

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE



NATIONAL AIDS CONTROL PROGRAMME



NATIONAL GUIDELINES FOR THE MANAGEMENT OF HIV AND AIDS

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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 Treatment
ARV	Antiretroviral
ATV	Atazanavir
AZT	Zidovudine
BBP	Blood Borne Pathogen
BCG	Bacille Calmette-Guerin
BMI	Body Mass Index
BMI	Body Mass Index
BP	Blood Pressure
CBO	Community Based Organization
CHBC	Community Home Based Care
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
CSF	Cerebrospinal Fluid
CTC	Care and Treatment Clinic
CTU	Care and Treatment Unit (NACP)
D4T	Stavudine
DACC	District AIDS Control Coordinator
DBS	Dried Blood Spots
ddl	Didanosine
DMO	District Medical Officer
DOTS	Directly Observed Therapy, Short course
ECG	Electrocardiogram
EFV	Efavirenz
EIA	Enzyme Immunoassays
EID	Early Infant Diagnosis
EPI	Expanded Programme of Immunization
EPTB	Extra pulmonary Tuberculosis
ESR	Erythrocytes Sedimentation Rate
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
HAD	Associated Dementia

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HBA	Home Birth Attendant
HBC	Home Based Care
HBCT	Home Based HIV Counselling and Testing
HCP	Health Care Provider
HIV	Human Immunodeficiency Virus
HIVRNA	Plasma Viral Load
HLD	High-Level Disinfectants
HSV	Herpes Simplex Virus
HTC	HIV Testing and Counselling
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
MOHSW	Ministry of Health and Social Welfare
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
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
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
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 Procedure
SP	Sulfadoxine Pyrimethamine
STI	Sexually Transmitted Infection
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

For the last three decades, HIV remains one among the leading cause of morbidity and mortality in Tanzania with negative demographic, social and economic consequences. According to the Tanzania HIV/AIDS and Malaria Indicator Survey (THMIS) 2012, HIV prevalence among all adults aged 15-49 in Tanzania mainland has declined progressively from 7% in 2003/04 to 5.1% in 2011/12. The decrease in HIV prevalence is a result of country's efforts, including putting in place a series of strategic plans and interventions in prevention, care, treatment and support. Since November 2004, the Ministry of Health and Social Welfare (MoHSW) is coordinating a nationwide care and treatment programme, aiming at providing Antiretroviral medicines (ARVs) to People Living with HIV and AIDS (PLHIV). The main focus of the program is to improve access to ART services at health facilities and through Home-Based Care (HBC), for as many PLHIV as possible. It is estimated that about 1.4 million people live with HIV in Tanzania and over 73,000 new HIV infections occur every year (SPECTRUM Estimates and Projections, 2014).

The MoHSW in collaboration with the implementing partners has realized significant achievements in this program that includes the enrolment for patients in HIV Care Treatment and support services. By September 2014 a cumulative number on care was 1,486,162 PLHIV, whereby, a total of 589,431 were on ARVs. For those who are not eligible, they are closely monitored at 1209 health facilities that are providing Care and Treatment services in the whole country.

This National Guidelines for Management of HIV and AIDS 5th edition 2015 has taken into consideration the WHO 2013 Consolidated guidelines recommendations of antiretroviral drugs for treating and preventing HIV infection on the use. It provide details on antiretroviral therapy for adults, children, and pregnant and breastfeeding women. In addition, it provides details on the use of ARV drugs (what to do) and operational aspects (how to do it) along the cascade of HIV-care related services. This includes testing, HIV prevention, linkage and enrolment into care, retention and adherence in general HIV care and treatment, management of co morbidities, when to start antiretroviral therapy and preferred ART regimens. It is also emphasizing integration of services, by providing ARVs at other clinics, such as; the Prevention of Mother to Child Transmission (PMTCT), Maternal, Newborn and Child Health (MNCH), TB/HIV, Medically assisted Therapy etc., as collaborative activities.

This Guideline covers key areas of Adult and Pediatric HIV and AIDS management; Nutrition; Management of Opportunistic Infections; Home Based Care and the Continuum of Care; Counseling for HIV Testing, as well as, ART adherence. Other areas covered include, standard precautions in care settings and laboratory services, post exposure prophylaxis, as well as, ARV logistics and dosages. There is also an emphasis on Positive Health, Prevention and Dignity, a strategy that is meant 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, and 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 used to revise, improve and update the guidelines, so as to keep abreast with the scientific and technological changes. For that reason, your timely feedback will be highly appreciated.



Dr. Margaret E. Mhando
ACTING CHIEF MEDICAL OFFICER

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CHAPTER 1: OVERVIEW

1.1 Epidemiology of HIV/AIDS

Sub-Saharan Africa is the world's most severely affected region with HIV. Though it is home to only 10% of the world's population, it shelters about two thirds of the total number of people living with HIV globally. One in 12 adults in this region is reported to be infected with HIV. Although HIV incidence is declining in a number of countries due to behavior and prevention programmes and scaling up of treatment programmes, the number of people living with HIV has continued to rise, due to population growth, and the life-prolonging effects of antiretroviral therapy.

Since the first three AIDS cases in Tanzania in 1983, the HIV epidemic has affected all sectors of the society making it not only a major public health concern, but also a socio-economic and developmental problem. In 2012 about 1.5 (1.3 - 1.6) million people were estimated to be living with HIV/AIDS¹, with approximately 450,000 (30%) in need of ART. Household surveys estimate the sero prevalence in adults aged between 15 – 49 years in Tanzania at 5.1%, with a wide variation among regions (THMIS, 2012). Heterosexual intercourse is the main mode of transmission and women being at a higher risk of infection than men.

The government has strengthened efforts to scale up care and treatment services. It is estimated that 21%-30% of PLHIV in Tanzania have registered at CTC, and 69% of eligible adults are receiving ARVs. Availability of ART has had great impact in prolonging lives. In analyzing adult deaths, the report found that the cumulative probability of mortality in the first year was around 10%, but in subsequent years mortality was lower, at around 3% per year (NACP, 2011).

1.2 Impact of HIV/AIDS

1.2.1 Health Impact

The HIV pandemic has had a profound impact on the health care system of all countries worldwide, but especially on those in Sub-Saharan Africa. For example, the pandemic has reduced resources available for other health problems, which has had an unfavorable effect on the overall quality of healthcare services. In Tanzania, where human and financial resources for the health system are constrained, the implementation of additional HIV care and management services has added to the overall health system challenges. Since HIV also affects health care personnel, we have noted an additional burden to the human resource crisis.

The HIV/AIDS pandemic interacts with other underlying public health problems, particularly tuberculosis (TB), which is one of the principal causes of death in persons with HIV infection. Despite a well-organized TB programme established in 1970's, the national TB infection rate in Tanzania has increase six-folds, reaching peaks of more than 400 cases per 100,000 individuals; this is similar to the situation in other sub-Saharan African countries. In some countries, up to 70% of patients with sputum smear-positive pulmonary TB are HIV-infected. The majority of hospital admissions in sub-Saharan Africa are due to HIV-related conditions, including TB.

1 UNAIDS 2013: Report on the Global AIDS epidemic.

1.2.2 Economic Impact

There is a close relationship between HIV/AIDS and economic development. HIV and AIDS negatively affect economic growth, which makes it difficult for countries and individuals to initiate adequate and comprehensive responses to the epidemic, due to a weak economic base.

Poverty is a powerful co-factor in the spread of HIV and AIDS. The economically and socially disadvantaged segments of the population, including women, youth and other marginalized groups, are disproportionately affected by the epidemic.

The health status and death due to AIDS are reported to have reduced the agricultural labour force, productivity and disposable incomes in many families and rural communities. Data from Kagera, one of the regions in Tanzania most severely affected by HIV/AIDS, during the early years of epidemic indicate that between 1983 and 1994, the annual Gross Domestic Product (GDP) declined from USD 268 to USD 91. Although this decline was multi-faceted, AIDS was believed to be a major cause. Similar trends of declining GDP associated with reduced agricultural production and increase in number of AIDS cases were observed in other regions.

1.2.3 Social Impact

AIDS is widespread in both urban and rural communities and mostly affects persons at the peak of their sexual and productive lives. The death of a young adult often means loss of family's primary income generator. Studies conducted in Arusha, Kagera and Mwanza regions show a serious and growing breakdown of social networks, which have up until now sustained African societies. Stigma associated with HIV continues to prevail. Orphans are not only subjected to material, social and emotional deprivation, but lack of opportunities for education and healthcare. Widows and orphans are deprived of their inheritance rights by relatives through the application of outdated traditional practices. Often, widows are even blamed for the deaths of their husbands. Despite these challenges experience has shown that the epidemic can be stabilized or reversed, even in countries with modest resources, if a supportive environment exists.

Programmes to mitigate the impact of HIV/AIDS should include: strong and high-level political leadership for HIV prevention; a national HIV/AIDS strategic plan; adequate funding for HIV/AIDS response; strong and sustained community involvement and initiatives; and supportive policies. Data from Kagera show that the decline in HIV prevalence rates has been a result of a combination of these factors.

The components of a minimum package for HIV and AIDS response include: blood safety initiatives, Sexually Transmitted Diseases (STDs) management and prevention and care and support of PLHIV including access to antiretroviral drugs. Other components are functional referral systems and linkages, education to the general community (particularly the youth), condom programming, Prevention of Mother to Child Transmission (PMTCT) and HIV Testing and Counseling (HTC).

1.3 National Response to Care and Treatment

The National response to HIV and AIDS includes interventions aimed at prevention, Care and Treatment. Since 2004, the Government, in collaboration with partners, initiated a care and treatment programme under the NACP. By September 2014,

a total of PLHIV current on ART were 589,431 out of them 38,848 were children in 1,209 health facilities throughout the country. The target is to enroll 818,886 patients current on ART by the year 2015. More vigorous efforts are needed to promote HTC; to reduce HIV stigma among the public and health professionals; to improve on the quality and quantity of human resources; to improve ARV supply management; and to integrate HIV care with other health services, such as TB and PMTCT.

1.4 Basic Facts about HIV

1.4.1 Aetiology of HIV

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

1.4.2 HIV Transmission

HIV infection is acquired through 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 from unprotected sexual intercourse with infected partners. Transmission of HIV through body fluids other than blood and genital secretions such as CSF (cerebrospinal fluid), pleural fluid, amniotic fluids etc. is also possible. However, unless blood is visibly present, saliva, sputum, sweat, tears, feces, nasal secretions, urine, and vomitus carry a very low risk of transmission of HIV.²

1.4.3 Pathophysiology of HIV Infection

Much has been learned about the pathophysiology of HIV and this understanding has led to more effective use of medications for controlling the disease in humans. Interaction between the viral envelope proteins (gp120) and receptors on the cell membrane is critical for the HIV to enter and infect the host cell. High concentrations of the CD4 molecule and co-receptors have been detected on the surface of T-lymphocytes and macrophages. Other cells that have been found to have CD4 molecules on their surface include the Langerhans cells (found in the skin) and the microglial cells of the brain.

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

CD4+ T lymphocytes, when stimulated by new HIV, other infections and infestations which would normally result in the CD4+ T lymphocyte reproducing itself, now respond 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

2 Lohiya GS, Tan-Figueroa L, Lohiya S, Lohiya S. Human bites: bloodborne pathogen risk and postexposure follow-up algorithm. *J Natl Med Assoc.* Spring 2013;105(1):92-5.

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.

1.4.4 Natural History of HIV Infection

During the past few years, major advances have been made in the understanding of the complex pathogenetic mechanisms leading to the spread of HIV infection overtime, and to the progression of HIV and AIDS within an individual.

Initial infection with HIV (primary HIV infection) is characterized by a relatively brief period of high-level acute virus replication. People newly infected are highly infectious, even though they may test negative for HIV; when using common tests that depend on detection of antibodies against HIV. The high level of viraemia present at the time of sero-conversion may persevere for about three months, but eventually stabilize at an individual “set point.”

This is followed by an asymptomatic phase of the infection, wherein the levels of CD4+ T-lymphocytes, the prime target cell for HIV, gradually decline. The rate of decline varies substantially among patients. Major factors known to influence the rate of CD4+ T-lymphocyte decline in a patient include genetic factors, viral load (number of HIV-RNA copies/unit volume) at the “set point,” viral characteristics, and age of the patient or existing co-morbidities such as tuberculosis.

Clinical and biological studies of patients have demonstrated that measuring the amount of circulating HIV, referred to as “viral load” (expressed as number of copies/ml) is the most powerful predictive indicator of disease progression. Viral load and number of circulating CD4+ T-lymphocytes/mm³ are the two most important laboratory parameters to consider when deciding whether to start treatment in an individual person. Viral load is the measure of disease activity that can be used to evaluate both the rate of immune system deterioration before and during treatment, and the risk for development of resistance during treatment. The CD4 count can be used to evaluate the health of the immune system or risk of development of opportunistic infections.

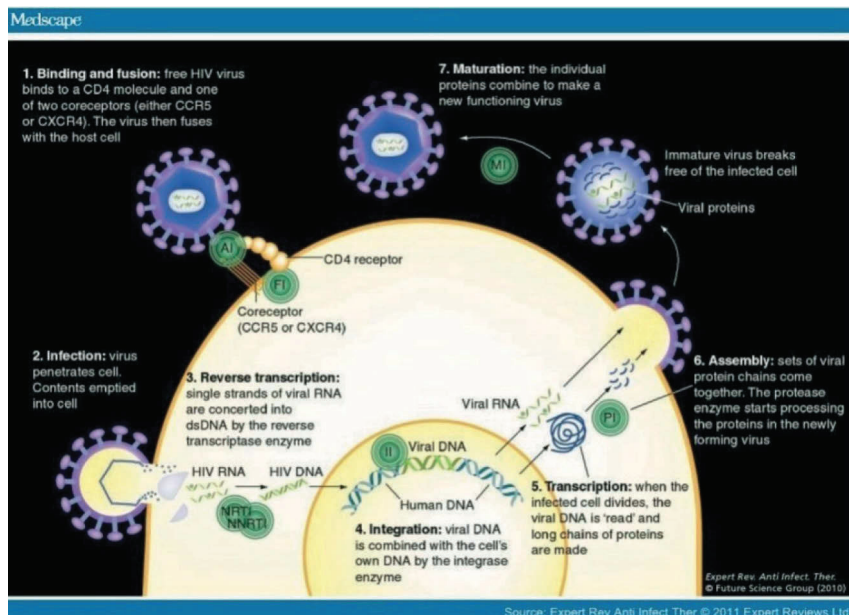
A high set point has been shown to be associated with rapid disease progression more than a low set point. Infection with syncytium forming viruses is associated with rapid rate of disease progression compared to non-syncytium forming viruses. Development of severe immuno- suppression could occur two to four years, but may be delayed for more than 15 years. In the era of effective treatment, it is not recommended to delay treatment until visible effects of the disease can be observed. Activation of the immune system by infections such as tuberculosis or worm infestation accelerates onset of immuno-suppression. Consequently, the institution of preventive therapy for OIs, plus early detection and administration of effective and appropriate treatment of OIs, does minimize the risk of rapid onset of immuno-suppression. Preventive therapies currently used include those for TB, bacterial infections, *Pneumocystis Jiroveci* (PJP), previously called *Pneumocystis Carinii* Pneumonia (PCP), toxoplasmosis and cryptococcal meningitis.

