of ARV drugs. Pre-existing mental disorders are associated with increased risk of acquiring HIV infection and drug use. PLHIV who present mental conditions often come to care and treatment services with special management needs.

13.1. Mental disorders secondary to neurological complication of HIV, OIs, and side effects of ARVs

13.1.1 Delirium

Definition: Delirium is a state of acute onset of impaired consciousness marked by anxiety, disorganized speech, disorientation and hallucinations. The distinguishing features include drowsiness, lethargy and a changing level of consciousness. All these symptoms usually develop over hours or days and the presentation fluctuates. Delirium is a medical emergency and may be life threatening, hence it requires immediate medical attention.

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Risk Factors: Risk factors for developing delirium include:

- Advanced stages of immune suppression
- Substance use/intoxication
- Head/brain injuries
- Previous episodes of delirium
- HIV-associated dementia or infections and malignancies of the CNS

- Drug interactions in AIDS patients taking multiple medications
- Drug overdose (accidental or deliberate)
- High fever from any cause
- Intoxication from any cause.

In children and adolescents, the common causes of delirium are medications or substance use.

Common differentials of delirium include:

- Cryptococcus meningitis
- Toxoplasmosis
- Space occupying lesions e.g. Primary cerebral lymphoma
- Cerebral tuberculosis
- Brain abscess
- Bacterial and fungal meningitis
- Alcohol withdrawal syndrome
- Psychoactive substance abuse

Management: The appropriate treatment of delirium involves identifying and correcting its underlying causes.

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13.1.2 HIV Associated Dementia (HAD)

Definition: HAD is an acquired impairment of intellectual/cognitive abilities in a sufficient degree of severity to interfere with social or occupational functioning where memory impairment is a predominant feature. Other cognitive functions (such as attention, learning, information processing, language, reasoning, judgment) are also affected. There is no clouding of consciousness in HAD.

Clinical Manifestations: Affective impairment is usually in the form of apathy, irritability and sometimes manic symptoms. Other common clinical features of late stage HAD are seizures, global cognitive deterioration, mutism, incontinence, and severe confusion.

Clinicians should exclude other treatable, reversible causes of change in mental status such as CNS opportunistic infections and malignancies before any diagnosis of HAD is made.

Diagnostic Tests: A lumbar puncture may be necessary to rule out acute infection, such as bacterial meningitis, TB- meningitis, Cryptococcal meningitis, and toxoplasmosis.

Management:

Continue with or start ART

If there are other causes treat them accordingly

Give haloperidol 1.5mg per day with slow increase in the dosage depending on the response to control agitation and hallucination.

If available, atypical antipsychotic agents such as olanzapine and respiridone can be used starting with low doses.

Involve family members /treatment supporters in the management of the client.

Note:

Avoid benzodiazepines, which tend to increase confusion and decrease concentration.

PIs and NNRTIs induce or inhibit liver enzymes and therefore tend to decrease or increase the levels of Psychotropic drugs.

13.1.3. HIV-Related Mania

Definition and Characteristic Features: AIDS related mania is secondary to HIV CNS involvement. It is characterized by loss of the ability to control mood, and it presents with elated or irritable moods, increased activity and energy regardless of the physical status, decreased need for sleep and an exaggerated sense of self-importance. The condition occurs with more advanced immunosuppression.

Management:

- Continue with ART treatment because it relieves the symptoms of AIDS related mania.
- Sodium valproate is useful for the control of acute symptoms in patients who are on ART
- Carbamazepine and lamotrigine can be used as mood stabilizers.

Note: Carbamazepine induces liver enzymes and increases its own metabolism as well as ART drugs. If possible, avoid in patients on ART.

13.2 Primary Mental Health Complications

In the absence of focal neurological deficits or meningitis, primary mental health complications should be considered when changes in mental status occur. The most common primary mental health complications that can occur at any CD4 level are adjustment disorder, depression, mixed depression and anxiety, and anxiety disorders.

13.2.1 Adjustment Disorder:

This condition occurs predominantly at the time of HIV disease diagnosis. These responses include fear of discrimination and imminent death, guilt over infecting others, exacerbation of existing mental health conditions and acute suicidal ideation. The nature of the adaptation response influences the client's ability to:

- Disclose HIV sero-status to others
- HIV-related self-stigmatization
- Adjustment disorder is a major barrier to sharing test results and hence limiting access to social support.

Management: Supportive medical/clinical counselling is the mainstay of more positive adaptive responses to HIV diagnosis.

13.2.2 Anxiety Disorders

Definition: Patients with HIV infection may have any of the anxiety disorders, but generalized anxiety, post-traumatic stress, and obsessive – compulsive disorders are particularly common. Symptoms of anxiety disorders are both psychological and physical. The physical manifestations include: shortness of breath, chest pain, increase of heart beats, dizziness and gastrointestinal disturbances. These symptoms may overlap with symptoms of other common medical disorders. In addition, the clients present with fear, worry, insomnia, impaired concentration and memory, diminished appetite, compulsive rituals and avoidance of situations that make them anxious.

Management:

- Re-assurance, psychoeducation and supportive counselling are effective when the level of anxiety does not interfere significantly with social or occupational functioning
- Medications can be used when anxiety interferes significantly with sleep or daily functioning. The clients may benefit from low doses of antidepressants like Tricyclic Anti depressant and Selective serotonin re-uptake inhibitors (SSRIs) (e.g. Amitriptyline and fluoxetine respectively) e.g. start with low doses of Amitriptyline 12.5mg daily to alleviate the symptoms
- Short acting benzodiazepines can be used but there is a risk of dependence
- Encourage the client to join psychosocial support groups.

13.2.3. Major Depressive Disorder

This is a mental disorder that affects the mind and the body, presenting with both psychological and physical symptoms. Behavioural changes that may alert a physician about possible depression include: change in treatment adherence, inability to make life/medical care choices, preoccupation with minor problems, change in functioning, social isolation, interpersonal problems, difficult behavior in the medical setting, or initiation/return to substance use.

Diagnostic Challenges

- Misconception that depression in HIV is normal
- Overlapping symptoms such as fatigue, weight loss and insomnia may be due to depression or physical illness, such as HIV
- Chronic pain and chronic physical syndromes co-morbid with mood disorders
- Medication related depression and anxiety
- Substance use (may be associated with depression).

Management:

- Reassurance, psychoeducation and supportive counselling are effective in offering services to clients with depression
- Always initiate treatment with low doses to minimize risk of serious side effects

- Tricyclic antidepressants (TCAs) like amitryptylline (25-75mg per day) and imipramine can be used
- Selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine and fluvoxamine are recommended because they have fewer side effects
- Ensure adequate doses and duration (maintenance drug treatment provided at therapeutic dose for six months after resolution of symptoms), combined with supportive counselling
- Adolescents with depression respond well with SSRIs compared to TCAs
- If depressive symptoms are not resolved within four weeks of initiating drug treatment, refer the client to a mental health facility.

Care should be taken for possible interactions between antidepressants and ARTs as shown in Table 13.1 below:

Table 13:1 Antidepressant dosage and possible ART interactions

Drug groups of antidepressants	Specific drugs registered in Tanzania	Dose range (mg)	Interactions with ARVs
1. Tricyclic Antidepressant	Amitriptyline Imipramine	25mg–75mg per day	Lopinavir/r & ritonavir increase antidepressant levels in serum
2. Selective Serotonin re-uptake inhibitors) Recommended in patients on ART	Fluoxetine Citalopram	10mg–20mg per day 10mg - 40mg per day	Nevirapine decreases level; AD increases levels of Amprenavir, Delavidine, Efavirenz, Indinavir, LPV/r, Ritonavir, Saquinavir

13.3. Loss, Bereavement and Crisis

Definition: Bereavement is defined as the state of perceived loss that often results from knowing that one has HIV. Adjusting to the new status of living with HIV is often very stressful.

Assessing for Loss, Bereavement and Crisis: this involves exploring the losses that the PLHIV have experienced. There are six stages of bereavement. These are: shock, denial, anger, bargaining, depression and acceptance. Among PLHIV the spectrum of loss often begins with the knowledge of their HIV positive diagnosis and consequent loss of their health, certainty, future hopes, relationships, lifestyles, and loss of hopes for children. PLHIV are also more likely to experience the loss of loved ones such as partners and their own children from AIDS defining conditions.

A *crisis* is a situation in which a person is unable to use his/her normal problem solving techniques to resolve a problem. When a crisis occurs it is overwhelming for the individual

both emotionally and cognitively. In case of HIV and AIDS, the triggers that lead to crisis might be death of another PLHIV, emergence of new symptoms, treatment failure or anything that is perceived by the patient as a severe life event.

Management: is through supportive counselling.

CHAPTER 14:

NUTRITION IN HIV AND AIDS

14.0 Introduction

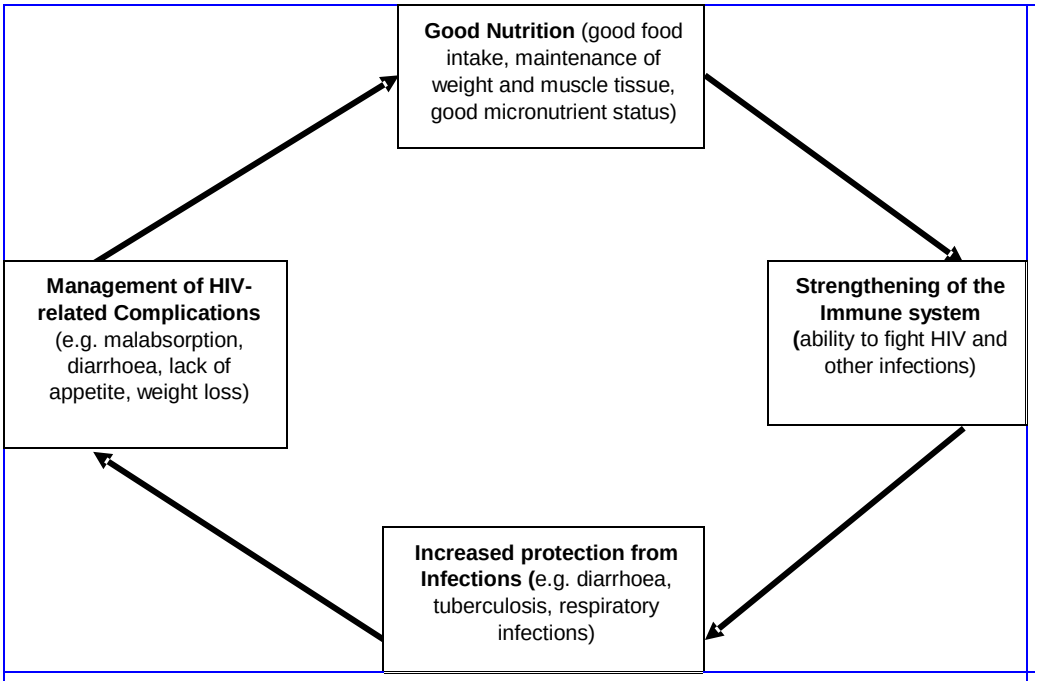
Malnutrition and HIV are related and aggravate one another in a vicious cycle. HIV infection can lead to undernutrition, and malnutrition affects HIV transmission and disease progression. HIV infection impairs the body immune system and thereby increasing vulnerability to infections. Infections lead to increased loss of nutrients which, if not replenished, may lead to malnutrition. Malnutrition, on the other hand leads to immune impairment. Further, when a malnourished person acquires HIV, the progression to AIDS is rapid as the immune system is already too weak to fight off infections. On the contrary, a well-nourished individual has strong immune system which delays the progression of HIV to AIDS. HIV and AIDS have direct and indirect effects on nutrition. The direct effects include reduced food intake, poor absorption of nutrients and increased utilization and loss of nutrients. The indirect effects are those which lead to household food insecurity related to inability to engage in food production activities.

This vicious circle contributes to repeated illnesses, deterioration of the health and eventual death of the infected individual. Timely improvement of nutrition can help strengthen the immune system, prevent weight loss and delay the disease progression.

14.1 Relationship between good nutrition and protection from Infections

Good nutrition enables persons with HIV and AIDS to strengthen their immune system manage HIV-related complications and increase protection to infections. The specific benefits of good nutrition in protection of infections are illustrated in Figure 14:1 below:

Figure 14:1. The Cycle of Good Nutrition and protection from infections in Context of HIV and AIDS



14.1.1 Nutritional consideration at different stages of HIV infection

At different stages of HIV infection, some health problems such as mouth sores (ulcerations), sore throat and diarrhoea, may be experienced. Infections increase the body requirements for energy and may cause deficiency of nutrients and further burdens the already weakened immune system. Table 14.1 below shows Nutrition, Care and Support Priorities by stages.

Table 14.1 Nutritional, care and support priorities by WHO HIV stages

HIV stage	Features	Nutritional Advice
Early Stage (stage 1 & 2 of WHO clinical staging)	Asymptomatic or mild symptoms weight loss under 10% of presumed or measurable body weight	Counsel on healthy diet and healthy lifestyle
Middle Stage (stage 3 of WHO clinical staging)	• Weight loss over 10% of presumed or measurable body weight • Opportunistic infections	• Counsel to minimize consequences • Counsel to maintain dietary intake during illness • Advise increased nutrient intake to recover and gain weight • Counsel on healthy lifestyle • Advise on food safety and hygiene • Advise on nutritional implication of ARV drugs • Provide therapeutic food when severely malnourished
Late stage (stage 4 of WHO clinical staging)	Weight loss Symptomatic	• Advise on treating opportunistic infections • Counsel to modify diet according to symptoms • Counsel on healthy lifestyle • Advise on food safety and hygiene • Advise on nutritional implication of ARV drugs • Provide therapeutic food when severely malnourished

14.2 Healthy eating for People Living with HIV

14.2.1 Recommendations on healthy eating for PLHIV

People living with HIV are encouraged to include foods from different food groups at each meal.

Variety-Recommend choosing different types of food within each food group whenever possible.

Balance - Recommend choosing foods from all food groups according to the recommended amounts.

Moderation – Recommend controlling portion size so that balance and variety are possible. This is essential to avoid over-nutrition or under-nutrition.

The main food groups are:

- Cereals, roots, tubers and bananas: these include maize, millet, rice, sorghum, cassava, yams, potatoes and cooked bananas
- Legumes, nuts and foods of animal origin: these include groundnuts, cashew nuts, beans, peas, meat and products, sea food, milk and products, poultry, eggs and edible insects such as *senene* and *kumbikumbi*
- Fruits: these include all types of fruits commercial and indigenous such as mangoes, oranges, guava, tangerines, bananas, baobab fruit (*ubuyu*), tamarind (*ukwaju), mabungo* etc. They are good sources of vitamins and minerals
- Vegetables: all types i.e. exotic and indigenous vegetables such as sweet potato leaves, pumpkin leaves, tomatoes, amaranth, okra, carrots, pumpkins, (*mlenda*), hare lettuce, (*figiri*), wild spinach (*mnavu*). The foods in this group provide vitamins and minerals.
- Sugar, honey, fats and oils, these are needed in small amounts; they include ghee, lard, butter, margarine, coconut oil, sunflower, sugars like honey etc. Such foods are very rich in energy.

Note:

A balanced meal is therefore defined as a meal which contains all food groups: cereals, green bananas, roots (cassava, *ming'oko*, etc.) and tubers (yams, potatoes, etc.) pulses, animal-source food, fruits, vegetables, sugar, honey, fats and oils. Sugar, honey, fats and oils are among food items which can be added in a meal to improve taste and also provide energy.

Although water is not part of the food groups it is important for life and is necessary every day. Water aids digestion, absorption and transportation of nutrients in the body. It is recommended that a person should drink at least eight glasses (1.5 litres) of water a day.

There is no single food that contains all the nutrients that the body needs, except breast milk for infants up to six months of age. For a balanced meal use at least one type of food from each food group.

14.2.2 Tips for health and nutritious lifestyle for PLHIV

- Eat **variety** of foods emphasized on nutrient-dense foods
- Eat **small** meals frequently (especially for a very sick person)
- Drink clean and safe water
- Be physically active
- Avoid alcohol, avoid smoking
- Add nutrient-dense foods (nuts, oil, fat, milk, oil seeds)
- Use **spices** for appetite and absorption: ginger, garlic, cardamom, lemon
- Germination and sprouting; fermentation (increases nutrient content and improves digestions and absorption)
- Manage stress
- Observe food safety, improve cooking methods and hygiene principles
- Manage specific disease symptoms promptly (e.g., nausea, vomiting, diarrhoea and constipation).

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14.3.1 Energy requirements

The HIV infected person has additional energy needs because of:

- Increased and altered metabolism
- Nutrient malabsorption.

14.3.1.1 HIV asymptomatic children and adults

In the absence of symptoms (WHO Stage 1), HIV-infected persons should increase energy intake by 10% over the level of energy intake recommended for HIV uninfected persons of the same age, sex and physical activity level.

HIV asymptomatic child:

A child should continue with breast feeding and eat a balanced meal.

With exception of fruits, fats/oils and sugar, an additional of 2 tea spoons of margarine/butter/oil should be added to each meal.

