

THE UNITED REPUBLIC OF TANZANIA



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

NATIONAL GUIDELINES FOR THE MANAGEMENT OF HIV AND AIDS

Sixth Edition October 2017



NATIONAL AIDS CONTROL PROGRAMME



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**Sixth Edition
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Ministry of Health, Community Development, Gender, Elderly and Children.

National AIDS Control Programme

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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	Bacilli 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	Cryptococcal Antigen
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
ETV	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
HVL	HIV Viral Load
IDU	Injection Drug Users
IEC	Information Education and Communication
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
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
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

Since November 2004, the Ministry of Health, Community Development, Gender, Elderly, and Children (MOHCDGEC) through the National AIDS Control Programme (NACP) is coordinating a nationwide care and treatment programme, aimed at providing antiretroviral medicines (ARVs) to people living with HIV and AIDS (PLHIV). The main focus of the programme is to improve accessibility to antiretroviral therapy (ART) services at health facilities and through community-based HIV services (CBHS). It is estimated that about 56,000 new HIV infections occurred in Tanzania Mainland in 2015, of which 8,500 were vertical infections. At the end of 2016, there were 839,544 adults and children enrolled on ART, which is 62% of the HIV-infected individuals countrywide.

This National Guidelines for Management of HIV and AIDS 6th Edition 2017 has adopted the 2015 WHO Treatment Guidelines that recommend treatment of all HIV-infected individuals upon diagnosis irrespective of the disease stage. It provides details on ART for adults, adolescents, children, and pregnant and breastfeeding women. In addition, it provides details on differentiated service delivery models to enhance provision of client-centred care. This includes HIV testing, prevention, linkage and enrolment into care, retention and adherence in general HIV care and treatment, management of comorbidities, when to start ART, and preferred ART regimens. It also emphasizes integration and decentralization of services, by providing ARVs up to the lower level and at other clinics, such as: the prevention of mother-to-child transmission (PMTCT), maternal, newborn, and child health (MNCH), TB/HIV, and Medically-assisted Therapy.

This Guideline covers key areas of adult, adolescent, and paediatric 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; as well as, art adherence and disclosure. Other areas covered include, standard precautions in care settings and laboratory services, post-exposure prophylaxis, and ARV logistics and dosages. There is also an emphasis on differentiated service delivery models to support PLHIV, so as to have a holistic care

approach. It is also presented in a style that will hopefully make it easy to read, while at the same time serve as a basic reference material for further information on HIV and AIDS management.

Since rapid changes will continue to take place in the field of HIV prevention, care, treatment, and support, contributions from users of these Guidelines is vital. The comments from users will be useful in revising, improving and updating the guidelines, so as to keep abreast of scientific and technological changes. For that reason, your timely feedback will highly be appreciated.



Prof. Mohammed Bakari Kambi
Chief Medical Officer

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This National Guidelines for Management Guideline of HIV and AIDS 6th Edition of 2017 is a result of the revision of the National Guidelines for Management of HIV and AIDS 5th Edition published in 2015. The revision considered recommendations from the WHO 2015 Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infections and on going in country best practices.

The MOHCDGEC appreciates and acknowledges the valuable technical and financial assistance from stakeholders during the process of revision of the Guidelines. It is difficult to mention all who played key roles in the revision of the Guidelines, hence I would like to recognise and congratulate all staff of the National AIDS Control Programme (NACP) who took on this task with great courage and passion. The strong leadership and guidance of Programme Manager Dr. Angela Ramadhani was critical in its success. I also, would like to appreciate the excellent coordination and support of Dr. Anath Rwebembera, without their commitment and dedication, it would have been very difficult to promptly accomplish this task.

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Last but not least, I wish to recognize all technical experts who participated in reviewing this Guideline. Your contributions are highly acknowledged.

We wish you the best, and look forward to your continued commitment and dedication in supporting the Ministry.

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President's Office Regional Administration and Local Government (PORAG)
National AIDS Control Programme (NACP)
National TB and Leprosy Programme (NTLP)
Tanzania Food and Nutrition Centre (TFNC)
Muhimbili National Hospital (MNH)
Bugando Medical Centre (BMC)
Mbeya Zonal Referral Hospital (MZRH)
Kilimanjaro Christian Medical Centre (KCMC)
International Centre for AIDS Care and Treatment Programs (ICAP)
Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
Ariel Glaser Paediatrics AIDS Health Care Initiatives (AGPAHI)
Clinton Health Access Initiative (CHAI)
Tanzania Health Promotion Support (THPS)
International Training and Education Centre for Health (I-TECH)
Management for Development and Health (MDH)
Baylor International Pediatric AIDS Initiatives (BIPAI)
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We thank all health care workers, who have been using the fifth edition and provided suggestions for improvement, leading to the review of the old version, and thus the development of this new edition. We still welcome and encourage more input and suggestions, during the use of this guideline. Your work is highly appreciated.



Dr. Neema Rusibamayila
Director for Preventive Services

Executive Summary

The 2017 (6th edition) of the National Guidelines for Management of HIV and AIDS in Tanzania reflects substantial changes and a paradigm shift in the treatment and prevention of HIV infections. These Guidelines have adopted the WHO 2015 Consolidated Guidelines recommendation for use of antiretroviral medicines for treating and preventing HIV infection.

These Guidelines, makes the following new recommendations in managing HIV and AIDS in the country:

HIV Testing Services (HTS) should be offered in health facilities and community settings. HIV testing and counselling should be provided by a trained health care provider.

HIV testing and counselling should be offered to key and vulnerable populations presenting to health facilities or through community outreach services. For those who test negative, re-testing should be recommended after 4 weeks and, thereafter, routine HIV testing should be offered every 6 months. All clients diagnosed HIV-positive should be re-tested using the same testing strategy and algorithm before enrolling into care and initiating ART.

Where available, viral load (VL) should be used to monitor ART. VL monitoring will be conducted at 6 and 12 months after initiation of treatment and, thereafter, yearly annually if the patient is virologically suppressed.

All adults and adolescents with a VL measurement of greater than 1000 copies/ml should be managed as possible treatment failure by enhanced adherence counselling and should repeat VL test after 3 months.

CD4 T lymphocytes count should be done at baseline to determine immunological stage and establish need for Cotrimoxazole prophylaxis therapy (CPT). For clients with CD4 count of < 350, the test should be repeated every 6 months. When CD4 is >350, stop CD4 monitoring and continue with VL monitoring.

In settings where routine VL monitoring is NOT available, CD4 T lymphocytes count should be done at baseline for all clients and repeated every six months.

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

All breast-feeding women (unless known HIV-positive) should be counselled and tested for HIV during breast-feeding. If a breast-feeding mother was tested for HIV during the third trimester or at labour and delivery, a repeat HIV test should be offered at 6-month post-partum.

For pregnant and breast-feeding women already on ART: Conduct VL on first ANC visit, review results in 2 weeks; if <1000, repeat every 6 months. If >1000, manage as possible treatment failure (enhanced adherence counselling), repeat VL test after 3 months. Pregnant and breast-feeding women not yet on ART/newly diagnosed: conduct VL after 3 months from ART initiation; if <1000, repeat at 6 months on ART. If >1000, manage as possible treatment failure (enhanced adherence counselling), repeat VL test after 3 months.

All infants born to mothers known to be HIV positive should be offered HIV DNA PCR test at 6 weeks.

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

When available and approved, Tanzania will introduce new, more efficacious ARV drugs such as the NNRTIs (Etravirine –ETV), the 2nd generation PI (Duranavir-DRV) and integrase inhibitor (Dolutegravir-DTG, Raltegravir-RAL).

A set of service delivery models (SDMs) designed to expand coverage and access to ART, ensure quality of care, improve

adherence and retention, and provide tailored care and support to PLHIV. The roll out of HIV services in dispensaries and health centres focus on increasing coverage of health facilities offering ART services.

Tanzania has defined stable clients on ART as those who are above five years of age who on first line ARVs for at least six months and have no adverse drug reactions that require regular monitoring and no current illnesses (opportunistic infections and comorbidities). These clients need to have demonstrated good adherence of 95% and good clinic attendance for the past six months with VL below 50 copies/ml or a CD4 cell count of above 350 (in absence of VL).

Chapter 1:

Overview of HIV and AIDS

1.1 Epidemiology of HIV and AIDS

It is estimated that by 2015 there were about 36.7 million people living with HIV (PLHIV) globally.¹ In Tanzania by 2016, it was estimated that around 1.35 million people were infected with HIV in the country². Tanzania mainland is experiencing a generalised HIV epidemic, with an HIV prevalence of 5.3% in the general population. Heterosexual sex is the most common route (attributing up to 80%) of all new HIV infections in Tanzania Mainland.

HIV prevalence is higher in sub-groups such as 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 disproportionately 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 the 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: 90% of all PLHIV will know their HIV status (diagnosed), 90% of those diagnosed to have HIV infection will start on antiretroviral therapy (ART), and 90% of those on ART will achieve sustainable viral suppression by 2020. Attainment of these targets will lead to reduction of new HIV infections by 90%, providing an opportunity to end the AIDS epidemic by 2030.

¹UNAIDS Global AIDS Report 2016

²UNAIDS Gap Report 2016

³The 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-Behavioral Survey Among People Who Inject Drugs in Dar es Salaam. April 16, 2014

⁴Leshabari et. 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

⁵National 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)

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

The government has strengthened efforts to scale up HIV prevention, care, treatment, and support services including the recent adaption of the 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 0.93% among 15-19 year-olds and 0.32% among adults (aged 15-49) in 2016.⁷ The country's goal is to reduce the incidence in the general population to less than 0.16% by 2017.

1.2 The Impact of HIV and AIDS

1.2.1 Health Impact

The HIV and AIDS pandemic predisposes people to other infections such as tuberculosis (TB) and non-communicable diseases (NCDs), which are among the leading causes of morbidity and mortality among the PLHIV. TB and HIV co-infection has remained at the rate of 35-36% for the last three years. In 2015, 93% of all people diagnosed with TB infections were also tested for HIV, 35% of whom 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 challenges to overall health system. 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 affects 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 infections. Economically and socially disadvantaged segments of the population, including women, youth, and other marginalized groups, are disproportionately affected by the epidemic. Health status and death caused by AIDS are reported to have reduced the work force, productivity, and disposable incomes in many communities.

⁷Tanzania Spectrum model file 2016

1.2.3 Social Impact

HIV and AIDS-related deaths among youths and middle-aged adults has resulted in thousands of 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 a family's primary income earner. The HIV and AIDS epidemic has caused breakdown 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 also lack of opportunity 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 the 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 has increased from 52% in 2005 to 62% in 2016.

By the end of 2015, the number of health facilities registered to deliver HIV care and treatment services was over 3000⁸. The country is implementing initiatives to increase HIV testing services through expansion of provider initiated testing and counselling (PITC) and community-based testing and counselling (CBTC). By June 2016, it was estimated that 839,544 (63%) of an estimated (1.34 million) adults and children living with HIV were receiving antiretroviral drugs (ARVs).

⁸NACP, Report no:4 Implementation of HIV Care and Treatment Services in Tanzania, 2016

Provision of long-life ART to pregnant and lactating mothers (LLAPLA) as part of prevention of mother-to-child transmission (PMTCT) programs programmes has contributed to the decrease of the transmission of HIV infections from mother to child at six weeks from 8.7% in 2012 to 4.4% in 2015. Reproductive and child health (RCH) sites providing PMTCT services 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 receiving ARVs increased from 71% in 2012 to 90% in 2014.⁹

1.4 Basic Facts about HIV

1.4.1 Aetiology of HIV

In Tanzania, HIV infection is caused by HIV-1 subtype. The common HIV-1 sub-types (clades) in Tanzania are A, C, D, and their recombinants. There is no HIV-2 subtype infection has been reported 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 HIV2.

1.4.3 Pathophysiology of HIV infection

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 Langerhan cells of the skin and the microglial cells of the brain.

⁹MOH, Prevention of Mother to Child Transmission of HIV, Annual Report 2014

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. 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 (>106 copies/ml), and the CD4 cell count drops rapidly.

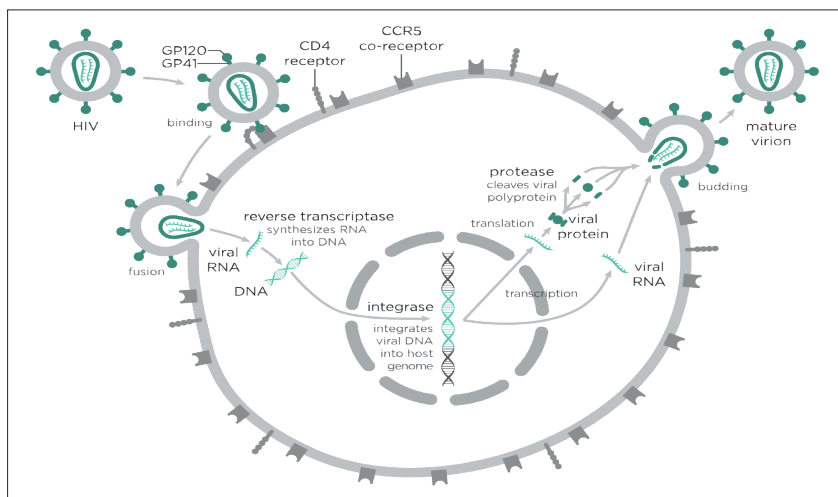
However, an immune response to HIV develops, that it restricts viral replication, resulting in a decrease in viral load and a return of CD4 T-cell numbers to near normal levels. Viral load remains relatively stable for a certain period (the "set point") and start rising again shortly before AIDS diagnosis.

For ART-naïve adults, a viral set point is reached after 6 weeks, and the median time to AIDS is 10 years. Paediatric patients, however, have much higher viral loads than adults: 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.¹⁰ (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 it easier for PLHIV to take more than one medication.

¹⁰Chan 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 This results in reduction of viral replication and a consequent reduction or reversal of destruction of in CD4+T lymphocytes.

1.5 Clinical Progression of HIV Infection

In the absence of ART, disease progression go through the following clinical stages: (Also s:(ee WHO Clinical Staging Criteria in Annexes 1 and 2).

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 - 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 1 and 2 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

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 are described.

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 required staff to run a CTC is composed of: Clinicians, Nurses, Laboratory Technologists, Pharmacists, Radiographers, and other support staff.

The minimum staff requirement to run a CTC includes one clinician, one nurse, and another health service provider. Roles and responsibilities of CTC staff are as stipulated in Annex 3

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

This section outlines the procedures starting with the client arrival to 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 health provider at the waiting area will do the following:

Inform clients about services provided and whom they can expect to meet
Inform clients on the clinic flow of services
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 client
Perform HIV verification test for all clients with a prior positive antibody test regardless of the place where the initial test was performed

Register the client in Appointment Register and in Pre-ART Register

Fill in correctly and complete CTC1 and CTC2 cards

Give CTC1 card to the client and tell the client to bring it 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

Link the client to the relevant service

Keep and retain the file in the facility registration unit

Conduct first session of adherence counselling

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 at each visit

Record clients in the appointment register

Check and ensure that CTC2 card, clinical forms, TB screening questionnaire, client physical address, laboratory results, and nutritional assessments forms are in the file

Assess willingness and readiness to start ARVs and address any pending issues

If willing and ready, preferably within 2 weeks

Continue with adherence counselling

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 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 soon if she/he is not feeling well

Confirm contact details and willingness to be tracked

Record in the appointment register the date and time for client next clinic visit

Ensure 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 health care workers (HCWs) when they have concern with health-related issues, and ensure availability of equipment and supplies (e.g., condoms, fliers, job aides, posters, etc.) at their clinics

2.3 Establishing Care and Treatment Service 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 4). 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 council health management teams (CHMTs) in collaboration with 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 standalone 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:

Outreach site

ART refill

2.4 Service Delivery Models (SDMs) for Differentiated Care

Service Delivery Models for differentiated 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.

With the new recommendation to “treat all”, and client centred approach there will be 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, different service delivery models have been developed to reach a diversity of clients, from those who present well, to those presenting with advanced disease, and from stable to unstable clients. Four groups of clients with different specific needs can be categorized through the differentiated service delivery models.

Table 2.1 Definitions of Different Categories of Clients to be Considered for SDM	
Clients with Early Disease: These are the clients who present with WHO Stage 1 or 2, and CD4 count ≥ 350 cell/mm ³ (or $\geq 35\%$ for children ≤ 5 years old). These clients require additional and targeted adherence support in order to commit to lifelong ART.	Clients with Advanced Disease: These are clients who present with low CD4 count ≤ 200 cells/mm ³ for adults and $\leq 25\%$ for paediatrics or WHO stage 3 and 4. This group requires expedited clinical investigations, management and prophylaxis of opportunistic infections prior to initiation of ART in order to reduce ill health and prevent death.
Stable Clients on ART: These are clients who meet all of the following criteria: - Age above five years, - Received ART for at least six months - Have no adverse drug reactions that require regular monitoring - No current illnesses (OIs and comorbidities) - Have good understanding of lifelong adherence of 95% and kept clinic visit appointments for the past six months - On first line ARVs, with undetectable viral load of below 50 Copies/ml. - In the absence of viral load monitoring, rising CD4 counts ≥ 350 cells/mm³. 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 on ART: These are the clients who meet any of the following criteria:
Age below 5 years,

Current ART for less than 6 months

Presence of an active OIs (including TB) 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 viral load monitoring decreasing CD4 cell count or $CD4 \leq 200$ cell/mm³

People Who Inject Drugs (PWID).

Pregnant women

Clients on second line regimen

These clients require additional clinical care, adherence support and timely switch to second-line 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.

Three elements considered in provision of client centred care; The clinical characteristics of the clients: Based on clinical characteristics, clients can be defined as stable, unstable, and those with co-morbidities or co-infections.

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.

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. 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:

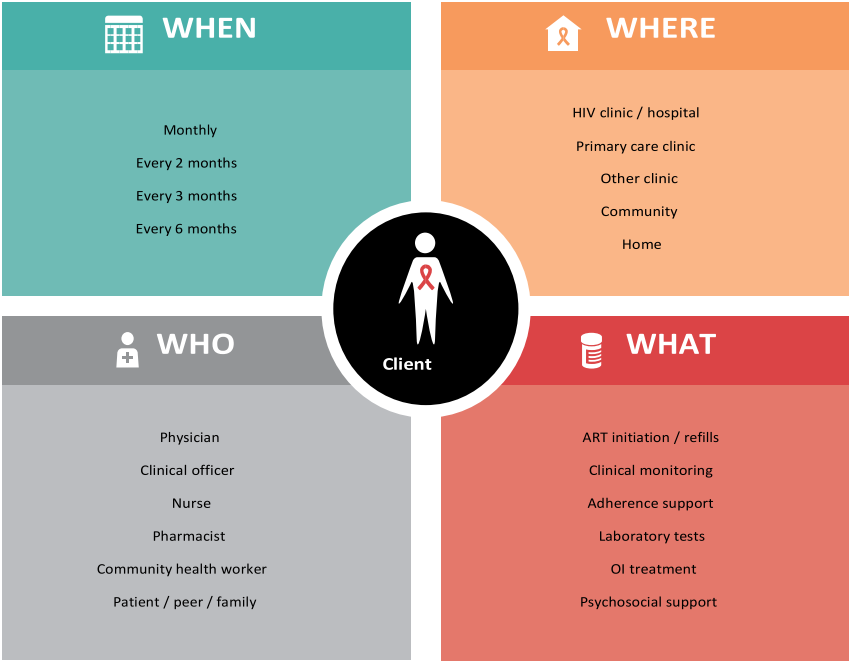
When is care provided?

Where is care provided?

Who is providing care?

What care or services are provided?