Comprehensive clinical care of persons with HIV disease requires health care personnel to have appropriate clinical knowledge, experience and laboratory support to identify patients with subtle or gross features of HIV disease. Once

diagnosis of HIV infection is made, the goal of any treatment aims at limiting or delaying progression and onset of AIDS for as long as possible, to reduce morbidity and to increase survival rate.

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. (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 the PLHIV to take more than one medication.

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



Anti-retroviral drugs currently available in Tanzania function by targeting either the reverse transcriptase enzyme or the protease enzyme. This results in halted viral replication and a consequent halting or reversal of further decline in CD4+Tlymphocytes.

1.5 Clinical Progression of HIV Infection

(See WHO Clinical Staging Criteria in Annexes 1 and 2)

In the absence of anti-retroviral therapy, HIV infected patients go through the following clinical stages:

1.5.1 Primary Infection, or Becoming HIV Infected

Most people who become infected with HIV do not immediately notice that they have been infected, but some have a short illness soon after they have been infected. This is called sero-conversion illness. It may last for a few weeks and is often accompanied by flu-like symptoms such as fever, malaise, enlarged lymph nodes, sore throat, skin rash and/or joint pains. This acute febrile illness is accompanied by widespread dissemination of the virus to different tissues, especially the lymphoid system. HIV blood tests that are designed to detect the presence of HIV antibodies, such as ELISA and rapid immunoassays, are usually negative.

1.5.2 Clinically Asymptomatic Stage

This stage may last for an average of eight to ten years, and is free of symptoms, except for the possibility of swollen glands (Persistent Generalized Lymphadenopathy, or PGL). At the initial stages of HIV infection, most patients are clinically asymptomatic in spite of this ongoing extensive immunologic battle that ensues once rapid viral replication begins. All HIV+ individuals can transmit the virus, but the chances of transmission are higher when the viral load is higher. This is WHO Stage 1.

1.5.3 Symptomatic HIV

Over time the immune system loses the struggle to contain HIV, and symptoms develop. Symptomatic HIV infection is often caused by the emergence of OIs. The most common symptoms include fever, respiratory infections, cough, tuberculosis, weight loss, skin diseases, viral infections, oral thrush, pain and lymphadenopathy. This stage is WHO Stage 2 or 3, depending on the particular OI seen. (See Annex 1 and 2 for reference.)

1.5.4 AIDS

Diagnosis of AIDS is confirmed if a person with HIV develops one or more of a specific number of severe OIs or cancers. Such conditions include Kaposi's sarcoma, cryptococcal meningitis, PCP, toxoplasmosis, CMV (Cytomegalovirus) retinitis etc. This is WHO Stage 4.

CHAPTER 2: ORGANIZATION OF HIV AND AIDS CARE AND TREATMENT SERVICE DELIVERY

2.1 Introduction

The provision of quality HIV and AIDS services at health care facilities across the country requires efficient organization of HIV Care and Treatment services. By the end of September 2014, a total of 1,300 health facilities were providing care and treatment services. Of those 220 were hospitals, and the remaining 1080 were primary health facilities.

2.2 Identifying People Living with HIV and AIDS (PLHIV) as an entry point to Continuum of Care

In order to meet the goals of the HIV and AIDS care and treatment program, an expanded multi-sectorial effort involving all sectors of development through CBOs, NGOs, the private sector and government structures is required to identify clients in need of HIV care and treatment. Health services exist within communities, for identification of people in need of care and treatment. These services are:

- HIV Testing and Counselling (HTC),
- Community and Home Based Care (HBC),
- Elimination of mother to child HIV transmission (eMTCT),
- Out Patient Department (OPD),
- In patient department (IPD)
- TB Clinics.

People need to be sensitized using all effective communication channels within community and health facilities to come forward for testing and counseling, HIV prevention and adherence to HIV care and treatment.

2.3 Scope of HIV Care and Treatment services

The provision of HIV Care and Treatment services, including ARVs should take place at assessed and registered healthcare facilities which have trained personnel. The care and treatment services should also be provided integrated with other services such as TB clinics, RCHS clinics, and Methadone assisted therapy clinics. It is also important to ensure effective linkages to a wide range of other services across the continuum of care including TB, Sexual and Reproductive Health, Family Planning, Prevention of Mother to Child Transmission (PMTCT), social welfare and spiritual support, legal support and home based care services.

- The core elements of HIV prevention, treatment and support that need to be available within HIV care and treatment services at any level include basic education about HIV transmission, disease progression, disease management and elements of Positive Health, Dignity and Prevention (PHDP) (see also chapter 4). These include the following:
- Education on behavioural risks and condom use

- Information of HIV care and treatment services availability.
- Education and counselling on treatment adherence; good nutrition, food safety, clean water and use of insecticide treated bed-nets.
- Early identification and management of co-morbidities (opportunistic infections, non-communicable diseases etc)
- Prophylaxis for OIs (e.g. co-trimoxazole, TB preventive therapy and cervical cancer screening).
- Assessing eligibility for ART (clinical staging, social eligibility and CD4 counts)
- Effective two-way referrals to essential hospital services such as antenatal clinics for PMTCT; family planning advice before and while on ART; STI/RTI; MAT or other specialized clinics.
- Recording and reporting patient information according to the established electronic and paper based systems.
- Registration, appointment and tracking systems for effective treatment continuation and preventing missed appointments.
- Referral to community services such as CHBC, social welfare and legal support.
- Service delivery should be organized to ensure efficiency, user friendliness, regular and standardized follow up.
- Use of Continuous quality improvement initiatives to strengthen services

2.4 Organization of HIV Care and Treatment Services

2.4.1 Staffing and Team Approach

For HIV services to function well, adequate and trained staff should have clear roles and responsibilities. The principles of chronic disease management should be followed. Team approach involving a patient, healthcare team of at least a triage nurse, clinician and treatment/adherence nurse, will ensure the building of a relationship between patient and the health care team for life-long care. Regularly scheduled visits ensure close follow up of patients.

Weekly CTC team meetings to discuss bottlenecks and case studies will help to build the team spirit; monthly staff meetings between heads of relevant units involved in HIV care such as CTC, TB, VCT, PRCH, STI, HBC, Pharmacy, Laboratory and in-patient will help to build better internal cooperation and patient referrals.

CHMT members need to conduct regular supportive supervision at least quarterly to assess and monitor of services delivery.

Mentorship should be done by district mentors according to needs.

The National Standard Operating Procedures manual outlines the following functions to be done by available staff within HIV care and treatment services:

- Registration and appointments management; filling of CTC 1 and CTC 2 cards; other relevant basic information.
- Triage: assessment of immediate medical needs, TB screening, support and referring the patient to the next relevant unit or staff at the clinic
- Clinical management
- Patient ART preparedness, adherence counseling and education
- All elements of Positive Health, Dignity and Prevention (PHDP)
- Referral management to other services within the health facility and relevant institutions and to other community support services

2.4.2 Patient Visits Plan

- Initial clinic visit:
- Assess patient's needs, record demographic information and patient contact details, issue relevant forms (e.g. CTC1, CTC 2, TB screening tool), weigh and direct patient to appropriate point of care.
- Do a confirmatory HIV test if there is doubt on their status, and CD4 cell count, or sputum smear if indicated, before the patient meets a counsellor and a clinician.
- Specimen for baseline investigation should be done within the facility or sent to a referral laboratory on the same day.
- Follow-up visit:
- Patients recommended for therapy will meet a counsellor/clinician to discuss adherence, dosing and adverse reaction management.
- Patients will be scheduled for follow-up monthly for the first six months depending on assessment by clinician. After the patient is clinically stable with good adherence for the at least six months or more and no history of drug toxicity or recurrent OI he/she may see at two-monthly intervals or more as agreed between clinicians and the patient.
- During the visits, patients will see a clinician, pick up medication, and meet a counsellor (see counselling section below). At six months intervals, CD4 counts, and other blood tests will be performed. Patients will be evaluated assess response to therapy.
- Patients not yet eligible for ART, require regular clinical and laboratory assessment (clinical staging and CD4 count) every 6 months.
- All patients should report to CTC if their condition deteriorates prior to the next scheduled visit.

2.5 Linkages across a Continuum of Care

Linkages should be made with other care-related providing units within the facility and community-based interventions. Regular dialogue between the CTC and community support programs need to be established within the district in order to ensure a continuum of care through functional referral mechanisms. Often members of PLHIV support groups or staff from HBC programs can assist at CTC service delivery sites to enable effective referrals and follow up

Dialogue can be promoted through the expanded Council Health Management Team (CHMT) or through continuum of care subcommittees. The following programmes or services should be considered when developing a continuum of care:

- PMTCT
- HTC (VCT, HBTC and PITC)
- STI
- TB Clinics
- Community and Home Based Care
- PLHIVs support groups
- Reproductive and Child Health and Family Planning services
- Legal and support services

Health care providers within Continuum of Care committees should develop a directory of actual comprehensive, prevention, support and care services available within the district with contact details to enable a prompt referral across the continuum of care. (More detailed of comprehensive services are also found in Chapter 5).

2.6 Process of Registering Health Facilities to Provide HIV and AIDS Care and Treatment Services.

In order for health facilities to qualify for the provision of HIV and AIDS Care Services to PLHIV, the National AIDS Control Programme (NACP) developed an assessment tool with a strengthening plan to be implemented stepwise as follows:

- Assessment of the availability and quality of essential elements to start and/or expand HIV and AIDS Services
- Identification of areas for strengthening and improvement to upgrade health facilities for the provision of comprehensive care to PLHIV
- Issuance of a code number to health facilities to enable them to start or expand care and treatment once they have met a minimum set of criteria
- Code numbers will be issued to the facilities providing Long Life ART for Pregnant and Lactating Mothers (LLAPLa) for registration and reporting. Eventually same code number will be used to initiate the Care and treatment services once the facility satisfies the minimum criteria.

Selection of health facilities for provision of HIV and AIDS Health Services is done by CHMT, and then communicated to the RHMT to arrange an assessment. RHMT

assessment focal person and implementing partners will conduct an assessment of the Health Facility.

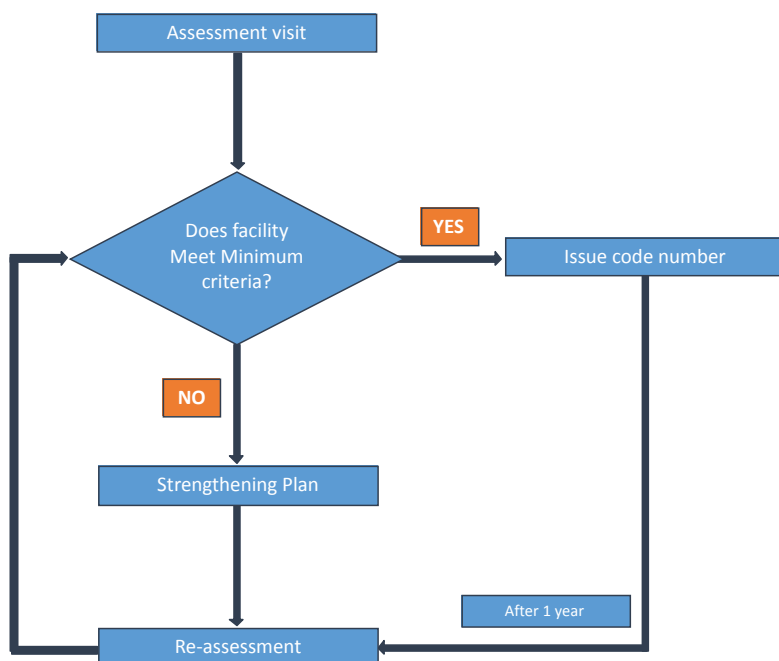
Assessment will be followed by development of a strengthening plan for the health facility by the health care workers with support from the assessment team. If a site providing LLAPLa is to be upgraded to a fully-fledged HIV CTC, then it should be assessed according to the prescribed assessment procedures.

Assessed facilities can be categorized into;

- A Care and Treatment initiating site
- An ART refilling site

Site providing Long Life ART for Pregnant and Lactating Mother (LLAPLa)

Figure 2.1: Preparing facilities for Care and Treatment Services



Facilities are categorized on the basis of the availability of the following:

1. Supervision from district level
 - Last visit from the District (CHMT, CTC staff) not longer than 3 months ago (so supervision at least quarterly)

2. Adequate human resource (staff levels and qualifications)
 - At least one clinician
 - At least one adherence counselor
 - At least one other health worker
 - Dedicated Care and Treatment team consisting of at least 3 members
 - The Care and Treatment team as mentioned in 2.3 has been trained according to approved national curricula
 - Guidelines available and seen: National guidelines for the clinical management of HIV and AIDS and other HIV interventions guidelines
3. Laboratory services
 - Adequate laboratory space, at least one large room or at least 2 smaller rooms
 - HIV testing (rapid)
 - Basic blood tests (haematology/biochemistry)
 - Malaria blood test
 - TB sputum smears (ZN stain) + STI test (Gram stain)
 - Routine testing of stool and urine
4. Infrastructure, including drug store
 - One or more confidential consultation rooms
 - Locked area for medical records with limited access
 - Secure storage space large enough for three month supply of ARVs and other medicines
5. Proper patient records and reporting system
 - An established and working medical record system
6. Counseling and testing services
 - One confidential room for counselling and testing
 - One VCT counsellor
7. Continuum of care (including community home based care)
 - Effective linkages between health facility and relevant community services

2.7 Management of Antiretroviral Medicines

2.7.1 Introduction

Proper management of medicines ensures optimal use of resources to avail quality medicines and other medical supplies to patients when they need them. The process of management involves identification of the medicines, other medical supplies needed, and acquisition of the needed medicines and supplies from reliable sources

(e.g. MSD) and ensuring their proper utilization by the to the end user.

HIV and AIDS related commodities are relatively expensive and therefore they require proper handling to ensure effective use.

2.7.2 Rational Use of Medicines

Rational drug use is the process of delivering medication that is appropriate to a patient's clinical needs at the appropriate frequency and duration and at the lowest cost.

ART is a lifelong treatment that is in constant development. It is therefore very important to use drugs rationally since irrational drug use may have unwanted consequences at both individual and population levels, including:

- Treatment failure
- Widespread drug resistance
- An increase in the risk of toxicity
- Increased cost for treatment of patients due to the need to use expensive medication as a result of irrational use and treatment failure.

2.7.3 Prescriptions

Only trained and authorized prescribers in certified health care facilities are allowed to write ARV prescriptions.

ARV prescription should indicate name, age, sex of patient, medicines and dosage, and should also include name, signature and prescriber's code.