For this group, it is recommended that:

- A balanced meal should be eaten three times per day
- In addition, a child should eat any healthy snack (e.g. a cup of milk, a slice of bread with peanut butter) between meals i.e. two times per day.

Note: A child should eat five or more times per day.

HIV asymptomatic Adult

- An adult person should eat a balanced meal.
- With exception of fruits, fats/oils and sugar additional of 2 tea spoons of margarine/butter/oil should be added to each meal. If the prepared food is porridge, add 1 tea spoon of margarine/butter/oil and 1 teaspoon of sugar.

For this group it is recommended that:

- A balanced meal should be eaten three times per day

In addition, a person should eat any of the following healthy snacks:

- 1 mug (250mls) of porridge with milk/sugar
- 2 medium sweet potatoes
- 2–3 large cups (250mls) of boiled full cream milk
- Healthy snacks should be given to a person two times per day (in between meals).

14.3.1.2 HIV symptomatic children and adults

In the presence of symptoms (WHO Stage 2 and above), HIV-infected persons, including those taking ARVs, should increase energy intake by 20-30% over the level of energy intake recommended for HIV uninfected persons of the same age, sex and physical activity level.

HIV symptomatic child:

- A child should continue with breastfeeding and eat a balanced meal.
- With exception of fruits, fats/oils and sugar, an additional of 2 tea spoons of margarine/butter/oil should be added to each meal. If the prepared food is porridge add 1 tea spoon of margarine/butter/oil and 1 teaspoon of sugar.

For this group it is recommended that:

- A balanced meal should be eaten three times per day.

In addition, a child should eat any of the following healthy snacks:

- 1 slice of bread with groundnut paste
- 1 cooked mashed banana added grinded groundnuts/pumpkins seeds
- 1 cup (100mls) of boiled full cream milk and for children aged six months to be given 2–3 tablespoons and for 7–8 months old: to be given 3–4 tablespoons
- Healthy snacks should be given to a child two times per day (in between meals).

Note:

If a child is on exclusive breast-feeding should continue up to six months

Amount of food needed for other age groups (above eight months), further research needs to be done, however it is advised to increase the amount of food according to the age of a child.

HIV symptomatic adult:

- An adult should eat a balanced meal.
- With exception of fruits, fats/oils and sugar an additional of 2 tea spoons of margarine/butter/oil should be added to each meal. If the prepared food is porridge add 1 tea spoon of margarine/butter/oil and 1 teaspoon of sugar.

For this group it is recommended that:

- A balanced meal should be eaten three times per day.

In addition, a person should eat any of the following healthy snacks:

- 2 mugs (500mls) of porridge with milk / 2 teaspoon of sugar
- 4 medium sweet potatoes
- 2-3 large cups (250mls) of boiled full cream milk
- Healthy snacks should be given to a person two times per day (in between meals).

14.2.3 Protein requirements

HIV-infected persons do not require more protein than the level recommended for HIV uninfected persons of the same age, sex and physical activities level.

14.2.4 Micronutrient requirements

HIV infected individuals are encouraged to include a variety of foods in the diet to prevent deficiency. There is an evidence that some micronutrient supplements such as vitamin A, zinc and iron at higher doses may produce adverse outcomes in HIV-infected persons (see also Annex 8,. The Role and Sources of Selected Micronutrients for additional information). Do not give high dose of Vitamin A if the clients with SAM are already receiving F75, F100 or RUTF which already have sufficient Vitamin A. (only give to those who are not provided F75, F100 or RUTF).

People infected with HIV may take several medications, including antibiotics, ARVs, anti-malarial, anti-helminths, anti-fungal, etc. Foods and medications can interact in 4 major ways. These are as shown in Table 14.2 below:

Table 14.2: Relationship between foods and medications

1. FOOD	(Affects)	MEDICATION ABSORPTION, METABOLISM, DISTRIBUTION, EXCRETION
2. MEDICATION	→ (Affects)	NUTRIENT ABSORPTION, METABOLISM, DISTRIBUTION,

		EXCRETION
3. MEDICATION SIDE EFFECTS	(Affects)	FOOD CONSUMPTION, NUTRIENT ABSORPTION
4. MEDICATION + CERTAIN FOODS	⟶ (Creates)	SIDE EFFECTS

14.3.3 Relationship between medication and feeding/dietary patterns

Medications have to be managed correctly in order to ensure that the prescribed drug combination improves drug efficacy, decrease side effects, and does not affect the nutritional status.

Annex 9 lists some of the medications used in Tanzania. The table shows their purposes, potential side effects and nutritional recommendations (more details are in Annex 10).

Proper dietary management can help to manage some side effects. The following are examples:

• Changes in taste: The protease inhibitors such as Ritonavir cause changes in taste and can cause food to taste metallic, sweeter, sourer, or too salty, which, in turn, may cause an individual to consume less food. This can be addressed by using flavour enhancers such as salt, sugar, spices, vinegar, or lemon to stimulate the taste buds, increase taste acuity, and mask any unpleasant flavour. Adding spices like onions to soup will boost flavour and can help to improve intake.

• Anorexia: Several medications, such as Isoniazid and the ARVs lamivudine may cause anorexia and lead to reduced food intake. The dietary management of anorexia requires eating small and frequent meals and favourite foods. PLHIV that experience anorexia should eat five to six small meals a day and should include energy and nutrient-dense foods at each meal to ensure adequate nutrient intake. It is also important to maintain as much physical activity as possible, such as walking in fresh air, which also helps to stimulate appetite.

Some ARVs e.g. Tenofovir have been associated with increased risk of osteoporosis and weakening of bones that may require medical and dietary responses. For osteoporosis, a balanced diet with high calcium foods, such as milk, yoghurt, cheese, and vitamin D supplement, is recommended along with medical care.

Note: Some side effects of ARVs are similar to symptoms of opportunistic infections, such as diarrhoea e.g. Tenofovir, Ritonavir, Lopinavir. Therefore, the health worker must continue to be alert to recognize symptoms of infections and treat these infections appropriately.

14.3.4 Nutritional advice in relation to multiple medications

Patients who are on multiple medications such as HIV and TB require taking many pills on a daily basis, which can make it difficult to maintain food intake. Multiple medications have diverse food-drug implications and side effects that necessitate specific selection of foods and timing of medications Health workers should counsel clients and parents/caregivers on the dietary management.

Table 14.3 Isoniazid: Relationship of food and side effects

Medication	Dietary interactions and the Medication Side Effects	Dietary advise
Isoniazid TB treatment	Food reduces absorption of Isoniazid	Do not take Isoniazid with food. Take one hour before or two hours after meals
	May affect vitamin B6 Metabolism	Daily consumption of food sources of vitamin B6 such as white beans, maize avocado, meat, and fish, or vitamin B6 (25 to 50mg daily) supplementation is recommended
	Increased risk of hepatitis when combined with alcohol	Avoid alcohol
	Anorexia (i.e. loss of appetite)	Eat small and frequent meals. Eat favourite foods
	Diarrhoea	Drink plenty of fluids and eat energy- and nutrient rich foods. Avoid fried foods.

14.4 Monitoring of nutritional status

Monitoring of nutritional status is an important aspect of nutritional care and support for PLHIV. This includes a comprehensive assessment by medical, psychosocial, dietary, review of patient file for biochemical results and anthropometry.

Medical history

Many diseases such as malaria or tuberculosis can affect an individual's nutritional status; hence, it is important to find out the past and present health status of the patient. It is also important to evaluate interactions between food and medications, as medications may interfere with nutrient absorption or increase the excretion of nutrients. Vitamin, mineral, and herbal supplementation can also affect nutritional balance.

Medical history should also be used to detect signs and symptoms associated with malnutrition including diet related opportunistic infections. The physical appearance of the hair, skin, and nails can assist in identifying nutritional deficiencies. For example, spoon-shaped, pale, and brittle fingernails may indicate iron deficiency. Opportunistic infections such as oral thrush or sore throat can affect a person's ability to eat and increase risk of

complications, such as wasting or weight loss. A person's weight history, such as rapid weight loss, can be an indicator of a nutritional problem.

PLHIV who are on ART need appropriate and adequate nutrition to achieve the full benefits of ART. Dietary intake should be modified to manage symptoms, by making the meal soft, mincing, boiling and use of herbs.

Psychosocial history

A psychosocial assessment includes reviewing a person's economic status, cultural background, living situation, education level, occupation, mental status, and access to adequate food sources to maintain good health. Each of these components plays a role in determining a person's ability to follow through on specific dietary plans.

Dietary history

A dietary history includes an assessment of a person's usual dietary intake. This can be done using a twenty-four-hour recall of food eaten. Reviewing food preparation methods is helpful in determining the amount of salt and oil/fat which when taken in excess is harmful to health. The frequency of meals eaten out is an important indicator of whether a person has access to cooking, or just prefers to eat out instead of cooking. These factors play a role in determining the details of a dietary counselling plan.

Biochemical assessment

Biochemical assessment of nutritional status is done in the laboratory where nutrient deficiencies are detected. Where available test for blood protein (e.g. Serum albumin), micronutrients (e.g. iron) and Lipid (e.g. Cholesterol), can be used to monitor nutritional status of PLHIV. Hemoglobin level is one of the indicators used to monitor anemia.

Anthropometry assessment

Anthropometry assessment includes recording of age, sex and anthropometric measurements (Mid Upper Arm Circumference, height, weight).

Patients who have a weight and height measured are plotted on a growth curve and designated low/high weight for height Z score (for children) or BMI Z score (older children), or BMI (adults). MUAC tapes are also used.

One can monitor weight loss by using body mass index (BMI) calculated as = Weight (kg) divided by height (m^2). A normal BMI is 18.5 – 24.9kg/m^2. A BMI <18.5 denotes underweight; that between 25.0 and 29.9kg/m^2 is overweight, and >30.0kg/m^2 is obesity. For patients with BMI <18.5 nutritional education is required and food supplementation to be recommended if any.

It should be noted though that even without using BMI, unintended weight loss of between 6-7kg in one month is not a good sign. Therefore, the weight of PLHIV needs to be closely monitored to ensure they do not lose a lot of weight due to disease progression and that appropriate nutritional intervention is made and in a timely manner.

14.5 Therapeutic foods for management of Acute Malnutrition

After the assessment of nutritional status, children below five years of age who will be categorized as severely malnourished, and have no medical complication (i.e. no other disease), will be given nutrition education and supplied with Ready to Use Therapeutic Food (RUTF) e.g. Plumpy nuts. Those with medical complications should not be given RUTF; instead they should be referred for in-patient treatment. Children under-five who are severely malnourished with acute or persistent diarrhoea in the rehabilitation phase, can be given or continue with RUTF both for in-patient or out-patient treatment. Severely malnourished children aged above five years and adult can be given RUTF if they are not severely sick and those who are severely sick should be referred for in-patient treatment. Moderately malnourished clients who have no medical complication will be given dietary counselling and those who have severe medical complications should be referred for further management.

For Prescription criteria refer national guidelines for management of acute malnutrition.

Table 14.4 Indicators for acute malnutrition

Group Category	Moderate	Severe
Children 6-59 months old	MUAC: 11.5cm to <12.5cm W/H -3 SD to <-2 SD ~~W/H -3 Z-scores to <-2~~	MUAC: <11.5cm W/H < -3 SD
Children 5 - 9 years	W/H -3 SD to <-2 SD	MUAC < 13.5cm W/H <-3 SD
Children 10 - 14 years	MUAC 16cm to <18.5cm W/H -3 SD to <-2 SD	MUAC <16.0cm W/H <-3 SD
Adolescents (15 years and above) and adults	MUAC 18.5cm to 22.0cm BMI 16 to <18.5	MUAC <18.5cm BMI <16.0
Pregnant women and women within the period of six months after delivery	MUAC: 19cm to <23.0cm	MUAC <19.0cm

Note:

- BMI is not used to assess nutritional status of pregnant women and women within the period of six months after delivery.
- Visual assessment is not recommended as the primary method for screening or nutritional assessment.

- MUAC is recommended as the primary method for screening or nutritional assessment for pregnant women
- Consideration for PLHIV with normal nutritional status; overweight or obese e.g. recommendations for reducing intake of sweetened foods and drinks, and increase regular physical activities.

CHAPTER 15:

COMMUNITY BASED HIV AND AIDS SERVICES

15.0 Introduction

This chapter describes Community Based HIV and AIDS services which is part of the comprehensive continuum of HIV care services. In this chapter, the role of CBHS providers in providing prevention, care, treatment and support is explained in relation to the facility based services. The chapter identifies and describes needs of people suffering from chronic illnesses and their family members, including those taking lifelong medications such as ARV drugs.

15.1 The Overall Goal, Objectives and Scope of Community Based Health Services

15.1.1 Goal:

People living with HIV in all councils have access to quality comprehensive Community Based HIV Services integrated with other services.

The objectives of the CBHS services are to:

- Intensify early identification of HIV positive clients and their index clients
- Promptly link HIV positive clients to care and treatment clinics
- Facilitate effective community and facility referral and linkages as well as other services such as psychosocial, legal, spiritual, food and nutrition support
- Track the clients who have missed appointments as well as Lost to follow up
- Support ART adherence and retention
- Participate and facilitate effective implementation of ART outreach refilling option for stable clients coming from hard to reach areas.

15.1.2 Scope of CBHS

PLHIV and their affected families and households have a variety of needs beyond mere clinical needs. Such needs include psychological, spiritual, nutritional, educational, economic and legal care and support. It is the CBHS that cater for these needs of PLHIV and the surrounding community.

In Tanzania, CBHS was formally introduced by the MoHCDGEC formerly known as MoHSW as Home Based Care Services, mainly for bedridden patients. Due to the advancement in the management of HIV and AIDS, the scope of HBC changed significantly, from taking care of bedridden clients to ambulatory

CBHS ensures the continuity of care provided to the PLHIV clients at the health facility through the continuum of care. This is a set of comprehensive and linked care, treatment, and support services provided at all levels: from health facility to community to home. Services are provided by the government, NGOs, Community-Based Organizations (CBOs), Faith-Based Organizations (FBOs), community members and by PLHIV and their family members. Furthermore, Care and support programmes are developed as a response to these

psychological, social, nutritional, economic, legal, clinical, and nursing-care needs and demands.

15.1.3 Target group

Community Based HIV and AIDS services target all HIV positive clients including HIV positive adults, paediatrics, exposed children, pregnant women, People Who Inject drugs (PWIDs), Sex Workers (SWs) as primary target groups and chronically ill clients as secondary target groups.

15.1.4 4 Community Based HIV Services Provider (CBHSP)

For many years, Community Based HIV Services Providers have been given different names by different HIV implementers, these included: Home Based Care (HBC) Providers, Peer Educators, Liaison Person, Client Tracking Person, Volunteers Community Based Distributor (CBD), etc. In addition to these, different community based HIV services providers were assigned different roles and responsibilities which in one way or another caused confusion and sometimes even conflicts among themselves.

This guideline recognizes the contribution of community members supporting HIV and AIDS services at community as well as at health facility, and sets standard for harmonized provision of Community Based HIV Services both at facility and in the community. In this regard, all providers volunteering to HIV and AIDS services are known as Community Based HIV and AIDS Services Providers. Also, currently, a new cadre has been introduced by the Ministry that will be providing all health services including HIV services at community level. This person who is permanently employed will be known as Community Health Worker. The Community Health Worker will work hand in hand with Community Based HIV and AIDS Service providers to achieve the goals set by the National Health Sector HIV and AIDS Strategic Plan.

15.1.5 Selection criteria

Community Based HIV and AIDS providers work under difficult conditions and for long hours, and they have access to sensitive and confidential information while performing their duties. This brings them to be selected using the following criteria:

- A community member with sound integrity who can maintain confidentiality
- He/she should know how to read and write
- Based in the communities they are going to serve
- Accepted and trusted by community members
- Capable of building good interpersonal relationships
- Interested in caring for sick people
- Willing to volunteer
- Reliable
- Possess coping skills.

Community Health Workers (CHW) will be selected according to NACTE endorsed criteria.

15.1.6 Training

All CBHS Providers are trained using the CBHS training curriculum, developed by the MoHCDGEC through the NACP, while CHW are trained for one year using the curriculum developed by NACTE.

15.2 Roles and responsibilities of CBHS Providers

Following the evolution of clinical management of HIV infection, CBHS providers have added up new roles and responsibilities so as to ensure continuity in quality ART service provision. New roles of CBHS providers include the following:

- to provide health education to all pregnant women with HIV infection
- to provide adherence counselling of ART to HIV positive pregnant women and adults who are enrolled in care and treatment/PMTCT
- to initiate and facilitate HIV Post Test Clubs/Support groups at the community and supporting them to have leadership, group constitution and registration
- to identify and refer all pregnant women to RCH clinics, or Health facilities at their catchment areas and then make follow-up
- to identify and refer all key and vulnerable population (e.g. PWIDs, and sex workers) to heath facilities for further management
- To track and refer back to PMTCT/RCH/Health facilities of the catchment areas all mothers who have delivered and have not come back for DBS results of their children
- To track all loss to follow up clients (adults and children) who were on care and treatment.