Figure 2.1 The Building Blocks of Service Delivery Models



Adapted from International AIDS Society (IAS). Differentiated Care for HIV: A decision framework for antiretroviral therapy delivery. July 2016.

Differentiated models of service delivery should be designed and implemented as a direct response to specific challenges or barriers identified for clients and/or health care workers. To decide which models are appropriate in any given setting, an assessment of local data, health care worker and client experience needs to be made. The following tables (1-5) summarize the recommended service delivery models that can be used in Tanzania.

Table 2.2 Differentiated HIV Testing Services			
When	Where	Who	What
General Population			
HTS should be available in all facilities during government defined opening hours. HTS should be available 24 hours (overnight and weekends) for facilities providing maternity and inpatient care.	Facility based testing: PITC should be offered in all entry points of the health facilities. The entry points should include OPD, IPD (including malnutrition and paediatric wards), 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 be offered as community based outreach testing monthly from all facilities.	Peers should be trained to mobilise communities to access HTS. All cadres of existing health care workers and other cadres identified by the Ministry of Health should be eligible to be trained to perform HTS. Every facility to ensure that there is always a HCW on duty who has been trained to perform HTS.	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		
	Targeted outreach testing to colleges, street children and orphanages should be included in monthly outreach planning.	Peer adolescent should be trained to mobilise adolescents for testing. All cadres of existing health care worker should be trained to prepare DBS samples for EID testing. All facilities should ensure there is always a HCW on duty who has been trained to provide HTS and 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		

	Re-testing of HIV negative pregnant and breastfeeding women should be integrated in facility and outreach EPI activities.		
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.	Districts should locate where specific KVP will access HTS and offer targeted outreach testing from the facility serving the defined location	KVP peers should be trained to mobilise their communities to access 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 treatment, GBV services, Prevention services (PEP).

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 Disease			
Eligibility Criteria for Early Disease: WHO Stage 1 or 2, and CD4 Count > 350 cell/L (or > 35% for Children ≤ 5 Years)			
When	Where	Who	What
General Population			
Starting ART will decrease risk of developing wasting and other infections. 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 preferably within 2 weeks of a positive HIV test, unless there is a medical or psychosocial contraindication. Follow up should be weekly until ART initiation, then week 2, then monthly until the patient is stable. Additional visits may be needed to address any medical or psychosocial concerns	At all facility levels Management of clients is done at any ART service delivery point	Initiation may be performed by a trained healthcare worker (doctor, AMO, clinical officer) Counselling including basic HIV and ART education and assessment for readiness to start ART (Nurses, 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.

Table 2.4b Differentiated ART Delivery for Clients with Advanced Disease				
Eligibility Criteria for Advanced Disease: WHO Stage 3 or 4, or CD4 Count ≤ 200 cell/ μ L (or $\leq 25\%$ for Children ≤ 5 Years)				
When	Where	Who	What	
ART is required to prevent further damage to the immune system Starting ART soon will decrease risk of disease progression, including wasting and OIs Initiation should take place preferably within 2 weeks of a positive HIV test, unless there is a medical contraindication or psychosocial contraindication. Weekly follow-up until ART initiation, and then at week 2 and 4 after ART initiation, and then monthly until the patient is stable. More frequent visits or hospitalization may be required to stabilize acute medical conditions and address psychosocial and other concerns	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 (Doctor, AMO, clinical officer,). Counselling including basic HIV and ART education and assessment for readiness to start ART (Nurses, doctor, AMO, clinical officer)	An assessment of both clinical and psychosocial readiness must be carried out before ART initiation. Assessment for Cryptococcal disease if CD4 < 100 cell/mm³ Counselling should include basic HIV and ART education and assessment of readiness to start ART.	

Table 2.5 Differentiated ART Delivery for Stable Clients

Eligibility Criteria for Stable Clients: Stable clients are defined as those clients who are above five years of age, received ART for at least six months and have no adverse drug reactions that require regular monitoring, no current illnesses (OIs and comorbidities), have good understanding of lifelong adherence of 95% and keeping clinic visit appointments for the past six months on first line ARVs, recent undetectable Viral Load (virologically suppressed) i.e. below 50 Copies/mls In the absence of viral load monitoring, rising CD4 counts and ≥ 350 cells/mm³.

Note: A stable patient should meet all the above eligibility 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 ART refills for stable clients should be provided for two months depending on supply 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 decentralised to existing facilities. This should include primary health facilities especially existing PMTCT sites. Additional dispensaries and health centres should be facilitated to become ART sites dependant on local demand and a clinic access assessment. Clients should receive ART at the health facility of their choice. In hard to reach areas, ART refills through a mobile outreach strategy by health care worker	Follow up on ART may be performed by any trained healthcare worker (Doctor, AMO, clinical officer, nurse).	Full clinical review should be done during clinical consultations. ART refills should be provided to clients according to service delivery model in use.

The following ART delivery models may be considered to differentiate ART delivery. The choice will depend on assessment of local data, HCW and client challenges. Recommended service delivery models for use in Tanzania include:

Facility based Individual fast-track from pharmacy - clients are seen individually within health care facilities and are fast-tracked for collection of the ARVs

Facility based health care worker managed group - clients are seen in a group managed by a health care worker, e.g. teen clubs, youth clubs

Community based individual ART delivery through mobile outreach - clients are seen individually outside of health care facilities by clinical staff as part of routine outreach

Family member or treatment supporter refill - client nominates a family member or treatment supporter to collect their ART refill from the pharmacy

Special Considerations for Children and Adolescents

Children aged <5 should receive one-month refills

Children ≥5 should receive two-three month refills. All sites providing paediatric ART services must have HCW trained on paediatric HIV

ART delivery should be provided outside school hours, during weekends or holidays.

Older children and their guardians should be booked on the same day. Group refill 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 refill approach and peer support. They should be grouped according to age and consideration of disclosure status. Group refill 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”. Women who were stable on ART and clinically stable before pregnancy will continue with ART refill model as a stable client from general population throughout the pregnancy whilst accessing their antenatal care.
Special Considerations for Key and Vulnerable Populations	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 particular key and vulnerable population 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 country.

Table 2.6 Differentiated ART Delivery for Unstable Clients			
Unstable Clients (any of the following): Current on ART for less than 6 months Any active OIs including TB in the past 6 months Poor or questionable adherence to scheduled clinic visits in the past 6 months Undetectable recent VL above 50 copies/mL Decreasing CD4 Count of CD4 < 350 cell/mm3 Age < 5 years PWID Pregnant women Clients on second line			
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 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 Second line initiation should be decentralised to all sites who have a qualified health care worker to switch	All levels of health care workers who have received training should be able to prepare a VL sample Clinician who have been trained to assess clients with treatment failure should be able to switch clients to second line	Case management to address reason/s for not meeting stable eligibility criteria Enhanced adherence counselling should be available both at facility and community level Viral load monitoring according to the national algorithm Appropriate switch to second line ART
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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 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 mistakes are found and corrected to avoid adverse outcomes.

Internal Quality Assurance

The facility in charge 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.

External Quality Assurance

National, regional and district QA team will visit CTC to conduct quality assurance supervisions visits. During such visit, 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 additional, the 5S and Improvement Collaborative approaches are deployed for improving the quality of the HIV and AIDS services

At regional, district and Health Facility level, QI Teams (QIT) and Work Improvement Team (WIT) should be formed and be active to carry out its 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

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 pre-test session, HIV testing, post-test session, referral and linkage services. The main approaches for HTS include Provider Initiated Testing and Counselling (PITC) and Client initiated Testing and Counselling (CITC). Both provided in facility or community.

3.1 HIV Testing Service Settings

HTS is the primary entry point for HIV diagnosis, counselling 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 targeted and refocus resources to most in need clients.

HTC 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. HTC 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, 2017.

3.2 Key Components of HTS Package

3.2.1: 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.

3.2.2 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, 2017.

Post-Test Session

Post-test counselling session is provided after the HIV test results are ready and shall be client-centred and based on the client's test results and on the specific risk of the client or patient stated risk behaviours, prior knowledge about HIV and AIDS is confirmed. People who test shall be encouraged to disclose their results to their sexual partners and encourage them to go for testing.

Refer to Table 3.1 for re-testing indications.

Table 3.1 Indications for Re-Testing		
Scenarios	When to Re-Test	Future Re-Testing
Have indeterminate HIV status	Immediately repeat the test following test instructions. OR immediately repeat test by another HTC provider or Laboratory technician	If still indeterminate status, retest in 2 weeks. If is indeterminate refer for ELISA test
Pregnant women in 2st trimester.	2nd, 3rd trimester or during labour or Delivery	For those whom were tested during third trimester or at labour and delivery, a repeat HIV test should be offered at 6 month and thereafter as per general population or with new pregnancy
Have specific incident of HIV exposure in last 3 months	4 weeks	With each new known exposure
Have on-going risk of infection (SW, IDU, MSM)	4 weeks	Annual
Have a spouse or partner with unknown HIV status or known HIV positive	4 weeks	After every 6 months
Have STI	4 weeks	With each new STI
Have clinical indication of HIV infection	4 weeks	With new exposure
Are victims of sexual violence or rape or experience occupational exposure	As per PEP guidelines	As per PEP guidelines

Post-Test Session for People who Test HIV Positive

Enrolment to care and treatment

Risk reduction counselling and positive living

Encourage disclosure to partner and family

Encourage partner and family testing

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 patients should be done for verification of test results before enrolment to care and treatment.

Treatment (ARV) is available and is recommended to all clients who have HIV Assess client readiness and willingness before initiation of ARV.

Start treatment as soon as possible (preferable within two weeks after testing positive).

ART should be taken as prescribed without missing a dose to allow long and productive life.

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.

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 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 11)

3.3.2 HIV Testing for Infants and Children Less than 18 Months

To establish 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 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 6 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 4 weeks and there after repeat after annually.

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.

However, the operationalization of this approach will be guided by the Standard Operating Procedure (SOP) document. Health care providers are required to use the SOP for guidance

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 ongoing HIV risk shall be linked to prevention services

Where possible trained health care workers or peers and 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 HTS.

Chapter 4:

Laboratory Tests for Diagnosis and Monitoring of HIV and AIDS

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 for while viral load is used to determine 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

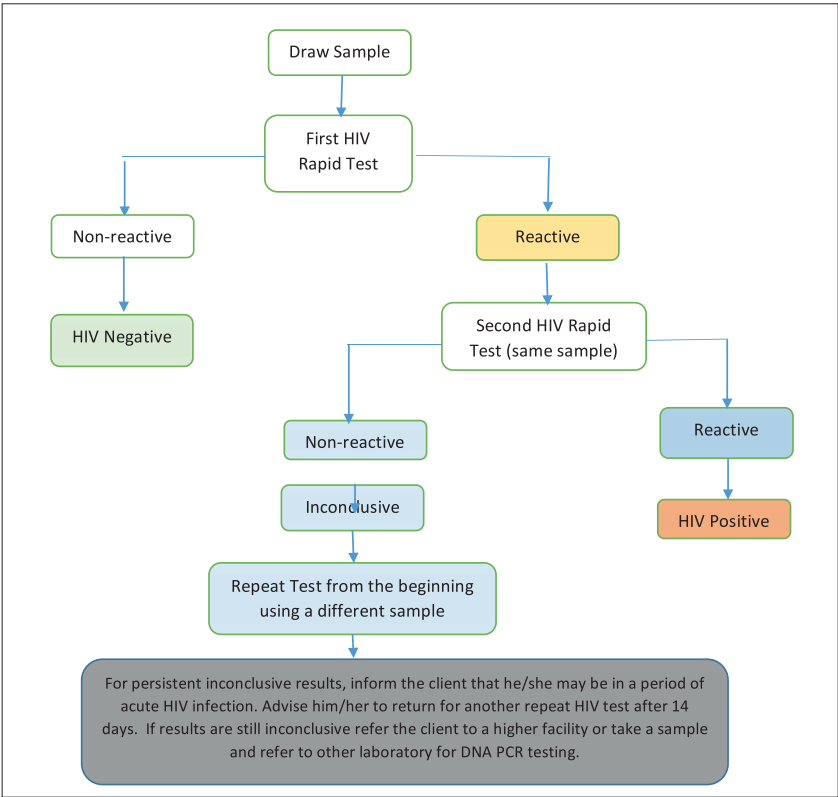
In adults and children older than 18 months, diagnosis of HIV infection is done by detection of antibodies using HIV rapid tests as indicated in the National HIV testing algorithms. Figure 4.1

HIV testing algorithm describes the number, type and order of tests that need to be performed. The first test 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 health service providers trained to performed HIV rapid tests.

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



4.1.2 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 6 weeks. Further detail on diagnosis of HIV infections in children under 18 months, is outlined in chapter 7 Section 7.1.1).

4.1.3 Retesting prior to initiation of ART

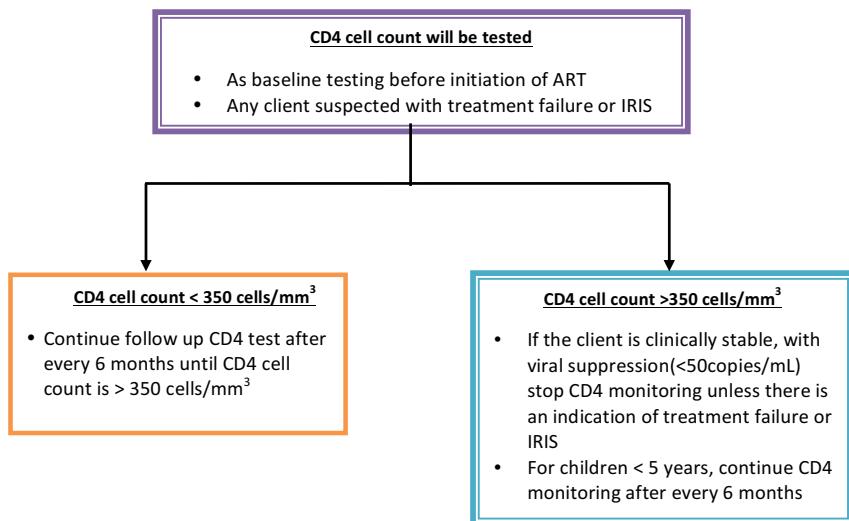
Conduct rapid HIV retesting for verification of HIV status to newly diagnosed HIV positive clients before or at initiation of ART using the national approved HIV testing algorithm, at CTC.

However, the operationalization of this approach will be guided by the Standard Operating Procedure (SOP) document. Health care providers are required to use the SOP for guidance

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 above 5 years while in children under 5 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 (Ref. Figure 4.2).

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



4.3 Tests for Monitoring Responses to Antiretroviral 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 monitoring approach to diagnose and confirm 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 HVL Testing Algorithm for Adolescents and Adults

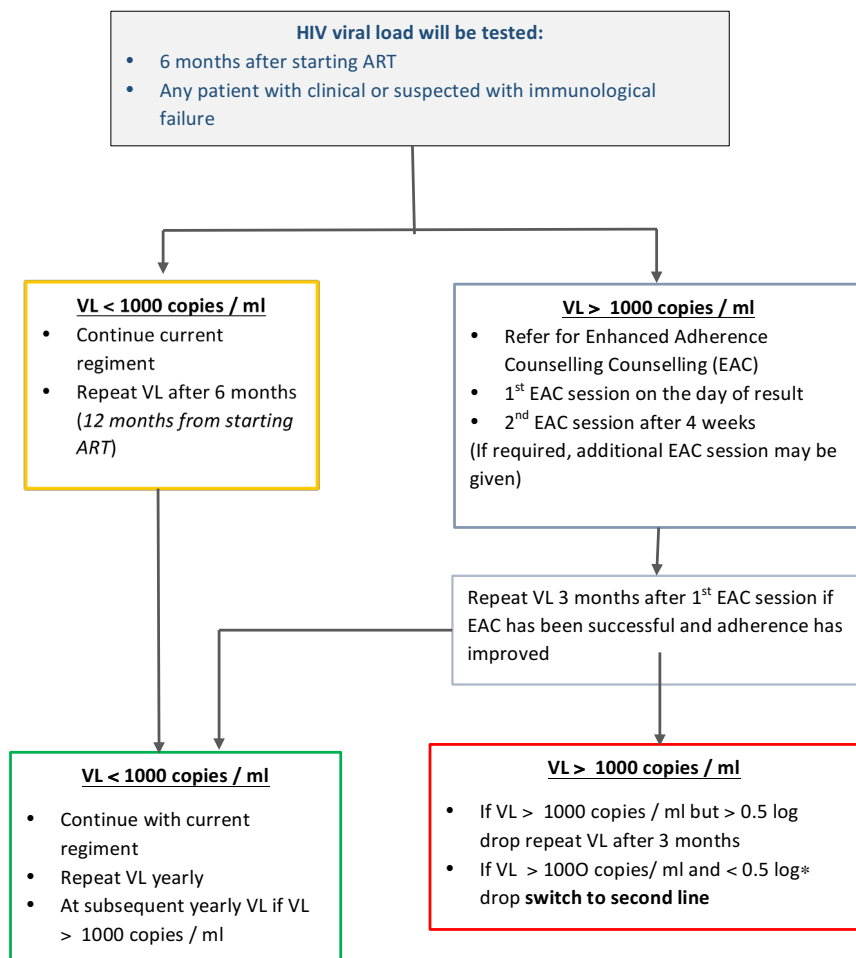
Perform 1st HVL test at six months after initiation of ART. Repeat HVL test six months later if the initial HVL test result was less than 1000copies/mL. Then HVL test will be performed annually if two preceding HVL test results were less than 1000copies/mL.

If the preceding HVL test result was more than 1000copies/mL, perform HVL test after 3 months of enhanced adherence counselling.

For clients, who have been on ART and immunological monitoring for more than 6 months without being tested for HVL test performed at any time at any first encounter.

NOTE: Thereafter, during subsequent HVL tests, if the results are more than 1000cp/ ml, the client should be subjected to Enhanced Adherence Counselling (EAC) and repeat the HVL test after 3 months.

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

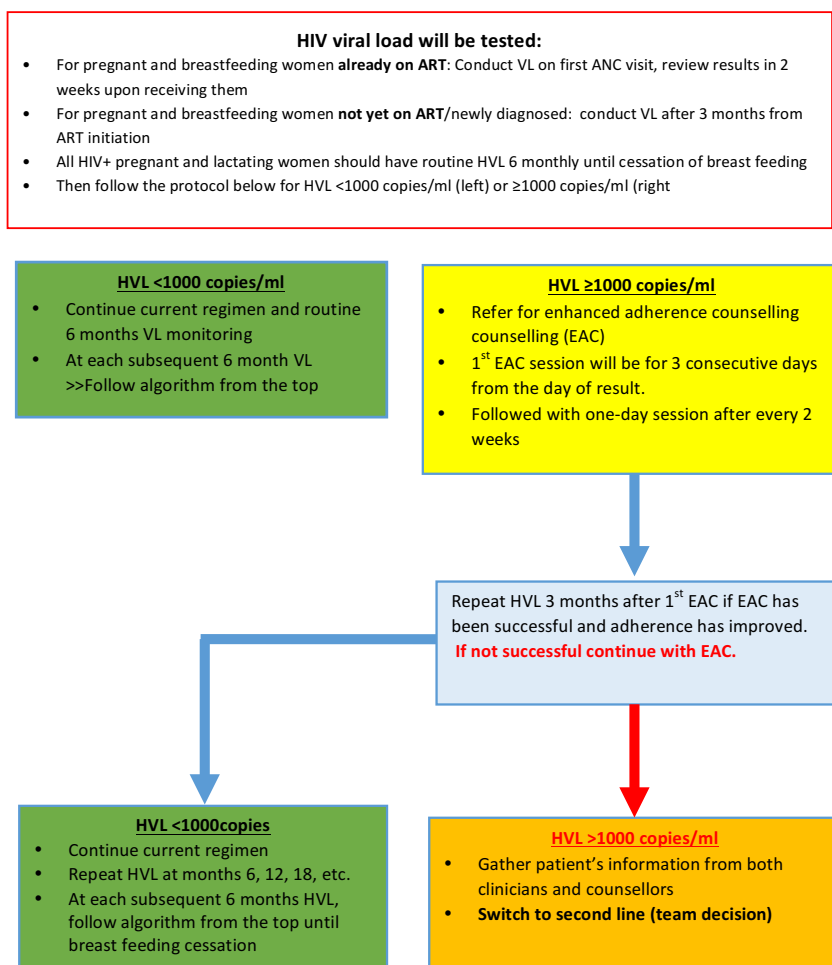
Figure 4.3 HVL Monitoring Algorithm for Adolescents and Adults

* See Annex 05 for Conversion of HVL to log₁₀ values.