2.7.4 Dispensing

Antiretroviral drugs are prescription-only medicines to be dispensed to treatment-ready patients with instructions and advice given through a named patient or appointed adherence assistant. Adequate time should be scheduled for antiretroviral dispensing and counselling.

The pharmacist/dispenser should ensure the patient understands the dosage and drug intake schedule and instructions for storage and food requirements. The dispenser should also inform patients about possible side effects, respond to specific questions and problems encountered by patients and advise on measures to be taken to reduce side effects including immediate return to the clinic when that happens.

2.7.5 Records

To facilitate efficient administration and management of ARVs, all information regarding ARV issuance should be recorded in a dedicated register book (Dispensing registers/ or in the pharmacy database-module) and ART patient card.

2.7.6 Dispensing Register

The pharmacist/dispenser should record all dispensed ARVs in a register. In the facilities where the pharmacy electronic database is available, patients' information and medication should also be recorded. Reports on medicines consumption and stocks of medicines should be kept to enable facilities understand their requirements. The reports should on a regular basis be sent to the MoHSW through the DMO for program monitoring and forecasting.

2.7.7 Patient Identification Cards

Each patient must be issued with a patient identification card for medication (CTC 1). Patients (or appointed adherence assistants) must present the cards to the dispenser every time they collect medicines and all medications must be recorded on the card.

2.7.8 Storage

For proper control and safety of ARVs, the following procedures should be followed by facility pharmacies:

- Stock must be stored in a secure area with one pharmacist/technician responsible for receipts and issues.
- Stock records be kept for all receipts and issues with running balances, and make a ledger for each item.
- ARVs must be stored at appropriate temperatures and refrigerated where recommended e.g. suspensions.
- Commodities must be stored according to first-to-expire first-out (FEFO) procedure and stock management.
- Damaged/expired commodities to be separated in the inventory and disposed off using laid-out procedures.
- Adequate stocks of ARVs (first line, second line, adults, pediatric etc) should be maintained at all times.

2.7.9 Procurement

Procurement of ARVs and Laboratory commodities is done by Medical Stores Department (MSD) or authorised donor agents. MSD also distributes these commodities to health facilities. Requisition of antiretroviral drugs from the facilities follows the same procedure as for other drugs except that a separate requisition form is used.

On delivery at the facility, the pharmacist shall check the ARVs brought by MSD and sign a delivery note and invoice.

An adequate stock levels of medicine must be maintained and closely monitored to avoid stock outs.

2.7.10 Ordering ARVs

Ordering of ARVs will be done by the pharmacist using the R&R Forms of the ARVs logistic systems (Hospitals) and “Integrated Logistic System” (ILS) forms for stand alone PMTCT option B+ sites. The built-in inventory control system is designed to ensure that drugs are ordered on quarterly basis using existing stock levels.

Data on the consumption of antiretroviral medicines must be kept and sent to the MOHSW yearly

Orders to MSD should be made with accordance to SOPs to enable continuous availability of commodities at health facilities.

2.7.11 Collaborating with Clinical Staff

The pharmacist works with clinical staff to estimate the number of expected patients to be initiated in ART.

The pharmacist needs to keep clinical staff informed of ARV stock levels on regular basis. Supply shortages should be communicated to clinical staff by the pharmacist so that the best course of action can be pursued.

Pharmacist and Clinician staff are expected to regularly share updates on guidelines changes or circular from MOHSW.

2.7.12 Adverse Drug Events

Monitoring involves continuous reviewing of program performance against its targets. Drug Management system monitoring helps to ensure that:

- clients get the health commodities they need when they need them
- planned logistics activities are carried out according to schedule
- records are well maintained and reports submitted in a timely manner for re-supply

Monitoring and reporting of adverse drug events should be done according to Tanzania Food and Drug Authority guideline. Adverse drug reactions reporting forms (yellow forms) will be distributed to all CTCs.

2.7.13 What should be expected during Audit

Review of documentation from Dispatch at MSD to usage at Health facilities i.e ledges, issue vouches, dispensing registers, etc.

Procurement, storage, distribution, dispensing procedures, records and stocks will be subject to internal and external audit. Given the cost and complexities of handling ARVs, frequent auditing is anticipated.

CHAPTER 3: HIV TESTING AND COUNSELING (HTC)

3.1 Introduction

People access HIV treatment, care, support and prevention services through the gateway of HIV testing and counseling. Through HTC people learn their HIV status and make informed decisions about their health, based on their HIV status and reinforce HIV prevention efforts by providing clients/ patients with key messages on risk reduction and behaviour change. The key components of all HTC services are pre-test session, HIV test, post-test session, linkage to follow-up services and on-going support. The primary approaches for providing HIV Testing and Counseling are: Provider Initiated Testing and Counseling (PITC); Client initiated Voluntary Counseling and Testing (VCT); Home Based HIV Testing and Counseling (HBCT); In line with national and international standards for health care service delivery and human rights principles, HIV testing and counselling (HTC) services shall be conducted with the best interests of clients and patients in mind, and shall respond to the needs and risks of clients and patients.

3.1.1 HIV Testing and Counselling: Guiding Principles

All forms of HIV testing and counselling should be voluntary and adhere to the five C's: Consent, Confidentiality, Counselling, Correct test results and Connections to care, treatment and prevention services. (For further details refer to National HTC guidelines 2014). People being tested for HIV must give informed consent to be tested; they must be informed of the process for HTC; services that will be available depending on the test results and their right to refuse testing and may not be denied access to other health services.

Mandatory testing is not permitted in Tanzania. This is with accordance to the *HIV/AIDS Prevention and Control Act (2008)*, the only situations in which mandatory testing are permitted are:

1. By court order;
2. For donors of human organs and tissues;
3. To sexual offenders;
4. If the person is unconscious and unable to give consent; and
5. The medical practitioner reasonably believes that such a test is clinically necessary or desirable in the interest of that person.

3.2 HIV Testing and Counseling approaches

3.2.1 Provider Initiated Testing and Counseling (PITC)

PITC contributes to increased rates of HIV testing and early identification of persons living with HIV (PLHIV). Health care provider recommends and offers HTC to individuals, couples, families, or groups attending clinical services in the public or private health facilities. Health care providers should recommend HIV testing as a standard of care to all patients attending a health care facility regardless of whether they have sign or symptoms of HIV infection. This allows Health care providers to make specific medical decision that would not be possible without knowledge of the patient's HIV status.

CHAPTER 3: HIV Testing and Counseling (HTC)

Under this approach, clients shall be tested for HIV by offering an informed consent. However in case of mature minor they shall consent on their own. As outlined in the National Guidelines for HIV Testing and Counselling 2013.

In order to implement PITC services the following should be taken into consideration:

- Should be provided by healthcare providers trained to provide PITC services
- PITC is provided within; OPD, IPD, CTC, TB, STI, RCH/PMTCT including referrals to other support services
- The first user of the test result is the health care provider who uses the HIV test to make diagnosis and provide appropriate treatment and/or referral.
- HIV testing and counseling is conducted in a health care setting and outreach using a blend of both open and close ended questions. This is because the session is not as long as it is during client initiated counseling (VCT).

3.2.2 Client Initiated HIV Testing and Counseling (CITC)

In this approach, also known as Voluntary Counselling and Testing (VCT), client(s) voluntarily make the decision to learn their HIV status as an individual, couple, or family and seeks counselling and testing services out of his or her own will for the purpose of prevention of HIV infection and personal life decision making.

- Client Initiated Counselling and Testing should be provided by a specifically trained counselor for VCT services.
- The counselling gives focus predominantly on addressing risk behavior and risk reduction aiming to prevent HIV transmission.
- The services offered can be distinctive (client may offer to reveal their identity) or anonymous (client may not reveal their identity)
- Counsellors need to strictly adhere to confidentiality
- Post testing counselling is equally important for clients who test HIV negative as well as who test HIV positive.
- HIV positive clients are referred to medical care services and other support services, some of which are in the community.

In case of couples and families, it will not include individualized risk assessment. Rather counsellors discuss the couple's HIV risk concerns, and focus the counselling on the present situation and plans for future.

3.2.3 Community-Based HIV Testing and Counselling

In addition to providing HIV testing and counselling in clinical settings, HIV testing and counselling can be offered in a variety of settings in the community. Community based testing approaches may reach people with HIV earlier in the course of HIV disease as well as reaching populations that may not normally attend health services. The scale up of community-based testing to complement facility based testing is an important consideration in achieving universal knowledge of HIV status and earlier diagnosis linked to care and treatment. Community-based testing should be implemented in addition to provider-initiated testing and counselling. Multiple

approaches shall be used including, home-based testing, mobile outreach (including in workplaces, schools, universities, special testing campaigns and events) and multi-disease campaigns tailored to epidemiological and social contexts.

3.2.3.1 Strategies for Home-Based HTC

Home-based HTC refers to a situation whereby an HTC provider visits a household and offers HTC services to individuals, couples, and families within the household setting. Alternatively, clients or patients may request HTC providers to visit their home to conduct HTC with themselves or their family members. Thus, home-based HTC testing includes aspects of both PITC and CITC.

3.2.3.2 Home-Based HTC Models

There are two primary models for conducting home-based HTC in Tanzania: *door-to-door* and via an *index-patient*.

- **Door-to-door model:** HTC providers aim to provide HTC services in all homes within a specific, pre-defined geographic area. This approach is best utilized in areas with high population density (for obtaining access to a large number of people and ease of getting around within the community), low numbers of people previously tested (to increase access to persons who don't know their HIV status), or to areas with high HIV prevalence (to increase identification and referral of PLHIV and discordant couples). This model requires strong community linkages and advance preparation to ensure acceptance into the community and homes.
- **Index patient model:** The trained health care professionals or HTC providers visit the home of a known HIV-infected person (e.g. a patient currently enrolled in pre-ART care or treatment) with their consent, and offer HTC services to their partner(s), spouse(s), or family member(s). The index patient model may be most effective for facilitating disclosure of HIV status among couples, and for increasing identification and referral of adults and children living with HIV and discordant couples.

3.2.3.3 Integrating Home-Based HTC

Home-based HTC shall be **integrated with other community health services**, or other health services may be added to home-based HTC. Examples of integrated services with home-based HTC include home-based HIV care, TB screening and treatment, immunization, malaria screening, or other community care or health education services. One advantage of this approach is that it shall build upon the community health platform and facilitate linkages with other health services. However, it shall also require additional training and extended roles for HTC, community health, or other health care providers. Programmes implementing community health services shall consider integrating home-based HTC to maximize access to HTC services and linkage to follow-up care, treatment, prevention and support services. However, HTC providers must undergo the relevant trainings to empower them to provide the services.

3.2.4 Couple HIV Testing and Counseling (CHTC)

Two or more persons who are in or are planning to be in a sexual relationship are considered a couple. Each of these persons is referred to as a "partner" in

the relationship. Services should be offered to married and cohabiting couples, premarital couples, polygamous unions and any other partnerships. As with all HIV testing and counselling approaches, couples HIV testing and counselling should be voluntary. Healthcare providers must be aware of the potential for intimate partner-based violence and should support individuals when they do not want to test with their partners. Couples HIV testing and counselling can be offered in all settings where HIV testing and counselling is provided, including antenatal care and TB services. Health Care workers should support and encourage the testing of the partners of people living with HIV who then can benefit from treatment. Furthermore, couples HIV testing and counselling can be an important intervention to increase access to earlier ART and reach more men with treatment.

There are many potential benefits to supporting couples to test together for HIV infection and to mutually disclose their HIV status. The most important thing is that, together they can then make informed decisions about HIV prevention and reproductive health, including contraception and conception.

Table 3.1: Comparison between Individual and Couple HTC

Individual HTC	Couples HTC
Individual learns only his/her own HIV status.	Individuals learn their own HIV status and the status of their partner.
Individual assumes burden of disclosing to partner.	Mutual disclosure is immediate.
Couple has to deal with issues of tension and blame on their own.	Counselor can help ease tension and diffuse blame.
Only one partner hears the information.	Partners hear information together, enhancing likelihood of shared understanding.
Counseling messages take into account only one partner's status; individuals may wrongly assume that their partner's status is the same as their own.	Counseling messages are tailored, based on the test results of both partners.
Counselor is not present to facilitate the couple's discussion about difficult issues.	Counselor creates a safe environment and can help couples talk through difficult issues that they may not have discussed before.
Prevention, treatment and care decisions are more likely to be made in isolation.	Prevention, treatment and care decisions can be made together.
Individual bears burden of getting family members, children tested.	Decisions about family or child testing, as well as family planning, can be made together.

It is important to understand the possible HIV test results during a couples HTC session:

- **A seroconcordant uninfected couple** is a couple in which neither partner is infected with HIV. CHTC will help concordant uninfected couples remain uninfected by reassuring them that they are uninfected and emphasizing that avoiding unprotected sex with people outside their relationship is important to keep their future free of HIV.
- **A seroconcordant infected couple** is one in which both partners are HIV-infected (HIV positive). These couples should receive care and treatment services according to the national treatment guideline, which recommend initiating ART at a CD4 count of <500 cells/ μ L.
- **A serodiscordant couple** is a couple in which one partner is HIV-positive and one partner is HIV-negative. Although one partner is currently HIV-negative, this does not mean that this partner is “immunized” or protected against getting HIV in the future.

When couples are discordant, infection could have occurred in different ways:

- The positive partner may have been infected before they became a couple.
- The positive partner may have other partners outside the relationship or may have acquired HIV non-sexually.

In CHTC it will be very important for you to emphasize and explain areas that are not widely understood, such as couple discordance. The HIV-negative partners in discordant couples are at very high risk for getting HIV if the couple does not take steps to protect the HIV-negative partner.

Many people do not understand the facts about discordance. Many myths about discordance exist that need to be corrected. It is important that counsellors make sure that discordant couples understand the facts about discordance:

Facts about Discordance

- It is of paramount importance for serodiscordant couples to avoid transmission to the HIV-negative partner.
- It is possible for couples to stay HIV serodiscordant indefinitely if they consistently practice safer sex using male and female condoms.
- The HIV-positive partner should receive ART treatment regardless of CD4 count
- In a serodiscordant couple the provision of ART to the positive partner can significantly decrease the risk of transmission to the negative partner.
- Treatment for the HIV-positive partner also is highly effective in reducing the risk of transmission to the HIV-negative partner.
- The couple also should receive information about family planning and

CHAPTER 3: HIV Testing and Counseling (HTC)

- Couples who test together and mutually disclose their HIV status are more likely than those testing alone to adopt behaviour to protect their partner.
- Couples can remain discordant for a long time—even more than 10 years.

In many cases, the couple enters the relationship when they are already discordant—discordance is NOT a sure sign of infidelity.

Follow-up services that shall be provided to all couples, in particular to discordant couples, include:

- Partners who are living with HIV shall be linked with care, treatment and support programmes.
- HIV-infected pregnant women shall be linked with Prevention of Mother-to-Child Transmission (PMTCT) services.
- HIV-uninfected male partners shall be linked with Voluntary Medical Male Circumcision (VMMC) programs.
- HIV-uninfected partners in discordant relationships shall be retested for HIV four weeks after the first discordance result, then each year, or 4 weeks after a potential exposure has occurred (e.g. unprotected sex).
- On-going risk reduction counselling and linkage to support groups.
- Condom demonstration, distribution and explanation of where to access more condoms as needed.
- Family planning counselling and distribution of contraceptives as appropriate.
- Pregnancy counselling and safer conception to couples who want to conceive.