CBHS providers shall provide patients with the following services, including those listed above:

- Nursing care
- Feeding
- Nutritional care and support (education, counselling, nutritional assessments, and attention to household food security)
- Alleviation of pain and other distressing symptoms
- Spiritual and emotional support
- Prevention of OIs
- Detection of complications and danger signs
- Linkages to healthcare facilities and other relevant services in the community
- Support for adherence to medication and clinic visit schedules
- Facilitate provision of financial and technical support for post-test clubs to engage in income generating activities
- Provide education on use of contraceptives, condoms, disclosure, GBV, TB and STIs

15.3 Contribution of CBHS in Care and Treatment services

The establishment of Community Based HIV and AIDS Services programmes by the MoHCDGEC is among the Ministry's strategies to compliment the initiatives of the government to combat HIV and AIDS. The following are the key areas that the CBHS are contributing in the HIV care and treatment services:

Early case identification and enrolment

The ultimate purpose of care and treatment programme in the context of 'Treat All' is to make sure that all HIV positive clients are enrolled into care and, are started on ART within two weeks. In order to achieve that, CBHS providers should:

- Identify and link clients to HIV testing services
- Identify and enrol KVPs to nearby KVP services and peer groups
- Provide pre-test information to the clients to facilitate HIV counselling and testing at home by the trained counsellors
- Enrol clients on ART and ensure that they regularly attend their clinics and support group meetings
- Ensure that all pregnant women, mothers and their exposed children return to the health facility for follow up. After enrolment to CBHS, the CBHS provider will ensure that the clients reach their first referral point (CTC/PMTCT/Paediatric HIV Clinics/TB Clinics, HIV post-test clubs).
- Facilitate referral services to care and treatment clinics for those who test positive in the community
- Retention of clients into care and treatment services.

ART is a lifelong treatment, and its success depends very much on how the clients adhere to the prescribed treatment regimen. For a patient to get the desired treatment results, they need to continue with ART throughout their lives. Achieving such results is a challenge; therefore, different approaches to improving adherence were established by the MoHCDGEC. These require the CBHS provider to:

- conduct community visits to provide adherence counselling and health education to the clients who are on treatment to stay on treatment.
- utilize CTC Desk for tracing miss appointment, Lost to follow, referral and linkages
- assist the client in choosing a primary care giver who is his/her relative to help by reminding or assisting him/her in taking medication.
- link HIV positive clients and those who are already on treatment to PLHIV support groups. This is a platform for PLHIV peer education, psychosocial support, and economic strengthening through income generating activities. Through these groups, the newly diagnosed clients will get experience and testimonies from other clients who are on treatment for a long time hence help them with adherence and acceptance of HIV status which will eventually help them in status disclosure.
- help adolescents in engagement to care and treatment. Also, to increase the level of retention among clients already on ART, to care and treatment clinic
- track Loss to follow up clients from CTC/PMTCT and TB clinics.

CBHS has a very important role to play in ensuring that clients who are loss to follow up are tracked back to the health facility. After identification of missed appointments and loss to follow up clients from appointment register by the health facilities, CBHS providers of the catchment areas should therefore:

- collect list of clients who have missed their appointments as well as lost to follow up
- follow up clients by phone calls or by physically visiting their households
- provide report/feedback through the recommended system.

In tracking loss to follow up clients, CBHS have increased efforts to those HIV positive mothers who have delivered and have not returned back with their children for DBS results of their children.

Referral and networking

CBHS services are part and parcel of the continuum of care and the provision of support at different levels. An effective continuum of care requires that a functional network and referral system are in place to improve access to appropriate services for all PLHIVs and chronically ill patients at all times. Through an effective and functioning referral system, these patients will continue to receive relevant services within their respective communities and homes after being discharged from healthcare facilities, and they can revert back to facility care as and when needed.

In order to strengthen this system, service providers will ensure that the national CBHS referral forms are used in all referrals. The CBHS provider should:

- fill in and issue a referral form to the client
- ensure that the feedback portion is completed in and returned to the referral provider
- refer the CBHS clients depending on what their needs are and what is available to them in their communities by way of spiritual, legal, income, nutrition and food, and socioeconomic support
- develop and regularly update the referral services directory within their location.

CHAPTER 16

SUPPLY CHAIN MANAGEMENT AND RATIONAL USE OF HIV AND AIDS COMMODITIES

16.0 Introduction

A comprehensive HIV and AIDS programme requires a wide range of commodities supporting a range of interventions that encompass prevention, care and treatment. Supply chain management of HIV and AIDS commodities is critical to support the national policy and to ensure adequate and continuous availability of quality and affordable essential medicines, diagnostics and other consumables at service delivery sites in the right quantities, at lowest possible cost and in timely manner. These commodities are relatively expensive and therefore they require proper handling to ensure effective use.

Since all people living with HIV will be initiated on ART, resources and strong Procurement and Supply Management (PSM) should be available at all levels of health system. Procurement and ART programme managers need to work together to ensure that the national supply system is functioning properly i.e. forecasting, procuring and distributing the quantities of ARV drug and other health commodities required to meet the increasing national demand and the 90–90–90 target.

The key components of procurement and supply management cycle include: (i) product selection (ii) forecasting and supply planning (iii) procurement (iv) storage and distribution (v) Logistics Management Information System (LMIS) (vi) Use or serving customers (vii) Quality monitoring, and (viii) Policy. Management support is integral to each component. It includes a variety of activities at all levels of the healthcare delivery system from the national programme level down to where medicines are dispensed and diagnostics are used. The main activities include managing the information system (LMIS), ensuring timely information flow between stakeholders at different levels and securing financial and other resources for procurement, storage and distribution of medicines and diagnostics needed for the programme.

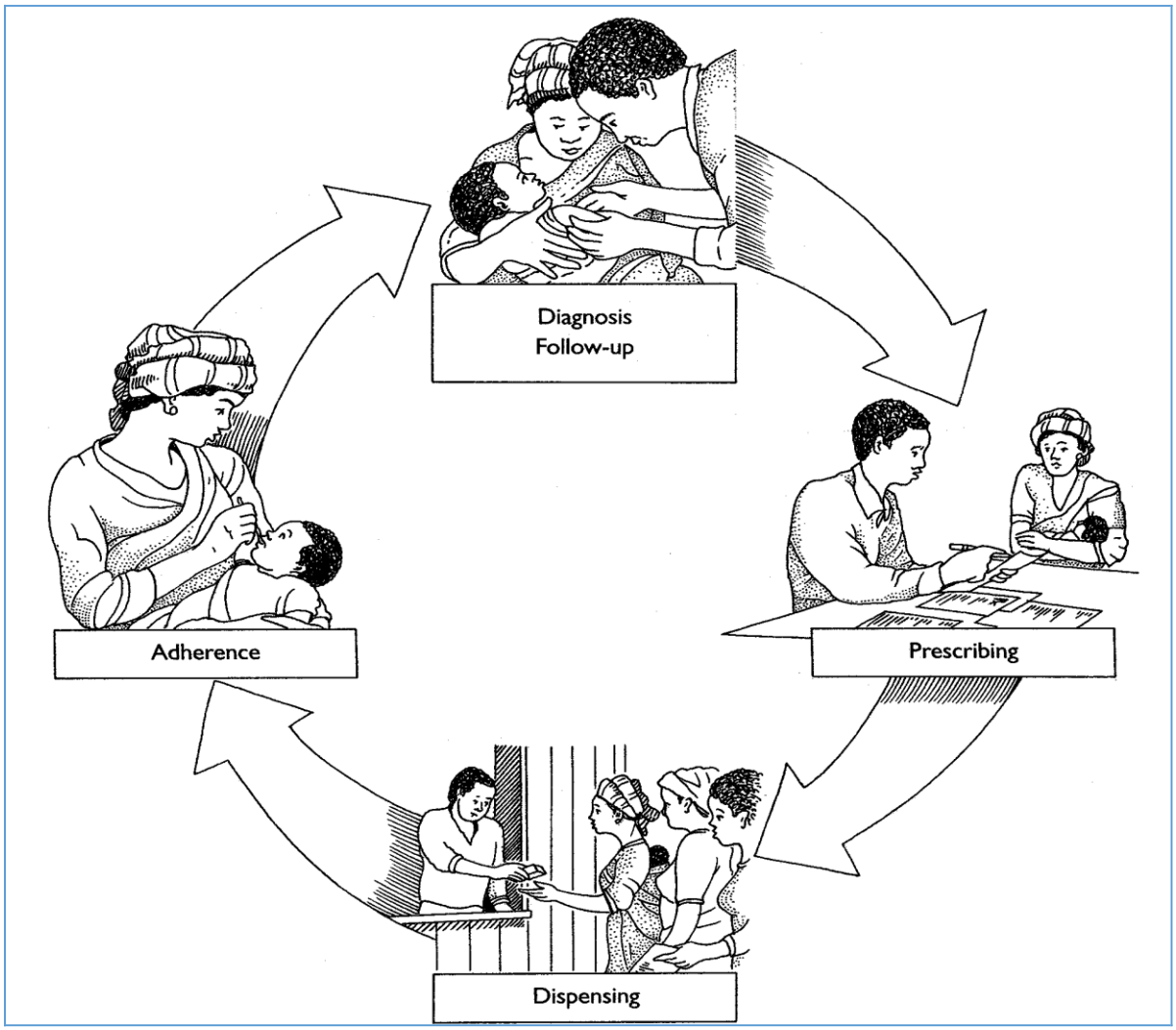
16.1 Rational Use of Medicines (RUM)

Rational use of medicines requires medications to be appropriate to the patient's clinical needs, doses meet the patient's own individual requirements, and medications are given for an adequate period of time and at the lowest cost to the patient and his or her community.

ART is a complex undertaking that involves a large variety and quantity of drugs. It is a lifelong treatment that is in constant development. It is therefore very important to use medicines rationally since irrational medicine use (especially in the context of ART) may have unwanted consequences at both the individual and the population levels. These may include:

- Treatment failure
- Rapid development of drug resistance
- An increase in the risk of toxicity
- Increase cost for treatment due to the need to use expensive medication after failure of first line regimen
- Spread of new HIV infection.

Figure16. 1. Medicine Use Process



Aspects of Irrational Use of Medicines

Diagnosis:

- Inadequate examination of a patient
- Incomplete communication between a patient and the doctor
- Lack of documented medical history
- Inadequate laboratory Resources.

Prescribing:

Irrational prescribing is observed when there is:

- Incorrect prescribing
- Diagnosis is inadequate

- Inappropriate medicines are prescribed
- Under prescribing
- Needed medications are not prescribed
- Dosage is inadequate
- Inadequate duration of treatment
- Over prescribing
- Prescribing inappropriate length of course
- Prescribing very high dose
- Extravagant prescribing
- Prescribing a more expensive branded medicines when there is a less expensive generic medicines
- Treating symptoms instead of treating the disease
- Multiple prescribing
- Two or more medications are prescribed when fewer would achieve the same effect.

Dispensing:

Incorrect interpretation of the prescription

- The dispenser does not pick up errors or the dispenser sees the error but does nothing about it
- Incorrect calculation of dosage
- Retrieval of wrong medicines
- Inaccurate counting
- Inadequate labelling
- Unsanitary procedures
- Inability to effectively communicate with patients on how to use the prescribed medicines and adherence to dose schedules.

Patient aspects of Irrational Use of Medicines

This occurs when:

- The patient demands prescription of more medicines than required
- Not following given instructions
- Sharing medicines with others
- Medicine misinformation
- Lack of patient readiness
- There is stigma
- Conflict between cultural values and therapy
- Misleading beliefs about HIV and AIDS
- Patients' misunderstandings about the medicines and their uses
- Patient concerns about side effects and ADRs.

16.1.1 Prescriptions

Only trained and authorized prescribers in certified healthcare facilities are allowed to prescribe ARVs. The prescription for ARVs should clearly indicate the name/Patient ID No., age, sex of the patient, body weight, medicines, dosage, and should include the name, signature and prescriber's code (where applicable).

16.1.2 Dispensing

Antiretroviral drugs are prescription-only medicines. They should only be dispensed to treatment-ready patients with clear instructions and advice. The dispenser should ensure that the prescription is appropriately written and signed by an authorized prescriber before dispensing. ARVs should only be given to the named patient or appointed adherence assistant. Adequate time should be scheduled for antiretroviral dispensing and counselling.

The pharmacist/dispenser should make sure that the patient understands the dosage and drug intake schedule as well as instructions regarding the storage and food requirements. The pharmacist/dispenser should also caution patients about possible side effects and drug-drug interactions and respond to specific questions and problems related to ARV treatment encountered by patients. It is also imperative for the dispenser to advice patients on measures to be taken to reduce the side effects, including immediate return to the clinic when they experience unwanted effects.

16.1.3 Patient Identification Cards

Each patient must be issued with a patient identification card (CTC1) for tracking the type of regimens given and scheduling next appointment visits for refill. Patients (o*r appointed adherence assistants where patients cannot collect the medication themselves*) must present the cards to the dispenser every time they collect medicines and all medications received must be recorded on the card.

16.2 Supply Chain Management

16.2.1 Serving the customers

The ultimate purpose of public health supply chain systems is to serve the customers with appropriate commodities at the right quantity, time, place and cost. In the context of HIV and AIDS programmes, this purpose means ensuring an uninterrupted supply of HIV and AIDS commodities to all people living with HIV and AIDS (PLHIV) whenever they need them. The ARVs need to be available all the time at service delivery points (Health facilities) for resupplying patients. This is because more than 95 percent adherence to ART is required for treatment regimens to be effective over the long term. Thus to implement and maintain a supply chain that is focused on the ultimate customer, the MOHCDGEC through NACP has designed supply chain systems and procedures and prioritize interventions around the concept of uninterrupted availability of the ARV drugs.

16.2.2 Selection of Pharmaceuticals and Diagnostics

The World Health Organization (WHO) has developed and updated guidelines for Scaling up Antiretroviral Therapy in Resource-Limited Settings. The treatment Guidelines for a Public Health Approach act as guidance for countries to facilitate the proper management and scale up of antiretroviral therapy (ART). The public health approach is geared towards universal access, standardization, and simplification of antiretroviral (ARV) drug regimens to support the

implementation of treatment programmes in resource-limited settings and to ensure that treatment programmes are using ARV drugs based on scientific evidence. The goal is to avoid the use of substandard treatment protocols and to reduce the potential for the emergence of drug-resistant virus strains.

The MOHCDGEC through NACP has updated the national ART guideline and medicine lists to include newly recommended ARV drug regimens and formulations and diagnostics that are appropriate to our settings. The process included extensive discussions during the clinical subcommittee meeting before quantification and in the workshops to review the guidelines. For example, the detailed national ART guidelines provide recommendations for managing toxicity or treatment failure and recommended formulations for weight and age that can help to standardize prescribing and dispensing practices and facilitate forecasting for ARV drugs.

Selection of ARV drugs, regimens, formulations and packaging will affect procurement, forecasting, and distribution, and these relevant supply chain issues should be considered in the process of selecting ARV drugs. Standard Treatment Guidelines (STGs) for ART should provide clear criteria for first, second, and third-line regimens, for the management of patients experiencing toxicity or failing treatment, and for the treatment of specific subgroups, such as patients with tuberculosis, pregnant women, children, and health workers who require post-exposure prophylaxis.

16.2.4 Forecasting and Supply planning (Quantification)

Programme managers must prepare medium term forecasts to be able to coordinate funding and procurement among the Government of Tanzania and multiple donors and to ensure uninterrupted supplies of HIV and AIDS commodities. Medium-term forecasts, which normally cover two years period can be prepared using Morbidity data (targeted numbers of patients identified for treatment in national strategies over a specific period of time or by using most current numbers of patients or number of new patients being initiated on treatment). These can then be combined with informed assumptions from key stakeholders and implementers.

The forecasts and procurement plans will need to be revised frequently with accordance to SOPs (after every six months) to allow for adjustments in the supply plan as experience with acceptability, tolerability, and efficacy of ART is gained and as supply chain and services data are more available. This will enable programmes to rapidly keep up with changing demands and requirements for ARVs.

16.2.5 Procurement

A uniform and harmonized procurement system is required to efficiently procure quality assured, affordable HIV and AIDS commodities (ARV drugs diagnostics and Lab consumables). Procurement should be based on selection of appropriate products and forecasted needs, considering consumption, expanding services, phasing in and phasing out of formulations and implementing new WHO recommendations.

The procurement of HIV and AIDS commodities will be done by the Medical Stores Department, which is also responsible for storage and distribution of the commodities to all health facilities across the country.

Transparent procedures should be adopted to achieve best-value procurement and a quality assurance system implemented to procure, store and distribute high-quality HIV and AIDS commodities.

Procurement systems should:

- Procure the most effective, heat-stable, fixed-dose quality-assured ARV drug formulations in the right quantities at the lowest possible cost and in a timely manner
- Request that the partners supporting the national HIV programme consolidate and harmonize ARV drugs and diagnostics procurement and supply management systems and pool demands for ARV drugs and diagnostics, exploring options for pooling under a common tender system
- Use a publicly accessible database to facilitate access to information about prices and support competition
- Follow the principles described in the United Nations interagency guidelines for donated drugs.