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 Test
Baseline investigation	Verification of HIV test results TB Screening CD4 count/percentages HbsAg Hematological test Biochemistry test (ALT, RFT) Cryptococcus antigen if CD4 count<100 cells/mm for children below 5 years 10% CD4 cell count Screening for sexually transmitted infections

During ART	Hb for AZT1 Creatinine clearance for TDF2 ALT Haematological test (FBP- Attn: Hemoglobin) Biochemistry test (Lipids, RFT) HVL
	HVL CD4 Haematological test Biochemistry test HBsAg serology
Treatment Failure	HIV Drug Resistance where accessible

4.5 Tests for Monitoring Antiretroviral Treatment Safety (Toxicity)

Antiretroviral 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 mmol/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 2 weeks after the initial test and re-assess		Continue ART Repeat test 1 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 be handled carefully 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 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), Retesting and on-site evaluation. The benefits of doing EQA include comparing performance among different testing sites, detection of the early warning signs for system testing problems, objective evidence of testing quality, areas that need improvement and training needs. EQA is mandatory for all tests that are done in monitoring of HIV clients, hence involving all areas that participate on testing and monitoring of HIV infected and AIDS clients (e.g. RCH, VCT, Laboratory, 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

Is a system whose sample testing is performed by one HF and then retested at the different HF or reference laboratory for comparison of results. The samples for inter laboratory 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 laboratory practices and provides assistance on problematic areas. This will include retesting of samples.

Chapter 5: HIV Prevention

Introduction

This chapter describes the Combination Prevention approach which include; 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 the 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 ensures 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 promotion

Messaging 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 change¹¹.

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

Table 5.1 Structural and Behavioural Drivers

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

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 level to promote enabling legislation and remove barriers to change.

Communication to 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 with individuals, groups and communities to encourage groundswell 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.

PLHIVs 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 behaviour). However, it is known that HIV-positive persons not on ARVs and having unprotected sex may have high viral loads and may be at high risk of transmitting HIV to their sexual partners.

PLHIV having once being very ill but are now on ART, generally, they 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 viral load suppression to undetectable levels which decrease likelihood of transmitting HIV. However, even while on ARTs, there are possibilities of PLHIV transmitting HIV, including drug resistant strains. So, it is important for health care 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

Health care 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, health care 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 health care 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 includes 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 infection 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).¹²Also 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 micturition, abnormal vaginal/urethral discharge, genital ulcerations, genital itching, 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.

¹²ANC Surveillance 2012

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 often overlooked Similar clinical features can be caused by a variety of causative agents Requires long term training Does not identify asymptomatic STI Atypical 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 none specificity of symptoms, stigma and social implications attached to STIs, health care 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 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 outlines the 9 common STI syndromes and their etiologic agents.

Table 5.2 STI Syndromes and their Aetiological Agents		
STI SYNDROME	SEX	COMMON AETIOLOG-IC AGENT
Urethral Discharge Syn- drome (UDS)	Males	Chlamydia trachomatis Neisseria gonorrhoeae
Painful Scrotal Swelling (PSS) (acute epididy- moorchitis)	Males	Chlamydia trachomatis Neisseria gonorrhoeae
Vaginal Discharge Syn- drome (VDS) ¹	Females	Candida albicans Chlamydia trachomatis Gardnerella vaginali Neisseria gonorrhoeae Trichomonas vaginalis
Pelvic Inflammatory Disease (PID) (Lower Abdominal Pain)	Females	Anaerobic bacteria Chlamydia trachomatis Neisseria gonorrhoeae
Genital Ulcer Dis- ease(GUD)	Males Females	Chlamydia trachomatis Haemophilus ducreyi Herpes simplex virus- type-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 (Ophthalmia 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 African countries in the year 2000 occurred in Tanzania.¹³ Furthermore, 80% of patients diagnosed with cervical cancer die within 5 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

¹³Parkin DM, Pisani P, Ferlay J: Estimates of the worldwide incidence of 25 major cancers in 1990. Int J Cancer 1999, 80:827-841.

cervical cancer 10 years earlier than HIV- negative women¹⁴. 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.^{15, 16} 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 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 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

¹⁴Kahesa 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.

¹⁵Hakama M, Chamberlain J, Day NE, Miller AB, Prorok PC: Evaluation of screening programmes for gynaecological cancer. *Br J Cancer* 1985, 52(4):669-673

¹⁶Chirenje ZM, Rusakaniko S, Kirumbi L, Ngwalle EW, Makuta-Tiebere P, Kaggwa S, Mpanju-Shumbusho W, Makoe 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

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 health care 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. (Note: More details are available in the national SRHS/FP guidelines.)

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 health care 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 health care settings from a patient to patient and patient to a health care 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 antiretroviral 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

antiretroviral 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 2 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, breast feeding, 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 should be offered.

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:

For Adults: TDF 300mg + 3TC 300mg + EFV 600mg* once a day for 4 weeks

For children (based on body weight):

Less than 3 years: AZT + 3TC + LPV/r twice daily for 4 weeks

More than 3 years: AZT + 3TC twice daily + EFV once daily for 4 weeks

* When available, TDF/3TC/EFV400 is preferred

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 tolerated 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.

5.8 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 heterosexual men. Three randomized controlled trials^{17, 18} 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 is about 72% [15]. This prevalence is largely a result of traditional male circumcision practices, which take place in almost a half of Tanzanian communities. The male circumcision rate is as low as 26% in non-circumcising communities. The coverage

¹⁷Bailey 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](#)]

¹⁸Citation 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](#)]

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.¹⁹

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.

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 client who test positive to a care and treatment clinic.

Refer clients who test positive to care and treatment for clients who test HIV positive.

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

¹⁹United Republic of Tanzania MoHSW, National AIDS Control Programme,. National Strategy for Scaling Up Male Circumcision for HIV Prevention. 2010.

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): KPs are defined groups 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 also essential partners in an effective response to the epidemic.

Vulnerable populations (VPs): are groups of people who are particularly vulnerable to HIV infection in certain situations or contexts, such as 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.²⁰

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)

²⁰WHO Consolidated Guidelines on HIV prevention, diagnosis, treatment and care for key populations 2016

Disabled persons in all forms
Street living or working children and displaced people.

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 health care 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

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 behaviour 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

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

Introduction

Antiretroviral 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 antiretroviral therapy regardless of CD4 cells count will prevent occurrence of OIs and other co-morbidities.

On the other hand, effective use of ART among PLHIV has resulted into improved survival and quality of life, thus leading to increased risk of NCDs associated with ageing^{21, 22} other risk factors for NCDs are raised blood levels of low density lipoprotein, total cholesterol (TC) and triglyceride, overweight/obesity, abnormal waist circumference, aged >40 years and ART20 NCDs in PLHIV are also related to side effects of some of ARVs²³ and HIV itself. Commonest NCDs in HIV include cardiovascular diseases, diabetes, chronic lung diseases and malignancies.^{24, 25} In Tanzania, the commonest NCDs reported among PLHIV were 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 comorbidities commonly seen among adolescent 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.

²¹WHO, Preventing and managing other comorbidities and chronic care for people living with HIV. World Health Organization 2013

²²Rabkin 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.

²³Nigatu, T., Integration of HIV and Noncommunicable Diseases in Health Care Delivery in Low- and Middle-Income Countries. Prev Chronic Dis, 2012. 9.

²⁴UNAIDS, Chronic care of HIV and non-communicable diseases. How to leverage the HIV experience? Joint United Nations Programme on HIV AND AIDS. 2011

²⁵Kagaruki, 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.

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

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 oxymeter 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-diarrhoeal 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 Headache

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 cryptococcal meningitis
Salmonella and syphilis serology
Blood cultures + sensitivity studies.
Serum Biochemistry where possible
Serum Cryptococcus Antigen test (CrAg)
CT brain scan/MRI brain 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	• BBenzyl benzoate Emulsion 25% (twice a day applications after bath for 2-3 consecutive days) • CCrusted scabies use Ivermectin 20mcg/kg once then repeated in two weeks If secondarily infected • CCloxacillin 250mg TID for 5-7days or Erythromycin 500mg TID for 5-7days
Dermatomy- coses		• WWhitfield's ointment • GGriseofulvin tablets 15-25mg/kg once daily for 6 weeks for Tinea • CClotrimazole or Miconazole cream for Candidiasis • TTerbinafine 250mg od for at least 2 weeks • FFluconazole 150mg or 200mg od for at least 2 weeks

Impetigo		Localized –use topical mupirocin ointment 2% BD for 5days • EExtensive – Cloxacillin 250mg TID for 5-7days • EErythromycin 500mg TID for 5-7days
Papular Pruritic Eruption (PPE)		• Antihistamine, e.g., Cetirizine 10mg once daily for 3 days or Loratidine 10mg • TTopical steroids, e.g., hydrocortisone, Mometasone cream Antibiotics if there is secondary bacterial infection, e.g. Cloxacillin or erythromycin
Seborrheic Dermatitis		Antifungal • kKetoconazole 2% lotion 2-3 times/week for 4 weeks Systemic antifungal if severe • TTopical 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 • CCryotherapy • EElectro cauterization
Kaposi's sarcoma (KS)	1. CCutaneous biopsies using punch biopsy 2. DDiagnosis 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: • AAnti-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: • FFever • LLymph node enlargement • SSsmall painful vesicles • PPainful ulcers on the mucosa and skin • PPain 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.	• AAcylovir 400mg orally 8 hourly for 7 days for mild and moderate cases of HSV (e.g. cold sores) • AAcylovir 800mg orally, five hourly for 5 days for severe and recurrent HSV(e.g. genital infection, gingivitis, pharyngeal tonsillitis) • AAntibiotics such as Erythromycin should be used when there is secondary bacterial infection • AAanalgesics 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 - o IV/oral Acyclovir 10 mg/kg/day 8 hourly for 7 days for disseminated VZV or ophthalmic nerve involvement - o Erythromycin or Cloxacillin 500mg 8 hourly for 7 days for bacterial super-infection - o Amitriptylin 25-50mg nocte for post-herpetic pain (neuralgia) or Carbamazepine start 100mg od - o Analgesics, e.g., Paracetamol, Aspirin, or Diclofenac to relieve pain Note: Use of steroids (prednisolone) in herpes zoster is not recommended.
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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	• PPatients 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. • WWhere available, a barium swallow X-ray/oesophago-gastro duodenoscopy (OGD) can be performed. • SSymptoms for trachea-bronchial and pulmonary candidiasis may include fever, non-productive cough, dyspnea, and tachypnea. Investigations include bronchio-alveolar lavage (BAL) for microscopy and biopsy using bronchoscopy. • FFor treatment, any of the following may be used: • FFluconazole oral/IV 150mg/day or 200mg/day for 2-3 weeks (for oro-pharyngeal candidiasis and others) • MMiconazole oral gel 3-4 times/day after meals for 7 days • NNystatin oral suspension 4-6mls 3-4 times/day continue for at least 2days after oral lesions have disappeared • GGentian 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.	• CClotrimazole pessaries • MMiconazole pessaries Fluconazole taken orally (in case of pessaries failure)
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Cryptococcal meningitis	• L Lumbar puncture-measurement of Cerebral Spinal Fluid (CSF) opening pressure and demonstration of positive CSF with Indian Ink preparation OR • R Rapid CSF cryptococcal antigen (CrAg) assay OR • R Rapid serum CrAg	The preferred regimen is in 3 phases: Phase 1: Induction phase • AAmphotericin B 0.7mg/kg/day IV + 5 Flucytosine 100mg/kg/day administered orally for 14 days Phase 2: Consolidation phase • FFluconazole 400mg/ day for 8 weeks or until CSF is sterile. Phase 3: Suppressive phase Give patient maintenance therapy with Fluconazole 200mg per day. In absence of Amphotericin B and Flucytosine, alternative therapy should be: Phase 1: Induction phase • FFluconazole 1200mg IV/ORAL once daily for 14 days Phase 2: Consolidation phase • FFluconazole 400mg/ day for 8 weeks or until CSF is sterile. Phase 3: Suppressive phase • GGive patient maintenance therapy with Fluconazole 200mg per day. Note: It is recommended to initiate ART 5 weeks after initiation of Cryptococcal meningitis treatment in ART naive patient to prevent IRIS and mortality.
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Pneumo-cystic 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 4times/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
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Protozoal conditions		
Toxoplasmosis	Clinical features include: - FFocal paralysis or motor weakness depending on the brain area affected - NNeuro-psychiatric manifestations corresponding to the affected area in the brain - AAAltered mental status (forgetfulness etc.) - DDiagnosis 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.	- AAcute infection - SSulphadiazine tabs 1 gm 6 hourly + Pyrimethamine tabs 100mg loading dose, then 50mg /day + Folic acid tabs 10mg /day for 6 weeks. - CClindamycin capsules 450mg -600mg 6 hourly + Pyrimethamine tabs 100mg loading dose, then 50mg /day for 6 weeks. - AAAfter six weeks of treatment - GGive 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 - DDiscontinue maintenance therapy when CD4 count is >200cells/ml, initial therapy is completed and patient is asymptomatic. - PPrimary 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 10 mg 3 times a week.

Cryptosporidiosis	• CCryptosporidiosis (<i>cryptosporidium parvum</i>, <i>cryptosporidium meleagridis</i> and <i>cryptosporidium hominis</i>) is the common cause of chronic diarrhoea.	• 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.
	• Diagnosis can be made by microscopic examination of the oocytes in stool or tissue with acid-fast staining or direct immunofluorescence	

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. pneumonias,
- 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:

1. 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.
2. Pregnant women who are receiving CPT do not need sulfadoxine pyrimethamine (SP), an additional medication to prevent malaria
3. 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 (160/800 mg) or two single strength tablets once a day on a daily basis. For those whose weight is <60 kg, 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. Isoniazid Preventive Therapy against TB in PLHIV:

There is sufficient evidence on the benefits of Isoniazid (INH) preventive therapy against *Mycobacterium tuberculosis* for HIV infected individuals in whom active TB has been excluded. In this category of HIV patients, Isoniazid Preventive Therapy (IPT) can be offered at a dosage of 300 mg daily for at least 6 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 IPT 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

The routine uses of antifungal primary prophylaxis for Cryptococcal disease in HIV-infected adults, adolescents and children with a CD4 count less than 100 cells/mm³ and who are CrAg negative or where CrAg status is unknown is not recommended prior to ART initiation.

Screening for CrAg in Tanzania

Screen for serum Cryptococcal antigen for all ART-naïve adults with CD4 cell count of <100 cells/mm³.

- If screening test is positive (bloodstream disease) but no evidence of meningitis give pre-emptive therapy with fluconazole 800mg once daily for 2 weeks, followed by 400mg once daily for 8 weeks. ART should be started after 2 weeks.
- If screening test is positive with evidence of meningitis give intravenous antifungal treatment for 2 weeks, followed by standard consolidation and maintenance antifungal treatment. ART should be started after 5 weeks.

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- 30-60minutes of aerobic exercises 4-5 times/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/week for men and 9/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 minimum 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 $\geq$ 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 <6mmol/L 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 modification does not successfully control the blood sugar levels, then 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 $>5.2\text{mmol/L}$, LDL $>3.4\text{mmol/L}$ or triglycerides $>2.2\text{mmol/L}$.

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 $<60\text{ml/min}$ or dipstick proteinuria ≥ 1 are indicative 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 made 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) share 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/HIV co-infection than people who inject drugs (PWIDs) or heterosexuals²⁶. 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. These 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 6 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).

²⁶Konopnicki 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.

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 antibody 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.

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 Nephrologist 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; and also 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/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 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. However, they are currently unavailable in our setting.

References:

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Chapter 7: Paediatric HIV and AIDS-Related Conditions

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 6 weeks of age or at any time thereafter when the child is first seen by health care worker.

Table 7.1 Summary of Diagnosis of HIV infection in breastfeeding children <18 Months where the mother is 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 an HIV test at 6 weeks after complete cessation of breastfeeding and a final rapid test at 18 months 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 6 weeks prior to virologic (DNA PCR) testing, a negative DNA PCR test excludes HIV infection.

Children between the age of 9 and 18 months or after cessation of breastfeeding should have a rapid HIV antibody test since maternal HIV antibodies diminish rapidly between 9-18 months of age.

For High risk 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 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 to 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

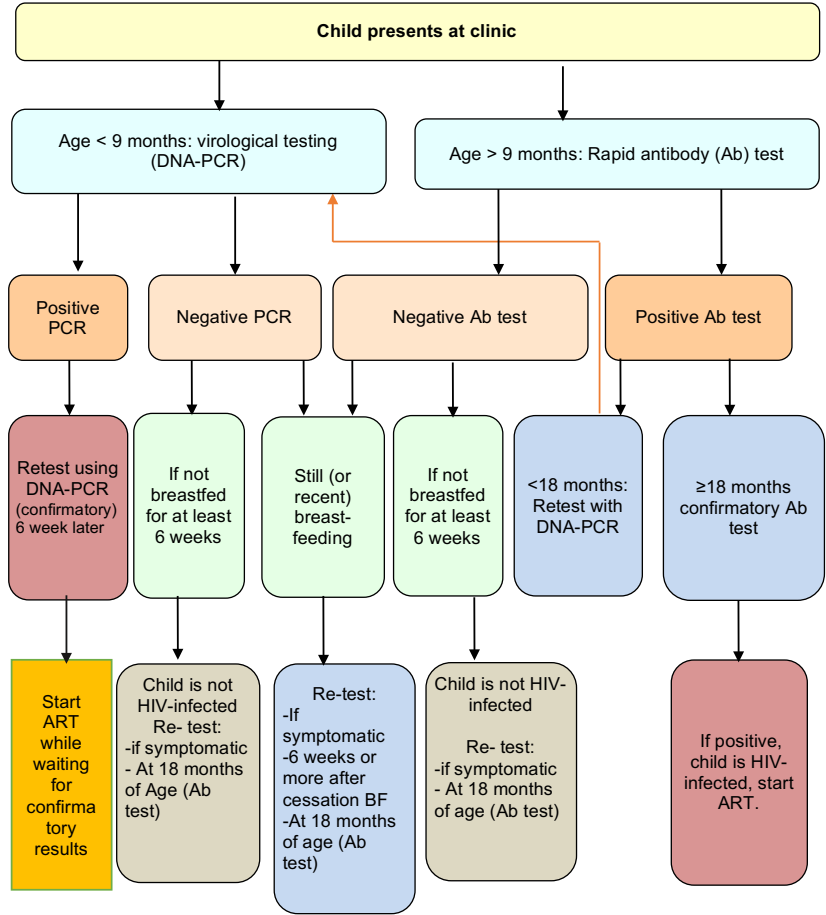
Since the mother's HIV status is unknown, the HIV exposure status of the baby needs to be established. The guardian/ care taker needs to be counselled for HIV testing of the child. If rapid test is positive, the child is exposed and should be started on cotrimoxazole prophylaxis.