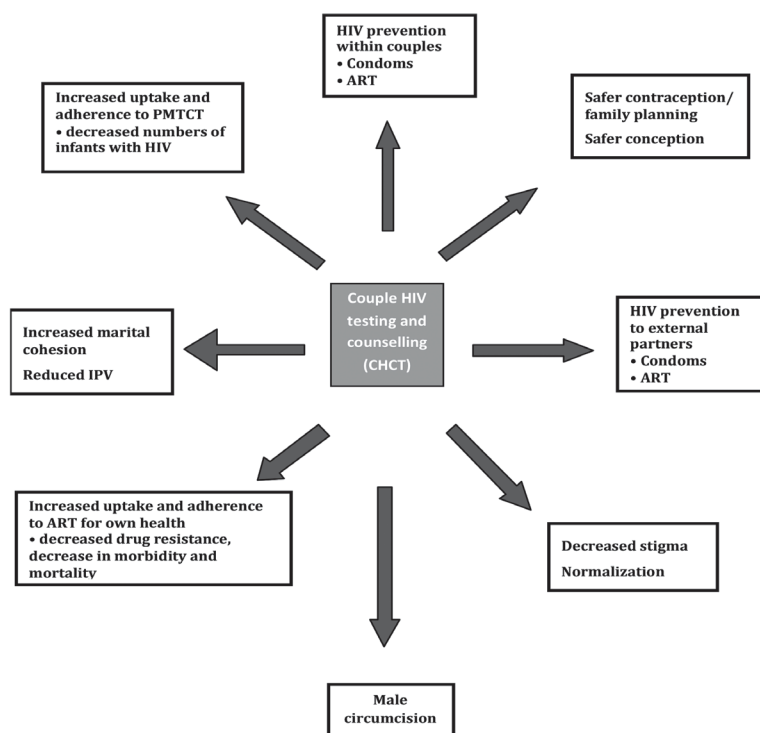
Combined, treatment and consistent condom use are likely to offer greater protection than either one alone. Serodiscordant couples who are having unprotected sex or who desire to have children, the use of ART to make conception safer (both to keep the partner negative and protect the child from HIV infection) is an important benefit. Serodiscordant couples who are aware of each other's HIV status may be able to support access and adherence to treatment, to give each other emotional support, and to support uptake of and adherence to PMTCT interventions.

The findings of many published studies suggest that people who learn their HIV status are more likely to adopt preventive behaviours than people who are unaware of their HIV status. Furthermore, couples who test together and mutually disclose their HIV status are more likely than those testing alone to adopt behaviour to protect their partner. In addition, in a serodiscordant couple the provision of ART to the positive partner can significantly decrease the risk of transmission to the negative partner. Another potential benefit of couples testing together and sharing their results is that they can support each other, if one or both partners are HIV-positive, to access and adhere to ART and interventions to prevent mother-to-child transmission (PMTCT) of HIV.

The importance of using condoms to prevent acquisition of other STIs and transmission of HIV in any sexual activities outside the relationship should be discussed.

Information about family planning should also be given to the couple, as should information regarding interventions to prevent mother-to-child transmission.

Figure 3.1 Potential benefits of couples HIV testing and counseling



3.2.5 HIV Testing and Counselling for Infants, Children and Adolescents

Early initiation of ART can save lives for infants, children, youth and adolescents that are living with HIV.

The benefits of expanded access to HTC for infants and children are numerous and include the following:

- Early identification of HIV infants and children as a first step to treatment

and care

- Identification of HIV exposed but uninfected infant, which facilitate follow up care and prevention measures that will help to ensure that, they remain uninfected and healthy
- Life planning for parents and/or children who are HIV infected; and
- Increase access to care and antiretroviral therapy for parents

In the paediatric setting, the entry points into HIV care are mainly through PITC. Health-care workers should see every patient encounter as an opportunity for providing PITC, parents and caregivers should be encouraged to learn their status, as well as that of their children and family members. Where PITC is practiced, more children are tested for and diagnosed with HIV, and can therefore access treatment services³. PITC should apply to all children attending the health care setting. In most instances, the parent/caregiver gives consent for an HIV test. Under some circumstances and depending on national legal requirements, a child considered to be sufficiently mature may give consent for an HIV test.⁴ (Refer to the National HTC guidelines, 2013).

Infants and children should be tested in the following circumstances: ⁵

- To identify the HIV-exposure status of all infants for the purpose of appropriate follow up, which includes provision of co-trimoxazole prophylaxis, antiretroviral prophylaxis and/or treatment;
- At around 4–6 weeks or as soon thereafter as possible for infants known to be exposed to HIV through mother-to-child transmission to enable early diagnosis of HIV with virological testing;
- To confirm the HIV infection status of children born to HIV-positive mothers six weeks after exposure to HIV has ceased or at eighteen months, whichever is sooner;
- For the purpose of individual diagnosis in a child who is ill (e.g. presenting with an HIV-associated illness, such as tuberculosis or malnutrition, or other recurrent common childhood illnesses such as pneumonia or diarrhea);
- For the purpose of individual diagnosis where another sibling or parent has been diagnosed with HIV or where there is a history that the parents have died as a result of AIDS or other undiagnosed debilitating illness in the family;
- In cases where a child has been exposed or potentially exposed to HIV
 - Through sexual abuse or
 - Through contaminated needle sticks or receipt of potentially infectious blood or blood products (or through other routes, e.g. wet nursing).

3 UNICEF 2010, Policy requirements for HIV testing and counselling of infants and young children in health facilities

4 WHO/UNICEF, 2010 Policy requirements for HIV testing and counselling of infants and young children in health facilities

Strategies to increase HTC for children should include:

- Increasing access to HIV testing through existing inpatient or outpatient health-care services and RCHS
- Provision of clear indications for HTC of infants, children and adolescents
- Increasing access of HIV prevention, care and treatment services including infant feeding for children
- Training of health-care workers to recommend HIV testing and counselling services for children and their parents or caregivers
- Developing and following procedures for disclosure to and counselling of children and adolescents according to their age and stage of cognitive development.
- Creation of child- and youth-friendly services to make HTC family-centred
- Provision of education and support for parents and caregivers

3.2.5.1 Counselling for HIV Testing of Infants, Children and Adolescents

Counselling offered within HIV services should include a brief explanation on why HIV testing is appropriate, the testing methods that will be used and when to return for the result. Types of counselling offered by an HIV service would include:

1. Pre-test and post-test counselling
2. Adherence counselling
3. Information on safer sex practices and risk reduction, advice on reproductive health (including STI) and family planning, partner and couples counselling for adolescents and emancipated minors
4. Disclosure support – the content of this will vary with the age and aptitude of the child
5. Information on male circumcision (adolescent males)
6. Information on PMTCT (pregnant adolescent girls)
7. Advice on infant-feeding and nutrition, which will depend on the age of the infant and whether or not the child is breastfed.

In the case of children and young people, HIV testing is often provider initiated (PITC) and the parent or main caregiver of the child gives consent for the HIV test on their behalf. Depending on the national law, adolescents and some older children deemed to be sufficiently mature may give consent for an HIV test themselves. The service provider should be aware of the legal age of consent for an HIV test in Tanzania. Likewise, depending on the law of the land, the presence of a parent or caregiver may not always be required to give consent for an HIV test.

CHAPTER 3: HIV Testing and Counseling (HTC)

Client-initiated HIV testing and counselling (CITC), where the client seeks an HIV test, is more relevant to adolescents. It is often beneficial for an adolescent to attend HTC services with a trusted adult to provide the support required.

3.2.5.2 Counselling parents/caregivers

Informed consent is required before all HIV testing. Informed consent refers to an individual's ability to arrive at the decision to undergo an HIV test after having received appropriate information on the benefits of HIV testing, the testing procedure and the implications of knowing their HIV status.

As part of pre/post-test counselling, the counselor should:

1. Assess the parent/caregiver's and child's knowledge of HIV and the diagnostic procedure.
2. Explain the indication and purpose of the test, and the benefits of knowing one's HIV status.
3. Explain the test/sampling procedure to the parent/caregiver and the child to allay anxiety. The parent/ caregiver's help may be enlisted in the sampling procedure.
4. Provide reassurance to the parent/caregiver that confidentiality will be respected.
5. Discuss the test result (positive or negative), and provide appropriate referrals for medical follow up.
6. Give an appointment for collection of results, if necessary.
7. Encourage the parent/caregiver to learn their own status and emphasize the importance of testing for partners or other family members.

3.2.5.3 Counselling Adolescents

Counselling of adolescents requires a non-judgmental attitude and assurance of confidentiality. It is preferable if the client is accompanied by a trusted adult able to provide support and assimilate information.

Information should be appropriate for the adolescent patient's level of understanding and education.

Adolescents may have concerns about sex, current and future relationships, fear of rejection and having a family in the future. All these fears can be addressed during post-test counselling and at subsequent visits.

Often, people need some time alone to assimilate a positive HIV test result, and formulate questions and concerns. The role of post-test counselling is to contain any anxieties, provide support and reassurance, and to initiate plans with respect to disclosure, and follow-up visits for treatment and counselling.

Children and adolescents who test HIV negative must be counseled and advised on how to protect themselves to stay negative, as well as the importance of re-testing and testing with any current or future sexual partners.

Disclosure

Disclosure refers to the process of informing the child about their HIV status. It also refers to person telling others of their HIV status. In HTC with infants and children, disclosure is an ongoing process continuing as the child matures. The parents/care givers, must be involved although the support of health care worker is also required. It is important for the child to be able to participate in their own health care. Many parents/care givers are reluctant to disclose the HIV test result and status to their young children and often seek to postpone the discussion well into the teens.

Health care providers should ensure that;

- Disclosure of the HIV status to the child should be discussed with the parents or guardians from the beginning. The process of disclosure should be done over time; beginning as early as possible. Usually, one can start mentioning to a 4 – 6 years old HIV-infected child that they have a chronic disease that requires regular clinic visits and medicines every day.
- Usually when the child starts asking questions about the disease or the medication he/she is taking or when acting in a way that suggests that he/she is feeling isolated from other children because of the disease. Close coordination with the guardian/parent of the child in question is crucial.
- At about 8 – 10 years it is recommended that full disclosure of HIV and AIDS be offered but in a caring and supportive manner and environment. Before their early teen years HIV-infected children should know that they are infected with HIV, how it is spread and how to stay healthy. It has been shown that children cope better with their HIV status when properly counseled.
- It is particularly important that adolescents be informed of their HIV status so that they can become active participants in their own care. Following challenges in disclosure, close coordination with the guardian/parent of the child is crucial.
- Parents/guardians should be offered with disclosure counseling to prepare and enable them to support disclosure in their children. Health care workers should be equipped with knowledge and skill on disclosure counseling.

3.2.6 HIV Testing and Counselling Related to High Risks Behaviour

Behaviours that put people at greater risk of HIV infection include multiple unprotected sexual partnerships, unprotected anal sex with multiple partners, and

injecting drugs with non-sterile equipment. Thus, high risk behaviours include:⁶

- People who Inject drugs (PWIDs)
- Males who have sex with other males (MSMs)
- Females and males sex workers
- Males who have unprotected sex with sex workers
- People who engage in multiple risk behaviours, such as both injecting drugs and having unprotected sex.

Provision of HIV counseling and testing services for groups with high risk behaviours should be a basic intervention wherever such groups are considered for HIV prevention and treatment/care.

3.2.6.1 Special Considerations for HTC for People with High Risk of acquiring HIV Infection

- **Semi-annual HIV re-testing for HIV negative at-risk people:** It is recommended that at-risk individuals who tested negative to be re-tested semi-annually.
- **Risk reduction counseling and skills building:** Since members of the Key Population (KP) often do not seek services as frequently as the general population, it is important that HTC service providers take the opportunity to conduct risk reduction counseling and skills building based on their risk assessment. Although in-depth risk reduction counseling is rarely offered during PITC, service providers should consider individualized counseling given the high-risk nature of anal sex and sex worker; or at a minimum, referral to counseling services should be done.
- **HIV testing for partners of at-risk people:** SWs, PIWD and MSM are encouraged to promote HTC with their regular partners. Couples counseling is an important intervention and may be appropriate for the individuals and their regular partners, but should be based on the sex worker's, PIWD, or MSM's comfort to disclose their status to their partner.

6 Inter-Agency Task Team on Young People, 2008, HIV Interventions for Most-at-Risk Young People

Table 3.2: Summary of HIV Testing and Counselling Recommendations for Generalized Epidemics

Who to test	When to test	Where to test
Everyone attending health facilities	Integrate in all health care encounters	All settings, including primary health care, outpatient medical and surgical wards, antenatal care and maternal and child health, TB, family planning and sexually transmitted infection clinics.
Partners and couples	Premarital, pregnancy, after separations, new partnerships and at the start of care and ART For the HIV-negative person in serodiscordant couples, offer re-testing every 6 months	Primary health care settings, voluntary counselling and testing sites, ART clinics, antenatal care, family planning clinics, sexually transmitted infection clinics, community and mobile outreach, home.
Families of index cases	As soon as possible after the family member is diagnosed	Primary health care settings, ART clinics, maternal and child health and antenatal care settings, homes and community and mobile outreach.
Key populations: people who inject drugs, men who have sex with men, transgender people, sex workers, prisoners, and partners of people who inject drugs	Every 6 months	Primary health care settings, sexually transmitted infections clinics and outreach services, including harm reduction and other sites providing services to key populations.
Pregnant women and male partners	At first antenatal care visit Re-test in third trimester or peripartum Offer partner testing	Antenatal care, delivery, postpartum

Infants and children <18 months	Early infant diagnosis at 4–6 weeks for all infants whose	Maternal and child health services
Old	mothers are living with HIV or if maternal HIV status is unknown; determine the final infant HIV infection status after 18 months and/or when breastfeeding ends	Paediatric clinics Immunization clinics
Children	Establish HIV status for all health contacts	Child inpatients and outpatients, immunization clinics.
Adolescents	Integrate into all health care encounters Annually if sexually active; with new sexual partners	Primary health care, outpatients, inpatients, voluntary counselling and testing sites, youth-friendly services, family planning and sexually transmitted infections clinics.

CHAPTER 4: LABORATORY TESTS FOR HIV AND AIDS

4.1 Introduction

Laboratory testing is an important integral part of HIV and AIDS prevention; care, and treatment; and support services. The tests that are done provide important information on an individual's HIV status, disease staging, treatment eligibility and patient monitoring (viral load and CD4 count levels, toxicities and adverse reactions), and detection of treatment failure.