16.2.6 Inventory Management

16.2.6.1 Ordering and Receiving HIV and AIDS commodities

HIV and AIDS commodities and related supplies should be ordered to MSD on quarterly basis through electronic Logistics Management Information System (eLMIS)

- Obtain stock on hand data from actual quantities of available commodities after conducting physical inventory at the end of the month and quarter
- Obtain consumption and usage data from dispensing register/pharmacy database and national HIV/Log book, respectively
- Prepare order by filling quarterly report and request forms (R & R's) for ARVs, Lab commodities and related supplies by 5th day of the ordering month of the next quarter according to the ordering schedule (ABC groups) and then enter the logistics data in the eLMIS
- Electronic reports and orders should be submitted electronically to MSD after being endorsed and approved by the Hospital In charge and DMOs, respectively.

Health Facilities with CTC and PMTCT services:

- PMTCT will collect ARVs and RTK's from CTC and Lab, respectively
- PMTCT will submit Monthly ARV consumption report (completed form A3) to CTC for refilling ARVs
- PMTCT will also submit Monthly Summary Report Form for HIV tests Kits to Laboratory for refill RTKs.
- Stand-alone PMTCT sites will follow ILS to order PMTCT commodities along with essential medicines from MSD.
- Ordering of other commodities (RTK's, Laboratory supplies, contraceptives, etc.) will follow the same system (ILS).

MSD will review orders, process and deliver the medicines and related supplies direct (DD) to the health facility

Upon receiving of HIV and AIDS commodities at the facility, the receiving officer will ensure that the following particulars of commodities and related supplies on the delivery note and invoice match with the delivered items in the following areas:

- Strength and dosage form
- Pack size(s)
- Batch numbers
- Expiry dates (remaining shelf life should at least be 8 months)
- Specifications
- Quantities delivered
- Condition of the commodities (not damaged).

After ensuring that all the areas are satisfactory, the receiving officer should sign, stamp and date the Invoice and Delivery Note. If not satisfied with any of the above, the officer should not receive or accept the item(s) that are in dispute; but sign against each disputed item(s) on the Delivery Note and write "*item not accepted*" and immediately record all discrepancies on the *verification and Claims form (Form 7)*. The completed form number 7 should be submitted accordingly i.e. to the supplier and copied to the facility for records.

16.2.6.2 Storage and Distribution

Facilities should have adequate storage space with conducive storage conditions, trained personnel, and the logistics tools (store's ledger-paper based/electronic system) to manage supplies effectively. Stock must be kept in a high security storage area with single Pharmacist / Pharmaceutical technician / Laboratory personnel (at any one time) responsible for receipts and issues. Commodities must be stored according to the first-to-expire first-out (FEFO) procedure of stock management. Accurate inventory records should be maintained and a system created to track products that enter and leave the supply system along with a running balance and ledgers maintained for each item.

At the end of each month, physical inventory shall be conducted and the available stock shall be checked against the stock records. The information from the physical inventory report must be entered into the store Ledger/bin cards-paper based and/or electronic system. Stocks that have short shelf life that cannot be used before their expiry dates shall be redistributed accordingly to facilities in need using a redistribution form.

Damaged and expired commodities should be immediately separated from usable ones in the inventory, recorded on suspensory ledger and disposed using the laid out procedures.

16.2.6.3 Assessing Stock status

Adequate stock levels of Max-Min of 6/3 (For ordering site) and 2/1 (For non-ordering site) Months of stock for each item for all required commodities shall be maintained at all times. If the stock level for a particular item is falling below the emergency order point (1.5 months of stock for ordering sites and two weeks stock level for non-ordering sites), an emergency order

shall be made to bring the stock to maximum level even if it is before the end of the review period (end of quarter or month for ordering and non-ordering sites, respectively).

HCP's should determine on monthly basis, the number of months (Months of Stock) HIV commodities will last based on present consumption/usage rate. The formula below should be used to determine Months of Stocks (MoS).

Months of Stocks (MoS) = Stock on Hand (SoH) ÷ Average Monthly Consumption (AMC).

The result of this calculation (Months of Stock-MoS) will guide HCP's to make decisions based on the standardized national stock levels as mentioned above.

16.2.6.4. Record keeping

In order to facilitate efficient administration and management of HIV commodities, all information regarding ARVs and OI medicine dispensed should be recorded in a dedicated register book (dispensing registers/ or in the pharmacy database) and ART patient card (CTC1).

All information regarding usage of RTK's and other Laboratory diagnostics should be recorded on National HIV Log book and Laboratory register, respectively.

At the store, all HIV commodity transactions should be recorded in the paper based store ledger and/or in the Pharmacy Module database.

Close monitoring of the consumption/usage data and stock levels of HIV and AIDS commodities is important for supplying the correct quantity and quality medicines, for responding to changes in demand, for managing increased volumes of commodities, and for minimizing pilferage and misuse.

Reports on HIV and AIDS commodities consumption and stocks should be kept and tracked by health facilities. Health facilities should use this information's to forecast and quantify their needs. On quarterly basis, these reports should be sent to MSD through the DMOs for programme decision making.

16.3. Logistics Management Information System (LMIS)

Logistics management information system (LMIS) collects processes and reports the supply chain information. A well-functioning LMIS provides decision makers throughout a supply chain with accurate, timely, and appropriate logistics data. The LMIS can be manual (paper based), or electronic (pharmacy data base). There are three essential LMIS data which are:

- Stock on Hand
- Losses and adjustment
- Consumption data

16.3.1. Logistics management tools used in HIV and AIDS commodities Logistics system

The tools are used for recording information about supplies in storage, reporting & requesting (R & R) commodities, issuing and receiving commodities. These tools include:

- Store's Ledger (and suspensory ledger for expired commodities)
- Form A1: ARV Daily Dispensing register
- National HIV Log book
- Laboratory register
- Reporting and Requesting (R & R) forms: Form A3 (Monthly) and Form A2 (Quarterly)
- Monthly summary report form for HIV test Kits
- Requisition and issue voucher
- Form 4: MSD sales invoice
- Form 6: Goods Received Note
- Form 7: Claim and Verification for Redistribution form.

Health facilities should ensure these tools are available and properly completed in timely manner.

16.4. Supply Chain Monitoring

Monitoring and evaluation is a cross-cutting function that is needed for all programmes and functions to ensure commodity security. National programmes and their constituent functions must be capable of measuring progress and outcomes if they are to ensure that targets are being met and to determine the corrective actions to be taken.

M & E of logistics activities should be done regularly to assess progress, identify and solve problems. This will ensure:

- Availability of commodities and quality of service provided to patients
- Planned logistics activities are carried out according to the schedule
- Proper record keeping, Logistics data collection, analysis, reporting in timely manner for decision-making and hence a way foward plan.
- Supply chain monitoring should be done regularly through supportive supervision and On the Job Training (OJT). Logistics Mentoring then follows to Health Facilities observed with problems in some areas of logistics activities.

Monitoring of supply chain management will also be done through the effective use of early warning indicators for monitoring and evaluations of procurement and supply management systems to prevent stock-outs and overstocks leading to expiry.

R/CHMT, LMU, MSD, NACP in collaboration with IP's should conduct quarterly review meeting supply chain management.

Procurement, storage, distribution and dispensing procedures and records, and stock on hand will be subject to internal and external audit. Given the cost and complexities of handling ARVs, frequent auditing is anticipated.

16.5. Pharmacovigilance

WHO defines *pharmacovigilance* (PV) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. Monitoring and reporting of adverse drug events should be done according to the Tanzania Food and Drug Authority (TFDA) guidelines. Adverse drug reactions reporting forms (yellow forms) will be distributed to facilities that have been certified to deliver ART. It is important for the health facilities to record the adverse drug reactions and report the information to TFDA. Reporting will be done through yellow forms/ or electronic reporting system by using smartphones or ADR Report Tool)

Furthermore, facilities are encouraged to use the information to monitor patients and switch regimens where necessary e.g. Patients experiencing drug induced nephrotoxicity should be switched to ABC based regimens and those experiencing DTG induced severe Hepatotoxicity should be switched to PIs (Refer to the diagram on Chapter 10).

In case the client became pregnant while on DTG based regimen and booked for antenatal clinic past the first trimester, the healthcare provider should maintain the client with high dose folic acid (5mg), also check the alpha fetal protein where available and at 20 weeks the client should do abdominal ultrasound and continue monitoring pregnancy outcome during pregnancy (miscarriage, intra uterine fetal demise) and after delivery (malformation –neural defect). Healthcare provider should document all this information during follow up of such kind of client using TFDA yellow form and also follow surveillance protocol.

16.6. Collaborating with Clinical Staff

The Pharmacist shall work closely with the clinical staff to ensure appropriate prescribing especially on dosage and appropriate ARV combinations (ARV regimens). Good collaboration will ensure correct estimates of the number of new patients to be initiated treatment for proper ordering of their medicines.

The Pharmacist and the Laboratory technologist/any HCWs dealing with supply chain issues within the health facility also needs to keep clinical staff informed of the current stock levels of ARVs, diagnostics and Laboratory consumables particularly of items nearing stock-out and those in excess and at risk of expiry.

In the event of nationwide supply shortage, Pharmacist/ Laboratory technologist/HCP dealing with supply chain within the facility should communicate this information to the clinical staff so that they can pursue the best course of action.

In addition to logistics related collaborative activities, the Pharmacist is expected to keep abreast of new information and changes in ARV regimens and act as a resource to clinicians and other healthcare workers in advising on possible drug related side effects, changes in formulations or regimens and informing clinicians on available formulations and drug combinations (ARV regimens).

CHAPTER 17

MONITORING AND EVALUATION

17.0 Introduction

Monitoring is a routine tracking of HIV and AIDS programme interventions through collecting, analysing, and reporting of data to assess progress against set plans. Monitoring aims at establishing trends, patterns, adaptation of strategies and inform decisions for programme management.

Evaluation is an assessment of an ongoing or completed project, programme or policy, its design, implementation and results. The aim of evaluating HIV and AIDS programme is to determine the relevance and fulfilment of objectives, developmental efficiency, effectiveness, impact and sustainability.

Indicators and targets have to be f formulated and targets set to track and assess progression of the implementation of HIV and AIDS interventions. Monitoring and evaluation generate information needed for decision-making at different levels of management of HIV and AIDS services.

Quality Data: Quality data are data that are reliably and accurately representing the measure it was intended to present. It also refers to the totality of features and characteristics of data that bears on its ability to satisfy a purpose for which the data was collected for. Data are considered to be of high quality when they are complete, accurate, consistent, relevant and timely reported. HSPs should strive to produce data of high quality. In order for the HFs to produce high quality data, Data Quality Assessments (DQAs) should routinely be conducted at all levels by using DQA tools that are approved by the MoHCDGEC.

17.1 Key Components of Monitoring and Evaluation

17.1.1 Data Recording

Collection of data on HIV and AIDS interventions is done by HSPs and community health workers at the HF and community levels using standardized tools and coordinated by DACCs and RACCs. Reporting is done on monthly and for some data on quarterly basis from the community and HF levels to the council level where it is posted to the DHIS2. From the DHIS2, data can be accessed by different authorities without necessarily contacting the national level.

The national level, through the NACP compiles HF and council data, which are then reported to other stakeholders within and outside the country.

Tools for Recording:

Recording of the data for the HIV and AIDS services uses the following tools:

a) Patient Identification Card (CTC1): This is a card with a unique patient identification number. It is issued at the registration section of the HF during the first visit of the client to the care and treatment clinic. It is then kept and used by the client for identification purposes when he/ she visit at the CTC.

b) Patient encounters' Record Form (CTC2): This is a form initiated when an HIV positive person attends for the first visit at the CTC. It is used for recording the management and monitoring of client's clinical outcome. The form has a client's unique ID number, as in the Patient Identification Card. CTC2 is kept in the client's file and retained at the HF registry or dedicated HIV and AIDS care and treatment cabinet.

c) Registers

There are five types of registers used at the CTC:

Appointment register

Tracking register

Pre ART register

ART register

Cohort Analysis Register

Appointment register

The standardized appointment register has been designed to help monitor clinic attendances for all clients who are enrolled into HIV care and treatment clinic, regardless of their being on ART or not.

Tracking register

This is a register that is used mostly by the community based HSPs to track back to care those clients who have missed their appointments and those who are confirmed as lost to follow up. It records how many clients have been tracked and returned to CTC, transferred out, or stopped using services.

Pre ART Register

This register records all clients who are attending to the CTC and are not yet started on ART.

The ART Register

A tool used for recording all patients who are attending at the CTC clinic and are started on ART.

The Cohort Analysis register

This register uses information from the ART register to compile reports for specific clients' cohorts at 6, 12, 24, 36, 48, 60 and 72 months.

d) Patient Referral Form

This is a form that is used when a client is transferred from one CTC to another to enable him/ her carry to the next HF the relevant information about care and/ or treatment given.

17.1.2 Data Storage

Data collected from clients receiving HIV and AIDS care and treatment services shall be stored either electronically through the CTC2, pharmacy module and the CTC3 macro database or on

hard copies of the tools used for data collecting purposes. The electronic means of data storage must be secured by passwords while hard copies must be kept in rooms where confidentiality will be ensured.

17.1.3 Data Analysis

Analysis of data on HIV and AIDS services is done from the HF to the national level. In high volume HFs data are entered into the CTC2 (HF based) database, which aggregates automatically and links them directly to DHIS2 database at the council level. Small volume HFs aggregate data manually and send reports to the office of the DMO for entry in to the DHIS2. Two forms of data analyses are done; indicator based and cascade analyses.

17.1.4 Data Reporting

Reporting of data for HIV and AIDS services is done either on monthly or quarterly basis. For HFs that use electronic system, its reports are generated automatically and thereafter directly linked to DHIS. For HFs that use paper base system, they aggregate data and submit to the office of the DMO by the 7th day of the following month. Data are reported from HFs to the council, region and finally to the national level.

17.1.5 Data Presentation:

Depending on the needs of the intended audience, presentation of the analysed outputs is done in the form of:

Notes

Tables

Graphs

Maps

Charts

Data should be presented in simple, interpretable and actionable form to facilitate its understanding and utilization.

17.1.6 Data Dissemination

After the data are presented in the different forms as shown above, they need to be disseminated so as to reach a greater number of the audience for them to use the data. Dissemination of the data is done by posting them on the notice boards that are placed in public places as well as through conferences.

11.1.7 Data Use

It is expected that data will be reported and presented/ disseminated on monthly and or quarterly basis. Data will be used at different levels by stakeholders for the purposes of planning and improvement of the delivery of HIV and AIDS services.

17.2 Roles and Responsibilities of Each Level in Relation to M&E

Activities for Monitoring and Evaluation of HIV and AIDS services are carried out at HFs, council, region and national levels. Each level has its roles and responsibilities as follows:

17.2.1 National Level (NACP)

Prepares and coordinates implementation of M&E framework for HIV and AIDS services including preparation of M&E guidelines and SOPs for C&T

Guides in the preparation, revision, printing and distribution of recording and reporting tools for HIV and AIDS care and treatment services

Coordinates supportive supervision, mentoring and data quality assessment activities for C&T services

Manages a national CTC 2 database in line with health sector data management guidance

Advocates for use of electronic database at HFs that provide C&T services

Coordinates capacity building to HSPs in electronic data management

Coordinates and guides dissemination of C&T output data at all levels

Guides sub-national levels on data management especially on analysis and dissemination; and advocate for data use

Provides feedback on the quality of reports generated by the lower levels

17.2.3 Regional and District Levels

There is a slight variation on the roles and responsibilities between the regional and council levels. Those which are specific for the regional level include:

Building capacity of the council and primary HFs on the management of the data

Support the HFs in the region and the council on the recording and reporting of HIV and AIDS services

Coordinate capacity building of the HSPs at the HFs on the M&E system of the HIV and AIDS services

Mobilize resources for strengthening M& E system of the C&T services

Coordinate the quarterly meetings on review of data

Disseminate HIV and AIDS C&T data at region and council levels

Strengthen communication with national level on all HIV and AIDS M&E matters at regional and council levels

Provide feedback on the quality of reports generated by the lower levels.

Health Facility Level

Ensures availability and effective use of the recording and reporting tools for HIV and AIDS care and treatment services

Ensures timely submission of the care and treatment reports to the council's office

Reports to the DMO on all challenges faced by the HF on all HIV and AIDS M&E system

Conducts on quarterly basis an internal data quality assessment and data review.

17.2.5 HIV and AIDS Implementing Partners

Comply with the national M&E system for HIV and AIDS care and treatment services

Support regions and councils to implement the care and treatment M&E system

Support regions and councils on analysis, dissemination and use of quality data reviews.

17.3 Supportive Supervision and Mentoring of the HIV and AIDS Services

A Manual on Comprehensive supportive supervision and mentoring of the HIV and AIDS services describes 'supportive supervision' as a "process of helping HSPs improve their work performance continuously." It is carried out in a respectful and non-authoritarian way to promote quality outcomes through strengthening communication, identifying and solving problems, facilitating teamwork, and providing leadership and support.