Table 7.2 Steps for diagnosis of HIV infection in children where the mother is not available

1. Do rapid HIV antibody test immediately the child is seen at the HF to determine HIV exposure
2. If HIV antibody test result is positive Do HIV DNA PCR. If the result is negative, repeat HIV PCR after 6 weeks for confirmation.
3. If rapid HIV antibody test is positive and the child has stage THREE or FOUR symptoms (PRESUMPTIVE DIAGNOSIS), do DNA PCR test and start ART immediately.
4. If child is younger than 18 months and is symptomatic, HIV DNA PCR should be taken even if the rapid antibody test is negative.
5. 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.

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 7.3. Criteria for Presumptive Diagnosis of Severe HIV Infection in Infants and Children <18 Months		
A presumptive diagnosis of severe HIV should be made if:		
1. A child has a positive rapid HIV antibody test result	[AND	2a. The child is symptomatic with two or more of the following: • Oral thrush • Severe pneumonia • Severe sepsis
		OR
		2b. Any child who is fulfilling WHO stage 3 or 4 criteria (criteria found in Annex 2, WHO Clinical Staging for Children)
Other findings that support the diagnosis of severe HIV infection in an HIV-infected child include: • Recent HIV-related maternal death; or • Advanced HIV infection (child's percent of CD4 count <20%)		
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.		

Definition of Symptoms in Table 7.3

- **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 fontanel, 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 breast-feeding by an HIV infected mother. The HIV exposure stops after complete cessation of breast-feeding. However, a child's HIV infection can be excluded by an HIV DNA PCR test at 6 weeks of age by rapid HIV antibody test at 6 weeks after cessation of breast-feeding and a confirmatory test at 18 months.

The HIV-exposure status of all infants attending RCH services should routinely be established and documented. The counselling of parents on the 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 should be seen monthly
- Children above 5 years and adolescents meeting the Multi Month Prescription (MMP) criteria should be seen every two months
- At each visit, a complete physical examination should be done, focusing on assessment and management of undercurrent 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 TFDA.
- 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 and Children 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/mm³.
- In children older than five years of age, discontinuation can be considered for those with CD4 count above 500/ cells/mm³ and adherent to ART.
- Isoniazid 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 pneumoniae*. 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 indrawing, cyanosis and lethargy).
- On auscultation of the chest one hears unilateral or bilateral crepitation (crackles), decreased breath sounds or bronchial breathing
- When pulse oxymeter is available it may demonstrate hypoxia (O₂ saturations less than 95%).

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 7 days.
- Cotrimoxazole should not be used to treat pneumonia unless PCP is suspected. If PCP is suspected, then high dose Cotrimoxazole 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 O₂ saturations and if below 90%, oxygen should be supplemented. If pulse oximetry is not available, children presenting with chest indrawing, 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 intravenous ampicillin (or benzyl penicillin) and gentamicin

- Ampicillin 50 mg/kg or benzyl penicillin 50 000 U/kg IM or IV every 6 h for at least 7 days
- Gentamicin 7.5 mg/kg IM or IV 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 IM or IV once daily)
- Use ampicillin and gentamicin for newborns or severely malnourished children)
- Antibiotic therapy for HIV-infected children needs to be longer 7-14 days
- If an infant present with severe pneumonia they should be treated for both bacterial pneumonia and PCP with high dose Cotrimoxazole and investigated for possible HIV. 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, or ceftriaxone.

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 indrawing, cyanosis, inability to drink)
- On auscultation clear chest or diffuse fine crepitations
- 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 chapter 8.5 of this guideline.

7.5.3 Diarrhea

Diarrhea is one of the most common causes of under-5 mortality. Diarrheal illness is more frequent in HIV-infected children, it tends to be more severe and prolonged, and it is often associated with other comorbid 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 diarrhea, 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 diarrhea – non-bloody diarrhea lasting <14 days
- Dysentery – diarrhea with visible blood mixed in stools
- Persistent diarrhea – diarrhea lasting >14 days

Investigations

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

Management

- Management of diarrhea in HIV-exposed and HIV-infected children should generally be the same as for HIV-uninfected children
- Dehydration 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 HIV-infected and exposed children with diarrhoea (10 mg per day for infants under 6 months of age, 20 mg per day for infants and children over 6 months).
- Emphasize continued or increased feeding during and after the diarrheal episode
- Ciprofloxacin 15mg/kg BD for 3 days is recommended for treatment of bloody diarrhoea.
- Daily micronutrients and multivitamins are recommended for 2 weeks for all HIV-infected and -exposed 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

- Miconazole oral gel
- Nystatin suspension
 - o Infants – 100,000 units in every 6 hours
 - o Children – 400,000 – 600,000 units in every 6 hours
- Clotrimazole oral drops

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
- 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

7.5.6 Suppurative 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.

Management

- Wicking
 - o Insert tissue or cotton wool in ear
 - o Remove and then reinsert new one until last one comes out clean

- Ciprofloxacin otic drops—use immediately after wicking
 - o Keep ear upright for 15 minutes after drops

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, refer to Section 6.4.1.

Management

- Acyclovir 20mg/kg/dose po or IV 4 times per day for 7 days
- Flucloxacillin po 25mg/kg/dose 4times 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

- o Children with KS should be referred to specialty centrescentres for chemotherapy
- o ART should be given
- o 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.

Clinical presentation of severe malnutrition

Severe malnutrition is characterized by the presence of any of the following: weight/height z score <-3 , visible wasting in infants of < 6 months of age or bilateral pitting edema. SAM is also defined by a MUAC of $<11.5\text{cm}$ in children of 6-59 months of age, as MUAC $< 12.9\text{ cm}$ in children 5-9 years of age and $<16.0\text{ cm}$ 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

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 global 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-%²⁷. 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). The most common type of TB in HIV is extra pulmonary TB.

8.1.2. Pulmonary TB

Pulmonary tuberculosis is defined as one sputum smear examination positive for acid-fast bacilli (AFB).

AFB Smear-negative pulmonary tuberculosis is defined as the presence of at least two sputum specimens negative for AFB but radiographical abnormalities consistent with active tuberculosis.

Pulmonary TB is also indicated when a clinician decides to treat with a full course of anti-tuberculosis chemotherapy OR when a patient has AFB smear-negative sputum which is culture-positive for *Mycobacterium tuberculosis*.

²⁷Manual for the Management of Tuberculosis and Leprosy, sixth edition, 2013

8.1.3. Extra-pulmonary tuberculosis (EPTB)

EPTB is defined as tuberculosis in organs other than the lungs proven by one specimen from an extra-pulmonary site culture-positive for *Mycobacterium tuberculosis* or smear-positive for AFB; or histological or strong clinical evidence consistent with active extra-pulmonary tuberculosis. The most common forms of EPTB are pleural effusion, lymphadenopathy, pericardial disease, millitary disease, meningitis, spinal TB (Pott's disease) and disseminated TB. Other sites of the body 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 2 approaches for TB diagnosis: Clinical and laboratory.

i. Clinical diagnosis

Clinical diagnosis of TB involves:

- A careful and extensive history-taking, which includes asking the patient relating to:
 - o Classical symptoms suggestive of TB disease among adults: cough for two weeks or more, night sweats, fever, and weight loss.
 - o If coughing, the sputum colour and quantity.
 - o History of TB disease and the outcome of treatment.
 - o The presence of other medical conditions such as HIV and AIDS and diabetes mellitus.
 - o History of TB contact(s).
 - o Tobacco-smoking, including amount and duration of smoking.
 - o History of substance abuse (drugs and alcohol).
 - o Alcohol ingestion, including amount and duration.
 - o 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 hepatosplenomegaly in order to screen for co-morbidities and rule out EPTB in all patients, including those with suspected PTB.

Note: Nearly a quarter of all TB patients may not have the classical symptoms of TB, including cough, and the diagnosis is based on an abnormal chest X-ray suggestive of TB.

ii. 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).

a) 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:

- o Diagnose people with active TB.
- o Monitor the progress of treatment.
- o Confirm whether cure has been achieved.

b) 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.

c) New technologies

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.

Drug Susceptibility Testing (DST)

In Tanzania, DST is done primarily for routine surveillance of drug resistance, through the Proportion Method using solid media. The drugs for which DST is carried out include the first-line drugs Isoniazid (H), Rifampicin (R), Streptomycin (S), and Ethambutol (E), and the second-line drugs Ofloxacin and Kanamycin.

Other New technologies adopted by the country for TB case detection and DST:

- Liquid culture using the Mycobacterium Growth Indicator Tube (MGIT): It allows rapid growth and detection of M. Tuberculosis.
- 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.

d) 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 6) 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 continuation. During the intensive phase, there is a rapid killing of the TB bacilli. Most patients with smear-positive TB become non-infectious after about 2 weeks of effective treatment. During the continuation phase, the drugs kill the remaining bacteria, and prevent relapse after completion of treatment.

- New adult TB patients should receive a six-month regimen containing rifampicin: 2RHZE/4RH. The regimen requires direct observed treatment by a health care worker or treatment supporter 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), and where available, culture and DST. All patients who are Rifampicin resistant should receive MDR TB treatment in a designated health facility.
- Patients with no Rifampicin resistance should be treated with a first-line retreatment regimen containing all five drugs (2SRHZE/1HRZE/5RHE) while waiting for DST

results. In the absence of GeneXpert®, all previously treated patients should submit a specimen for culture and DST.

- Previously treated patients with treatment failure will be initiated MDR TB treatment immediately, while waiting for DST results.
- Previously treated patients who are relapses and return after loss to follow-up (defaulters) will be initiated on an interim first-line retreatment regimen containing all five drugs (2SRHZE/1HRZE/5RHE) while waiting for DST results. Once DST results are available, treatment should be modified accordingly. Patients who are resistant to Rifampicin alone or Rifampicin and Isoniazid (MDR TB) will change to an MDR TB treatment regimen. Those who are not MDR TB will continue with the first-line retreatment regimen and resistance will be monitored for three to five months.
- Other previously treated patients (others) will be treated with a first-line retreatment regimen (2SRHZE/1HRZE/5RHE) 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/HIV activities. The strategies adopted in these guidelines are in line with global efforts to combat dual TB/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/HIV) and reduce the burden of HIV in patients with presumptive and diagnosed TB. The following collaborative TB/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/HIV planning to integrate the delivery of TB and HIV services
 - Engage NGOs and CBOs in implementation of TB/HIV activities
 - Establish and integrate national M&E system for collaborative TB/HIV activities that informs both NTLP

- and NACP annual operational plans
 - Address the need of Key populations for TB/HIV
 - ii) Reduce the burden of TB in PLHIV and initiate early ART (the Three I's for TB/HIV):
 - Intensify TB case-finding implemented at all HIV care and treatment clinics and all other health care facility settings
 - Provide TB treatment for HIV infected TB patients
 - Initiate TB prevention with Isoniazid Preventive Therapy (IPT) for both adults and children
 - Initiate TB prevention through early initiation of ART as per national guidelines
 - Ensure control of TB infection in health-care facilities
 - Ensure control of TB infection in congregational 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 IPT 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 6). 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 available for children older than 6 years and adults (Annex 11).

Furthermore, the diagnosis of childhood TB may be done clinically in the absence of bacteriological confirmation by using the score chart (Annex 10).

8.2.2 Isoniazid Preventive Therapy (IPT)

Isoniazid Preventive Therapy (IPT) is an intervention that should be part of the package of care for PLHIV. IPT involves giving Isoniazid (INH) tablets to eligible individuals in order to prevent progression of active TB disease. In individuals with HIV, IPT reduces the risk of developing tuberculosis for about 60% and prolongs survival. The protective effect is expected to last for about 18 months from the last dose of Isoniazid²⁸.

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.

²⁸Mayele 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

Eligibility for IPT among adults and adolescents

For patients with no history of TB treatment:

- All HIV positive individuals with no signs or symptoms suggestive of active TB are eligible for IPT.
- 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 IPT.

For patients with history of TB treatment:

- Patients who had active tuberculosis within 2 years ago should not be considered for IPT
- Patients who were treated for tuberculosis more than for the past 2 years ago should be considered for IPT because they may have already been re-infected with TB.

Other exclusion criteria for IPT include:

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

IPT 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.

IPT in pregnancy

IPT is not contraindicated in pregnancy. However, it should be avoided during the first trimester of pregnancy as there is no enough evidence on safety of INH during the first trimester.

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%^{29, 30, 31}. Initiation of ART for all those with HIV and TB co-infection, if accompanied by high levels of coverage and ART adherence, reduces the number of TB cases, TB mortality rates and TB transmission at the population level.

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. Refer to chapter 9 on ART.

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

²⁹Lawn 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][PubMed][PMC free article][PubMed]

³⁰Gupta 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]

³¹Van 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]

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–drug interactions to reduce the potential for overlapping toxicities, and whether 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 required³²

8.2.4 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 health care workers, prison staff, police and their clients, and other persons in the congregate settings.

³¹HIV AND AIDS Treatment and Care for Injecting drug users. Clinical Protocol for WHO European Region 2007.

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 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 patients and HIV positive patients by separating them.

- **Separation of TB patients from HIV patients can be done through one of the following modalities;**
 - A) If the TB clinic is providing ART, channel PTB/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 of the TB treatment to ensure continuum of care (general HIV care, CPT, ARV provision, HBC, etc.)⁴
 - B) If the TB clinic is not providing ART, evaluate PTB/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.³³

³³ Guidelines for Tuberculosis Infection Control in health care facilities, MOHSW Tanzania, 2010

- **Clinic operating procedure:**

Patients who report at CTC for registration should be observed and 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 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 health care 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 health care 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 health care 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, military TB, and widespread tuberculosis lymphadenopathy may occur.

8.4.1 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.

i. IPT in children

In order to prevent active TB, children should be considered for IPT as follows:

- All newborns with no signs and symptoms of active TB disease that are 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 wherever 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 IPT (IPT 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 the clinic if they feel ill whilst on IPT, 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 6 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 the 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.

8.4.3 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.

Prompt initiation of anti-TB therapy is critical .because TB in young children can rapidly disseminate resulting into serious sequelae, Appropriate regimens, dosing, and duration are outlined in Tables 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 new pulmonary and extrapulmonary TB* (except TB meningitis and TB of the spine/bones/joints)	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
Previously treated TB (relapse, treatment after failure, treatment after lost to follow-up, other previously treated)**	3 months of daily RHZE***	5 months of daily RHE
MDR TB	See Section 5.2, “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 “Tuberculous meningitis” on Table 8.1**

******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

When treating 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 8.2 below.

When 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 discolouration 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, 75/50/150 mg) and Rifampicin and Isoniazid (R/H, 75/50 mg). 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, 300/150/400/275 mg). 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 ≥ 25 kg: 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
≥ 25 kg	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, 2016.

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/m² (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

Chapter 9:

Prevention of Mother-to-Child Transmission of HIV

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 (eMTCT) 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, Tanzania in 2013 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. Hence it is envisaged that 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 RM-NCAH, Tuberculosis and other services; and use a wide range of health workers to administer treatment and follow up care.

The programme is keen at 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

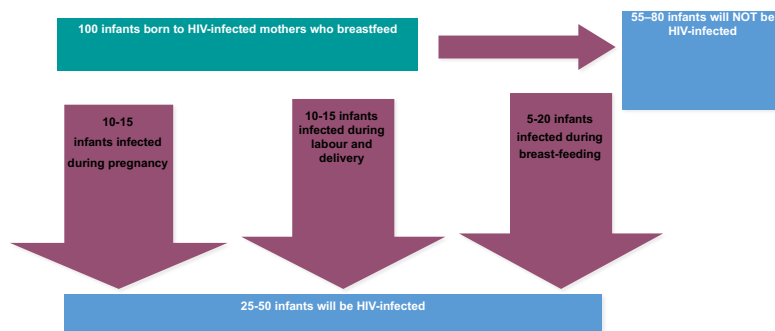
In addition, the country plans to introduce gradually the PCR test

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) services and Gene Xpert machines in order to expand HIV early testing within regions with high volume of HIV + pregnant women. 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% 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:

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

3. 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 (newly infected individuals or advanced AIDS) • Viral, bacterial or parasitic placental infections (e.g. Malaria) • Sexually transmitted Infections (STIs)	• High maternal viral load and low CD4 cell count (new infection or advanced AIDS) • Chorioamnionitis (from untreated STIs or other infections) • Rupture of membranes for more than 4 hours before delivery	• High maternal viral load and low CD4 cell count (new infections or advanced AIDS) • 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:

1. Increase the proportion of pregnant women and breast-feeding mothers who know their HIV status
2. Increase the proportion of HIV positive pregnant and breast-feeding women who receive ARVs
3. Ensure access to care and treatment for mothers and babies living with HIV
4. Improve child survival among HIV exposed 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 2 years.

9.3 Four elements of a comprehensive approach to PMTCT

A comprehensive approach to PMTCT consists of 4 elements that are discussed in this chapter:

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.
- 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 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 unintended pregnancies. A woman's/couple's choice of contraceptive methods should be based on her health status and personal preference. The family planning 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 use of more than one contraceptive methods (Barrier and non barrier) that prevents STIs, (including HIV) and unintended pregnancy. For example, the use of birth control pills and condoms (male or female) would provide dual protection.

Practice Points

- Couples/women living with HIV should be empowered to make informed decisions on the method of choice for family planning.
- Dual protection should be recommended form of contraception for couple/women living with HIV.
- All pregnant HIV-infected women and their partners (HIV infected and uninfected) should be encouraged to use condoms during pregnancy to prevent STIs and HIV infection or re-infection.
- Every woman living with HIV who intends to stop the use of contraceptives and become pregnant should be provided with adequate counselling on PMTCT.
- When pregnancy is desired, conception should be advised when viral suppression is attained in both partners in concordant couples and in the HIV infected partner in discordant couples.

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 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 HIV-positive pregnant 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 clinical and immunological evaluation 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 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.
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 Counselling to Counsels mothers on optimal nutrition Provides preventative methods such as (CPT) for PCP 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 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 6 weeks of age Ensures infant testing 6 weeks 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). Children and other family members to receive HIV care, treatment and support
Family planning	Reduces risk of unintended pregnancy by giving proper counselling to both partners on family planning and a chosen method, preferably dual protection

9.4 Integrating PMTCT into routine Reproductive and Child Health Services

Antenatal Care (ANC) improves the general health and well-being of pregnant mothers and their unborn children. Determining a woman's HIV status part and parcel of ANC services. This should be provided on a routine basis with proper information to allow the mother to consent. Counselling about the test result is essential to improve maternal health and prevent MTCT of HIV. Second is to provide ART to HIV+ pregnant and lactating mothers for their own health and preventing MTCT. Adoption of safer ANC, delivery and breastfeeding practices will contribute greatly to the prevention MTCT of HIV.

9.4.1 Specific Interventions to prevent MTCT in the ANC setting

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 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.

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
Physical examination	Assess the current signs or symptoms of illnesses including HIV, TB, malaria, cancer of cervix and STIs.
Laboratory testing	Conduct routine tests and HIV-specific laboratory tests: • Syphilis • Confirmatory HIV testing (if indicated) • Urinalysis • Full Blood Picture (FBP) • CD4 cell count and viral load • Liver and renal function tests
HIV staging	Conduct clinical and immunological staging according to the WHO clinical staging system.
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 lactation.
Adherence to ART, CPT and IPT	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 IPT. Ensure accurate knowledge of maternal ART and infant antiretroviral (ARV) prophylaxis (schedule, dosing etc.).
Nutrition	Conduct nutritional and dietary assessment and provide counselling and supportive services. Give iron, folic acid and multivitamin supplements according to national guidelines.
Delivery at a health facility	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. 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
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 All HIV-exposed infants should receive ARV prophylaxis from birth or as soon as possible thereafter up to 6 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 Chapter 4 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 health care 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.