4.2 Tests for HIV Diagnosis

4.2.1 HIV Testing in Adults and Children over 18 Months

Diagnosis of HIV infection using a single HIV test is not sufficient; it requires confirmation through approved HIV testing algorithms. In adults and children older than 18 months diagnosis is commonly done by detection of antibodies to HIV using rapid tests or Enzyme Immunoassays (EIA).

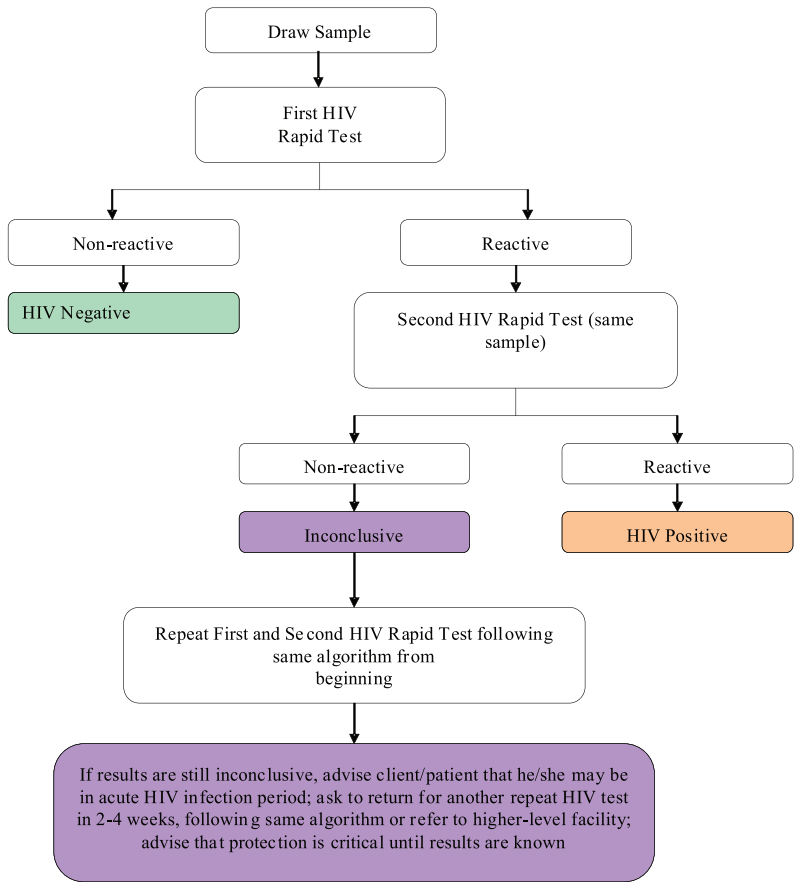
A testing algorithm describes the number, type and order of tests that need to be performed. The first test conducted is **highly sensitive**, and the second test is **highly specific**. All HIV testing facilities whether in public or private must adhere to national HIV testing algorithms.

The national HIV rapid testing algorithm utilizes a 'serial' testing strategy. That is, blood sample is tested with one HIV test kit first, and a second test kit is used only when the first HIV test kit revealed an HIV-positive test result. The actual tests used in the national HIV testing algorithm may change from time to time, based on the availability of quality assessment results and introduction of new technologies.

NHLS and NACP will conduct periodic or whenever necessary evaluation of the HIV rapid testing technologies and will update the national testing algorithm based on the results of these evaluations.

The rapid tests can be done using whole blood, serum or plasma samples. Whenever possible, rapid testing will be done with a finger prick sample. HIV rapid testing can be performed in the laboratory or in non-laboratory hospital, clinic or community settings by licensed health care workers trained to performed HIV rapid tests. However, all testing done outside a laboratory setting must be supervised by qualified laboratory personnel to ensure accurate and quality results.

Figure 4.1: Tanzania National Testing Algorithm for persons Aged more than 18 months



The national testing algorithm for HIV enzyme linked immune sorbent assays (ELISA), the blood sample is tested with Vironostika antigen/antibody combination assay first, the Enzygnost Integral II is used only when the first HIV test revealed an HIV-positive test result.

4.2.2 Diagnosing HIV infection in children under 18 months

A positive antibody test (rapid test or EIA) in infants below 18 months does not confirm HIV infection, rather exposure to HIV (see for details chapter 7). The laboratory diagnosis of HIV infection in infants and children aged <18 months is done by detection of viral nucleic acid (RNA or pro-viral DNA) or viral antigens (p24).

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 by the age of 4 weeks. Capacity for PCR testing has been developed at the three zonal consultant hospitals (Mbeya, Bugando and KCMC), one national hospital (Muhimbili) and the national reference laboratory (NHL-QATC). Samples for PCR testing can be whole blood or dried blood spots (DBS) on special filter paper cards which need to be transported to the zonal hospital laboratories.

HIV infection can be diagnosed in most infected infants by the age 4 weeks by using the DNA PCR technique where available

4.3 Tests for HIV Disease staging

CD4 cells progressively decrease as HIV disease advances and immune status deteriorates. Measurements of CD4 counts will be important immunological markers of disease progression and assist in decision making on when to start antiretroviral treatment. In adolescents and adults, CD4 counts are reported in absolute numbers (for details see chapter 8) while for children under 6 years CD4 are reported in CD4%. (For details see chapter 7, table 7.1).

Capacities for measuring absolute CD4 counts have been established at all zonal, regional and district hospital laboratories.

4.4 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 and then monitoring their treatment response and possible toxicity of ARV drugs. Viral load is a preferred monitoring approach to diagnose and confirm ARV treatment failure. Successful antiretroviral therapy results in decrease of viral load, immune recovery and therefore increases in number of CD4 cells. Virological Viral load (VL) tests will be used for monitoring response to antiretroviral treatment. Patients should have 1st VL test 6 months after initiating ART. Patients who have been on ART for more than 6 months but have not yet had a VL test should have a VL test to the next scheduled visit. After first HIV VL test the next VL test will be performed 12 months later if the initial VL test result was less than 1000cp/ml. A repeat HIV VL test will be performed after 3 months of intensive adherence counseling if the preceding HIV VL test result was more than 1000 cp/ml. An HIV VL test will be performed annually if the preceding HIV VL test results were less than 1000 cp/ml.

Where viral load monitoring is unavailable, clinical monitoring and CD4 monitoring are recommended, however, where VL is accessible a targeted viral load strategy to confirm failure suspected based on immunological or clinical criteria should be used to avoid unnecessary switching to second-line ART.

4.4.1 Tests for Monitoring Disease Progress and Treatment Safety

Guiding Principle

1. The availability of laboratory monitoring is not a prerequisite for the initiation of ART
2. Viral load testing is essential for monitoring patients on ART.
3. Viral load testing should be done 6 months after initiation of ART and then at least after every 12 months
4. Use viral load to confirm suspected treatment failure where is accessible

Table 4. 1. Laboratory monitoring before, during and after initiating ART

Phase of HIV management	Recommended test	Desirable test
At HIV diagnosis	TB Screening	HBsAg Cryptococcus antigen if CD4 count < 100 cells/mm ³ Screening for sexually transmitted infections
Pre-ART	CD4 Haematological test Chemistry test	
At start of ART	CD4 Haematological test Biochemistry test	Hb for AZT ¹ Creatinine clearance for TDF ² ALT for NVP ³
On ART	HIV viral load (at 6 months after initiating ART and every 12 months thereafter)	Hb for AZT ¹ Creatinine clearance for TDF ² ALT for NVP ³

Suspected Treatment failure	HIV VL where accessible	HBsAg serology (before switching ART regimen if this testing was not done or if the result was negative at baseline)
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1. Recommended test in patients with high risk of adverse events associated with AZT (low CD4 or low BMI).
2. Recommended test in patients with high risk of adverse events associated with TDF (underlying renal disease, older age group, low BMI, diabetes, hypertension and concomitant use of a boosted PI or nephrotoxic drugs).
3. Recommended test in patients with high risk of adverse events associated with NVP (ART-naïve HIV+ women with CD4 of >250 cells/mm³, HCV co-infection).

Patients who are not yet eligible for ART should have CD4 count measurement every six months and more frequently as they approach the threshold to initiate ART. If feasible, HBsAg should be performed in order to identify people with HIV/ HBV co-infection and who, therefore, should initiate TDF-containing ART.

4.4.2 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 crucial supported by laboratory investigations. Capacity for testing haematology indices and clinical biochemistry has been developed at all laboratories in facilities providing Care and Treatment in the country. The frequency of monitoring depends on the ART regimen used and is summarized in table 8.5 in chapter 8.

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 drugs toxicity for adults and children.

Table 4.2: Grading adverse reactions in adults

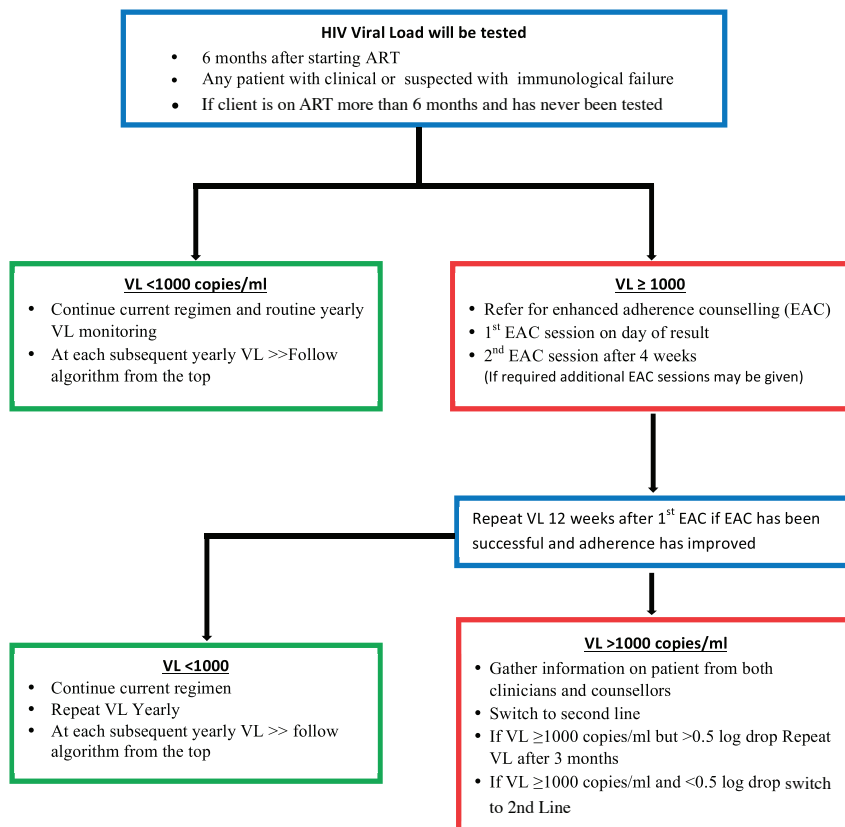
LABORATORY TEST ABNORMALITIES				
Item	Grade I Toxicity	Grade II Toxicity	Grade III Toxicity	Grade IV Toxicity
Haemoglobin	8.0-9.4 g/dL	7.0-7.9 g/dL	6.5-6.9 g/dL	<6.5 g/dL
Absolute Neutrophil Count	1-1.5 x 10 ⁹ /L	0.75-0.99 x 10 ⁹ /L	0.5-0.749 x 10 ⁹ /L	<0.5 x 10 ⁹ /L
ALT	1.25-2.5 IU/L upper normal limit	>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 the severity of adverse reactions in children

LABORATORY TEST ABNORMALITIES

ITEM	GRADE I TOXICITY	GRADE II TOXICITY	GRADE III TOXICITY	GRADE IV TOXICITY
Haemoglobin >3 month - < 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

Figure 4.3: Viral load testing strategies to detect or confirm treatment failure and switch ART regimen in adults, adolescents and children



4.5 Tests for diagnosing Opportunistic Infections

Common Opportunistic Infections including the laboratory investigations is used to confirm diagnosis, as discussed in chapter 6. For laboratory diagnosis of common OIs such as TB, upper respiratory tract infections, meningitis, diarrhoeas and septicaemia, diagnostic protocols are available as standard operating procedures and should be used. Laboratory capacity for TB diagnosis (sputum for AFB) and general microscopy examination exists at all hospitals and health centers. Culture for bacterial infections can be performed at all zonal and regional hospitals.

Close team work between laboratory and clinical staff at the CTC is required to optimize diagnostic capacities.

4.6 Laboratory Safety Precaution

Adherence to safety precautions in the laboratory should be done at 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 can be minimized if laboratory workers observe safety precautions at all times. All specimens should be treated as infectious. For more details, see Chapter 4.

4.6.1 Sample Storage

All samples should be stored in tightly closed and well labeled 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 specimen. Always dispose used or old specimens timely by autoclaving and incineration.

4.6.2 Sample Transportation

Patients' specimens should be referred to the nearest laboratory if a CTC does not have diagnostic capacity. Laboratory protocols and Standard Operating Procedures (SOPs) should be followed when transporting samples from facility to hubs and hubs to facility:

- A specimen delivery checklist should be used to verify that there is a requisition form for all samples transported.
- Specimens should be packed appropriately according to the Standard Operating Procedures (SOPs) and put in appropriate and safe containers before transporting them by road (bus or vehicle) or air
- Dried blood spots samples (DBS) on blotting paper are considered to be non-infectious and can be put in a letter envelope and transported by mail or courier. Consult courier and receiving laboratory for tracking the sample receiving status and feedback report. procedures and timing.
- Dispatch and receipt records of transported samples should be maintained.

CHAPTER 5: HIV AND AIDS PREVENTION

5.1 Behavioral HIV Prevention and Special Circumstances

5.1.1 Introduction

HIV prevention through behavior change is an important component to be reinforced across health facility and community settings. This chapter addresses behavioral prevention as it relates to the continuum of HIV prevention, care and treatment. Good examples of such interventions are those incorporated as positive health, dignity and prevention (PHDP); promotion and supply of male and female condoms and compatible lubricant; Social Behavioral Change Communication (SBCC), HIV testing and counseling activities.

5.1.2 Positive Health, Dignity and Prevention (PHDP)

Positive Health, Dignity and Prevention focus 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. This is indirect contrast to previous approaches to 'positive prevention', which could be construed as treating people living with HIV as vectors of transmission. By focusing on the journey experienced by people living with HIV 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.

PHDP also advocates for programs and services to be available, accessible and relevant to the diverse populations of PLHIV. The majority of new HIV infections in Tanzania (80%) are from sexual transmission, and all infections from sexual transmission are the result of the sexual union between an individual with HIV and an uninfected individual. Therefore it makes sense to focus prevention efforts on those who have the virus, as we do with other communicable diseases such as tuberculosis (For more details please refer National PHDP guideline).

For PHDP programming to be successful, it must include a synergistic combination of three types of interventions.

1. Central level interventions

These 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, counseling 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. More 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 sex partners and infants born to HIV-infected mothers, as well as to protect the health of HIV-infected individuals.

2. Health Facility Interventions

Changes in the risk behaviours of HIV infected individuals are likely to have larger effects on the spread of HIV than comparable changes in the risk behaviours of HIV-negative individuals. By addressing prevention with HIV-positive patients in care and treatment, providers can impact the HIV epidemic in their communities.