Mentorship is described as a process of practical training and consultation that fosters on-going professional development to yield sustainable high quality health outcomes.

It is crucial that all levels of health service delivery adhere to the implementation of the supportive supervision and mentoring of HIV and AIDS services as stipulated in the Manual of the Comprehensive Supportive Supervision and Mentoring of the HIV and AIDS Services (2017 Edition).

Annexes

Annex 1: List of acknowledged Organizations and insititution.

AMREF Health Tanzania

Baylor International Pediatric AIDS Initiatives (BIPAI)
Benjamini Mkapa Hospital (BMH)
Bugando Medical Centre (BMC)
Catholic University of Health and Allied Sciences- Bugando (CUHAS)
Centers for Disease Control and Prevention- Tanzania (CDC-TZ)
Centres for Disease Control and Prevention (CDC)
Clinton Health Access Initiative (CHAI)
DED- Temeke
Deloitte- BoreshaAfya
Department of Defense – USG (DOD)
Elizabeth Glazer Pediatric AIDS Foundation (EGPAF)
Henry Jackson Foundation Medical Research International (HJFMR/Walter Reed)
International Training and Education Centre for Health (I-TECH)
Johns Hopkins Program for International Education in Gynaecology and Obstetrics (JHPIEGO) - SAUTI Project
Kilimanjaro Christian Medical Centre (KCMC)
Lugalo General Military Hospital
Management for Development and Health (MDH)
Mbeya Zonal Referral Hospital (MZRH)
Muhimbili National Hospital (MNH)
National AIDS Control Programme (NACP)
National TB and Leprosy Programme (NTLP)
Njombe-RAS
President's Office Regional Administration and Local Government (PORALG)
Ruvuma- RAS
Songea Regional Referral Hospital
Tanzania Food and Nutrition Centre (TFNC)
Tanzania Health Promotion Support (THPS)
University of Maryland Baltimore (UMB)
US Agency for International Development (USAID)
World Health Organisations (WHO)

Annex 2: WHO Clinical Staging of HIV Disease in Adults and Adolescents

<table>
<tr>
<td>Stage I
• Asymptomatic
• Persistent generalized lymphadenopathy (PGL)
Unexplained, asymptomatic hepatosplenomegaly</td>
<td>Stage II
• Moderate unexplained weight loss (< 10% of presumed or measured body weight)
• Minor mucocutaneous manifestations (seborrheic dermatitis, popular pruritic eruptions, fungal nail infections, recurrent oral ulcerations, angular cheilitis)
• Herpes zoster
• Recurrent upper respiratory tract infections (sinusitis, tonsillitis, bronchitis, otitis media, pharyngitis)</td>
</tr>
<tr>
<td>Stage III
• Unexplained severe weight loss (over 10% of presumed or measured body weight)
• Unexplained chronic diarrhoea for longer than one month
• Unexplained persistent fever (intermittent or constant for longer than one month)
• Persistent oral candidiasis
• Oral hairy leukoplakia
• Pulmonary tuberculosis
• Severe bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)
• Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
• Unexplained anaemia (below 8 g/dl), neutropenia (below 0.5 x 109/l) and/or chronic thrombocytopenia (below 50 x 109 /l)</td>
<td>Stage IV
Conditions where a presumptive diagnosis can be made using clinical signs or simple investigations:
• HIV wasting syndrome
• Pneumocystis jirovecipneumonia (PCP)
• Recurrent severe bacterial pneumonia (≥ 2 episodes within 1 year)
• Cryptococcal meningitis
• Toxoplasmosis of the brain
• Chronic orolabial, genital or ano-rectal herpes simplex infection for > 1 month
• Kaposi’s sarcoma (KS)
• HIV encephalopathy
• Extra pulmonary tuberculosis (EPTB)

Conditions where confirmatory diagnostic testing is necessary:
• Cryptosporidiosis, with diarrhoea > 1 month
• Isosporiasis
• Cryptococcosis (extra pulmonary)
• Disseminated non-tuberculous mycobacterial infection
• Cytomegalovirus (CMV) retinitis or infection of the organs (other than liver, spleen, or lymph nodes)
• Progressive multifocal leucoencephalopathy (PML)
• Any disseminated mycosis (e.g. histoplasmosis, coccidiomycosis)
• Candidiasis of the oesophagus or airways
• Non-typhoid salmonella (NTS) septicaemia
• Lymphoma cerebral or B cell Non-Hodgkin’s Lymphoma</td>
</tr>
</table>

	• Invasive cervical cancer • Visceral leishmaniasis • Symptomatic HIV-associated nephropathy or HIV associated cardiomyopathy

Annex 3: WHO Clinical Staging of HIV/AIDS for children with confirmed HIV infection

Stage I • Asymptomatic • Persistent generalized lymphadenopathy (PGL) Unexplained, asymptomatic hepatosplenomegaly	Stage II • Papular pruritic eruptions (PPE) • Seborrheic dermatitis • Fungal nail infections • Angular cheilitis • Linear gingival erythema • Extensive HPV or molluscum infection (>5% of body area/face) • Recurrent oral ulcerations (>2 episodes/ in 6 months) • Parotid enlargement • Herpes zoster (>1 episode/12 months) • Recurrent or chronic upper respiratory infection (URI): otitis media, otorrhoea, sinusitis (>2 episodes/6 months)
Stage III • Unexplained moderate malnutrition (-2SD or Z score) not responding to standard therapy • Unexplained persistent diarrhoea (>14 days) • Unexplained persistent fever (intermittent or constant, > 1 mo.) • Oral candidiasis (outside neonatal period) • Oral hairy Leucoplakia • Pulmonary tuberculosis • Severe recurrent presumed bacterial pneumonia (>2 episodes/12 months) • Acute necrotizing ulcerative gingivitis/ periodontitis • Lymphoid interstitial pneumonitis (LIP) • Unexplained anaemia (<8g/dL), neutropenia (<1000/mm3), or thrombocytopenia (<30,000/mm3) for >1 mo.	Stage IV • Unexplained severe wasting or severe malnutrition (-3 SD or Z score) not responding to standard therapy • Pneumocystis pneumonia • Recurrent severe bacterial infections (>2 episodes/12 months, excluding pneumonia) • Chronic orolabial or cutaneous HSV (lasting > 1 mo) • Extra-pulmonary tuberculosis • Kaposi's sarcoma • Oesophageal candidiasis • CNS toxoplasmosis • Cryptococcal meningitis • Any disseminated endemic mycosis • Cryptosporidiosis or Isosporiasis (with diarrhoea > 1 month) • CMV infection of organ other than liver, spleen, lymph nodes (and onset age >1 month) • Disseminated mycobacterial disease other

• HIV-related cardiomyopathy • HIV-related nephropathy	than tuberculosis • Candida of trachea, bronchi or lungs • Acquired recto-vesicular fistula • Cerebral or B-cell non-Hodgkin's lymphoma • Progressive multifocal leucoencephalopathy (PML) • HIV encephalopathy

Ref: http://www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf

Annex 4:. Roles and Responsibilities of CTC Staff

CTC staff	Roles and responsibilities
CTC in-charge	The CTC In-charge will report to the OPD In-charge and will perform the following duties: • Monitor all CTC related activities, supervise, support and mentor all CTC staff • Coordinate linkage of CTC services with HTC, STI, RCH, PMTCT, TB clinics, IPD, FP, OPD services, PLHIVs support groups and CBHS programs • Conduct weekly and monthly CTC staff meetings and ensure minutes are documented and disseminated • Coordinate Work Improvement Teams and participate in Facility Quality Improvement activities • Participate in the facility monthly meetings where all other units (OPD, IPD, RCH, TB/STI /Skin/ Dental clinics are represented. • Ensure availability of ARVs, OI medicines and other essential medical supplies by collaborating with relevant sections. • Ensure availability of HIV and AIDS service delivery guidelines, SOPs, job aids and protocols • Ensure proper documentation and timely reporting of data. • Ensure appointments and lost to follow up tracking system are functional • Conduct data analysis and utilize the findings for planning and implementation • Ensure implementation of infection prevention control plan
CTC receptionist	• Sort client files and open file for new clients • Ensure all relevant client cards/forms are attached in client file e.g. Continuation forms and TB screening tool, Investigations forms etc. • Ensure referral forms for all referred clients are attached in the files • Fill demographic information of the clients • Manage patient files systematically for easy and quick retrieve

	• Direct clients to a respective area of services • Direct all new clients without referral forms or relevant information to counselor Keep appointment register and alert the CBHS contact person on missed appointments for follow up • Conduct initial client assessment (weight, Height, vital signs) and record in CTC cards and other relevant forms
Triage nurse	• Identify serious sick clients from the waiting area and immediately refer to relevant units/staff at the clinic for treatment • Direct clients to respective clinicians or appropriate/required services
Clinician	• Perform detailed clinical assessment (screen for OIs) and monitoring of clients • Provide comprehensive prevention, treatment and care. • Record all client information into the CTC1, CTC2 and clinical sheets • Fill in the feedback section of the referral forms • Identify and document referral needs for clients • Consult/refer complicated cases to specialized services • Identify and manage treatment failure • Fill in prescription for ARVs and OIs for clients • Order required Laboratory and Radiological investigation appropriately
Nurse counsellor	• Assess individual client treatment readiness using adherence counselling check list • Provide adherence counselling and other aspects of PHDP at every clinic visit • Record all required information into CTC2 and adherence counselling checklist • Link the client to other support services according to the need. • Identify and document referral needs for clients • Fill in prescription for ARVs for clients as needed/indicated
CBHS provider	• Link clients to other services and support groups for People Living with HIV and AIDS (PLHIV) • Maintain and update directory of referral and support services • Ensure early identification of missed appointment and lost to follow up clients are traced back • Supervise and mentor community based HIV service providers
Pharmaceutical personnel	• Ensure continuous availability of HIV commodities through appropriate record keeping, ordering and receiving process • Store commodities in spacious room under appropriate condition • Handle prescription, dispense ARVs and OI medicines, and counsel the client on appropriate use of medicines • Assess adherence to medicine, occurrence of side effects, and take appropriate measures

Data Clerk	• Check CTC 2 card for completeness and correctness • Enter CTC2 data in the database • Perform data cleaning and provide regular reports to monitor progress towards achieving performance targets. • Participate in the facility monthly meetings where all other units (OPD, IPD, RCH, TB/STI /Skin/ Dental clinics are represented.
CTC exit staff	• Check if laboratory investigations were done and ARVs were correctly administered • Check, discuss and agree with client on the next clinic visit date, time, and record it in appointment register • Fill in daily appointment summary report forms, analyze missed appointment and report them to CBHS contact person • Link and refer clients to CBHS provider and other support services
Medical attendant	• Keep CTC clean at all times • Escort client to and from relevant units when necessary e.g. laboratory, pharmacy, RCH, TB clinic, IPD wards, FP, PMTCT • Assist with sorting of files and follow up laboratory results • Perform general cleanliness of the clinic

Annex 5. Health Facilities Accreditation for initiation of ART

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

ASSESSMENT TOOL FOR HEALTH FACILITY TO PROVIDE HIV CARE AND TREATMENT SERVICES

Minimum Criteria for a Health Centre and Dispensary

Name of health facility: **Type of facility …….**
District:
Region: ——

Date of assessment:_____
☐ **Baseline visit** ☐ **re-assessment visit**
Instruction

1. Theanswerstotheminimumcriteriashould be derivedfromthehealthcenter and Dispensary assessmenttool(version3,October 2015).
2. Thenumbersinbracketsrefertothequestion numbersinthe Health center and Dispensary Assessment tool.
3. Circle the appropriate response (yes/no) as recorded in the assessment tools
4. If the response is yes, circle the appropriate score
5. Sum all circled yes score to make a total of minimum score
6. Cut of point
    - If the facility scored 60% and above with consultation room, at least three staff (Clinician, nurse and other health worker) the facility qualify for initiation.
    - If the facility scored below 60% action plan for improvement should be in place before 2nd assessment.

1 Organization of HIV and AIDS care services within facility			
1.a One or more confidential consultation rooms			**Score**
One clinical consultation rooms available (4.2.1)	yes	no	3
Consultation rooms with visual privacy (4.2.4)	yes	no	3
Consultation rooms with Auditory privacy (4.2.5)	yes	no	2
1.b Space/room and register for registration of HIV and AIDS patients*(1.8.1and1.8.2=yes, seen)*	yes	no	3

2 Human resource capacity and training			
2.a Atleast one clinician (ACO,CO, AMO, MO)*(2.3.1)*	yes	no	8
2.b At least one nurse (EN,RN) *(2.3.3)*	yes	no	8
2.c At least one other health worker*(2.3.4,2.3.5,2.3.6or 2.3.7)*	yes	no	8
2.d At least two staff (Clinicians and Nurse) trained on National Curriculum on ART (CTC/PMTCT)*(2.2)*	yes	no	8

3 HIV Testing and Counselling services			
3.a One confidential room for testing and counselling*3.2.1 1and3.2.3+3.2.4=yes, observed)*			Sco
One confidential room for testing and Counselling (3.2.1)	yes	no	re 2
Testing & Counselling rooms with visual privacy (3.2.2)			2
Testing & Counselling rooms with Auditory privacy (3.2.3)	yes yes	no no	2
3.b At least one HTC provider (PITC/CITC) *(3.3.3)*	yes	n	4

4 Clinical HIV and AIDS care and treatment services			
4.a Availability of PMTCT services (4.8.1)	yes	no	8

5 Patient records and reporting systems			
5.a An established and working medical record system *(5.1.1-5.1.5,=yes)*	yes	no	2
5.b Locked area for medical records with limited access *(5.2.1=yes)*	yes	no	3

6 Continuum of Care			
6.a Availability of CBHS (*at least one = 6.2.1 & 6.2.2)*	yes	no	5
6.b Functional system for patients tracking *(5.5.2)*	yes	no	5

7 Laboratory services			
7.a Adequate laboratory space*(7.2.1=yes,7.2.3=yes),*at least oner oom	yes	no	2
7.b HIV testing (rapid)*(7.4.1)*	yes	no	2
7.c Basic blood tests (haematology/biochemistry) *(7.5 and 7.6)*	yes	no	2
7.d Malaria blood test*(7.4.14)*	yes	no	2
7.e TB sputum smears (ZNstain)+STItest(Gramstain) *(7.4.13)*	yes	no	2
7.f Routine testing of stool and urine*(7.4.12)*	yes	no	2
7.g Pregnancy Test*(7.4.10)*	yes	no	2

8 Pharmacyservices			
8.a Secure storage space large enough for 6 months supply ofARVs *(8.6.1=yes,seen)*	yes	no	5
8.b Refrigerator in pharmacy*(8.6.2)*	yes	no	5

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

Name of Health Facility: ……..

Type of facility:

Health Centre ☐ **Dispensary** ☐

Address:

P.O.Box:……

Government ☐ **Private** ☐ **FBO** ☐ **Other(specify:** ☐

City/Town /Village: ……

Ward: ……. **Health Service**

Population: ……..…….……

District: ……... **Nearest referral**

facility: ……

Telephone number: …….. **and is:**

Hospital ☐ **Health Centre** ☐

Fax number: ……..

E-mail: …….. **CTC NACP Code number**:……..……..

Key contact person:……....

Function:……..…**Mobile:**……

Name of medical staff member in charge of HF:

……....

Date of assessment (dd/mm/yy):

……..…../……..……/……..……/

Assessment team members (name, organisation, expertise):

1.……....

2.……....

3.……....

4. RHMT Member:……....
5. CHMT Member:……...

General Information

6. IMPLEMENTIG PARTNER…….

Objectives of the assessment visit are to:

- determine the availability and quality of the essential elements of the facility.
- assess the current capacity of the health facility for provision of HIV care and treatment
- identify are as for strengthening and improvement to upgrade the health facility to be able to provide comprehensive care and support to Persons Living with HIV/AIDS
- Issue certification to health facilities to enable them to support ART, once they have met a standard set of criteria

Procedure

1. Complete this assessment tool by visiting the relevant health centre or dispensary; conduct an interview with the in-charge/ representative of the facility, observe and assess the infrastructure and equipment/supplies.
2. If the facility provides already HIV/AIDS Care and Treatment services, all the questions in the tool need to be asked and the answers filled in as completely as possible.
3. If these services are not yet provided, you can skip the sections.
4. Try to be brief when writing comments. Use if possible only keywords. If this pace to write comments is not enough, write on the back of the previous page.
5. Compile and analyse the data, using the Minimum Criteria and the Assessment Report.
6. Develop, with the facility, a Strengthening Plan and discuss the plan with the heads of units and the in-charge at the health facility.
7. Fill the tool in duplicate and let the i.c .of the HF and team members sign these.

   Provide a copy of the tool to the facility at the end of the visit.
8. Send copies of the **assessment tool**, the **minimum criteria**, the **assessment report** and **strengthening plan** to

   a. The higher level health facility linked to this facility, by the DMO,

   b. the RMO,

c. the supporting partner in the region and

d. NACP.