Psychological and social support	Assess and address needs for psychological and social support. 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 or at labour and delivery. A third test at 6 months post-partum 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 6th month after the first test and thereafter as per general population.

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 an initial negative test who were not retested after three months
- Administration of ART to HIV positive pregnant women and ARV prophylaxis to infants
- Implementation of safer obstetric practices.

Labour and delivery care

Labour management 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 patients care.	Use protective gear, safely use and dispose of sharps, sterilize equipment and safe disposal of contaminated materials
Minimize vaginal examinations	Perform vaginal examinations only when necessary, using sterile technique
Avoid prolonged labour	Consider use of oxytocic medications to shorten labour when appropriate Use non-invasive foetal monitoring to assess need for early intervention Use a program to monitor the progress of labour, and record all medications used during labour, including ART.
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 Oxytocin, Ergometrine or Misoprostal medications 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 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 facilities where skilled HCWs can address potential complications and provide specialized care to reduce the risk of MTCT. In the interest of women who choose to give birth at home, pregnant women and home birth attendants should be trained to deliver basic 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 for the infant 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
- Consider the use of antibiotics after uterine evacuation
- Conduct family planning counselling

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, administer dual prophylaxis with AZT syrup (twice daily) and syrup NVP (once daily) for the first 6 weeks of life, then continue with daily NVP alone up to 12 weeks of life

High-risk infants are those who are:

- a. born to women with established HIV infections who have received less than four weeks of ART at the time of delivery; or
- b. born to women with established HIV infection with viral load >1000 copies/mL in the four weeks before delivery, if viral load measurement is available; or
- c. born to women with incident HIV infection during pregnancy or breast-feeding; or
- d. identified for the first time during the postpartum period, with or without a negative HIV test prenatally.
 - 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	10mg once daily
• Birth weight 2000–2499g	15mg once daily
• Birth weight ≥ 2500 g	

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

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

Table 9.6 Infant AZT dosing

Infant AZT dosing recommendations	
Infant age	AZT twice daily dosing
Birth to 6 weeks	10mg twice daily
• Birth weight 2000–2499g	15mg twice daily
• Birth weight ≥ 2500 g	

Low birth weight infants (<2000 g) should receive mg/kg dosing, suggested starting dose is 4mg/kg twice daily.

Practice Point

Infants who are diagnosed with HIV infection should be initiated to ART by a trained clinician 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:

Dosage forms	Dose 0-6 weeks AZT and NVP	Dose 6-12 weeks NVP only
Fixed Dose Combination AZT/3TC/NVP 60/30/50 mg	¼ tab twice daily	NVP - 2ml once daily
FDCs and single drug tablets	¼ tab twice daily	NVP - ½ tab once daily

- Remember to tell the mother that she should keep the remaining quarter of a tablet for the evening dose

Perinatal care for HIV exposed newborn

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

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 100 mm Hg pressure or bulb suction, rather than mouth-operation suction.
- Place the infant on the mother's breast immediately if she is going to breast-feed. If 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.

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.

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 breast-feed.

- 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 how she will cope with possible stigmatisation 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 ART 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 with counselling about 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 six weeks after complete cessation of breastfeeding and a confirmation test at the age of 18 months.

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, should immediately be initiated on ART. For those who are HIV – they should receive a second test at 6 weeks of age; 6 weeks after cessation of breastfeeding and a fourth performed at the age of 18 months (A confirmation).

In addition, all HIV-exposed infants should begin CPT at the age of 6 weeks.

Counselling about postpartum family planning:

Women living with HIV should receive counselling on preventing unintended pregnancy. Use of condom In addition, all HIV-exposed infants should begin CPT at the age of 6 weeks. dual protection should be discussed in order to (prevent HIV re-infection and pregnancy).

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 that mother knows the time, location, contact person and purpose of all follow-up appointments.

Incase the services required are not available at the health facility, health care worker should facilitate referrals and linkages to HIV treatment, care and support services.

Practice Point

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

Practice Points

- 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 7, 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 be immediately referred to a nearby CTC.
 - All infants should have their HIV exposure status recorded on their RCHcards/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
- 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) + Efavirenz (EFV). This regimen 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. Available alternative first line ART regimen includes AZT+3TC+NVP.

Practice point

When a NVP based regimen is used, close monitoring for liver toxicity is required in patients with high CD4 cell counts.

For clients on 2nd and 3rd line ART regimens should continue with their current regimens.

9.5.2. Monitoring patients on ART

Successful ART results in viral load decrease, immune recovery and therefore an increase in the number of CD4 cells/mm³. In settings where routine Viral Load monitoring is available, CD4 T lymphocytes count should be done at baseline to determine immunological stage and establish need for CPT. For clients with CD4 count of <350 cell/mm³, the test should be repeated every 6 months and when CD4 >350 cell/mm³, stop CD4 monitoring and continue with VL monitoring.

Refer Chapter 4: Table 4. Viral Load Monitoring during Pregnancy and Breastfeeding

Chapter 10:

Antiretroviral Therapy for Adolescents and Adults

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 and mother to child transmission (MTCT).

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. Chapter 11 described recommendations in managing children and adolescents below 15 years of age.

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) 1st and 2nd generation Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
- d) Protease inhibitors (PIs)
- e) Integrase strand transfer inhibitors (INSTI)/ Integrase inhibitors

Other antiretroviral drugs used elsewhere include:

- f) Fusion inhibitors
- g) Chemokine receptor inhibitors/ CCR5 inhibitors

10.1.1 Nucleotide Reverse Transcriptase Inhibitors (NtRTIs)

Nucleotide analogues resemble nucleoside analogues (NRTIs). 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 and 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 (ETV)

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) Currently used Protease Inhibitors (PIs)
 - Atazanavir (ATV).
 - Lopinavir (LPV),
 - Ritonavir (usually used as a booster with other PIs)
- b) Newer 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 this guideline 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 re-constituting and maintaining immune capacity.

HIV and AIDS cannot be cured by using currently available ARV regimes because early on during acute HIV infection some viruses hide in certain tissues (sanctuaries), where they stay dormant or with a very minimal replication for a life time. Very early initiation of ART reduces the number and size of sanctuaries. Therefore, once patients are initiated on ART, they need to be maintained on ART indefinitely. However, for individuals with severe immunosuppression or Tuberculosis co-morbidity, ART should be started as soon as possible. Notably, for patients with Cryptococcus meningitis, ART should not be started concurrently with treatment for Cryptococcus Meningitis to avoid increased mortality. ART should be initiated after five weeks of Cryptococcus Meningitis treatment.

The primary goals of combination antiretroviral therapy are:

- Maximal and durable suppression of viral load to < 50 copies/ml
- Restoration and/or preservation of immunologic function by attainment of CD4 recovery to normal thresholds ≥ 500 cells/mm³
- Reduction of HIV-related morbidity and mortality
- Improvement of 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.
- Reduce 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.
- Increase uptake of early voluntary testing and counseling with more people knowing their status and practicing safer sex
- Reduce transmission in discordant couples.

10.3 Rationale for early initiation of ART

Early initiation of combination treatment (ART) is associated with health benefits in terms of reduced morbidity and mortality in all age groups. In addition, ART is effective for preventing HIV transmission. It also helps to drastically reduce TB incidences. Therefore, a Treat All approach regardless of CD4 cell count and clinical stage has both individual health and community benefits in terms of reducing HIV and TB incidences.

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 near by health facility to provide ART services.

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 will be used to provide baseline clinical information but it will not be used to determine eligibility for ART. In addition, the TB screening questionnaire should be administered. Patient data will be recorded in the CTC2 cards and in the patient file.

After initiation of ART

The following laboratory tests are recommended:

- In settings where routine viral load monitoring is available, CD4 T lymphocytes count should be done at baseline for all clients. For those clients with <350 CD4 cells/

mm3 repeat the test every 6 months until CD4 >350 cells/mm3, and if the client is stable and virologically suppressed (<50copies/ml), stop CD4 monitoring.

- In settings where routine viral load monitoring is NOT available, CD4 T lymphocytes count should be done at baseline for all clients and repeated every six month
- HVL for adults and adolescents should be done 6 months after initiation of ART:
 - o If results of the test are >1000 copies/mL, manage as suspected treatment failure by conducting enhanced adherence counselling and repeating the test after 3 months.
 - o If results of the test are <1000 copies/mL, repeat test after 6 months then yearly.

(For further details see Chapter 4: Figure 4.3)

- A complete blood count (If not available, conduct hemoglobin test for patients on AZT based regimens)
- Urinalysis to exclude proteinuria (HIV associated nephropathy or HIVAN) and glycosuria (Diabetes Mellitus).
- Tests to rule out active TB (sputum AFB, GeneXpert, CXR) in cases where there is suspected TB from the screening tool
- Urine pregnancy test (to women of reproductive age) in order to identify PLHIV requiring EFV 600mg.
- Liver function tests (serum alanine aminotransferase, ALT) if on anti-TB drugs or requiring NVP based treatment
- Renal function tests (serum creatinine, blood urea nitrogen (BUN)) for patients requiring TDF based regimens
- Lipids test (for clients requiring PIs)
- Rapid test for syphilis.

The following could be done if available:

- Serology for Hepatitis B surface antigen and Hepatitis C antibody.

Treatment decisions should be based on HIV status, readi-

ness of the patient and a solid adherence support plan. The gold standard for monitoring ART will be virologic monitoring.

The tests mentioned above should be done at baseline and as needed for clinical care (e.g. in case of toxicity or to rule out IRIS manifestations) and at least every 6 months for patients on ART.

10.3.2 When to start ART in adults and adolescents

The current scientific evidence removes previous reliance on clinical stage or CD4 cell count as eligibility criteria for ART. Therefore, all HIV infected individuals regardless of age, clinical stage, HIV risk group, pregnancy status, associated comorbidities and degree of immunosuppression are eligible for ART.

A. Patients related Considerations

Before the patient is initiated on ART, the following psychosocial conditions should preferably be met:

- i. The patient has to disclose his/her HIV serostatus to a treatment assistant and or a self-chosen family member
- ii. The patient is willing and ready to adhere to lifelong ART
- iii. The patient commits him/herself to attend clinics as per schedule.
- iv. The patient is not abusing alcohol and if he/she does is willing to stop it
- v. HIV infected PWID patients should be willing to attend medically assisted therapy e.g. methadone replacement therapy.

B. Health Services Delivery Settings Considerations

- i. The patient, his/her treatment assistant and other family members (with patients' 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 patient, his/her treatment assistant and other family members an adherence plan for his/her treatment.

- iii. Provide general orientation to the patient, 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 services delivery and support services
- iv. Link the patient to a PLHIV support group
- v. Provide depression treatment and support for depressed patients
- 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 patients and those who have received treatment before, involves the use of a combination of antiretroviral drugs. 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 /mm³). Triple therapy consisting of 2 NRTI + 1 NNRTI or 2 NRTI + 1 PI. A combination of three NRTIs is recommended in children with Tuberculosis. It is important to remember that there is no single combination that is best for every patient and/or that can be tolerated by all patients. Prescriptions of ARV regimens should be recommended on the basis of a patient'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 regimen for ART naive adults and adolescent patients

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 ARV drug combinations are recommended for first line treatment for

adults and adolescents:

- TDF+3TC+EFV600
- TDF+FTC+EFV600
- TDF+(3TC or FTC) +DTG
- ABC+3TC+(EFV600 or DTG)
- AZT+ 3TC+(EFV600 or DTG)
- AZT+3TC+NVP

Note: The following ARV drugs may appear in fixed drug combinations (FDC):

- TDF/3TC/EFV600
- TDF/FTC/EFV600
- TDF/3TC/DTG
- TDF/3TC
- TDF/FTC
- ABC/3TC
- AZT/3TC/NVP
- AZT/3TC

Table 10.1 Recommended first line regimens for adults and adolescents

RECOMENDED FIRST LINE REGIMENS FOR ADULTS AND ADOLESCENTS		
Patient group	Preferred (De-fault) Regimen	Alternative Regimen
Adults and adolescents (≥ 15 years), Pregnant/lactating mothers	TDF/3TC/EFV600mg	TDF/FTC/EFV600mg TDF/ (3TC or FTC) +DTG ABC/3TC+EFV600 or DTG AZT/3TC+EFV600 or DTG AZT/3TC/NVP
TB coinfections	TDF/ (3TC or FTC) / EFV600mg	TDF/FTC/EFV600mg TDF/ (3TC or FTC) +DTG AZT/3TC+EFV600 or DTG ABC/3TC+EFV600 or DTG
People who Inject Drugs (PWID)	TDF/(FTC or 3TC) +DTG	TDF/ (FTC or 3TC) +ATV/r

NOTE:

- Clients on TDF/3TC/EFV600 can be switched to TDF/3TC/EFV400 (when available) to reduce CNS related toxicity with exception of Pregnant women and TB-HIV Co-infected patients
- TDF 300mg based regimens should not be initiated on patients with weight less than 35kg.
- EFV400 based regimens should not be initiated on patients with weight below 20Kg
- DTG does not interact with methadone, whereas EFV dramat-

ically reduces methadone levels; that is why DTG is preferred to EFV in this population group.

- DTG dosing is 50mg od but it should be administered twice a day at a dose of 50mg for patients on Rifampicin based treatment because of drug interaction.

The default first line regimen in Tanzania is:

Tenofovir (TDF) 300 mg / Lamivudine (3TC) 300 mg / Efavirenz (EFV) 600mg once daily at night

EFV is safe in pregnant and in women of reproductive age. The TDF+3TC+EFV combination is the default combination to be prescribed to all adult patients if there is no any contraindication. The regimen can also be used in patients with TB/HIV and HIV/HBV co-infection.

Note:

Since TDF is available in 300mg only, adolescents below 35kg should not use this drug.

Children below 25kg also cannot use EFV400 combinations while those below 35kg cannot use EFV600 combinations.

Alternative first line regimens can be:

- i) Tenofovir (TDF) + Emtricitabine (FTC) + Dolutegravir (DTG)

This regimen can be prescribed for non-pregnant adults and adolescents >35kg when Efavirenz is contraindicated, e.g. in neuropsychiatric complications of Efavirenz.

The major concern with Tenofovir based treatment is renal safety. Tenofovir 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 -morbidity which may also be associated with renal dysfunction such as 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.

- ii) Abacavir (ABC) + Lamivudine (3TC) + Efavirenz (EFV)
- iii) Zidovudine (AZT)+Lamivudine(3TC) +Nevirapine (NVP)

This regimen can be prescribed for pregnant women when Efavirenz is contraindicated, e.g. in neuropsychiatric complications of Efavirenz.

The risk of Nevirapine toxicity is increased in treatment naïve patients with CD4 above 250cells/ml and 400cells/ml for females and males, respectively.

Note: Nevirapine challenge dosing is required during the beginning of treatment. In the first two weeks of treatment only half of the required daily dose of Nevirapine should be administered, and a full dose begun thereafter if there are no side effects such as skin rash or hepatic toxicity. In summary, this means:

(Zidovudine 300mg/Lamivudine 150mg/Nevirapine 200mg in the morning + Zidovudine 300mg/Lamivudine 150mg. in the evening for the first 2 weeks. And if there are no problems, then Zidovudine 300mg/Lamivudine 150mg/Nevirapine 200mg twice daily).

In cases where patients need switching from NVP due to severe NVP associated adverse effects such as Stevens-Johnson's syndrome or hepatotoxicity, Efavirenz should not be used due to overlapping toxicities with Nevirapine. The patient should be introduced to DTG.

Note: some of the drugs are not yet available in the country but they will be in use once they are available.

10.4.3 ART in women of childbearing potential or pregnant women

All HIV infected pregnant women and lactating mothers are eligible for ART regardless of CD4 cell count and clinical stage. The recommended first-line regimen for this patient subgroup is: TDF + 3TC + EFV. Alternative regimens for this group are the same as in adolescents and adults.

Note: 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. Clearance of many drugs including EFV is increased during pregnancy; therefore EFV 600mg should be used.

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. HAART 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 Medical Assisted Therapy (MAT) Clinics. For the ART naïve patient ART should be initiated when the patient has been stabilised and his /her methadone dosage has been determined. This usually takes between 2-3 months after starting MAT. The currently 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 up to 50% overtime. Use of combined TDF back borne 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/ (FTC or 3TC) +DTG

All treatment experienced patients on other regimens who are identified to be PWID during the course of treatment should be introduced to TDF/ (FTC or 3TC) +DTG regimen because of the methadone and ARV drug interactions.

10.5 Second line ART

Treatment failure will be based on virological criteria of more than 1000copies /ml after two successive tests, at least three

months apart with assurance of good adherence, in areas where there is access to routine viral load monitoring.

Before treatment failure is confirmed and a particular regimen discarded, every effort should be made to rule out causes other than drug resistance. Patients should be evaluated for correctable factors, such as:

- Inappropriate dosing schedules
- Drug interactions that may reduce the efficacy of some of the ARV
- Non adherence
- Evidence of malabsorption

Each of the above scenarios could result in sub-therapeutic drug levels and poor clinical response. It is therefore important to identify the causes and correct them appropriately. If clinical assessment indicates the presence of treatment failure based on the set criteria, the best approach is to switch to a second line regimen after ruling out non-adherence. The new regimen should be comprised of at least two effective drugs. Choosing two effective drugs to which the patient is naïve. Before changing to the second line drug regimen, the patient needs to go through the treatment readiness education process and adherence again. This needs to be carefully monitored as some patients might hide their non-adherence.

10.5.1 Second-line antiretroviral therapy in adults and adolescents

Drugs used as the second line in Tanzania include:

NRTIs/NtRIs

- Zidovudine (AZT)
- Tenofovir (TDF)
- Abacavir (ABC)
- Lamivudine (3TC)
- Emtricitabine (FTC)

PIs

- Atazanavir boosted by Ritonavir (ATV/r)
- Lopinavir boosted by Ritonavir (LPV/r)

INSTIs

- Dolutegravir (DTG)

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/lactating mothers	AZT/3TC+ATV/r: if TDF was used in first line. TDF/FTC+ATV/r: if AZT was used in first line	AZT/3TC+LPV/r in Case of TB ABC/3TC+ATV/r ABC/3TC+LPV/r TDF/FTC+LPV/r
HIV and TB co-infection	AZT/3TC+LPV/r ABC/3TC+LPV/r TDF/FTC+LPV/r	Note: double dosage of LPV/r to 800/200mg for Rifampicin based TB treatment.
People Who Inject Drugs (PWID)	ABC/3TC + ATV/r	DTG+(ABC/3TC)+ATV/r

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 Appendix 4.

Note that ATV/r, LPV/r, ABC/3TC and TDF/FTC are currently available as FDC formulations which simplify dosing and administration.

10.6 Third-line ART

Patients failing 2nd line regimens may have extensive NRTI and NNRTIs associated resistance mutations (RAMS) which preclude/minimise their use in third line regimens. Therefore, 3rd line regimens, in order to have at least two or preferably three effective drugs, need to be constructed using other new classes of drugs or second generation formulations of previous drugs. These second generation drugs usually have a higher genetic barrier to resistance and their efficacy is not compromised by RAMs associated with the first generation formulations.

For example, ETV is a second generation NNRTI with minimal cross resistance to First generation NNRTIs EFV and NVP. Similarly, Darunavir (DRV) without cross resistance to PIs 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 Fusion Inhibitors require parenteral administration while the Chemokine Inhibitors (CCR5) 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 Dolutegravir (DTG) and Raltegravir (RAL), PIs Darunavir/Ritonavir (DRV/r), and a Second generation NNRTI Etravirine (ETV).