The important HIV prevention components of a comprehensive package for the clinical setting are:

- Condom promotion and provision
- Messaging and counselling support for health behaviours including: sexual risk reduction; retention in care, adherence to medications, and partner HIV testing and counselling
- Screening and treatment of STI
- Safer pregnancy counselling and family planning service integration
- Identification of social needs and referral for community- based services
- Cervical cancer screening with visual inspection with acetic acid (VIA)

There are several reasons why HIV care and treatment clinics provide such an important setting for HIV prevention. Clinics reach a large number of HIV-positive persons who attend regularly. Secondly, integrating prevention strategies into the HIV clinic ensures comprehensive and consistent quality of care. Finally, Prevention messages can be reinforced at every visit.

5.1.2.1 Condom promotion and provision

Both male and female condoms are highly efficacious in preventing sexual transmission of HIV and other STIs. 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
- Education on the strengths and weakness of condoms as a method of contraception, and recommendations of dual method use to avoid pregnancy and protect against HIV/STIs
- Mass media marketing and promotion of condoms in order to increase availability, accessibility and establish social norms.

5.1.2.2 Messages and counseling to support healthy behaviors

Sexual risk behavior

Many persons living with HIV who are not ill remain sexually active and desire a healthy sex life. One of the first steps toward providers taking a PHDP approach in the clinical setting is to recognize that PLHIV have a human right to be sexually active and need ongoing education and support from their health care providers on how to protect themselves and their sexual partners.

Many people find it difficult to change their behaviors, especially around sexual practices. Changes surrounding sexual behavior are particularly challenging, as the issues are considered private, often require the participation of both partners, and are typically shaped by gender dynamics. Women, in particular, are vulnerable within their partnership(s) with regard to their level of control over their partner's sexual practices and risk of becoming infected with HIV. PLHIV and their partners may not feel comfortable discussing sexual risk reduction with one-another, their social support networks, or health care providers. The stigmatization of HIV remains a real issue and even admitting sexual activity can be difficult for PLHIV.

PLHIV may not be ready to adopt new practices immediately, and sustaining safer sexual behaviors can be difficult. Adopting and maintaining provider-recommended practices can be a slow and challenging process that requires continual reminders and support from providers. However, studies have shown that PLHIV will adopt many recommendations on risk reduction when health care providers are committed to deliver prevention messages and counseling at every visit. Specific risk reduction messages that providers can promote include partner reduction, condom use, disclosure and knowing your partner's status and reduced alcohol consumption.

Retention in care and adherence to medications

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 enrollment into care, retention, and adherence to ART is a key component of HIV prevention.

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

PLHIV who had once been very ill but are now on ART generally enjoy better health and longer, more active lives, which may lead to a renewed interest in sexual activity, and new partnerships. Thus, adherence to medication and retention in care is critical to ensuring that patients continue to receive life-saving medicines, and risk reduction message reinforcement.

Another important benefit of treating HIV is that viral load decreases. This has been shown to decrease patient's likelihood of transmitting HIV. However, even PLHIV on

ARVs can still transmit HIV, including drug resistant strains of the virus. So again, it is important for health care providers to help PLHIV understand that they can still transmit HIV and recommend that they take precautions, even when they are on treatment.

Couple HIV Testing and Counselling

Health care providers should encourage PLHIVs to bring in their partners for HIV testing and counseling. This provides an opportunity to counsel couples together, and helps to identify discordant couples.

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

In concordant relationships where both partners are HIV-positive, there is a potential consequence of unprotected sex to the HIV-infected partner is that he or she may become “re-infected” with a different strain of HIV (including even virus resistant to some ARVs), or STIs. There is still much that is not known about re-infection, for example, how often it occurs and how it affects disease progression. Re-infection is only a risk to partners who have unprotected sex with HIV-positive partners.

5.1.2.3 Screening and Treatment of STI

Sexually Transmitted Infections (STIs) are a group of infections that are predominantly transmitted through unprotected sexual contact with an infected person. Some STIs can increase the risk of transmission or acquisition of HIV infection. To ensure that PLHIV have access to comprehensive disease prevention and treatment services, STI screening and treatment should be integrated into routine CTC services.

Integration of STI screening and treatment within the CTC is important for many reasons.

First, some STIs may be more severe in people who are HIV-positive requiring close follow-up and treatment in the context of their overall HIV care. Second, an STI infection can be a marker for unprotected sex. This is especially true for new or incident cases of STIs but may be less true for recurrent incurable STIs like Herpes Simplex Virus (HSV). Health care providers should counsel patients with an STI on the importance of using condoms to prevent spread of HIV and/or other STIs to their partner(s). It is also important to treat the STI in both the patient and his/her partner(s) to prevent further transmission and re-infection of the STI between the couple members.

Third, many STIs can have harmful effects on pregnant women and/or their unborn children. The presence of some STIs during pregnancy may have permanent neurologic and developmental effects on the baby. Moreover, current or past STIs in men and women can cause decreased fertility. Thus, women and their partners

should be assessed and treated for STIs before becoming pregnant.

It is highly recommended that all clinicians working at CTC should be trained on STI management so as to offer these services as a “one-stop shop”. HCW should ensure provision of quality STI services for PLHIV at CTC through the use of the simple diagnostic procedures and the syndromic approach according to the National Guidelines for Management of Sexually Transmitted and Reproductive Tract Infections.

CTC counselors and clinicians should work hand-in-hand in providing support to STI patients for notifying their partner(s) about the need for treatment.

5.1.2.4 Family Planning and Safer Pregnancy Counselling Services Integration

Family planning refers to the practice of individuals or couples deciding when and whether to have children and how to safely prevent unintended pregnancy. Safer pregnancy refers to ways that couples can get pregnant while limiting HIV transmission risk, or ways that PLHIV can plan safer pregnancies according to their health status and current medications.

Because PLHIV often have healthy and normal sexual desires, and PLHIV have the right to bear children, they need support from health care providers to safely plan for wanted pregnancies and to safely avoid unwanted pregnancies. Since many PLHIV attending CTCs do not make visits with their partner, 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 couples and emphasize shared decision-making and open communication about pregnancy and contraception. This is particularly important for couples with HIV (concordant or discordant), because safer pregnancy planning and contraceptive method choice affect sexual and perinatal HIV transmission risk.

One of the key strategies for ensuring that infected HIV positive couples have access to contraception and advice about pregnancy is to provide family planning and safer pregnancy counseling within the CTC following an integrated model of service provision. To ensure that PLHIV receive these vital services, HIV care and treatment providers need to assess fertility desires and unmet need for contraception at every visit and provide advice and services as appropriate.

Safer pregnancy

It is essential that HIV infected couple's desires for childbearing are frequently assessed so that they can receive the appropriate information, counselling support and services needed for making informed decisions that protect their own health, their partner's health, and ensure the highest likelihood of a healthy pregnancy and uninfected child. For example, before pregnancy, couples should consider:

- **The health of each partner.** For example, if the woman's own illness is advanced, she is at higher risk for transmitting HIV to her

child. If the woman, man, or both are ill, caring for a child could be more burdensome. Encourage the woman to continue using contraceptives and condoms until she is healthy enough to become pregnant.

- **The feelings of each partner.** Many people have strong feelings about whether or not they want to have a child. When possible, a couple should think through these feelings together before making a decision.
- **The long-term well-being of a child.** It is important for couples to make a plan for who will care for their children, in case they are unable to care for them.

For the mother and baby, the safest time for having a child is when the woman's CD4 count is not low (<200) or viral load is low; there are no signs of TB; and the woman is on ART or prophylaxis according to guidelines.

Contraception to avoid unwanted pregnancies

Even though many couples do not want to become pregnant, they may not be using any contraception, or may report using methods that leave them at risk of unintended pregnancy or STIs.

For HIV-infected women who are sexually active but do not want to become pregnant, there are many contraceptive methods that are safe and effective. These include the common contraceptive methods such as oral contraceptives, injectable, intrauterine devices (IUDs), implants, and permanent methods. Although condoms also prevent pregnancy they are not as effective in practice as hormonal contraception or IUDs.

Therefore, it is recommended that HIV infected couples who wish to avoid pregnancy use a highly effective form of contraception plus condoms. This is often referred to as dual method use. Using condoms and another form of contraception is the most effective way of preventing pregnancy, HIV and STI transmission.

5.1.3 Key Population

Key populations (KP) are identified sub-populations that play an important role in the HIV epidemic due to relatively high HIV prevalence, frequent high risk behavior, and social and structural barriers to conventional health services that render them at higher risk of acquiring and transmitting HIV. Health care workers (HCWs) need to provide non-judgmental, non-discriminatory services to be able to identify and address the special needs of key populations within and beyond the health care setting. Focus key populations include persons who inject drug (PWID), men who have sex with men, sex workers, and prisoners.

5.1.3.1 Persons who inject drugs (PWID)

- Provide medication-assisted treatment (MAT) and other drug dependence treatments in line with the national guidelines.

- Provide HIV testing and counselling in health facilities and through community-based outreach in line with national HTC guidelines.
- Provide ART to HIV infected PWID.
- Screen and manage STIs and cervical cancer.
- Promote and provide male and female condoms and compatible lubricant.
- Provide information, education and communication for HIV prevention and care.
- Screen for Hepatitis B and C and provide vaccination for Hepatitis B as appropriate.
- Screen for tuberculosis and manage accordingly.
- Link with complementary facility and community-based services for PWUD.
- Screen for sexual violence and provide post-exposure prophylaxis (PEP) along with other interventions for gender-based violence in line with national guidelines.
- Persons who inject drugs (PWID) should additionally be provided access to sterile injection equipment. through needle syringe programs (NSP)

5.1.3.2 Sex Workers

- Provide HIV testing and counselling in health facilities and through community-based outreach in line with national HTC guidelines.
- Provide ART to HIV infected sex workers.
- Screen and manage STIs and cervical cancer.
- Promote and provide male and female condoms and compatible lubricant.
- Provide information, education and communication for HIV prevention and care
- Screen for Hepatitis B and C and provide vaccination for Hepatitis B as appropriate.
- Screen for tuberculosis and manage accordingly.
- Link with complementary facility and community-based services for sex workers
- Provide integrated reproductive health services, including family planning and PMTCT.
- Screen for sexual violence and provide post-exposure prophylaxis (PEP) along with other interventions for gender-based violence in line with national guidelines.

5.1.3.3 Men who have Sex with Men (MSM)

- Provide HIV testing and counselling in health facilities and through community-based outreach in line with national HTC guidelines.
 - Provide ART to HIV infected MSM.
 - Screen and manage STIs.
 - Promote and provide male and female condoms and compatible lubricant.
 - Provide information, education and communication for HIV prevention and care
-
- Screen for Hepatitis B and C and provide vaccination for Hepatitis B as appropriate.
 - Screen for tuberculosis and manage accordingly.
 - Link with complementary facility and community-based services for MSM.
 - Screen for sexual violence and provide post-exposure prophylaxis (PEP) along with other interventions for gender-based violence in line with national guidelines.

5.1.3.4 Prisoners

- Provide HIV testing and counselling in health facilities and through community-based outreach in line with national HTC guidelines.
- Provide ART to HIV infected prisoners.
- Screen and manage STIs.
- Provide information, education and communication for HIV prevention and care
- Screen for Hepatitis B and C and provide vaccination for Hepatitis B as appropriate.
- Screen for tuberculosis and manage accordingly.
- Link with complementary facility and community-based services for upon release from prison.
- Screen for sexual violence and provide post-exposure prophylaxis (PEP) along with other interventions for gender-based violence in line with national guidelines.

5.1.4 Community HIV Prevention Interventions

Community involvement in HIV prevention includes community-based programs such as home-based care; community mobilization for participation in HIV related activities such as testing and counseling campaigns; PLHIV support organizations; community and local level interpretation and implementation of centrally managed structural reforms, and mass media campaigns to increase knowledge of HIV and change attitudes toward PLHIV.

5.1.4.1. Identification of social needs and referral for community-based services

Health care facilities should have a directory of supplementary services available in the catchment area to ease referral and allow informed choice. Health care providers find that a patient is in need of services outside the health care setting, s/he should make appropriate referrals for community support services. Among the services that may suit the need of PLHIV include legal and human right services, nutritional and economic support, PLHIV peer support group/club, and orphan and vulnerable children groups.

5.1.4.2. Support PLHIV to Voluntarily Disclose Sero Status

- Support community mobilizers and counsellors to conduct couple HIV testing and counselling (CHTC) and/or voluntary mediated disclosure of HIV serostatus to primary partners during post-test counselling
- Enable peers to support disclosure of HIV positive serostatus to significant family members
- Support peers in NGOs and CBOs to create opportunities for PLHIV to develop skills in promoting voluntary disclosure of HIV serostatus to persons they choose
- Counsel PLHIV on optimal conditions necessary for disclosing their HIV status

5.1.4.3. Link Facility Based Services for PLHIV to Community Based Service

- Conduct Integrated Management of Adolescents and Adults Illness (IMAI) training to health care workers on how to identify training assistants, and then train them in supporting ART adherence and PHDP for PLHIV
- Train PLHIV on non-medical tasks at the CTC so as to lessen dependency of HIV care delivery on trained health care workers only
- Support PLHIV and peer educators to become treatment assistants, prophylaxis adherence and treatment supporters
- Enable PLHIV to be advocates for PHDP in the community

5.1.4.4 Prepare PLHIV as Treatment Assistants to Support Adherence

- Provide ART literacy and PHDP to PLHIV, peer educators and counsellors
- Empower PLHIV to publicly disclose and testify to raise awareness on how to manage and cope with HIV infection and treatment
- Support community outreach campaigns to fight HIV- related stigma and discrimination against PLHIV and key population.

5.1.4.5 Promote Empowerment of People Living with HIV and their Communities

- Support PLHIV and peers in developing skills in HIV and AIDS literacy using low literacy friendly methods.
- Develop skills of PLHIV in assessing safe spaces for discussions of safe sex options
- Create opportunities for PLHIV and peers to strengthen communication skills in negotiating for safer sex
- Enable PLHIV and peers to discuss actions to reduce individual, couple and community risk for HIV acquisition in community venues
- Support PLHIV and peers in identifying actions to reduce vulnerability to lifestyle illnesses like hypertension and diabetes
- Promote PLHIV understanding of health-related effects of alcohol consumption, tobacco use, regular exercise, good hygiene practice, use of safe water and consistent use of bed nets
- Empower PLHIV to develop and be trained in the use of an inventory of community-based services to meet their health, economic, social and psychological needs
- Create opportunities for PLHIV, HBC and counsellors to train leaders and community members on PHDP, use of community services and how to refer people in need as required
- Conduct prevention interventions aimed at HIV stigma reduction in the context of de-stigmatization of HIV in the community.