9. Based on the results of the assessment visit, the NACP may certify the facility.

10. ANY questions regarding drug shipments, training, laboratory equipment, etc. Should be directed to the Health Centre in-charge or District Medical Officer.

Signatures of facility staff who have provided information:

The person in charge of the HF or her/his representative:

Name: _____ Title: _____ _____ _____

Signature: Date:

Name: _____ Title: _____ _____ _____

Signature: Date:

Signatures of assessors:

Name: _____ Area(s) of expertise: _____ _____
Signature: Date:

Name: _____ Area(s) of expertise: _____ _____
Signature: Date:

Name: _____ Area(s) of expertise: _____ _____
Signature: Date:

Name: _____ Area(s) of expertise: _____ _____
Signature: Date:

Signatures of additional members of the assessment team:

Name: _____ Area(s) of expertise: _____

Signature: Date:

Name: _____ Area(s) of expertise: _____

Signature: Date:

Name: _____ Area(s) of expertise: _____

Signature: Date:

Organization of HIV and AIDS Services		
1.1 General		
1.1.1 How many OPD patients seen in the last reporting month?		Patients
1.1.2 How many OPD patients in the last reporting year?		Patients
1.1.3 How many under 5 patients attended OPD in the last reporting year?		Patients
1.1.4 How many patients have been admitted in the last reporting month?		Patients
1.1.5 How many in-patients have been admitted in the last reporting year?		Patients
1.1.6 How many under 5 patients have been admitted in the last reporting year? Jan-Dec		Patients
1.1.7 What is the farthest distance in Kilometres in your catchment area?		Km
1.1.8 Is public transport available to reach your facility from the farthest distant area?	**Yes**	**No**
1.1.9 Does the area have special accessibility difficulties?	**Yes**	**No**

1.2 HIV services	**Observed**	**Reported not seen**	**At nearby referral**	**Outreach from referral HF**	**Not available**
1.2.1 HIV testing &Counselling					
1.2.2 Care, treatment &support for PLHIV					
1.2.3 Collaborative TB/HIV services					
1.2.4 Community Based HIV services					
1.2.5 PMTCT services					
1.2.6 Reproductive and Child Health					
1.2.7 Adolescent youth friendly reproductive health services					
1.2.8 STI diagnosis and treatment					
1.2.9 Nutrition assessment, Counselling and support					
1.2.10 Orphans and Vulnerable Children services (OVC)					
1.2.11 If ART provided the HF is	**Initiation site**				

1.3 Functional plan for patient flow		
1.3.1 Is there a clearly described patient flow plan for the facility in general?	Yes	No
1.3.2 Assess the patient flow plan, with an emphasis on C&T services	P Score:	

1.4 Supportive Supervision		
1.4.1 Does the CHMT supervise your health facility (HF) quarterly?	Yes	No
1.4.1.1 If *yes*, how many months ago was the last visit?		Months
1.4.1.2 Is there a written report of this CHMT visit in the HF?	Yes	No
1.4.2 Does your HF receive comprehensive supportive supervision, mentorship or coaching services?	Yes	No
1.4.2.1 If *yes*, how many months ago was the last visit?		Months
1.4.2.2 Is there a written report on comprehensive supportive supervision, mentorship or coaching?	Yes	No
1.4.3 Does the region or district provide laboratory support to your facility?	Yes	No
1.4.3.1 If *yes*, is the visit aimed for lab supervision?	Yes	No
1.4.3.2 Is the visit for repair and maintenance/?	Yes	No
1.4.3.3 Is the visit meant to bring supplies?	Yes	No
1.4.3.4 Is the visit for another purpose? (if yes specify:)	Yes	No

1.5 Infrastructural capacity		
1.5.1 Does the Dispensary / Health Centre have the following rooms:		
1.5.1.1 Reception and medical records room*	Y	N
1.5.1.2 Consultation room (if > 1 room, see 1.5.3)	es Y	o n
1.5.1.3 Laboratory room (main working room)	es Y	o n
1.5.1.4 Dressing room	es Y	o n
1.5.1.5 Injection room	es Y	o n
1.5.1.6 Dispensing room with drug store	es Y	o n
1.5.1.7 Store	es Y	o n
1.5.1.8 Reproductive Child Health Care (RCHC) room	es Y	o n
1.5.1.9 Delivery room (with waiting beds(s) and post-delivery beds	es Y es	o n o

1.5.2 Does the **Health Centre** have the following **additional** rooms/services**:**		
1.5.2.1 Functioning Minor theatre	Yes	No
1.5.2.2 Functioning major theatre	Yes	No
1.5.2.3 RCHC room	Yes	No
1.5.2.4 Female wards	Yes	No
1.5.2.5 Male wards	Yes	No
1.5.2.6 Delivery room with maternity ward	Yes	No
1.5.2.7 X-ray block	Yes	No
1.5.2.8 Office of i/c health centre	Yes	No
1.5.2.9 Office of i/c nursing service	Yes	No
1.5.3 How many consultation rooms are available at the facility?	Yes	No Rooms
1.5.4 How many **service providers** share a consultation room?		clinicians

1.6 CTC in charge & AIDS services		
1.6.1 Is a CTC in charge/ appointed to coordinate the HIV & AIDS care and treatment services at the facility (member of the Care and Treatment team, see next paragraph Human Resources)?	Yes	No
1.6.2 Name: Cadre		

1.7 Referral and linkage to CTC		
1.7.1 Does the HF have referral and networking system?	Yes	No
1.7.2 Does the facility refer PLHIV to a nearby (referral) HF with a CTC?	Yes	No
1.7.3 What is the distance in km from the nearest referral HF with a CTC?	Yes	No Kms
1.7.4 Is public transport available to reach the referral facility?	Yes	No
1.7.5 How many referrals to the referral CTC took place in the last quarter?	Yes	No Referrals

1.8 Space for registration of HIV & AIDS patients			
1.8.1 Is there separate room for reception and registration of PLHIV attending the HF for C&T?	Yes, seen	Yes, not seen	No
1.8.3 Assess the registration process and location		P Score:	

1.9 Medical waste disposal and sanitation			
1.9.1 Do consultation rooms and HTC rooms have sharps disposal containers?	Yes,seen	Yes, not seen	No
1.9.2 Does the HF segregate non infection and infectious wastes?	Yes, Seen	Yes, not seen	No
1.9.3 Does the facility have a functioning	Yes, seen	Yes, not seen	No
1.9.4 Does the HF have functional toilets or	Yes, seen	Yes, not seen	No
1.9.5 Does the HF have reliable sources of water?	Yes, seen	Yes, not seen	No
1.9.6 Is there any hand washing water (running)?	Yes, seen	Yes, not seen	No
1.9.7 Is the sewage system operational?	Yes, seen	Yes, not seen	No
1.9.8 Assess sanitation, incinerator and medical waste disposal in		P Score:	

1.10 Bio-safety at health facility			
1.10.1 Waiting area for CTC adequate space and well ventilated?	Yes, seen	yes, not seen	No
1.10.2 Waiting area for OPD adequate space and well ventilated?	Yes, seen	yes, not seen	No
1.10.3 Does the HF have an Infection Control Plan	Yes, seen	yes, not	No
1.10.4 Is there an adequate space and well ventilated waiting area for lab?	Yes, seen	yes, not seen	No
1.10.5 Are personal protective equipment (gloves, boots, apron, mask) available in sufficient quantity?	Yes, seen	yes, not seen	No
1.10.6 Is the laboratory well ventilated?	Yes, seen	yes, not	No
1.10.7 Does the lab have a safety cabinet (hood)?	Yes, seen	yes, not	No
1.10.9 Are (*Hepa*) masks for lab staff or for infective MDR-TB Patients available?	Yes,seen	yes,notseen	No
1.10.10 Assess the overall bio-safety status at HF		P Score:	

1.11 Information Technology			
1.11.1 Does the facility have a functional computer for CTC2 and pharmacy module database entry related to care and treatment?	yes, seen	yes, not seen	No
1.11.2 Are CTC data entered and analyzed	yes,seen	yes,not seen	No
1.11.3 Does the HF have access to internet?	yes, seen	yes, not	No
1.11.4 Assess the overall IT capacity of the HF		P Score:	

1.12 Power Supply			
1.12.1 Does the facility have Electrical power supply?	yes, seen	yes, not seen	No
1.12.2 Does the HF have a functional backup power?	yes, seen	yes, not seen	No
1.12.3 Does the HF has one or more functioning refrigerators (if there Is no Tanesco or working generator)	yes, seen	yes, not seen	No
1.12.4 Assess the overall availability of power		A Score:	

2. Human Resource capacity and Training							
2.1 Staff currently employed at facility and their involvement in C&T	**Staff establishment**			**Actual number currently employed**	**Number of staffs working at PMTCT/CT**	**Total working hours per week for this category of staff at**	
	HOSP	**H/C.**	**DISP.**				
1. Medical Officer							Hours
2. Assistant Medical							Hours
3. Clinical Assistant							Hours
4. Clinical Officer							Hours
5. Public Health Nurse							Hours
6. Registered Nurse							Hours
7. Enrolled nurse							Hours
8. Laboratory							Hours
9. Laboratory Technician							Hours
10. Laboratory Assistant							Hours
11. Pharmacist							Hours
12. Pharmacy Technician							Hours
14. Pharmacy assistant							Hours
15. Radiographer							Hours
16. Data clerk for							Hours
17. HTC providers							Hours
18. HBC staff							Hours
19. Admin/finance staff							Hours
20. Medical records staff							Hours
21. IT staff-Other Data							Hours
22. Medical Attendants							Hours
23. Nutritionist							Hours
23. Other							Hours

3. HIV Testing and Counselling Services		
2.3 Dedicated Care and Treatment team		
2.3.1 assessing/ prescribing clinician (CA, CO AMO or MO)	Yes	No
2.3.2 triage nurse	Yes	No
2.3.3 At least one nurse)	Yes	No
2.3.4 laboratory technologist/laboratory technician/lab assistant	Yes	No
2.3.5 pharmaceutical technician/assistant	Yes	No
2.3.6 data clerk (ARV data-entry)	Yes	No
2.3.7 CBHC provider	Yes	No

2.4 Guidelines available and easily accessible for use	Yes		No
	seen	Not seen	
2.4.1 National guidelines for the management of HIVAIDS(2015)			
2.4..2 National comprehensive guidelines for HIV Testing and counselling(2013)			
2.4..3 National guidelines on PMTCT(2013)			
2.4..4 National guidelines on CBHS (2018)			
2.4..5 National standard guidelines for health laboratory			
2.4..7 National TB/HIV guidelines			
2.4..8 Pocket handbook for HF Infection Prevention & Control in Tanzania (MoHSW2007)			
2.4..9 National TB/Leprosy Manual(NTLP)			
2.4..10 National STI guidelines			
2.4..11 HIV care primary booklets(acute, chronic, palliative,			
2.4.5.12 SOP for HIV Testing and counselling manual			
2.4.13 Other(mention):			
2.4.14 Assess the overall availability of relevant guidelines		A	

3.2 Client Initiated Counselling and Testing (CITC) services		
Does the facility:		
3.2.1 Provide CITC services? *If no go to 3.1.4*	yes	No
3.2.2 Provide pre-test counselling?	yes	No
3.2.3 Provide post-test counselling?	yes	No
3.2.4 Refer persons or patients for counselling and testing to another site?	yes	No
How many referrals took place:		
3.2.5 from the CITC services to the CTC within the last reported quarter?		Referrals
3.2.6 Assess the CITC capacity of the facility in general	P score:	

3.2 Counselling room			
3.2.1 Number of separate rooms available for counselling			Rooms
	Observed	**Reported available, but not seen**	**Not available**
3.2.2 Means of visual privacy of rooms			
3.2.3 Means of auditory privacy of rooms			
3.2.4 Is furniture present and comfortable?			
3.2.5 Is the room well ventilated?			
3.2.6 Assess the overall quality of the counselling room(s)		A Score:	

3.4 CITC counsellor		
3.4.1 How many counsellors were trained according to the national CITC curriculum?		Counsellors
3.4.2 How many counsellors received CITC training using different curriculum? *Mention organization and duration of training*		Counsellors
3.4.3 How many trained CITC counsellors are actually working as CITC Counsellors?		Counsellors
3.4.4 How many counselors are practicing without training on CITC?		Counsellors
3.4.5 Assess the overall availability of counsellors and their training status	P Score:	

3.5 Provider Initiated Testing and Counselling (PITC)		
3.5.1 Is PITC practiced at this Health Facility?	Yes	No
3.5.2 Is PITC provided at:		
OPD	Yes	No
IPD	Yes	No
RCH	Yes	No
CTC	Yes	No
TB clinic	Yes	No
STI clinic	Yes	No
Family planning clinic	Yes	No
Others mention…….		
3.5.3 How many patients were referred for C&T after undergoing PITC during the last reported quarter?		Patients
3.5.4 How many Health Workers received the 5 days PITC training?		HCW
3.5.5 Assess the practice of PITC in general	P Score:	

4. Clinical care

4.1 Staffing currently working at the CTC	**Number**	**NO.**	**Category**
4.1.1 Medical Officers(MO)			MO
4.1.2 Assistant Medical Officers(AMO)			AMO
4.1.3 Clinical Officers(CO)			CO
4.1.4 Clinical Assistant (CA)			CA
4.1.4 Adherence Counsellors(C)			C
4.1.5 Nurses			N
4.1.6 Others (CBHS providers)			O

4.2 Consultation room		**Number**	**Category**
4.2.1 How many clinical consultation rooms are available in the			Rooms
4.2.2 How many clinicians share one room at the same time?			Clinicians
4.2.3 How many dedicated rooms for C&T activities only?			Rooms
Privacy and outfit of consultation rooms	**Observed**	**Reported, not seen**	**Not available**
4.2.4 Means of visual privacy in consultation rooms?			
4.2.5 Means of Auditory privacy in consultation rooms?			
4.2.6 Water and hand cleaning utensils available?			

4.2.7 Weighing scale and height measure present?			
4.2.8 Assess capacity and quality of examination rooms		A	

4.3 HIV Testing	Observed	Reported, notseen	Not available
4.3.1 Rapid HIV test algorithm 2019 available?			
4.3.2 1st test SD Bioline HIV 1-2. 3.0			
4.3.3 2nd test Uni-Gold HIV			
4.3.4 Internal Quality Control system for rapid algorithm			
4.3.6 External Quality Assessment system for rapid			
4.3.7 Does the HF use R&R system for ordering HIV test			
4.3.8 Does the HF receive the HIV test orders as	Yes	No	
4.3.9 Did the HF experience stock outs of any of the test kits in the past 6 months?	Yes	No	
4.3.9 Assess the status of HIV test supply	A Score:		

4.4 Referral & linkage between inpatients and CTC		
4.4.1 How many patients diagnosed with HIV at the ward were registered at the CTC within the last 3 months		Referrals
4.4.2 Does HF have referral forms?	yes	No
4.4.3 Does the HF uses referral forms?	Yes	No
4.4.4 Is there feedback mechanism for referrals made?	Yes	No
4.4.5 Assess the referral and registration system between the ward and the C&T and vice versa	P Score:	

4.5 Opportunistic Infections and TB diagnosis and treatment		
4.5.1 can the HF provide OIs prophylaxis (CPT, IPT)to HIV positive clients	yes	No
4.5.2 Is the HF able to diagnosis and manages common OIs?	yes	No
4.5.3 Does the HF provide collaborative TB/HIV services?	yes	No
4.5.4 Is this a TB diagnosis (AFB) and treatment (DOTS) health	yes	No
4.5.5 Is this a TB treatment only (DOTS) health facility?	yes	No
4.5.6 Is there an active TB/HIV coordination structure (e.g. committee)	yes	No
4.5.7Assess over all status of OI and TB diagnosis & treatment at HF	P Score:	

4.6 Referral pattern between TB and CTC/PMTCT		
4.6.1 How many successful referrals took place from the TB services to the CTC (in the HF or at the referral HF for CTC) within the last		referrals
4.6.2 How many successful referrals took place from CTC to the TB services (in the HF or at the referral HF for CTC) within the last		referrals

4.6.3 Are all identified PLHIV at C&T site and at CITC sites screened	yes	No
4.6.4 Assess overall status of TB/HIV collaborative activities in HF	P Score:	

4.7 STI diagnosis and treatment		
4.7.1 Does the facility provide STI diagnosis?	yes	No
4.7.2 Does the facility provide STI treatment?	yes	No
4.7.3 How many referrals for STI cases diagnosed with HIV took place from the STI-services to the CTC (in the HF or at the referral HF for CTC) within the last reported quarter?		referrals
4.7.4 Assess overall status of STI services in HF	P Score:	

4.8 PMTCT services		
4.8.1 Does the facility provide PMTCT services?	yes	No
4.8.2 What is a total number of pregnant and lactating mothers received HIV testing at this HF for the last one year?		Number
4.8.3 How many HIV positive Pregnant and lactating mother received ART services for the last one year?		Number
4.8.4 How many male partners were tested for HIV for the last one year?		Number
4.8.5 Does HF have referral mechanism for infants, HIV positive pregnant and breast feeding mothers between PMTCT and CTC services?	yes	No
4.8.6 Does the HF provide EID services?	yes	No
4.8.7 Did the HF experience any stock out of DBS Kits in the past 3 months?	yes	No
4.8.8 What is a turnaround time for DBS results at this HF?		Days
4.8.9 Assess the implementation status of PMTCT	P Score:	