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) and.	DTG+DRV/r+ ETV	DTG+ATV/r+ ETV	
Pregnant women/lactating mothers	(DTG or RAL)+DRV/r+ ETV	DTG+ATV/r+ ETV	
HIV and TB co-infection	DTG+ ETV+ (3TC or FTC)		
People Who Inject Drugs (PWID)	DTG+DRV/r+ ETV	DTG+ATV/r+ ETV	
Note: 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.			

Note: 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 ART

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

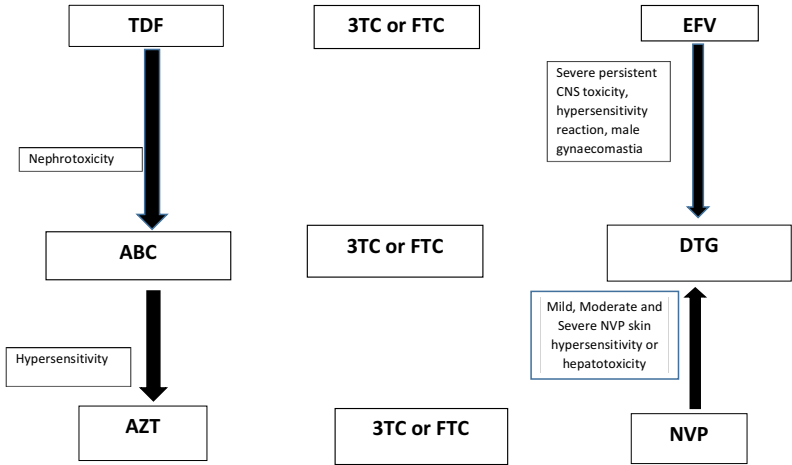
10.7.1 Changing antiretroviral therapy due to toxicity

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 provides guidance on ARV drug combinations with some common toxicity substitution within first line regimens.

Table 10.4: Common toxicity substitution in first line drugs

First Line	Problem	Substitution
TDF + (3TC or FTC) + EFV 600	Nephrotoxicity due to TDF	ABC + 3TC + EFV AZT + 3TC + EFV
	Severe CNS effects due to EFV600	TDF+(FTC or 3TC)+DTG AZT+3TC+NVP
		TDF+3TC+EFV400
AZT + 3TC + (EFV or NVP)	Anemia due to AZT	TDF + FTC + EFV
	Lipodystrophy due to AZT	TDF + FTC + EFV
	Severe CNS effects due to EFV600	AZT+3TC+(DTG or NVP)
	Mild to Moderate Hypersensitivity due to NVP	AZT + 3TC + EFV
	Severe Hypersensitivity e.g. Steven-Johnson Syndrome or Hepatotoxicity due to NVP	AZT+3TC+ DTG AZT+3TC+ (ATV/r or LPV/r)
AZT or TDF based regimens	Both Anemia and Nephrotoxicity	ABC+3TC+ EFV ABC+3TC+DTG

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. 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. Advice should be given on how to minimize side effects, such as taking EFV on an empty stomach before bedtime to avoid daytime dizziness. These first category symptoms can be mild headaches, mild gastric upset, nausea, fatigue and the CNS disturbances particularly with EFV. 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, neurolept-

tics (e.g. Amitriptyline) and other medicines. ARV interruption is usually not indicated in this situation and often symptomatic treatment is only temporary. The mild rash associated with NVP (dealt with under a separate paragraph below) can often be treated with medical intervention.

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 2 gm/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 3 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.

This also includes the hypersensitivity reaction to NVP which can include a severe rash or liver function test (LFT) elevations to grade III or >5 times the upper limit of normal range.

10.7.1.2 NVP hypersensitivity reactions

NVP hypersensitivity reactions can manifest as a rash and/or elevated LFTs. The rash can occur in up to 20% of patients and usually occurs in the first 2 weeks of therapy. NVP will be initiated at a lower dose for the first 2 weeks when only half of the dose (200mg) NVP is given per day for 14 days. If there are no clinical signs or symptoms of a NVP hypersensitivity or allergy, the LFT (ALAT) will be checked and the NVP dose will be escalated to 2 doses per day starting the second week.

There are commonly two levels of severity in NVP-induced rashes.

i) Mild NVP hypersensitivity reaction

A mild rash is defined as erythema, urticaria, intact skin, no blistering or sloughing of skin or desquamation, no involvement of mucous membranes, no angioedema, and no systemic signs (body aches, arthralgias, myalgias, fevers,

lymphadenopathy or significantly elevated Transaminases). If a mild drug-reaction type rash occurs, patients will continue treatment with caution and careful monitoring. Transaminases that are less than grade III (<5 times the upper limit of normal) can usually be followed until it is resolved. This rash will be treated with patient assurance, antihistamines and close follow up until resolved. NVP dose escalation will be delayed for up to one week until symptoms disappear. If symptoms worsen, this may indicate that the patient has severe hypersensitivity reaction and NVP will have to be stopped immediately and other medical interventions considered.

ii) Severe NVP hypersensitivity reaction (Stevens - Johnson syndrome, SJS):

A severe rash is defined as severe erythema, urticaria, moistening of skin (desquamation), skin blistering, sloughing of skin, exfoliative dermatitis, erythema multiforme (when severe and involving the mucous membranes known as SJS), anaphylaxis, involvement of mucous membranes, angioedema, cracked/fissured lips, or systemic signs (body aches, arthralgias, myalgias, fevers, lymphadenopathy or significantly elevated Transaminases) Transaminases can be grade III (>5 times the upper limit of normal) or higher. If a severe drug-reaction type rash occurs, patients will discontinue NVP treatment, begin high dose prednisolone, antihistamines, analgesics, and be admitted to the hospital for IV fluids and careful monitoring. NVP will be stopped immediately and not re-introduced. Continue with remaining two drugs for one week then stop all. Once the patient recovers, 3 ARV drugs, which do not include NVP, will be started. Instead of NVP, DTG or a boosted PI (ATV/r or LPV/r) will be prescribed. EFV will not replace NVP because of overlapping toxicities.

10.7.1.3 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 6 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. Hy-

persensitivity 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.

10.7.1.4 EFV (Efavirenz) Side effects

EFV can cause CNS side effects such as dizziness, vivid dreams, nightmares, vertigo, or confusion. Other manifestations include suicidal ideation and frank psychosis. Many EFV side effects are dose dependent, 400mg formulations being associated with fewer adverse effects compared to 600mg formulations. Rare side effects include gynecomastia. These symptoms are often mild and transient. Patients may benefit from assurances that these symptoms are common and will decrease over time. Both NVP and EFV can cause skin hypersensitivity and hepatotoxicity adverse effects, it is, therefore advised that for severe NVP associated hypersensitivity and hepatotoxicity adverse effects EFV should not be used as an alternative, because these side effects are more commonly observed from EFV amongst those with severe NVP reactions.

Table 10.5: Types of toxicities associated with first and second 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 AZT or ABC If TDF is being used in second-line ART (AZT use in first line ART), substitute it with ABC
	Decreases in bone mineral density	History of osteomalacia and pathological fracture Risk factors for osteoporosis or bone loss	
	Lactic acidosis or severe hepatomegaly with steatosis	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			Genetic predisposition (HLA-B 5701 gene)	If ABC is being used in first-line ART, substitute with TDF or AZT
AZT	Anaemia, neutropenia, myopathy, lipoatrophy or lipodystrophy		Baseline anaemia or Neutropenia CD4 cell count ≤ 200 cells/mm ³	If AZT is being used in first-line ART, substitute it with TDF or ABC 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	
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, severe diarrhea and risk of prematurity	Risk factors unknown	
ATV/r	Indirect hyperbilirubinaemia (clinical jaundice)	Underlying hepatic disease HBV and HCV co infection Concomitant use of hepatotoxic drugs	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
	Nephrolithiasis and risk of prematurity	Risk factors unknown	Replace it with LPV/r

EFV	Persistent central nervous system toxicity (such as dizziness, abnormal dreams, depression or mental confusion)	Depression or other mental disorder (previous or at baseline) Taking with high fat meal	Replace it with DTG or NVP. If the person cannot tolerate either INSTI or NNRTI, use boosted PIs
	Hepatotoxicity	Underlying hepatic disease – HBV and HCV co infection Concomitant use of hepatotoxic drug	
	Convulsions	History of seizure	
	Hypersensitivity reaction, Stevens-Johnson syndrome	Risk factors unknown	
	Potential risk of neural tube birth defects (very low risk in humans)		
	Male gynecomastia		

NVP	Hepatotoxicity	Underlying hepatic disease HBV and HCV co-infection Concomitant use of hepatotoxic drugs CD4 >250 cells/mm ³ in women CD4 >400 cells/mm ³ for men First month of therapy (if lead-in dose is not used)	EFV. If the person cannot tolerate either NNRTI, use DTG or a boosted PI
	Severe skin rash and hypersensitivity reaction (Stevens-Johnson syndrome)	Risk factors unknown	
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

ETV	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 based on two consecutive viral load measurements after 3 months, with adherence support	An individual must be taking ART for at least 6 months before it can be determined that a regimen has failed.
Immunological	CD4 cell count falls to the baseline (or below) or Persistent CD4 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 6 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 >6 months of treatment above 1000 copies/mL within an interval of 3 months and after adherence intensification.

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 multidisciplinary 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 out 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

10.8 Monitoring Patients on ART

Monitoring of patients on ART is based on clinical and laboratory parameters.

Clinical Monitoring:

In most cases, treatment will be 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. Switch-

ing to subsequent regimens should mainly be based on virological criteria, however, in setting 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. Baseline CD4 cell count should nevertheless be determined to monitor immunological response. For patients with CD4 cell count less than 350 cell/mm³, the CD4+ T lymphocyte count should be repeated after 6 months, until patient is stable (CD4+ T lymphocyte count more than 350cell/mm³ and two consecutive viral load less than 50copies/ml). However, in cases of suspected IRIS, CD4 can be tested at intervals less than six months. IRIS is diagnosed if CD4 cell count shows rising trends.

Viral load (VL) testing is recommended as the preferred monitoring approach to diagnose and confirm treatment failure compared to immunological and clinical monitoring because it provides an early and more accurate indication of treatment failure and the need to switch to second line regimens, therefore reducing accumulation of drug resistance mutations. This improves clinical outcomes and preserves second line options. Routine viral load testing is highly recommended in all facilities. Treatment should be considered successful if the viral load is <50 copies/mL.

Discordant viral load and CD4 cell count response to ARV

Usually, concordant viral load and CD4 response to ARV is indicated by suppressed viral load and subsequent gain in CD4 cell count. When, suppressed viral load without accompanied gain in CD4 cell count is termed discordant response; which is associated with increased morbidity and mortality. Discordant viral load and CD4 cell count response is associated with more than 50 years of age, co-morbidities such as Hepatitis B, CMV, TB, high viral load at treatment initiation and late treatment initiation of WHO clinical stage 3 and 4.

10.8.1 Clinical and laboratory monitoring of patients on first line drug regimen

(I) Scheduled visits

The first six months of ART

Patients will attend the appropriate clinic (CTC, RCH, TB, MAT) monthly for the first six months for clinical and laboratory evaluation and drug refills. In the minority of patients who will be initiated on NVP, they should be seen at 2 weeks after initiation of NVP based regimen and thereafter as scheduled.

Six months after starting ART

After six months of ART, if the patient is clinically stable, 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 an appointment of two to three months as agreed between clinicians and patients. During this period, appropriate clinical and laboratory assessment should be done.

(ii) Unscheduled visits

Beyond the scheduled visits, it is also important for the patients to present themselves to the clinic for management should they develop any unexpected symptoms and complications. Clinical judgment will be used to assess if additional clinical or laboratory interventions are required.

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 have been shown to improve adherence. Also, the tracking registers should be used effectively to reduce loss to follow up. A good referral mechanism should therefore be established between the clinic and other levels of health care delivery, including home based care teams.

Table 10.7: Summary of Adult and Adolescent ART Laboratory Monitoring of Patients on First Line Regimen

Regimens	Monitoring Tests	Frequency	Rationale
I. TDF/3TC or FTC/EFV	CD4	Baseline, 6-monthly where there is no HVL Baseline, 6-monthly if CD4 <350 where HVL is available	ART monitoring Screening for early renal toxicity
	Serum creatinine	Baseline, and after every 6 months.	
II. AZ-T/3TC+EFV AZT/3TC/NVP TDF/FTC+DTG AZ-T/3TC+DTG AB-C/3TC+DTG	CD4	Baseline, after every 6-months where there is no HVL Baseline, after every 6-months if CD4 <350 where HVL is available	ART monitoring
	FBP/Hb (For patients on AZT)	Baseline, week 4, thereafter 6 monthly	Anemia
	ALT (For patients on NVP)	Baseline, after every 6 months and whenever symptomatic	Liver toxicity
	ALT (For patients on DTG)	Baseline, after every 6 months and whenever symptomatic	Liver toxicity

Note: See Chapter 4 for more details on criteria and sequence of CD4 testing.

10.8.2 Laboratory monitoring of patients on second line drugs

The following laboratory tests are recommended for Monitoring of patients on second line drugs:

- CD4, baseline, if less than 350 cells/ml after every 6 months until more than 350cells/ml
- FBC, baseline, then monthly for 3 months, then after every 6 months (with CD4 and viral load)
- Fasting cholesterol and triglyceride, baseline, 6 months and thereafter every 12 months
- Liver function tests, (ALT) 6 monthly
- Fasting glucose, every 12 months
- Urinalysis at baseline and after every 3 months
- Serum creatinine at baseline and once a year.

When changing treatment, the following should be observed:

- Never change a single drug in the combination if the reason for changing is treatment failure. Change at least two drugs, preferably change all three drugs
- If changing due to toxicity, change only the drug suspected to be causing the problem.
- Never change to monotherapy (i.e. single drug)
- 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 therefore it may be retained when changing the failing regimen

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) 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 $< 50 \text{ cells/mm}^3$

- 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.

NB: Any OI may present as IRIS

For patients 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.

NOTE: When using high dose steroids, it is important to rule out *Strongyloides stecolaris* infection to avoid disseminated strongyloidiasis.

- 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

Introduction

ART in children has been proven to increase survival and decrease HIV-related morbidity and mortality. Children should be started on ART as soon they are diagnosed including those who are presumably diagnosed. This chapter discusses ART for children and adolescents below 15 years of age.

11.1 Goals of Antiretroviral Therapy in Children

The goals of antiretroviral therapy for children 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
- Prolong the survival of HIV-infected children and improve their quality of life

NOTE: In most children, viral load decline is followed by rising CD4 cell counts after ART initiation. Generally, CD4 cell count increase over the course of the first year of treatment, reach a plateau and then continue to rise further over the second year. However, in some children, severe immunosuppression may persist. The lower the CD4 cell count 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:

- Adequate counselling of the parent/caregiver/child
- Identify barriers to adherence and implement supportive strategies for caregivers and clients to maximize adherence to the antiretroviral regimens

- Rational sequencing of drugs for the preservation of future treatment options
- Monitoring of drug resistance in selected clinical settings
- Monitoring of toxicities and adverse drug reactions
- Start to disclose HIV commences to a child when he/she is eight years old.

11.2 When to start ART in children 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 under 15 years

Among children under 15 years, there are 2 groups for eligibility to begin treatment:

- i. Confirmed diagnosis of HIV: All children below fifteen years of age who have a confirmed diagnosis of HIV, regardless of WHO clinical stage or CD4 cell count
- ii. Presumptive HIV infection:
 - o All HIV exposed children below 18 months old with a presumptive HIV infection. (see criteria for presumptive diagnosis of severe HIV infection in infants and children <18 months of age in Chapter 7) Infants with initial positive DNA-PCR test awaiting a second confirmatory DNA-PCR results.

Table 11.1: When to start ART in children 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 awaiting for DNA-PCR confirmation test results.

11.2 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 1L	Justification	Alternatives	Justification
Children under 3 years	ABC/3TC+LPV/r	- Higher genetic resistance barrier - Avoids NNRTI transmitted resistance from mother during PMTCT - Possibility of malaria prevention - Spares AZT for second line	AZT/3TC+LPV/r AZT/3TC/NVP	
Children 3 to 15 years	ABC/3TC+LPV/r	- Higher genetic resistance barrier - Avoids NNRTI transmitted resistance from mother during PMTCT - Possibility of malaria prevention - Spares AZT for second line	AZT/3TC+EFV ABC/3TC+EFV TDF/3TC/EFV AZT/3TC+LPV/r AZT/3TC/NVP	

For TB co-infected children 3 to 15 years already on LPV/r based regimen	ABC/3TC+LPV/r	☐ Continue with ABC/3TC+LPV/R but the dose of LPV/r should be doubled due to the interaction between ritonavir and rifampicin		
For newly initiated TB co-infected children 3 to 15 years	ABC/3TC+EFV		ABC/3TC+LPV/R but the dose of LPV/r should be doubled due to the interaction between ritonavir and rifampicin	

For dosing of ARV regimens see Annex 7, Paediatric Antiretroviral Dosing

NOTE: Children > 2 years with weight above 35kg can use TDF

11.2.1 Special Considerations for LPV/r syrup and tablets

- The LPV/r liquid requires a cold chain only during storage at the facility
- After dispensing, the liquid is stable at room temperature for 1 month so patients should be given a maximum of 1-month supply
- Patients do not have to refrigerate the LPV/r liquid
- LPV/r tablet is heat stable but must be swallowed whole and should not be split or crushed as it loses effectiveness
- LPV/r has shown protection benefit against malaria³⁴.

11.3 Changing ARV Therapy in children under 15 years

11.3.1 Drug toxicity

The principles for changing ARVs and the managing drug toxicity in children 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 is adherent to the current ART regimen, for 6 months or more and has two consecutive viral load measurements over 1000 copies/ml at 3 months apart. For more details on routine HVL see chapter 4 section 4.4.

³⁴Achan J et al. antiretroviral agents and prevention of malaria in HIV infected Ugandan Children. New England Journal of Medicine 2012; 367:2110-2118.

Changing a child 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 6 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 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 percent 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 percent (< 5%); and if there is no failure to thrive: do not change medication, instead maintain close monitoring.

11.3.3 Clinical treatment failure

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 6-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
- Advancement from one clinical stage to another or new evidence of new WHO stage 3 or 4 disease (see Annex 2 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 should have received the regimen for at least 6 months.

11.4 Laboratory parameters for monitoring children 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 regimen	Every six months	As required or symptom-directed
HIV diagnostic testing	✓			✓
Haemoglobin ^a	✓	✓		✓
WBC and differential count				✓
%CD4+ or absolute CD4 cell count	✓			✓ ^e
Pregnancy testing in adolescent girls		✓ ^c		✓
Full chemistry (including, but not restricted to, liver enzymes, renal function, glucose, lipids, amylase, lipase and serum electrolytes) ^e				✓
HIV VL measurement			✓ ^d	✓
OI screening (where possible)	✓	✓	✓	✓

Routine monitoring (every six months) of full chemistry, particularly lipid levels, liver enzymes and renal functions, should be considered for infants and children on second-line drugs.

^eCD4 cell count should be taken on emergence of WHO stage 3 or 4 disease

^dViral load monitoring is annual if the first two successful VL results 6th month apart are ≤1000 copies/mL

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 include:

- 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.

11.6 Recommended Second-Line ARV Therapy for Infants and Children under 15 years

- After failure of a first line LPV/r-based regimen, children younger than 3 years should remain on their first line regimen, and measures to improve adherence should be taken. (PI based regimen have high genetic barrier for mutation and virological suppression can still be achieved.)
- After failure of a first line LPV/r based regimen, children of 3 years and above should switch to a second-line regimen containing an NNRTI plus two NRTIs; EFV is the preferred NNRTI
- After failure of a first-line regimen of ABC or TDF + 3TC, the preferred NRTI backbone option for second line ART is AZT + 3TC
- After failure of a first-line regimen containing AZT + 3TC, the preferred NRTI backbone option for second line ART is ABC or TDF + 3TC

Note: Infant and children take longer time to attain adequate viral suppression. Before confirming treatment failure, calculate drop in VL (using 0.5 log for 2 years and above, 0.7 log below 2 years- for further details on how to convert VL into numbers see Annex 05).