5.1.4.6 Strengthen Referral Systems to Ensure Access to Comprehensive Services and Support

- Support creation of community interventions to facilitate collaboration with health facilities to promote integration with health care interventions.
- Create ongoing linkages between the community and health facilities and districts that address how best to collectively meet PLHIV prevention needs.
- Map health providers by types of services and their availability within their catchment areas and develop referral linkages with community services.
- Refer to PLHIV support groups that have the capacity to address issues of HIV prevention and risk transmission reduction.
- Support non-governmental and community based organisations to provide supplementary feeding for mild-to-moderately malnourished adults and therapeutic nutrition for severely malnourished PLHIV.

5.1.5 Social Behaviour Change Communication (SBCC)

Social and behaviour change communication is the developmental practice of enabling individual and societal change through engaging with communities to determine what changes are necessary to address their specific challenges and identifying localized strategies to facilitate the required change⁷.

There are structural and behavioral drivers that contribute to the social environment in which individuals grow and live and variously constitute barriers to health and wellness. Together these structural and behavioral drivers fuel the spread of the HIV/AIDS epidemic.

<i>Structural drivers include:</i>	<i>Behavioral drivers include:</i>
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	Low 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. Unpublished.

Behaviour change may be triggered by various questions an individual may have in relation to their knowledge of HIV and HIV prevention. Such questions are:

⁷ Coxswain Social Investment Plus. *Situation and Response Analysis Report on SBCC for HIV and AIDS, TB and STIs in SADC Member States*. Unpublished.

- How likely is it that I will catch HIV?
- How serious is HIV?
- How effective is the suggested action (e.g. practicing safe sex) in preventing infection?
- What barriers do I have to overcome to take preventive action?

Where an individual places themselves in relation to these triggers will determine their readiness to change their behaviour. The structural and behavioral drivers identified above have a strong influence on whether or not an individual is able to take preventive action. Hence the importance for SBCC of addressing structural issues, for example, gender and economic inequality, as well as inter-personal behaviours since it is often these factors that constitute the biggest barriers to behaviour change⁸.

Communication is an essential element of AIDS prevention, treatment and care efforts. It is defined as *'the exchange of information, ideas or feelings'* (Collins Dictionary of the English Language). 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 behaviour change that often uses multiple channels including TV, radio, print, drama, peer education, story telling etc.
- **Social Mobilisation** with individuals, groups and communities to encourage groundswell support to address barriers to change.

5.2 Biomedical prevention of HIV

5.2.1 Introduction

It is estimated that, as many as 5–10% of new HIV infections in low-and middle-income countries may be attributable to exposures in health care settings, including unsafe injections, unsafe blood and occupational exposures, this varies by regions. In health care settings, transmission of HIV can be prevented through primary prevention measures such as standard precautions, injection safety, blood safety and safe waste disposal; as well as secondary prevention measures such as post- exposure prophylaxis for occupational exposure. Furthermore, biomedical interventions such as Voluntary Medical Male Circumcision (VMMC), STI and cervical cancer screening and management are important in prevention of HIV. Comprehensive infection control strategies and procedures can dramatically reduce the risk of transmission associated with health care.

⁸ Ntuli A, What is Social and Behaviour Change Communication? http://www.hivsharespace.net/system/files/imce/2013%2010%2030%20_What%20is%20SBCC_final.docx.

5.2.2 Voluntary Medial male Circumcision (VMMC)

Male circumcision reduces a man's risk of heterosexual acquisition of HIV by about 60%⁹. In 2007, the WHO and UNAIDS recommended medical male circumcision services to be a priority in addition to HIV prevention strategies in countries with high HIV prevalence and low male circumcision prevalence. In Tanzania, VMMC services were introduced in year 2010, the national target was to circumcise 2.8m men by 2015.

The prevalence of male circumcision (MC) among males aged 15-49 years is 72% with considerable variation between regions (THMIS 2012).

Ecological comparisons have shown a pattern of lower HIV prevalence in areas where circumcision is a common practice than in areas where it is not commonly done. Since evidence suggests that MC can reduce HIV transmission by up to 60%, the government of Tanzania has prioritized and is scaling up VMMC in twelve regions (Geita, Iringa, Kagera, Katavi, Mara, Mbeya Mwanza, Njombe, Rukwa, Shinyanga, Simiyu and Tabora). VMMC has been reasonably accepted especially among boys in the targeted regions and it has been noted that VMMC campaigns are more successful when they are conducted during the dry season and at times that are convenient to adults. VMMC also provides an important opportunity for HIV counselling and testing and as an entry point for access to early HIV care and treatment services by males. It could also serve as an entry point to recruit voluntary non-remunerated regular blood donors. HIV-negative males aged 15 - 34 years are given priority for free comprehensive VMMC services as an HIV prevention strategy. By September 2013, in the twelve regions undertaking VMMC, 676,625 were circumcised.

The MC for HIV prevention is delivered as a minimum comprehensive package with;

- HIV testing and counselling
- Active exclusion of symptomatic Sexual Transmitted Infections (STIs) and treatment where necessary
- Promotion and provision of male condoms
- Counselling on risk reduction and safer sex
- MC surgical procedures

Careful monitoring and evaluation, as well as supportive supervision, of the program should be in place to quickly address any increase in adverse events or other problems with service delivery.

5.2.3 Management of STI and cervical cancer

5.2.3.1 Sexually transmitted infections (STIs)

Sexually Transmitted Infections and Reproductive Tract Infections remain a public health problem of major significance in many countries of the world. Failure to diagnose and treat STIs/RTIs at an early stage may result into serious complications and consequences including infertility, foetal wastage, ectopic pregnancy, anogenital cancer, premature delivery, as well as neonatal and infant infections. STIs are also known to enhance the spread of HIV infection in communities.

9 WHO, 2013 Guideline on the use of devices for adult male circumcision for HIV prevention

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STI screening and management should be integrated in all HIV services. HIV infected individuals should be screened for STIs and treated to reduce risk for HIV transmission. Similarly, HIV testing and counseling services should be integrated in STI clinics for early identification of individuals infected with HIV.

The concept of syndromic management of STIs was introduced in Tanzania in 1995.

The service providers are introduced to various types of syndromes with their respective common causative agents as follows.

STI SYNDROME	SEX	AETIOLOGICAL
1. Urethral Discharge Syndrome (UDS)	Male	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>
2. Painful Scrotal Swelling (PSS) (acute epididymoorchitis)	Male	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>
3. Vaginal Discharge Syndrome (VDS)	Female	<i>Candida albicans</i> <i>Chlamydia trachomatis</i> <i>Gardnerella vaginalis</i>) <i>Neisseria gonorrhoeae</i> <i>Trichomonas vaginalis</i>
4. Pelvic Inflammatory Disease (PID) (Lower Abdominal Pain)	Female	<i>Anaerobic bacteria</i> <i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>

5. Genital Ulcer Disease (GUD)	Male/Female	<i>Chlamydia trachomatis</i> <i>Haemophilus ducreyi</i> Herpes simplex virus type-2 <i>Treponema pallidum</i> <i>Klebsiella granulomatis</i>
6 Inguinal Bubos	Male/Female	<i>Chlamydia trachomatis</i> <i>Haemophilus ducreyi</i>
7. Neo-natal Conjunctivitis (Ophthalmia neonatorum)	Newborns Males and Females	<i>Neisseria gonorrhoeae</i> <i>Chlamydia trachomatis</i>

For management of common syndromes, see Flow Chart for Syndromic Management of STI's/RTI's.

5.2.3.2 Cervical cancer

Cervical cancer is the most common cancer in Tanzania, and the leading cause of cancer-related morbidity and mortality in women, in the country. Tanzania is among countries with, the highest cervical cancer burdens in East Africa and in the world, with an age specific standardized incidence rate (ASR) of 50.9 cases per 1 00,000 women, and age specific standardized (ASR) mortality rate of 37.5 Per 100,000 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. Furthermore, 80% of patients who were diagnosed with cervical cancer, died within five years of diagnosis. This low survival rate is likely due to the advanced stage of the disease, at presentation and limited access to cervical cancer screening, diagnosis and treatment services. The highest burden of the HIV epidemic, is currently in sub-Saharan Africa, including Tanzania, where more than half of the people who are infected, are women. The association between HIV and invasive cervical cancer is complex, with several studies clearly demonstrating an increased risk of precancerous cervical lesions and a more rapid progression to cancer, amongst HIV-infected women.

Cervical cancer is sexually transmitted diseases with no immediate visible symptoms and occurs more frequently in HIV infected women. Cervical cancer originates from a sexually transmitted disease named Human Papilloma virus (HPV) which silently grows in the cervix and later develops to invasive cervical cancer.

A difference between HIV/AIDS positive and HIV negative women is that HIV positive women commonly show invasive cancer ten years earlier than women who are HIV negative. It has been observed that the incidences of HPV related cell changes are related to the functioning of the immune system. Thus, when the immune function declines or CD 4 count lowers in HIV positive women the HPV cell changes increases.

Researchers suggest that as women are living longer due to access to HAART, 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 are at a much greater risk for developing cervical cancer and 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 as noted previously, be integrated with national policy as part of routine care for HIV-positive women. Care and treatment clinic (CTC) sites should be closely linked with sites providing cervical cancer prevention services, or ideally, provide the services themselves. Also for HIV-positive women:

- Start screening at HIV diagnosis, regardless of age, once sexually exposed
- Screen annually regardless of results.

5.2.4 Infection prevention and control (IPC)

Health workers exposure to the blood of those receiving care occurs most often via accidental injuries from sharps, such as syringe needles, scalpels, lancets, broken glass or other objects contaminated with blood. Poor patient care practices by HIV-infected medical staff may also expose the patient to infection. Also, when injecting and other equipment is poorly sterilized, HIV may be passed from an HIV-infected individual to an uninfected patient within the health care setting.

Protecting HCW's from occupational exposure and ensures 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 a health care worker, from a health care worker to a patient or from a patient to a patient. The occupational risk of becoming HIV infected from patients in health care settings is mostly associated with injuries from sharps such as needle stick injuries, splashes of blood or other body fluids. Patient to patient transmission is iatrogenic (usually results from contaminated equipment and other materials that have been incorrectly or inadequately processed) by health care workers.

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); and observing safe work practices. The use of such measures will help to minimize the risk of HIV transmission in the health care setting.

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

- A good occupational health programme aims to identify, eliminate and control exposure to hazards in the workplace
- Provision of training to health care workers in identifying and controlling hazards
- Promotion of health workers' knowledge of their own HIV, hepatitis and TB status through employment/pre- placement screening
- 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

5.2.4.1 Safe injections

Injection is one of the most common health procedures. In certain regions of the world, use of injections has overtaken the real need, reaching levels that are not based on rational medical practice. Unsafe injections expose millions of health care patients to infections, including hepatitis B and C viruses, and HIV. To ensure safe injection practices facilities managers and providers should:

- Develop a behavioural change strategy targeting health care workers and patients. This includes culturally adapted communication strategies targeting health workers and the community to reduce injection overuse and create consumer demand for safety devices.
- Ensure continuous availability of good quality equipment and supplies. Simply increasing the availability of safe injection equipment can stimulate demand and improve practices.
- Manage waste safely and appropriately. Waste disposal is frequently not an integral part of health planning, and unsafe waste management is common.

5.2.4.2 Prevention of HIV Transmission through Standard Precautions

Standard precautions are a simple set of effective practice guidelines that create a physical, mechanical and chemical barrier to protect health care workers and patients from infection with a range of pathogens including blood borne pathogens. Standard precautions are used when caring for all patients regardless of diagnosis (WHO).

Components of Standard Precautions

The key components of standard precautions include:

- Considering every person (patient or staff) as potentially infectious and susceptible to infection.

- Hand hygiene practices including hand washing, use of hand antiseptics, alcohol hand rub and surgical hand scrubs.
- Use of PPE such as gloves, masks, goggles, caps, gowns, boots and aprons.
- Use of antiseptic agents for cleansing skin or mucous membranes prior to surgery, cleaning wounds, or doing hand rubs or surgical hand scrubs.
- Safe work practices such as avoiding recapping or bending used needles, proper handling of sharps, linens, and equipments for patient resuscitation and patient care.
- Safe disposal of infectious waste materials and sharp wastes.
- Processing of instruments by decontaminating, thoroughly cleaning and sterilizing them with HLDs using recommended procedures.

5.2.4.3 Implementation of Standard precautions

In practice, implementation of standard precautions includes the following interventions:

I. Hand Hygiene

Hand hygiene techniques significantly reduce the number of disease-causing micro-organisms on hands and minimize cross-contamination of healthcare-related infections, such as those from health care worker to patient. Common hand hygiene procedures include routine hand washing, hand washing with antiseptics.

The need to apply hand hygiene procedures is determined by:

- intensity of contact with patients and/or blood and bodily fluids
- likelihood of microbial transmission
- patients' susceptibility to infections
- procedures being performed

II. Personal Protective Equipment (PPE)

Personal protective equipment safeguards clients and health care staff from being contaminated or infected by disease-causing micro-organisms. Examples of PPE include:

- Gloves (surgical, examination, elbow-length or heavy duty)
- Fluid impermeable aprons
- Masks and caps
- Protective eyewear
- Boots

a) Gloves

The use of a separate pair of gloves for each patient helps prevent the transmission of infection from person-to-person. HCWs should use gloves when:

- they anticipate contact with blood, other bodily fluids, mucous membranes, broken or cut skin
- handling items contaminated with blood, other bodily fluids and/or secretions
- performing housekeeping activities
- handling healthcare waste (should use utility gloves)
- they have skin lesions on their hands, and
- performing surgical procedures and vaginal examinations in labour (must use sterile gloves)

Gloves are not required for routine care activities during which contact is limited to a patient's intact skin.

b) Aprons

Rubber or plastic aprons provide a protective waterproof barrier for the healthcare worker.

c) Protective Eyewear

Eyewear such as plastic goggles, safety glasses, face shields, or visors that protect the eyes should be used when a splash of blood is anticipated such as during labour and delivery and in surgical or casualty units.

d) Boots

Rubber boots or leather shoes provide extra protection from injury by sharps or heavy items that may accidentally fall. They must be kept clean. Healthcare workers should avoid wearing sandals or shoes made of soft materials.

III. Handling and Disposal of Healthcare Waste, Such as Sharp Instruments

The most common mode of transmission of blood borne pathogens in a healthcare setting is through skin puncture with contaminated needles or sharps. Such injuries often occur when sharps are recapped, cleaned, or inappropriately discarded.

The following should be taken into consideration when using sharps:

- Use a sterile syringe (preferably a retractable syringe) and needle for each injection and reconstitution of each unit of medication.
- Never leave a needle inserted in a vial cap when withdrawing multiple doses.

- Minimize handling of injection equipment whenever possible.
- Always keep your fingers behind the needle.
- Do not disassemble needles and syringes after use.
- Do not recap, bend or break needles prior to disposal.
- Do not over-fill sharps containers; filling them more than three-quarters (3/4) full may cause needle stick injuries. It is also forbidden to press overflowing waste bins in order to push waste down.
- If it is necessary to recap needles, such as when using a vacutainer in venopuncture, use the single-handed scooping method.