4.9 Post Exposure Prophylaxis (PEP)	**Observe**	**Reported available, notseen**	**Not availabl e**
4.9.1 Is a PEP protocol available at the HF?			
4.9.2 Does the HF regularly updated PEP			
4.9.3 Assess PEP practice		P	

5. Patients Records and Administration

5.1 Medical records system			
5.1.1 Does the facility keep medical records (chart, files ystem) for all patients?	Yes,	Yes, not	No
5.1.2 Does the facility keep DBS results records?	Yes,	Yes, not	No
5.1.3 Does the facility use ILS/MTUHA for the facility record?	Yes,	Yes, not	No

5.1.4 Does the HF keep clinical records for C&T/PMTCT patients?	Yes, seen	Yes, not seen	No
5.1.5 Are these records computerized at the HF	Yes,	Yes, not	No
5.1.6 Assess completeness/correctness and management of these	P Score:		

5.2 Accessibility of medical records		
5.2.1 Are medical records stored in a place that can be locked?	yes	No
5.2.2 Assess how medical records are kept (locked area, access, filing	P Score:	

5.3 Current number of PLHA registered at the CTC		
5.3.1 Start date of ART at the facility	l l	
5.3.2 Number of HIV-positive persons registered for care		
5.3.3 Number of HIV-positive persons who are eligible for ART, but did not start		
5.3.4 Number of patients to date who ever started ART		
5.3.5 Number of patients who started ART, who visited at least once during the last quarter and were on treatment during the last visit date		
5.3.6 Assess data recording process at C&T Clinic	P Score:	

5.4 Current number of PLHIV registered at the PMTCT/PEDIATRIC ART		
5.4.1 Start date of ART at the facility	l l	
5.4.2 Number of partners tested HIV positive enrolled in care		
5.4.3 Number of children under 15 yrs diagnosed		
5.4.4 Number of HIV exposed infants registered at the facility		
5.4.5 Number of HIV-positive persons including partners who are eligible for ART but did not started		
5.4.6Number of patients ever started on ART at this facility to date		
5.4.7 Assess data recording process at C&T Clinic	P Score:	

	5.5 System for patient tracking		
5.5.1 Is appointments register available and in use?	Yes in use	Yes not in use	No
5.5.2 Is tracking register available and is used?			
5.5.3 Assess system for patient follow-up and		P Score:	

6. Continuum of Care

6.1 Referral system and linkage with community, NGOs, FBOs and other community based organizations

6.1.1 Partnerships:Are there any **formal** partnerships (any correspondence, MOU, meeting minutes, etc.) with NGOs, CBOs, FBOs, patient support groups etc. Please indicate below with whom:

Specify name of organization:	Organization type (NGO, CBO, and FBO etc.)	Supported services (spiritual, material, education, nutrition, IGAs, legal)	Documentation on partnership seen	
			yes	No
			yes	No
			yes	No
			yes	No
			yes	No
			yes	No

6.1.2 Indicate whether it is formal(written)referral	yes	No
6.1.3 In case referral system is formalized, documentation/referral slips	yes	No
6.1.4 Do FBO, NGO, CBO provides information about care, services and how to access these services?	yes	No
6.1.5 Does the facility work with a ward or a council AIDS Committee?		Month
6.1.6 Assess the referral system	P Score:	

6.2 Community Based HIV and AIDS Services (CBHS)

6.2.1 Is there a CBHS supervisor at the facility?	Yes	No
6.2.2 Is there a CBHS provider?	Yes	No
6.2.3 How many PLHIV were visited in the last reporting month?	Yes	No
6.2.4 How many LTFU clients were tracked and linked back to the health facility during the previous quarter?	Yes	No
6.2.5 Does the CBHS provider receive transport support? (If yes mention type of support such as bicycle or transport money)? ……..	Yes	No
6.2.6 Assess the Community Based HIV and AIDS Services (CBHS)	P Score:	

7. Laboratory		
7.1 Staffing		
7.1.1 How many laboratory technologists, lab technicians, lab assistants and lab attendants work in the laboratory?		Technologis
		Technicians
		Assistants
		Attendants

7.2 Laboratory space		
7.2.1 How many rooms does the laboratory have?		Rooms
7.2.2 Is there a separate section/room for specimen collection?	yes	No
7.2.3 Is the available space sufficient to carry out the lab work?	yes	No
7.2.4 Assess general condition of laboratory building	AScore:	

7.3 Laboratory record management and storage		
7.3.1 Is there a lockable room or cabinet for record storage?	Yes	No
7.3.2 Assess status of laboratory record management	P Score:	

7.4 Test capacity of laboratory	**Available**		**If not available, referred to where?**
7.4.1 HIV testing (rapid)	Yes	No	
7.4. 2 CD 4 count	Yes	No	
7.4.3 Viral load	Yes	No	
7.4.4 Syphilis screening	Yes	No	
7.4.5 Haemoglobin	Yes	No	
7.4.6 WBC-total	Yes	No	
7.4.7 WBC-differential	Yes	No	
7.4.8 Blood sugar	Yes	No	
7.4.9 Urinalysis (glucose, proteins, sediment)	Yes	No	
7.4.10 Pregnancy testing	Yes	No	
7.4.11 Is there a working microscope in the lab(*if No, go to 7.3.14)*	Yes	No	
7.4.11 Stool (direct microscopy for organisms, worm eggs, occult blood)	Yes	No	
7.4.12 Sputum smears(TB)	Yes	No	
7.4.14 Malaria blood smear/rapid test	Yes	No	
7.4.15 Does the lab have a method for preservation and temporarily storage of specimens	Yes	No	
7.3.16 Is a functioning mechanism for transportation of specimens to another/referral CTC in place?	Yes	No	
7.3.17 If other tests are available, specify:			

7.5 Haematology						
Class of equipment		**Available?**				**Remarks**
		yes	**Operating?**		**Not seen**	
			yes	**no**		
Haematology	7.5.1 Manual haematology + diff.					
	7.5.2Automatedhaematologycounter					
7.5.3 Is the availability of supplies for haematology equipment regular?					yes	no
7.5.4 Stock-out for haematology supplies in the past 6 months seen?					yes	no
7.5.5 Assess the status of haematology equipment and supply chain					A	

7.6 Biochemistry						
Class of equipment		**Available?**				**Remarks**
		yes	**Operating?**		**Not seen**	
			yes	**no**		
Blood Chemistry	7.6.1 Manual (spectrophotometer)					
	7.6.2 Automated chemistry analyzer					
	7.6.3 Water bath					
7.6.4 Is the availability of supplies for biochemistry equipment regular?					yes	No
7.6.5 Stock-out for biochemistry supplies in the past 6 months seen?					yes	No
7.6.6 Assess the status of biochemistry equipment and supply chain					A	

7.7 Microbiology/parasitology						
Class of equipment		**Available**				**Remarks**
		yes	**Operating?**		**Not seen**	
			yes	**no**		
Urine, stool, malaria, TB	7.7.1 Routine testing					
	7.7.2 Routine test urine (manual					
	7.7.3 Malaria blood smears					
	7.7.4 TB sputum (microscopy)					
	7.7.5 Pregnancy testing (manual					
7.6.6 Is the availability of supplies for microbiology/parasitology					yes	No
7.6.7 Stock-out for microbiology/parasitology supplies in the past 6					yes	No
7.6.8 Assess status of microbiology/ parasitology equipment and					A	

7.8 Refrigeration and storage			
7.8.1 4^{O}C refrigerator with a compartment for	yes, seen	yes, not	No
7.8.2 4^{O}C refrigerator &freezer compartment for	yes, seen	Yes ,not	No
7.8.3 Are thermometers in place and temperature logs kept Lockable store?	yes, seen	yes, not seen	No
7.8.4 Is an Itemized inventory of the store available?	yes, seen	yes, not	No
7.8.5 Assess refrigeration and storage capacity		P Score:	

7.9 Laboratory Quality Assurance			
7.9.1 Does the laboratory have and use *Standard Operating Procedures* for all the tests performed?	yes,seen	yes,notseen	No
7.9.2Are any *internal quality control* arrangements in	yes, seen	yes, not	No
If yes, specify:	monthly	weekly	Daily
7.9.2.1 HIV-tests:			
7.9.2.2 Haematology:			
7.9.2.3 Biochemistry:			
7.9.3 Are any *external quality control* arrangements and/or assessments in place?	yes,seen	yes,notseen	No
Ifyes,specify:	From	How often per year:	
7.9.3.1 HIV-tests:			
7.9.3.2 Haematology:			
7.9.3.3 Biochemistry:			
7.9.4 Assess QA system for lab	P Score:		

7.10 Back-up capacity for laboratory			
7.10.1 Emergency water reserve (1000litre) for lab?	yes, seen	yes, not	No
7.10.2 Electricity power back-up (generator/solar)?	yes, seen	yes, no tseen	No
7.10.3 Assess back-up capacity for lab		A	

8.1 Staffing		
8.1.1 How many pharmacists, pharmaceutical technicians, assistants and attendants work in the pharmacy?		Pharmacist
		Pharmacy technician
		Pharmacy attendant
		Nurse
		Medical attendant
		Other staff
8.1.2 Assess the staff situation at the pharmacy	A	

8.2 Functional ARV tracking system			
8.2.1 Is dispensing register for ARV & OIs available and used?	observed	Not observed	N
8.2.2 Is ledger book for ARVs & OIs available and	observed	Not	N
8.2.3 Are bin cards available and updated?	observed	Not observed	N
8.2.4 Is there a first in first out (FIFO) &FEFO	observed	Not	N
8.2.5 Is there a system to manage nearly expired ARVs & OI drugs?	observed	Not observed	N o
8.2.6 Assess the pharmacy ARV& OI drugs management system		P Score:	

8.3 Dispensing practice			
8.3.1 Do pharmacy staffs provide information on the use of medicines to the patient?	observed	Not observed	No
8.3.2 Do pharmacy staffs verify/asses prescriptions provided, if they adhere to Rational use of Medicine and current National Guidelines	observed	Not observed	No
8.33 Does Pharmacy staffs have forms to report ADRs (Adverse Drug Reactions) Yellow Forms & Green			
8.3.3 Are ARVs dispensed by a pharmacy staff at CTC pharmacy?	observed	Not observed	No
8.3.4 Are ARVs dispensed at the	observed	Not	No
8.3.5 If pharmacy dispenses ARVs, assess the practice		P Score:	

8.4 Pharmacy Supplies			
Did the facility in the last half year have stock-out so far of the following drugs? (*NBtickinthe1st column if this drug is part of the essential drugs list for the facility*)			
8.4.1 Cotrimoxazole syrup		yes	No
8.4.2 Cotrimoxazole tabs		yes	No
8.4.5 Isoniazid		yes	No
8.4.6 RHEZ(Rifampicin/Isoniazid/Ethambutol/Pyrazinamide) FDCTB		yes	no
8.5.7 RH (Rifampicin/Isoniazid) FDC for continuation phase TB		yes	no
8.4.9ARVs for standard1st line treatment TLE		yes	no
8.4.10 Nevirapine syrup		yes	no
8.4.11Assesstheeffectivenessofthesupplychainsystem		P Score:	

8.5 Guidelines and SOPs			
8.5.1Arethere Guidelines and SOPs available?	yes, seen	yes, not seen	no
8.5.2 Does the pharmacy have and use national ARV Pharmacy instructions?	yes, seen	yes, not seen	no
8.5.3 Assess the status and quality of SOPs and policy		P Score:	
8.6 Storagecapacityfor6months'supplyofARVs			
8.6.1 Is therestoragespacefora6-months'supplyofARVs?	yes, seen	yes, not seen	No
8.6.2 Does the storage room have a refrigerator?	yes, seen	yes, not seen	N
8.6.3 Is the storage room cool, well ventilated?	yes, seen	yes, not seen	N
8.6.4 Assess storage capacity for ARs in the facility		A Score:	

9.1 Budget earmarked for strengthening clinical HIV and AIDS services		
9.1.1 Does the facility have a budget which has been earmarked for strengthening activities for HIV and AIDS services?	Yes	No

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

NATIONALHIV/AIDSCAREANDTREATMENTPLAN

Assessment Report for Health Centers and Dispensaries

Version3, October 2015

Name of health facility: _____
City/Town: _____
District: _____
Region: _____
Date of assessment: _____
Names of assessors: _____
_____

Enclosures

Completed assessment tool: ☐ Completed minimum criteria checklist: ☐

Fill in the strengths and weaknesses. Do not attempt to identify perse 3 of each. If less than 3 identified, present these. If more than 3 identified, prioritize or write in additional space.

Summary:

A summary on location (rural, urban) and structure of the facility

1. Organization of HIV/AIDS services within facility, infrastructure

Strengths:

1.
2.
3.

Weaknesses:

1.
2.
3.

2. Human resource capacity and training

Strengths:

1.
2.
3.

Weaknesses:

1.
2.
3.

3. Counseling and Testing services

Strengths:

1.
2.
3.

Weaknesses:

1.
2.
3.

4. Clinical HIV/AIDS care and treatment services

Strengths:

1.
2.
3.

Weaknesses:

1.
2.
3.

5. Patient records and administration

Strengths:

1.
2.

3.

Weaknesses:

1.
2.
3.

6. Continuum of Care

Strengths:

1.
2.
3.

Weaknesses:

1.
2.
3.

7. Laboratory services

Strengths:

1.
2.
3.

Weaknesses:

1.
2.
3.

8. Pharmacy services

Strengths:

1.
2.
3.

Weaknesses:

1.
2.
3.

9. Financial & legal issues

Strengths:

1.
2.

Weaknesses:

Table2.**Strengthening Plan (minimum criteria):** Enter the items to strengthen in the table below

The minimum criteria have been defined as the minimum conditions needed to initiate, refill or outreach ART. However, other items to strengthenresultingfromtheassessmenttoolcanbeadded.Foreachitemto strengthen; enter the minimum criterion number in the 2nd column.

*The responsible person for the strengthening, and for obtaining resources should be a representative from the health facility itself (not NACP/MOH).

**Indicate whether funds are available (Yes),N(No),NR(Not Required).

***Name the source of funding (health facility budget, CHMT budget, PEPFAR organization, Global Fund, etc.).

Item to strengthen and action to be taken (includingpossiblecomments/explanatio	Min. Crit.	Responsible person(s) (name)*,including position	Required budget	Funds available? Y/N/NR	Name of source of funding**	Responsible person(s) to obtain resources*	Date to be completed
1. Actio							
2. Actio							
3. Actio							
4. Actio							
5. Actio							
6. Actio							
7. Actio							
8. Actio							
9. Actio							
10. Actio							
11. Actio							
12. Actio							

Comments:

Participants during this visit

Assistant Medical Officer / Clinical Officer in Char of Health Facility Name: Signature: Date:	Name: Function: Signature: Date:
Assessment Coach: Name: Function: Signature: Date:	District Representative: Name: Function: Signature: Date:
Regional Representative: Name: Function: Signature: Date:	Third party / Partner Organization Name: Function: Signature: Date:

Annex 6: Viral load – converting log values to numbers

The range of viral load is so wide that results are often given as results from a logarithmic (log) scale.

This is an easier way to deal with very large and very small numbers at the same time. Below 50 copies/mL for most people on treatment is 1.7 logs. In very early infection, a viral load of 10 million copies is 7.0 logs.

Log value is a measurement used to describe HIV and expresses the viral load values as a power of ten (written log10). The scale is used because large changes can only be captured on graphs or diagrams by using a log scale. This turns large numbers of copies/mL into 'manageable' figures.