Table 11.5: Recommended second-line ART regimens for children under 15 years

Patient group	If is on the following first line	Preferred 2L	Justification
Children under 3 years	ABC/3TC+LPV/r	ABC/3TC+LPV/r AZT/3TC+LPV/r	• For children who were on PI based first line regimen, maintain the same regimen
	AZT/3TC/NVP		• For children who were not on PI-based first line regimen
Children 3 to 15 years	ABC/3TC+LPV/r	AZT/3TC+EFV	
		ABC/3TC+EFV	
		TDF/3TC/EFV	

For dosing of ARV regimens see Annex 5, Paediatric Antiretroviral Dosing

Note:

- TDF may only be given to children > 12 years and above 35kg
- ATV/r can be used as an alternative to LPV/r in children above 6 years old if paediatric formulation if available but adolescents >30kg can take adult formulation.

11.7 Third Line ARV regimens in children under 15 year

The national HIV care and treatment programme has achieved significant coverage in terms of health facilities providing child friendly HIV services as well as the number of children living with HIV reached for care and treatment services. There is a significant scale up of first line ART whereby over 90% of PLHIV served by the programme use first line ART regimens. Furthermore, there is gradual increase of health facilities providing second line ART.

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.

Patients 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 example, ETV is an NNRTI with minimal cross resistance to other NNRTIs (EFV and NVP). Similarly, 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), and an NNRTI (ETV).

11.7.1 Criteria for Change to Third-line

Failing any 2nd 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.

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 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 a hospital.

- 2- At the hospital, 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.

Third line regimens paediatrics and adolescents

Selection of third line regimen should consider genotype resistance test results as well as treatment history.

Patient group	3L Options	Justification
Children <12 years	RAL+DRV/r+ETV RAL + 2 NRTIs DRV/r + 2 NRTIs DRV/r + RAL $\pm$ 1-2 NRTIs	DRV/r • High genetic barrier • Effective for patients with resistance to LPVr and ATVr • Cannot be used in children < 3 years of age
Children 12 years and above	DTG+DRV/r+ETV DTG (or RAL) + 2 NRTIs DRV/r + 2 NRTIs DRV/r + DTG (or RAL) $\pm$ 1-2 NRTIs	ETV • Effective for patients with NNRTI resistance RAL • Can be used for children under 12 years DTG • Can be used for children > 12 years

11.8 Adverse reactions in children

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.

Major Types of ARV Toxicity in Children:

ABC	ABC is associated with hypersensitivity reactions. Patients may have severe skin rashes or other non-specific symptoms such as fever, arthralgias and lymph node 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 with low body weight, low CD4 cell counts and advanced HIV disease. Patients with severe anaemia 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, 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 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 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 higher risk. The other side effect is severe skin and hypersensitivity reactions. Patients with sulfonamide allergy are at higher risk
ETV	ETV's potential toxicity has severe skin and hypersensitivity reactions
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 higher risk.

Principles in the management of ARV drug toxicity

1. Determine the seriousness of the toxicity
2. Evaluate concurrent medications and establish whether the toxicity is attributable to an ARV drug or drugs, or to a non-ARV medication taken at the same time

3. Consider other disease processes (e.g. viral hepatitis in a child on ARV drugs who develops jaundice). Not all problems that arise during treatment are caused by ARV drugs
4. Manage the adverse reactions according to its severity
5. In general:
 - a. 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
 - b. Severe reactions: Substitute the offending drug without stopping ART
 - c. 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
 - d. Mild reactions: Reassure a child and 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 11.6: 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	NVP	EFV
Severe or life-threatening rash (Stevens-Johnson syndrome)		If the patient cannot tolerate either NNR-TI, use boosted PI
Hypersensitivity reaction		boosted PI
Lipoatrophy/metabolic syndrome	ABC	AZT
	LPV/r	If LPV/r is used in first line ART for children, use an age appropriate NNRTI (NVP for children below 3 years and EFV for children with 3 years and above)
		ATV/r can be used for children above 6 years
Severe anaemia or neutropenia	AZT	Substitute with ABC if < 35 kg
Severe gastrointestinal intolerance		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
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Chapter 12:

Adherence Counseling to ART and Retention across Continuum of Care

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 health care 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 adults, children, adolescents and youth.

12.1 Factors and Strategies that Influence Adherence Counseling 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 adherence counselling and health education.

12.1.1 Predictors of good adherence to ART:

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 influence Enhance Adherence Counselling

Factors that enhance adherence Counselling 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 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.)
 - Fit of the regimen into the daily routine

12.2 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 and preferably within 2 weeks initiation of ART. These benefits include much prolonged survival, better clinical outcomes, early restoration of immunity, community prevention of TB and new HIV infections.

12.2.1 Three Sessions on Adherence Counselling for Adults prior ART initiation:

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 and agreed between HCW
- 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)
- 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 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 after initiation of ART
- Remind the client to bring the remaining pills when attending the scheduled visit.

iv) Follow-up Adherence Counseling 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 and walk or carry CTC 1 card.
- Schedule with the client on the next visit using block appointment

12.2.2 Monitoring Adherence

Optimal adherence requires full participation by the health care 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 on-going 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 come with their drug stocks 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 health care 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.

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
Unexpected hospital admissions	• Carry pills to hospital • Inform health care 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	• 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 • 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:

a) 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.

b) 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 parent/caregiver to disclose.

c) 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
- 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 counselling 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
- Regularly, review 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 attend to the clinic with the child.

Table 12.3. Common Challenges and Strategies to Improve Adherence in Children

CHALLENGE	STRATEGIES
1. 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 the importance of adherence for the child's survival • Simplify adherence information to ensure 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 for expert advice about changing the regimen • Utilize visiting nurse/HBC provider 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 • 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.
1. Parent/caregiver is ill or absent and other family members cannot give medications to the child	• Treat 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.
1. Complexity of measuring paediatric 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.

12.3.5 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 with 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 HCW.
- Supportive community that do not stigmatize HIV clients
- Adequate support during transition period from 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 clinics
- 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 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 adolescent 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/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 change their normal schedule and therefore always 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 Counseling Issues among Pregnant and Lactating 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 Counseling 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 population:

- Assuring access: Create demand for HIV testing Services 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 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.

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 fail-

- 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 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 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 Counseling 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 least 6 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 twelve weeks. An enhanced adherence 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 and one additional enhance adherence counseling.

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 Counseling:

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.

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.

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 drug substance abuse) ▪ Motivation ▪ Mental health screening (screen for depression) ▪ Discuss patient's support systems • Referrals and networking • Assist the patient to develop adherence plan to address the identified issues.
Session 2	• Review adherence plan from the first session and discuss any challenges • Identify other possible gaps and issues emerging • 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 < 1,000 copies/ml: continue with the current regimen with enhanced adherence counselling, repeat VL after 6 months - If HVL $\geq$ 1,000 copies/ml: prepare the patient for the change of regimen.

Chapter 13:

Mental Health Conditions in HIV and AIDS

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/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.

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.

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 risperidone can be used starting with low doses
- Involve family members /treatment supporters in the management of the client.

Note

1. Avoid benzodiazepines, which tend to increase confusion and decrease concentration
2. 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, exacer-

bation 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 disorder, post-traumatic stress disorder, and obsessive – compulsive disorder 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, 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, psycho education 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. 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 behaviour 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, psycho education 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 amitriptyline (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 6 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 12.1 below:

Table 13:1 Antidepressant dosage and possible ART interactions

Drug groups of antidepressants	Specific drugs/registered 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 to 40mg per day	Nevirapine decreases level; AD increases levels of Amprenavir, Delavirdine, 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

Introduction

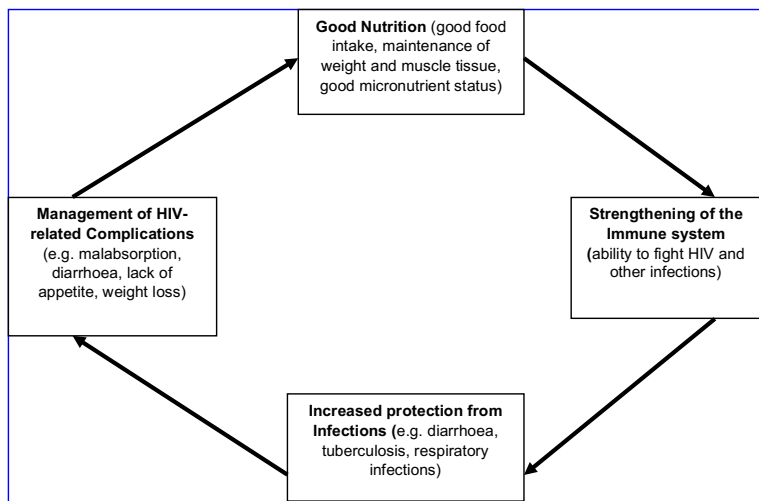
Malnutrition and HIV are related and aggravate one another in a vicious cycle. HIV infection can lead to under nutrition, and malnutrition affects HIV transmission and disease progression. HIV infection impairs the body immune system and thereby increasing vulnerability to infections. Infections lead 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 diarrhea, 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 mal-nourished

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
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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 cooking bananas: these include maize, millet, rice, sorghum, cassava, yams, potatoes and 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 is one of the food items which can be added in the food to improve the taste and provides 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.

14.3 Nutrient requirements for People Living with HIV (PLHIV)

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.

i) 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.

ii) 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.

i) HIV symptomatic 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. 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 6 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.

ii) 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 tea-spoon 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 7), 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-helminthes, anti-fungal, etc. Foods and medications can interact in 4 major ways. These are as shown in Table 13.2 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

14.3.1 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 8 lists some of the medications used in Tanzania. The table shows their purposes, potential side effects and nutritional recommendations (more details are in Annex 9).

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 diarrhea e.g. Tenofovir, Ritonavir, Lopinavir. Therefore, the health worker must continue to be alert to recognize symptoms of infections and treat these infections appropriately.

14.3.2 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 13:3. 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.
	Diarrhea	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), micro-nutrients (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 that are Mid Upper Arm Circumference (MUAC), height and weight).

Weight and height measured are plotted on a growth curve and then classified accordingly as low or high weight for height, Z score (for children) or BMI/Z score (older children), or BMI for adults. MUAC tapes are also used.

One can monitor weight loss by using body mass index (BMI) calculated as = Weight (Kg) divided by height (m²). A normal BMI is 18.5 – 24.9kg/m². A BMI <18.5 denotes underweight; that between 25.0 and 29.9kg/m² is overweight, and > 30.0kg/m² 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 don't 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 diarrhea 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 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: 11.5 cm to < 12.5 cm W/H -3 SD to <-2 SD W/H -3 Z-scores to < -2 SD	MUAC: < 11.5 cm W/H < -3 SD
Children 5 - 9 years	MUAC 13.5 to <14.5 cm W/H -3 SD to <-2 SD W/H -3 Z-scores to < -2 SD	MUAC < 13.5 cm W/H < -3 SD
Children 10 - 14 years	MUAC 16 cm to < 18.5 cm W/H -3 SD to < -2 SD	MUAC < 16.0 cm W/H < -3 SD
Adolescents (15 years and above) and adults	MUAC 18.5 cm to 22.0 cm BMI 16 to < 18.5	MUAC < 18.5 cm BMI < 16.0
Pregnant women and women within the period of 6 months after delivery	MUAC: 19 cm to <23.0 cm	MUAC <19.0 cm

Note:

- BMI is not used to assess nutritional status of pregnant women and women within the period of 6 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 intakes of sweetened foods and drinks, and regular physical activities.

Chapter 15:

Community based HIV and AIDS Services

Introduction

This chapter described 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 has identified and described 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:

- 1) to intensify early identification of HIV positive client
- 2) to promptly link HIV positive clients to care and treatment clinics
- 3) to facilitate effective community and facility referral and linkages as well as other services such as psychosocial, legal, spiritual, food and nutrition support.
- 4) to track clients who have missed appointments
- 5) to support ART adherence and retention
- 6)

15.1.2 Scope of CBHS

PLHIV and their affected families and households have a variety of needs beyond the 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 MoHC-DGEC 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 client 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 targets 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(C-BHSP)

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 conflict 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 be supposed to 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 1 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:

- i. To provide health education to all pregnant women on HIV infection
- ii. To provide adherence counselling of ART to HIV positive pregnant women and adults who are enrolled in care and treatment/PMTCT .
- iii. To initiate and facilitate HIV Post Test Clubs/Support groups at the community and supporting them to have leadership, group constitution and registration.
- iv. To identify and refer all pregnant women to RCH clinics/ Health facilities of the catchment areas and make follow-up.
- v. To identify and refer all key and vulnerable population (e.g. PWIDs, and sex workers) to health facilities for further management.
- vi. To track and refer back to PMTCT/RCH/Health facilities of the catchment areas all mothers who have delivered and haven't come back for DBS results of their children.
- vii. To track all loss to follow up clients (adults and children) who were on care and treatment.

Community HBC 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.

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:

i. 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
- identification and enrolment 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

ii. 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 home visits to provide adherence counselling and health education to the clients who are on treatment to stay on treatment.
- 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 clients who are HIV positive with those who are on treatment to PLHIV support groups which 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 helps 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 clinics.

iii. Tracking Loss to follow up clients from CTC/PMTCT 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 appointment 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
- 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 haven't returned back with their children for DBS results of their children.

iv. 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.

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 filled in and returned to the referral provider
- Refer of CBHS clients will depend 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

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 managers and ART programme managers need to work together to ensure that the national supply system 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 includes 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 health care 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.

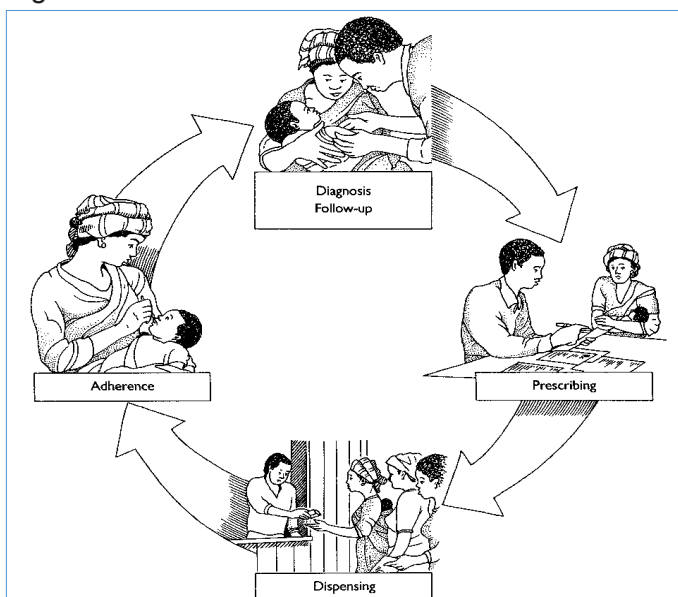
16.1. Rational Use of Medicines (RUM)

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



- o Inadequate examination of a patient
- o Incomplete communication between a patient and the doctor
- o Lack of documented medical history
- o Inadequate laboratory Resources.

Prescribing

Irrational prescribing is observed when there is:

- o Incorrect prescribing
 - Diagnosis is inadequate
 - Inappropriate medicines are prescribed.
- o Under prescribing
 - Needed medications are not prescribed
 - Dosage is inadequate
 - Inadequate duration of treatment.
- o Over prescribing
 - Prescribing inappropriate length of course
 - Prescribing very high dose.
- o Extravagant prescribing
 - Prescribing a more expensive branded medicines when there is a less expensive generic medicines
 - Treating symptoms instead of treating the disease.
- o Multiple prescribing
 - Two or more medications are prescribed when fewer would achieve the same effect.

Dispensing:

- o Incorrect interpretation of the prescription
- o The dispenser does not pick up errors or the dispenser sees the error but does nothing about it
- o Incorrect calculation of dosage
- o Retrieval of wrong medicines
- o Inaccurate counting
- o Inadequate labelling
- o Unsanitary procedures
- o 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:

- o The patient demands prescription of more medicines than required
- o Not following given instructions
- o Sharing medicines with others
- o Medicine misinformation
- o Lack of patient readiness
- o There is stigma
- o Conflict between cultural values and therapy
- o Misleading beliefs about HIV and AIDS
- o Patients' misunderstandings about the medicines and their uses
- o Patient concerns about side effects and ADRs.

16.1.1. Prescriptions

Only trained and authorized prescribers in certified health care 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 (or 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 keep up with rapidly 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 inter-agency 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 to MSD electronically after being endorsed and approved by the Hospital In charge and DMOs, respectively
- Health Facilities with CTC and PMTCT services:
 - o PMTCT will collect ARVs and RTK's from CTC and Lab, respectively
 - o PMTCT will submit Monthly ARV consumption report (completed form A3) to CTC for refilling ARVs
 - o PMTCT will also submit Monthly Summary Report Form for HIV test Kits to Laboratory for refill RTKs.
- Stand-alone PMTCT sites will follow ILS to order PMTCT commodities along with essential medicines from MSD.
 - o 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:

- o Strength and dosage form
 - o Pack size(s)
 - o Batch numbers
 - o Expiry dates (remaining shelf life should at least be 8 months)
 - o Specifications
 - o Quantities delivered
 - o 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 can’t 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 2 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).

- $\text{Months of Stocks (MoS)} = \text{Stock on Hand (SoH)} \div \text{Average Monthly Consumption (AMC)}$.

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 of 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:

- o Stock on Hand
- o Losses and adjustment
- o 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:

- o Store's Ledger (and suspensory ledger for expired commodities)
- o Form A1: ARV Daily Dispensing register
- o National HIV Log book
- o Laboratory register
- o Reporting and Requesting (R & R) forms: Form A3 (Monthly) and Form A2 (Quarterly)
- o Monthly summary report form for HIV test Kits
- o Requisition and issue voucher
- o Form 4: MSD sales invoice
- o Form 6: Goods Received Note
- o Form 7: Claim and Verification form 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:

- o Availability of commodities and quality of service provided to patients
- o Planned logistics activities are carried out according to the schedule
- o Proper recordkeeping & Logistics data collection, analysis and reporting in timely manner for decision-making & planning.

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 be done also 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 the health facilities record the adverse drug reactions and report the information to TFDA. Furthermore, facilities are encouraged to use the information to monitor patients and switch regimens where necessary e.g. Patients experiencing drug induced anemia should be switched to TDF based regimens and those experiencing NVP induced severe rash should be switched to EFV.

16.6. Collaborating with Clinical Staff

The Pharmacist shall work closely with 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 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 clinical staff so that they can pursue the best course of action.

In addition to logistics related collaborative activities, Pharmacist is expected to keep abreast of new information and changes in ARV regimens and act as a resource to clinicians and other health care 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

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 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 visits 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:

- i. Appointment register
- ii. Tracking register
- iii. Pre ART register
- iv. ART register
- v. Cohort Analysis Register

I. 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.

II. 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.

III. Pre ART Register

This register records all clients who are attending to the CTC and are not yet started on ART.

IV. The ART Register

A tool used for recording all patients who are attending at the CTC clinic and are started on ART.

V. 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.

17.1.7 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.

17.2.2 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.

17.2.3 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.

17.2.4 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 : WHO Clinical Staging of HIV Disease in Adults and Adolescents

Stage I • Asymptomatic • Persistent generalized lymphadenopathy (PGL) Unexplained, asymptomatic hepatosplenomegaly	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)
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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)	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 • Invasive cervical cancer • Visceral leishmaniasis • Symptomatic HIV-associated nephropathy or HIV associated cardiomyopathy
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Annex 2: WHO Clinical Staging of HIV/AIDS for children with confirmed HIV infection

Stage I	Stage II
• Asymptomatic • Persistent generalized lymphadenopathy (PGL) Unexplained, asymptomatic hepatosplenomegaly	• 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/ periondontitis • Lymphoid interstitial pneumonitis (LIP) • Unexplained anaemia (<8g/dL), neutropenia (<1000/mm³), or thrombocytopenia (<30,000/mm³) for >1 mo. • HIV-related cardiomyopathy • HIV-related nephropathy	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 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
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Ref: <http://www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf>

Annex 3. 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 counselor	- Assess individual client treatment readiness using adherence counseling check list - Provide adherence counseling and other aspects of PHDP at every clinic visit - Record all required information into CTC2 and adherence counseling checklist - Link the client to other support services according to the need. - Identify and document referral needs for clients

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
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Annex 4. Assessment tool for Health Facilities to provide HIV and AIDS care and treatment Services.

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: _District:

Region:

Date of assessment: _____

Type of facility

Baseline visit re-assessment visit

Instruction

1. The answers to the minimum criteria should be derived from the health center and Dispensary assessment tool (version 3, October 2015).
2. The numbers in brackets refer to the question numbers in the 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 (1.8.1 and 1.8.2 = yes, seen)	yes	no		3

2 Human resource capacity and training				
2.a	At least 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, 2.3.6 or 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 counseling 3.2.4 = yes, observed)	3.2.1	3.2.3 +	Score
One confidential room for testing and Counseling (3.2.1)	yes	no	2
Testing & Counselling rooms with visual privacy (3.2.2)	yes	no	2
Testing & Counselling rooms with Auditory privacy (3.2.3)	yes	no	2
3.b At least one HTC provider (PITC/CITC) (3.3.3)	yes	no	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
5.b	Locked area for medical records with limited access (5.2.1=yes)	yes	no
6 Continuum of Care			
6.a	Availability of CBHS (at least one = 6.2.1 & 6.2.2)	yes	no
6.b	Functional system for patients tracking (5.5.2)	yes	no
7 Laboratory services			
7.a	Adequate laboratory space (7.2.1= yes, 7.2.3 = yes), at least one room	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 (ZN stain) + STI test (Gram stain) (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 Pharmacy services				
8.a	Secure storage space large enough for 6 months supply of ARVs (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 AND SOCIAL WELFARE

Name of Health Facility:	Type of facility:		
Other name (if often used):	Health Centre		Dispensary
Address:	Government	Private	FBO
P.O. Box:	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:

6. IMPLIMENTIG PARTINER.....

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 areas 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 key words. If the space 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, b. 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? Jan-Dec	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 Kilometers 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
	Initiation site		Outreach from referral HF
1.2.1 HIV testing & Counseling			
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, Counseling and support			
1.2.10 Orphans and Vulnerable Children services (OVC)			
1.2.11 If ART provided the HF is			

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*	Yes	No
1.5.1.2 Consultation room (if > 1 room, see 1.5.3)	Yes	no
1.5.1.3 Laboratory room (main working room)	Yes	no
1.5.1.4 Dressing room	Yes	no
1.5.1.5 Injection room	Yes	no
1.5.1.6 Dispensing room with drug store	Yes	no
1.5.1.7 Store	Yes	no
1.5.1.8 Reproductive Child Health Care (RCHC) room	Yes	no
1.5.1.9 Delivery room (with waiting beds(s) and post-delivery beds	Yes	no
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?		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?		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?		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 segregates non infection and infectious wastes?	Yes, Seen	Yes, not seen	No
1.9.3	Does the facility have a functioning incinerator?	Yes, seen	Yes, not seen	No
1.9.4	Does the HF have functional toilets or latrines?	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 general	PScore:		

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 seen	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 seen	No
1.10.7 Does the lab have a safety cabinet (hood)?	Yes, seen	yes, not seen	No
1.10.9 Are (Hepa) masks for lab staff or for infective MDR-TB Patients available?	Yes, seen	yes, not seen	No
1.10.10 Assess the overall bio-safety status at HF	PScore:		

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, notseen	No
1.11.2	Are CTC data entered and analyzed electronically?	yes, seen	yes, notseen	No
1.11.3	Does the HF have access to internet?	yes, seen	yes, notseen	No
1.11.4	Assess the overall IT capacity of the HF		P 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/ CTC	Total working hours per week for this category of staff at PMTCT/CTC
	HOSP.	H/C.	DISP.			
1. Medical Officer						Hours
2. Assistant Medical Officer						Hours
3. Clinical Assistant						Hours
4. Clinical Officer						Hours
5. Public Health Nurse						Hours
6. Registered Nurse						Hours
7. Enrolled nurse						Hours
8. Laboratory Technologist						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 CTCM&Ecards										Hours
17. HTC providers										Hours
18. HBC staff										Hours
19. Admin/finance staff										Hours
20. Medical records staff										Hours
21. IT staff–Other Data clerks										Hours
22. Medical Attendants										Hours
23. Nutritionist										Hours
23. Other										Hours

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 HIV/AIDS(2015)				
2.4..2 National comprehensive guidelines for HIV Testing and counseling (2013)				
2.4..3 National guidelines on PMTCT(2013)				
2.4..4 National guidelines on CBHS (2014)				
2.4..5 National standard guidelines for health laboratory services(2003)				
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, TB/HIV)				
2.4.5.12 SOP for HIV Testing and counseling manual				
2.4.13 Other(mention):				
2.4.14 Assess the overall availability of relevant guidelines		A Score:		

3.2 Client Initiated Counselling and Testing (CITC) services			
<i>Does the facility:</i>			
3.2.1 Provide CITC services? <i>If no go to 3.1.4</i>	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
<i>How many referrals took place:</i>			
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 counseling		Reported available, but not seen	Rooms
3.2.2	Means of visual privacy of rooms			Not available
3.2.3	Auditory 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 counselor			
3.4.1	How many counselors were trained according to the national CITC curriculum?		Counselors
3.4.2	How many counsellors received CITC training using different curriculum? <i>Mention organization and duration of training</i>		Counselors
3.4.3	How many trained CITC counsellors are actually working as CITC Counsellors?		Counselors
3.4.4	How many counselors are practicing without training on CITC?		Counselors
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	Nr.trained	Category
4.1.1 Medical Officers(MO)	t		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 OPD?				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
	<i>Privacy and outfit of consultation rooms</i>		Observed	Reported, notseen	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 Score:	

4.3 HIV Testing			Observed	Not
4.3.1	Rapid HIV test algorithm 2015 available?			
4.3.2	1 st test SD Bioline HIV 1-2. 3.0			
4.3.3	2 nd test Uni-Gold HIV			
4.3.4	Internal Quality Control system for rapid algorithm			
4.3.6	External Quality Assessment system for rapid algorithm			

4.3.7 Does the HF use R&R system for ordering HIV test kits			
4.3.8 Does the HF receive the HIV test orders as requested?	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	AScore:		

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	PScore:		

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 manage 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 facility?	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) in the HF?	yes No
4.5.7	Assess 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 reported quarter?	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 reported quarter?	referrals
4.6.3	Are all identified PLHIV at C&T site and at CTC sites screened for TB?	yes No
4.6.4	Assess overall status of TB/HIV collaborative activities in HF	PScore:

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	PScore:	

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 provides 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	PScore:	

4.9 Post Exposure Prophylaxis (PEP)	Observed	Reported/available, not seen	Not available
4.9.1 Is a PEP protocol available at the HF?			
4.9.2 Does the HF regularly updated PEP registers?			
4.9.3 Assess PEP practice		P Score:	
5. Patients Records and Administration			
5.1 Medical records system			
5.1.1 Does the facility keep medical records (chart, files/system) for all patients?	Yes, seen	Yes, not seen	No
5.1.2 Does the facility keep DBS results records?	Yes, seen	Yes, not seen	No
5.1.3 Does the facility use ILS/MTUHA for the facility record?	Yes, seen	Yes, not seen	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, seen	Yes, not seen	No
5.1.6 Assess completeness/correctness and management of these records	PScore:		

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 system)	P Score:

5.3 Current number of PLHA registered at the CTC		
5.3.1	Start date of ART at the facility	I I
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 ART	
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	I I
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	

5.4.6 Number 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 tracking:		PScore:	

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, 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	Incase referral system is formalized, documentation/referral slips seen?		yes	No
6.1.4	Do FBO, NGO, CBO provide 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?			Months
6.1.6	Assess the referral system		PScore:	

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) for the HF	PScore:	

1. Laboratory

7.1 Staffing	
7.1.1 How many laboratory technologists, lab technicians, lab assistants and lab attendants work in the laboratory?	Technologist
	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	PScore:

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(<i>if No, go to 7.3.14</i>)	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?			
		yes	no		
Haematology	7.5.1 Manual haematology + diff.		Not seen		

	7.5.2Automated-haematologycounter								
7.5.3 Is the availability of supplies for haematology equipment regular?									
7.5.4 Stock-out for haematology supplies in the past 6 months seen?									
7.5.5 Assess the status of haematology equipment and supply chain		A Score:							
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 Score:	

7.7 Microbiology/parasitology

Class of equipment		Available				Remarks
		Operating?		Not seen		
Urine, stool, ma-	7.7.1 Routine testing stool (microscopy)					
	7.7.2 Routine test urine (manual sticks)					
	7.7.3 Malaria blood smears (microscopy)					
	7.7.4 TB sputum (microscopy)					
	7.7.5 Pregnancy testing (manual sticks)					

7.6.6 Is the availability of supplies for microbiology/parasitology regular?	yes	No
7.6.7 Stock-out for microbiology/parasitology supplies in the past 6 months?	yes	No
7.6.8 Assess status of microbiology/ parasitology equipment and supply chain	A Score:	

7.8 Refrigeration and storage

7.8.1 4°C refrigerator with a compartment for samples?	yes, seen	yes, not seen	No
7.8.2 4°C refrigerator & freezer compartment for reagents?	yes, seen	yes, not seen	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 seen	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 <i>Standard Operating Procedures</i> for all the tests performed?	yes, seen	yes, not seen	No
7.9.2 Are any <i>internal quality control</i> arrangements in place	yes, seen	yes, not seen	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 <i>external quality control</i> arrangements and/or assessments in place?	yes, seen	yes, not seen	No
If yes, specify:	From where:	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	PScore:		

7.10 Back-up capacity for laboratory

7.10.1 Emergency water reserve (1000litre) for lab?	yes, seen	yes, not seen	No
7.10.2 Electricity power back-up (generator/solar)?	yes, seen	yes, not seen	No
7.10.3 Assess back-up capacity for lab		A Score:	

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
8.1.2 Assess the staff situation at the pharmacy		Other staff
	A Score:	

8.2 Functional ARV tracking system			
8.2.1 Is dispensing register for ARV & OIs available and used?	observed	Not observed	No
8.2.2 Is ledger book for ARVs & OIs available and updated?	observed	Not observed	No
8.2.3 Are bin cards available and updated?	observed	Not observed	No
8.2.4 Is there a first in first out (FIFO) & FEFO system?	observed	Not observed	No
8.2.5 Is there a system to manage nearly expired ARVs & OI drugs?	observed	Not observed	No
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
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
8.3.3	Does Pharmacy staffs have forms to report ADRs (Adverse Drug Reactions) Yellow Forms & Green Forms		
8.3.3 A r e	ARVs dispensed by a pharmacy staff at CTC pharmacy?	observed	Not observed
8.3.4 A r e	ARVs dispensed at the general pharmacy?	observed	Not observed
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-outs of any of the following drugs? (NB tick in the 1 st 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) FDC TB intensive phase	yes	no
8.5.7	RH (Rifampicin/Isoniazid) FDC for continuation phase TB	yes	no

8.4.9 ARVs for standard 1 st line treatment TLE		yes	no
8.4.10 Nevirapine syrup		yes	no
8.4.11 Assess the effectiveness of the supply chain system	P		

8.5 Guidelines and SOPs

8.5.1 Are there Guidelines and SOPs available?	yes, seen	yes, not seen	no
8.5.2 Does the pharmacy have and use national ARV Pharma-	yes, seen	yes, not seen	no
8.5.3 Assess the status and quality of SOPs and policy	P Score:		

8.6 Storage capacity for 6 months' supply of ARVs

8.6.1 Is there storage space for a 6-months' supply of ARVs?	yes, seen	yes, not seen	No
8.6.2 Does the storage room have a refrigerator?	yes, seen	yes, not seen	No
8.6.3 Is the storage room cool, well ventilated?	yes, seen	yes, not seen	No
8.6.4 Assess storage capacity for ARVs 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 Yeses	No
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**THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE**



**NATIONAL HIV/AIDS CARE AND TREATMENT PLAN
Assessment Report for Health Centres and Dispensaries
Version 3, October 2015**

Name of health facility: _____

City/Town:

District:

Region:

Date of assessment: _____

Names of assessors: _____

Enclosures

Completed assessment tool: ☐ Completed minimum criteria check list: ☐

Fill in the strengths and weaknesses. Do not attempt to identify per se 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. Organisation 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. Counselling 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.
3.

Weaknesses:
1.
2.
3.

Table 2. 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 strengthen resulting from the assessment tool can be added. For each item to 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: Y (Yes), N (No), NR (Not Required).

*** Name the source of funding (health facility budget, CHMT budget, PEPFAR organisation, Global Fund, etc.).

Item to strengthen and action to be taken (including possible comments/explanations)	Min. Crit. No.	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. Action:							
2. Action:							
3. Action:							
4. Action:							
5. Action:							
6. Action:							
7. Action:							
8. Action:							
9. Action:							

10. Ac- tion:									
11. Ac- tion:									
12. Ac- tion:									

Comments:

Participants during this visit

Assistant Medical Officer / Clinical Officer in Charge 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 5: 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. Less than 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 $\log_{10}$). 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	1,000	4.0	10,000	5.0	100,000
5.1	125,893	6.1	1,258,925		
5.2	158,489	6.2	1,584,893		
5.3	199,526	6.3	1,995,262		
5.4	251,189	6.4	2,511,886		
5.5	316,228	6.5	3,162,278		
5.6	398,107	6.6	3,981,072		
5.7	501,187	6.7	5,011,872		
5.8	630,957	6.8	6,309,573		
5.9	794,328	6.9	7,943,282		
6.0	1,000,000	7.0	10,000,000		

Annex 6: 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 by 200 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 7: 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	4 mg/kg/dose TWICE daily	8 mg/kg/dose TWICE daily	ONCE daily for children > 3 years	160-200 mg/m ² /dose TWICE daily	
	600 mg ABC/300 mg 3TC tablet	120 mg ABC/60 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	300 mg	150 mg tablets	300 mg tablets	50, 200 and 600 mg tablets	10 mg/ml syrup	
3-4.9		0.5 tab BD		1 tab BD		1 tab BD						5 ml BD	3-4.9
5-5.9		0.5 tab BD		1 tab BD		1 tab BD						6 ml BD	5-5.9
6-6.9		0.5 tab BD		1.5 tab BD		1.5 tab BD						7 ml BD	6-6.9
7-7.9		0.5 tab BD		1.5 tab BD		1.5 tab BD						8 ml BD	7-7.9
8-8.9		1 tab BD		1.5 tab BD		1.5 tab BD						9 ml BD	8-8.9
9-9.9		1 tab BD		1.5 tab BD		1.5 tab BD						9 ml BD	9-9.9

10-10.9		1 tab BD	2 tab BD		2 tab BD		2 tab BD								200 mg OD	10 ml BD	10-10.9
11-11.9		1 tab BD	2 tab BD		2 tab BD		2 tab BD								200 mg OD	10 ml BD	11-11.9
12-13.9		1.5 tab	2 tab BD		2 tab BD		2 tab BD							0.5 tab BD	200 mg OD	11 ml BD	12-13.9
14-16.9		1.5 tab BD	2.5 tab BD		2.5 tab BD		2.5 tab BD							0.5 tab BD	200 mg + 50 mg OD		14-16.9
17-19.9		1.5 tab BD	2.5 tab BD		2.5 tab BD		2.5 tab BD							0.5 tab BD	200 mg + 50 mg		17-19.9
20-24.9		2 tab BD	3 tab BD		3 tab BD		3 tab BD							1 tab AM, 0.5 tab PM	300 mg OD		20-24.9
25-29.9	1 tab OD					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	400 mg (200 mg x 2) OD		30-34.9
35-39.9	1 tab OD					1 tab BD						1 tab OD	1 tab OD	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	Abacavir + Lamivudine (ABC/3TC Adult)	Abacavir	Weight range (kg)
	10-16 mg/kg/dose TWICE daily			Dose is ONCE daily	208mg/m ² /dose ONCE daily	Dose is TWICE daily	Dose is ONCE daily	8 mg/kg/dose	
	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	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	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 8: Third line Paediatric Formulation Dosing

Drug	Paediatric 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 kg		20-24.9					
		am	pm	am	pm	am	pm	am	pm	am	pm				
		am	pm	am	pm	am	pm	am	pm	am	pm				
RAL	Chewable tablet 25 mg					3	3	4	4	6	6	400 mg	1	1	
	Chewable tablet 100 mg							1	1		1.5	400 mg	1	1	
	Granules 100 mg/ sachet	0.25	0.25	0.5	0.5							400 mg	1	1	
DRV/r _a	Tablet 75 mg					3	3	5	5	5	5	600 mg + 100 mg ritonavir	1	1	
	Syrup 100 mg/ mL					2.5 ml	2.5 ml	3.5 ml	3.5 ml			600 mg + 100 mg ritonavir	1	1	

^aDRV/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

^bDTG is currently approved for patients 12 years and above.

^cETV 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.

^dDose of ETV for 16 kg to < 20 kg is 100 mg twice daily

^eDose 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 9. 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 folic acid (leucovorin), the active form of folate (5-10 mg/ day)		Nausea, vomiting, taste loss and diarrhoea; not recommended if folate deficient; not recommended for breastfeeding women

Fluconazole	Treatment of	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 NRTI	ARV	Can be taken with food, but do not take with a high	Alcohol	Elevated blood cholesterol levels, elevated triglycerides levels, rash, dizziness, anorexia, nausea, vomiting, diarrhoea, dyspepsia, ab-
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 hepatotoxicity
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
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

Annex 10. 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	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N
1. Adults (5 years above)	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: assess 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)		3. IPT inclusion (tick appropriate box)	
Y	N	Y	N
Current past history of hepatitis		☐ Eligible (Answered NO to all questions in box 2)	
Non-adherence to long term treatment		☐ Not eligible (Answered YES to any question in box 1)	
Alcohol abuse (regular and heavy alcohol consumption)		Patient accepted IPT: Yes ☐ No ☐ If accepted, date IPT started: ____/____/____	
Medical contra- indication to INH			
Symptoms of peripheral neuropathy			



MINISTRY OF HEALTH AND SOCIAL WELFARE

Patient's name: Age: Sex: M/F Date: / / Reg. Number:

[illegible]

- If 'Yes' to one or more questions continue evaluation according to the Pediatric TB diagnostic flowchart of the National Tuberculosis Program (NTLP) by filling table number 2.
- If 'No' to all questions asses for IPT contraindications in table 3 and repeat TB screening at the subsequent visit (very month)

2. Action taken for presumptive TB.	Date	Result	Date	Result	Date	Result	Date
Sputum smear /Gene expert							
TB Score (Paediatric 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)	4. IPT inclusion (tick appropriate box)	
	Y	N

Annex 11: HIV testing Algorithm for HIV Exposed Infants