Table: HIV RNA viral load log value–number conversion

Log_{10}	**copies/mL**				
0.1	1	1.1	13	2.1	126
0.2	2	1.2	16	2.2	158
0.3	2	1.3	20	2.3	200
0.4	3	1.4	25	2.4	251
0.5	3	1.5	32	2.5	316
0.6	4	1.6	40	2.6	398
0.7	5	1.7	50	2.7	501
0.8	6	1.8	63	2.8	632
0.9	8	1.9	79	2.9	794
1.0	10	2.0	100	3.0	1,000
2.1	126	3.1	1,259	4.1	12,589
2.2	158	3.2	1,585	4.2	15,849
2.3	200	3.3	1,995	4.3	19,953
2.4	251	3.4	2,512	4.4	25,119
2.5	316	3.5	3,162	4.5	31,623
2.6	398	3.6	3,981	4.6	39,811
2.7	501	3.7	5,012	4.7	50,119
2.8	632	3.8	6,310	4.8	63,096
2.9	794	3.9	7,943	4.9	79,433

3.0		4.0	10,000	5.0	100,000
5.1		6.1	1,258,925		
5.2		6.2	1,584,893		
5.3		6.3	1,995,262		
5.4		6.4	2,511,886		
5.5		6.5	3,162,278		
5.6		6.6	3,981,072		
5.7		6.7	5,011,872		
5.8		6.8	6,309,573		
5.9		6.9	7,943,282		
6.0	1,000,000	7.0	10,000,000		

Annex 7: Dosages of Antiretroviral Drugs for Adults and Adolescents

Generic Name	Strength and Dose
NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NRTIs)	
Abacavir (ABC)	300 mg twice daily or 600 mg once daily
Zidovudine (AZT)	300 mg twice daily
Emtricitabine (FTC)	200mg once daily
Lamivudine (3TC)	150 gm twice daily or 300mg once daily
NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS (NtRTIs)	
Tenofovir (TDF)	300 mg once daily
NON – NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIs)	
Efavirenz (EFV)	400 - 600 mg once daily
Nevirapine (NVP)	200 mg once daily for 14 days, followed by200 mg twice daily
Etravirine (ETV)	200 mg twice daily
PROTEASES INHIBITORS (PIs)	
Atazanavir + ritonavir (ATV/r	300 mg + 100 mg once daily
Lopinavir/ritonavir (LPV/r)	400 mg/100 mg twice daily **Considerations for individuals receiving TB therapy** In the presence of rifabutin, no dose adjustment required. In the presence of rifampicin, adjusted dose of LPV/r: (LPV 800 mg + RTV 200 mg twice daily or LPV 400 mg + RTV 400 mg twice daily) with close monitoring.
Darunavir + ritonavir (DRV/r)	800 mg + 100 mg once daily[a] or 600 mg + 100 mg twice daily[b]
INTEGRASE STRAND TRANSFER INHIBITORS (INSTIS)	
Dolutegravir (DTG)	50 mg once daily
Raltegravir (RAL)	400 mg twice daily

a For individuals with no previous use of protease inhibitors.

b For individuals with previous use of protease inhibitors

Annex 8: Paediatric Antiretroviral Dosing

Chart 1

Weight range (kg)	Abacavir/ 3TC Adult	Abacavir/ 3TC Baby	Combivir Adult	Combivir Baby	Duovir N Adult	Duovir Baby	TLE or Atripla	Truvada	Lamivudine (3TC)	Abacavir (ABC)	Efavirenz (EFV)	Nevirapine (NVP)	Weight range (kg)
	Dose is ONCE daily	Dose is TWICE daily	Dose is TWICE daily	Dose is TWICE daily	Dose is TWICE daily	Dose is TWICE daily	Dose is ONCE daily (TDF 208 mg/m2)	Dose is ONCE daily (TDF 208 mg/m2)	4 mg/kg/dose TWICE daily	8 mg/kg/dose TWICE daily	ONCE daily for children > 3 years	160-200 mg/m2/dose TWICE daily	
	600 mg ABC/300 mg 3TC tablet	60 mg ABC/ 30 mg 3TC tablet	300 mg AZT/ 150 mg 3TC tablet	60 mg AZT/ 30 mg 3TC tablet	300 mg AZT/ 150 mg 3TC/200 mg NVP tablet	60 mg AZT/ 30 mg 3TC/ 50 mg NVP tablet	300 mg TDF/200 mg FTC (used with NNRTI or PI)	300 mg TDF/300 mg 3TC (or 200 mg FTC)/600 mg EFV	150 mg tablets	300 mg tablets	50, 200 and 600 mg tablets	10 mg/ml syrup	
3-4.9		1 tab BD		1 tab BD		1 tab BD						5 ml BD	3-4.9

5-5.9		1 tab BD		1 tab BD		1 tab BD						6 ml BD	5-5.9
6-6.9		1.5 tab BD		1.5 tab BD		1.5 tab BD						7 ml BD	6-6.9
7-7.9		1.5 tab BD		1.5 tab BD		1.5 tab BD						8 ml BD	7-7.9
8-8.9		1.5 tab BD		1.5 tab BD		1.5 tab BD						9 ml BD	8-8.9
9-9.9		1.5 tab BD		1.5 tab BD		1.5 tab BD						9 ml BD	9-9.9
10-10.9		2 tab BD		2 tab BD		2 tab BD					200 mg OD	10 ml BD	10-10.9
11-11.9		2 tab BD		2 tab BD		2 tab BD				0.5 tab BD	200 mg OD	10 ml BD	11-11.9
12-13.9		2 tab BD		2 tab BD		2 tab BD			0.5 tab BD	0.5 tab BD	200 mg OD	11 ml BD	12-13.9
14-16.9		2.5 tab BD	0.5 tab BD	2.5 tab BD		2.5 tab BD			0.5 tab BD	0.5 tab BD	200 mg + 50 mg OD		14-16.9
17-19.9		2.5 tab BD	0.5 tab BD	2.5 tab BD		2.5 tab BD			0.5 tab BD	0.5 tab BD	200 mg + 50 mg OD		17-19.9

20-24.9		**3 tab BD**	**1 tab AM, 0.5 tab PM**	**3 tab BD**		**3 tab BD**			**1 tab AM, 0.5 tab PM**	**1 tab AM, 0.5 tab PM**	**300 mg OD**		**20-24.9**
25-29.9	**1 tab OD**		**1 tab AM, 0.5 tab PM**		**1 tab BD**				**1 tab BD**	**1 tab BD**	**300 mg + 50 mg OD**		**25-29.9**
30-34.9	**1 tab OD**		**1 tab BD**		**1 tab BD**				**1 tab BD**	**1 tab BD**	**400 mg (200 mg x 2) OD**		**30-34.9**
35-39.9	**1 tab OD**		**1 tab BD**		**1 tab BD**		**1 tab OD**	**1 tab OD**	**1 tab BD**	**1 tab BD**	**400 mg (200 mg x 2) OD**		**35-39.9**

Chart 2

Weight range (kg)	Lopinavir/ritonavir (Kaletra®, Aluvia® – LPV/r)			Atazanavir/ ritonavir (Anzavir-R® – ATV/r)	Tenofovir/ emtricitabine (Truvada®)	Abacavir + Lamivudine (ABC/3TC Pediatric)	Abacavir + Lamivudine (ABC/3TC Adult)	Abacavir (ABC)	Weight range (kg)
	10-16 mg/kg/dose TWICE daily			Dose is ONCE daily	208mg/m2/dose ONCE daily	Dose is TWICE daily	Dose is ONCE daily	8 mg/kg/dose TWICE daily	
	SYRUP 80 mg LPV/20 mg ritonavir/mL	PEDIATRIC 100 mg LPV/25 mg ritonavir tabs	ADULT 200 mg LPV/50 mg ritonavir tabs	300mg ATV/ 100mg ritonavir	300mg TDF/200mg emtricitabine	60 mg ABC/ 30 mg 3TC	600 mg ABC/ 300 mg 3TC	300 mg tablets	
3-4.9	0.5mL BD					1 tab BD			3-4.9
5-5.9	1 ml BD					1 tab BD			5-5.9
6-6.9	1.5 ml BD					1.5 tab BD			6-6.9
7-7.9	1.5 ml BD	1 tab BD				1.5 tab BD			7-7.9
8-8.9	2 ml BD	1 tab BD				1.5 tab BD			8-8.9
9-9.9	2 ml BD	1 tab BD				1.5 tab BD			9-9.9
10-10.9	2 ml BD	2 tabs BD				2 tabs BD			10-10.9
11-11.9	2 ml BD	2 tabs BD				2 tabs BD		0.5 tab BD	11-11.9
12-13.9	2 ml BD	2 tabs BD	1 tab BD			2 tabs BD		0.5 tab BD	12-13.9
14-16.9	2 ml BD	2 tabs BD	1 tab BD			2.5 tabs BD		0.5 tab BD	14-16.9
17-19.9	2.5 ml BD	2 tabs BD	1 tab BD			2.5 tabs BD		0.5 tab BD	17-19.9
20-24.9	3 ml BD	2 tabs BD	1 tab BD			3 tabs BD		1 tab in AM, 0.5 tab in PM	20-24.9

25-29.9	**3.5 ml BD**	**3 tabs BD**	**2 tabs in AM, 1 tab in PM**				**1 tab OD**	**1 tab BD**	**25-29.9**
30-34.9	**4 ml BD**	**3 tabs BD**	**2 tabs BD**				**1 tab OD**	**1 tab BD**	**30-34.9**
35-39.9	**5 ml BD**	**4 tabs BD**	**2 tabs BD**	**1 tab OD**	**1 tab OD**		**1 tab OD**	**1 tab BD**	**35-39.9**

Annex 9: Third line Paediatric Formulation Dosing

Drug	Pediatric Formulation	Number of tablets by weight-band morning and evening (kg)										Adult formulation	Adult Tablets	
		3-5.9		6-9.9		10-13.9		14-19.9		20-24.9			25-34.9	
		am	pm	am	pm	am	pm	am	pm	am	pm		am	pm
RAL	Chewable					3	3	4	4	6	6	400 mg	1	1
	~~tablet 25~~ Chewable							1	1		1.5	400 mg	1	1
	~~tablet 100~~ Granules 100	0.25	0.25	0.5	0.5					~~1.5~~		400 mg	1	1
DRV/r [a]	Tablet 75 mg					3	3	5	5	5	5	600 mg + 100 mg	1	1
	Syrup 100					2.5	2.5 ml	3.5 ml	3.5 ml			600 mg + 100 mg	1	1
DTG[b]	50 mg												1	
ETV[c]	Tablet 25 mg, 100 mg, 200mg							100 mg[d]	100 mg[d]	125 mg	125 mg	200 mg	200 mg	200 mg[e]

[a]DRV/r must be administered with 0.5 ml of RTV mg/mL oral suspension if the child weighs less than 15 kg and with RTF 50 mg solid formulation for children weighing 15-30 mg. DRV/r should not be used in children younger than 3 years of age

[b]DTG is currently approved for patients 12 years and above.

[c]ETV is not recommended in patients less than 6 years of age or less than 16 kg. Dosing reference for ETV comes from Etravirine. In Lexicomp Online Database in Up To Date. Hudson (OH): Lexicomp Inc.: 2017.

[d]Dose of ETV for 16 kg to < 20 kg is 100 mg twice daily

[e]Dose of ETV for 25 kg to < 30 mg: 150 mg twice daily; ≥30 kg is 200 mg twice daily

Consult pharmacist for locally available formulations.

Annex 10. Modern Medications and Recommended Food Intakes and Side Effects

Medication	**Purpose**	**Nutrition Recommendations**	**Foods/Beverages/Herbs to Avoid**	**Potential Side Effects**
Sulfonamides: Sulfamethoxazole, Cotrimoxazole	Antibiotic for treating pneumonia and toxoplasmosis	Take with food		Nausea, vomiting, abdominal Pain
Rifampin	Treatment of TB	On an empty stomach one hour before or two hours after meals	Alcohol	Nausea, vomiting, diarrhoea, loss of appetite
Isoniazid	Treatment of TB	One hour before or two hours after meals Supplement with 10 mg vitamin B6 daily	Alcohol	Anorexia, diarrhoea; may cause possible reactions with foods such as bananas, beer, avocados, liver, smoked or pickled fish, yeast, yogurt; may interfere with vitamin B6 metabolism, therefore will require vitamin B6 supplement to prevent peripheral neuropathy and anaemia
Quinine	Treatment of Malaria	With food		Abdominal or stomach pain, diarrhoea, nausea, vomiting; lower blood sugar
Sulfadoxine and Pyrimethamine (Fansidar ®)	Treatment of Malaria Pyrimethamine is also used to treat toxoplasmosis	With food and consume large quantities of water Supplement daily with folinic acid (leucovorin), the		Nausea, vomiting, taste loss and diarrhoea; not recommended if folate deficient; not recommended for breastfeeding women

		active form of folate (5-10 mg/ day)		
Fluconazole	Treatment of thrush	With food		Nausea, vomiting, diarrhoea; can be used during breastfeeding
Nystatin ®	Treatment of thrush	With food		Infrequent occurrence of diarrhoea, vomiting, nausea
Antiretroviral drugs				
Abacavir (ABC) NNRTI	ARV	Can be taken without regard to food		Nausea, vomiting, fever, allergic reaction, anorexia, abdominal pain, diarrhoea, anaemia, rash, hypotension, pancreatitis, dyspnea, weakness and insomnia, cough, headache
Lamivudine (3TC) NNRTI	ARV	Can be taken without regard to food	Alcohol	Nausea, vomiting, headache, dizziness, diarrhoea, abdominal pain, nasal symptoms, cough, fatigue, pancreatitis, anaemia, insomnia, muscle pain, and rash
Zidovudine (AZT) NNRTI	ARV	Can be taken with food, but do not take with a high fat meal	Alcohol	Anorexia, anaemia, nausea, vomiting, bone marrow suppression, headache, fatigue, constipation, fever dizziness, dyspnea, insomnia, muscle pain, rash
Efavirenz	ARV	Can be taken	Alcohol	Elevated blood

NRTI		with food, but do not take with a high fat meal		cholesterol levels, elevated triglycerides levels, rash, dizziness, anorexia, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence
Nevirapine (NVP) NRTI	ARV	Can be taken without regard to food	St John's wort	Nausea, vomiting rash, fever, headache, skin reactions, fatigue, stomatitis, abdominal pain, drowsiness, paresthesia; high hepatoxicity
Lopinavir PI	ARV	Can be taken without regard to food	St John's wort	Abdominal pain, diarrhoea, headaches, headache, weakness, nausea; may increase the risk of lipodystrophy and or diabetes
Nelfinavir PI	ARV	Take with meal or light snack	St John's wort	Diarrhoea, flatulence, nausea, abdominal pain, rash; may increase the risk of lipodystrophy
Ritonavir PI	ARV	Take with meal if possible	St John's wort	Nausea, vomiting, diarrhoea, hepatitis, jaundice, weakness, anorexia, abdominal pain, fever, diabetes, headache, dizziness; may increase the risk of lipodystrophy

Saquinavir PI	ARV	Take with meal or light snack; take within two hours of a high fat meal and high calcium meal garlic supplements	St John's wort	Mouth ulceration, taste changes, nausea, vomiting, abdominal pain, diarrhoea, constipation, flatulence, weakness rash, headache; may increase the risk of lipodystrophy

Annex 11. TB Screening tools for HIV/AIDS Patients

TB SCREENING & IPT ELIGIBILITY TOOL FOR HIV/AIDS PATIENTS ABOVE 5 YEARS OLD

MINISTRY OF HEALTH AND SOCIAL WELFARE  COLLABORATIVE TB/HIV ACTIVITIES

Patient's name: .....Age:..... Sex: M/F ..... Date: ...../...../..... Reg. Number: .....

Date																			
1. Adults (5 years above)	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N
Cough of any duration?																			
Fever of any duration?																			
Noticeable weight loss for new patients or a 3 kgs weight loss in a month (in subsequent visits)?																			
Excessive night sweats of any duration																			

- If 'YES' to one or more questions: Do sputum examination and continue evaluation according to the TB diagnostic flowchart of the National Tuberculosis and Leprosy Program (NTLP)
- If 'No' to all questions asses for IPT eligibility and repeat TB screening at the subsequent visit (every month)

Action taken for presumptive TB.	Date	Result	Date	Result	Date	Result	Date	Result
Sputum smear /Gene expert								
Chest x – ray (if available)								
Refer for clinical assessment								
Started broad spectrum antibiotics								
Started anti – TB treatment								

2. IPT *contraindications* (tick all that apply)	Y	N	3. IPT inclusion (tick appropriate box)
Current/ past history of hepatitis			☐ Eligible (Answered NO to all questions in box 2)
Non-adherence to long term treatment			
Alcohol abuse (regular and heavy alcohol consumption)			☐ Not eligible (Answered YES to any question in box 1)
Medical contra- indication to INH			Patient accepted IPT Yes I No
Symptoms of peripheral neuropathy			If accepted, date IPT started__/__/__

TB SCREENING & IPT FORM FOR HIV INFECTED CHILDREN 5 YEARS AND BELOW

MINISTRY OF HEALTH AND SOCIAL WELFARE  COLLABORATIVE TB/HIV ACTIVITIES

Patient's name: .....Age:..... Sex: M/F ..... Date: ..... /...../..... Reg. Number:

.....

Date																	
1.For children 5 years and below	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N
Cough of any duration?																		
History of household contact with TB?																		
Fever of any duration?																		
Reduced activities or irritability for 2 weeks or more?																		
Inadequate weight gain, weight faltering? Weight loss?																		

- If 'YES' to <u>one or more</u> questions continue evaluation according to the Pediatric TB diagnostic flowchart of the National Tuberculosis an Program (NTLP) by filling table number 2.
- If 'No' <u>to all</u> questions asses for IPT contraindications in table 3 and repeat TB screening at the subsequent visit (every month)

2. Action taken for presumptive TB.	Date	Result	Date	Result	Date	Result	Date
Sputum smear /Gene expert							
TB Score (Paedatric TB score chart)							
Chest x – ray (if available)							
Started broad spectrum antibiotics							
Started anti – TB treatment							

- After ruling out TB disease, assess for IPT contraindications in table 3 and repeat TB screening at the subsequent visit (every month)

3. IPT ***contraindications*** (tick all that apply)	Y	N	4. IPT inclusion (tick appropriate box)