IV. Sharps containers (safety boxes)

Using safety boxes helps to prevent injuries from sharps waste. Safety boxes should be puncture-proof, leak-proof, and tamperproof. In other words, difficult to open or break.

SAFE USE OF SHARPS CONTAINERS (SAFETY BOXES)

1. All sharp containers should be clearly marked “SHARPS” and/or have pictorial instructions for the use and disposal of the containers.
2. Place sharp containers away from high-traffic areas and within arm’s reach to where the sharps will be used.
3. Do not place containers near light overhead fan switches, or thermostat controls where people might accidentally touch them.
4. Never reuse or recycle sharps containers for other purposes.
5. Dispose safety boxes when 3/4 full.
6. Ensure that no sharp items are sticking out of containers.
7. Dispose sharps containers by incineration, burning, encapsulating, or burying.

V. Safe Disposal of Waste Contaminated with Bodily Fluids

Proper waste management involves the following steps:

- Segregation
- Handling and Storage
- Transport
- Treatment or Destruction
- Final disposal

Segregation

This refers to separation of waste by type at the point and time it is generated. Different types of waste should be placed in containers that are color-coded. In the absence of color-coded containers, other containers may be used but they should be properly and visibly labeled.

Note: The segregation of waste at the point and time it is generated will help to achieve proper waste disposal of infectious waste and protect other staff at the workplace and the neighboring community.

VI. Home-based Healthcare Waste Management

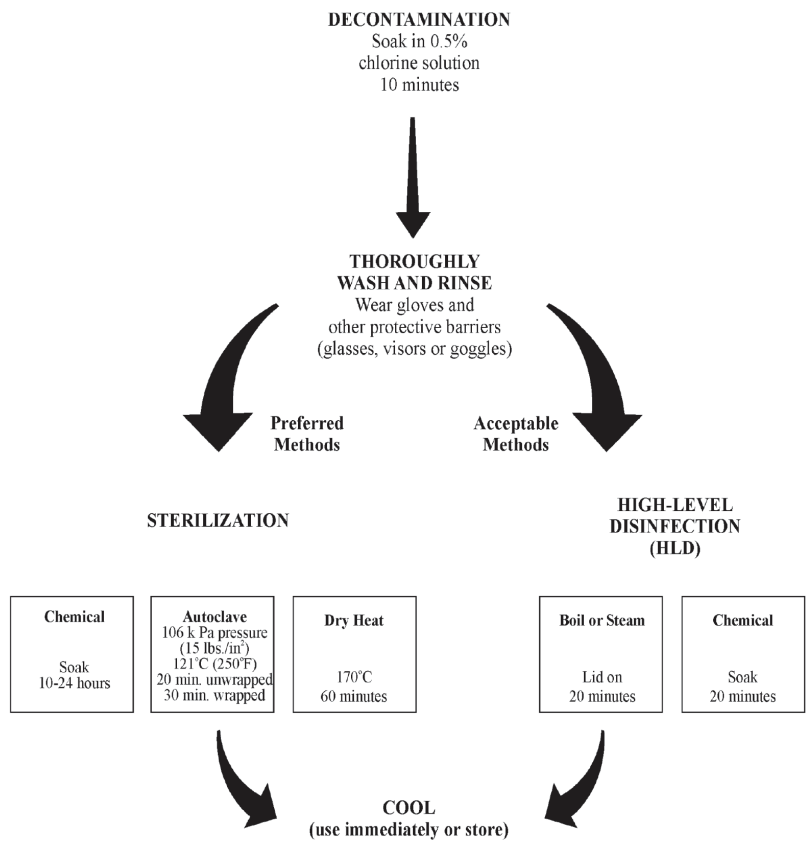
Community Health Nurses and other healthcare service providers providing care in homes and the community should handle and dispose sharps and other infectious waste (such as soiled dressings and supplies) in the same manner it is done in a healthcare setting.

VII. Proper Processing of Instruments and Other Contaminated Equipment

There are three basic infection prevention processes recommended for the reduction of disease transmission from soiled instruments and other reusable items. These are: decontamination, cleaning, and sterilization or high-level disinfection (HLD).

Regardless of the operative procedure, the steps in processing surgical instruments and other items are the same. See Figure 4.1.

Figure 4.1: Infection prevention processes for instruments and reusable items



Decontamination is a process that makes inanimate objects safer to be handled by staff before cleaning. It inactivates HBV, HBC and HIV and reduces, but does not eliminate, the number of other contaminating micro-organisms.

Cleaning is the physically removal of all visible dirt, soil, blood or other bodily fluids from inanimate objects. Cleaning also removes a sufficient number of micro-organisms hence reducing risk of infection by those who touch the skin or handle the object. The process entails thoroughly washing with water, soap or detergent, rinsing with clean water and drying.

High-level disinfection (HLD) is a process that eliminates all micro-organisms except some bacterial endospores from inanimate objects. It entails boiling, steaming or the use of chemical disinfectants.

Sterilization is a process that eliminates all micro-organisms (bacteria, viruses, fungi and parasites) including bacterial endospores from inanimate objects through the use of high-pressure steam (autoclave), dry heat (oven), and chemical sterilants or radiation.

VIII. Proper Handling of Soiled Linen

- Housekeeping and laundry personnel should wear utility gloves and other personal protective equipment as indicated when collecting, handling, transporting, sorting and washing soiled linen.
- When collecting and transporting soiled linen, personnel should handle it with minimum contact to avoid accidental injury and spreading of micro-organisms.
- All cloth items (such as surgical drapes, gowns, wrappers) used during a procedure should be considered as infectious. Even if there is no visible contamination the item must be laundered.
- Soiled linen should be carried in covered containers or plastic bags to prevent spills and splashes, and confined to designated areas (interim storage area) until transported to the laundry.
- All linen in the laundry area should be carefully sorted before washing. Do not pre-sort or wash linen at the point of use.
- When hand-washing soiled linen, soak in hot water with 0.5% sodium hypochlorite solution for 30 minutes, wash separately in hot water and then air dry.
- Clean linen must be wrapped or covered during transportation to avoid contamination.

IX. Cleaning Floors

Detergents and hot water are adequate for routine cleaning of floors, beds and toilets. In case of spillage of blood or other bodily fluids, the area should be cleaned with a chlorine-based disinfectant followed by thorough cleaning with soap and hot water.

All health care workers must be familiar with standard precautions.

5.2.5 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 the immediate administration of antiretroviral agents.

5.2.5.1 Occupational Exposure

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. Effective post-exposure management entails the following elements: Management of Exposure Site, Exposure Reporting, Assessment of Infection Risk, Appropriate Treatment, Follow-up and Counseling.

i. Management of Exposure Site

Wounds and skin sites that have been in contact with blood or bodily fluids should be washed with soap and water and mucous membranes flushed with water. There is no evidence that using antiseptics for wound care or expressing fluid by squeezing the wound reduces the risk of blood-borne pathogen transmission. While the use of antiseptics is not contraindicated, the application of caustic agents (e.g. bleach) or injection of antiseptics or disinfectants into the wound is not recommended.

ii. Exposure Reporting

When an occupational 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. Information to be recorded in the health worker's confidential medical report should include:

- Date and time of exposure
- Details of the procedure being performed and the use of protective equipment at the time of exposure
- Type, severity and amount of fluid that the healthcare worker was exposed to
- Details of the exposure source person
- Medical documentation that provides details about post exposure management

iii. Risk Assessment for Occupational Exposure

In addition to the type of bodily fluids, the risk of acquiring HIV also depends on the type and severity of exposure and the HIV status of the source person.

Depending on the sero-status of the source person, the following criteria can be used to determine the risk of exposure:

- Percutaneous injury
- Mucus membrane exposure
- Non intact skin exposure
- Bites resulting to blood exposure to either person involved

Table 5.1 Risk of transmission after occupational exposure

	Mode of Exposure	Risk of Infection/Exposure
HIV	Percutaneous	0.3%
HIV	Mucous membrane	0.03 – 0.09 %
HBC	Percutaneous	10 – 30 %
HBC	Mucous membrane	0 – 10 %

Note: Standard precautions should be adhered to when contact with any type of body fluid is anticipated.

iv. Evaluation of the Exposed HCW

Healthcare workers exposed to HIV should be evaluated within hours rather than days. A starter pack should be initiated within 2 hours after exposure and before testing the exposed person. Thereafter, exposed healthcare workers should be counseled 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 the case of large volume needle-stick injury.

v. Evaluation of the Source Person

Evaluation of the source person should be performed when the exposed healthcare worker 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.

vi. Drugs for HIV PEP

The ideal HIV PEP regimen is one that has a favourable side-effect profile, fewer potential drug- drug interactions, and expected efficacy equivalent to the existing first line ARV regimens, most of which contain Tenofovir (TDF) and Efavirens (EFV).

Evidence from countries with successful PEP programs has increasingly shown that tolerability is one of the most important factors for selection of PEP regimen. Furthermore, recent studies have shown increased rates of adherence and completion when tenofovir + emtricitabine/or lamivudine + raltegravir (an integrase

inhibitor, not included in the National ARV drug list as of yet) are used in combination or as individual components of HIV PEP regimen.

In addition, several systematic reviews carried out in support of the WHO 2013 consolidated guidelines have given preference to an ARV regimen composed of a once daily fixed-dose combination of tenofovir + lamivudine (or emtricitabine) + efavirenz as a single preferred first-line therapy (WHO 2013).

Therefore, in view of these findings and in alignment with WHO guidance (i.e., choice of ARV regimen for PEP should be based on the country's available first-line ARV regimen), MoHSW recommends tenofovir + lamivudine + efavirenz as the preferred HIV PEP first choice regimen. Zidovudine and PI-containing regimens are only reserved for special cases.

Table 5.2. Recommended Regimen for HIV PEP Following Occupational and Non-Occupational Exposures

HIV PEP (ARV) REGIMEN	CURRENT MOHSW RECOMMENDATIONS ^{\$}	COMMENTS
Tenofovir 300 mg, Lamivudine 300 mg & Efavirenz* 600 mg PO OD for 28 days	Preferred first option for HIV PEP	Studies have shown increased efficacy in preventing post-exposure HIV transmissions, rates of adherence and regimen completion when Tenofovir and lamivudine have been used as components of HIV PEP regimen.
Pediatrics < 3 years AZT+3TC+LPVr > 3 years AZT+3TC+EFV		Avoid NVPs, ABC

vii. Timing of Post Exposure Prophylaxis (PEP)

PEP should be initiated as soon as possible preferably within 2 hours after exposure. Studies suggest that PEP may be substantially less effective if started more than 24-36 hours post-exposure and not effective after 72 hours.

viii. Follow-up of HIV Exposed Persons

Follow-up is based on clinical examination and laboratory testing to determine the sero-conversion and adverse effects of the ARV drugs.

HIV antibody tests should be performed for at least 3 months post-exposure (i.e. at 6 weeks and 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 by testing at baseline and 2 weeks after starting PEP. Minimally, it should include a full blood picture (FBP), renal function test (RFT) and hepatic function tests (LFTs).

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

Prophylaxis should be continued for four weeks if tolerated. If ARV prophylaxis fails and the exposed person becomes HIV infected, he/she should be referred to a CTC for proper HIV care and management.

5.2.5.2 HIV PEP in Sexual Exposure

Sexual exposure comprises an act of unprotected voluntary or forced sexual intercourse (rape/sexual assault), as well as in the case of slipped or broken condom during sex with discordant partner. The consequences of sexual exposure include a potential risk of acquiring sexually transmitted diseases including HIV/HBV and unwanted/unplanned pregnancy.

i. Appropriate Management of Exposed Persons

Informed consent (whenever possible) should be obtained before examination and collection of any forensic evidence that might be needed in subsequent investigations. Younger children need to be managed at specialized sites that have the expertise in dealing with traumatized children and the prescription of ART.

Healthcare providers are responsible to provide appropriate comprehensive care for rape survivors, including

- Management of life threatening conditions and sustained injuries,
- Immediate detailed history taking, precise documentation of the victim's details and circumstances of the assault as well as confidential reporting to appropriate institutions,
- Thorough physical and genital examination as well as collection of specimen (blood/saliva/hair/semen/high vaginal swab/dry and wet mount preparations, etc.) for laboratory investigations for STIs and forensic evidence, as soon as possible (within 24 hours) after the rape incident,
- Evaluation and prophylaxis for HIV, HBV, STIs and pregnancy when

indicated, i.e. PEP using antiretroviral therapy, presumptive treatment of STIs and emergency contraception,

- Counselling, crisis prevention and provision of on-going psychosocial support to rape survivors, so as to reduce/minimize immediate rape trauma disorder and long-term post-traumatic stress disorder,
- Provision of mental health care,
- Follow-up care to monitor other possible infections and provision of psychological support, regardless of whether PEP prophylaxis has been started or not,
- Referral of the survivor to appropriate organs (police/legal services), according to local laws and regulations.

ii. Risk of HIV Transmission after Sexual Exposure

Risk of transmission of HIV varies with type of sexual exposure as shown in the table below:

Table 5:5 Risk of HIV Transmission after Sexual Exposure

Types of exposure (from an HIV positive source)	Risk of infection per exposure
Receptive oral sex	0-0.04%
Insertive vaginal sex	0.03-0.09%
Receptive vaginal sex	0.1-0.3%
Insertive anal sex	0.03%
Receptive anal sex	0.5-3%

When deciding whether to offer PEP or not, consider that risk of transmission following sexual exposure is high if any of the following factors were present:

- Blood
- Survivor or assailant with a sexually transmitted disease with inflammation such as gonorrhoea, chlamydia, herpes, syphilis, bacterial vaginosis, trichomoniasis, etc.
- Multiple assailants or multiple penetrations by assailant(s)
- Ejaculation by assailant
- Anal penetration

- Obvious trauma to the genital area
- The assailant(s) is HIV positive

iii. **Factors to be Considered Before Initiation of PEP**

Factors to be considered before initiation of PEP for non-occupational exposure are similar to those for occupational exposure. They include HIV status of potentially exposed person and HIV status of exposure source person if available. If unknown, PEP can be initiated while the status is being assessed and discontinued if serostatus of exposure source person is confirmed negative.

The decision to begin PEP should not be based on the likelihood that the perpetrator is infected or delayed pending the test results of the exposure source (unless immediately available). Rather, it should be based on the perpetrator's transmission risk behavior and the presence of other sexually transmitted diseases, particularly genital ulcers, which can facilitate HIV transmission.

Note: Exposure to persons who have recently seroconverted may carry a higher risk of transmission because of high HIV viremia.

iv. **Basic Steps to be Taken after Sexual Exposure**

- Perform counseling and testing at baseline before administering PEP. It is important to establish survivor's baseline.
- Determine HIV status before administering PEP in order to prevent the potential for developing drug resistance, should the individual be HIV positive.
- If the rape survivor is HIV negative administer the initial (first) dose of PEP as early as possible. The efficacy of PEP decreases with the length of time. Offer PEP promptly, preferably within 2 hours but not later than 72 hours of being raped. If the rape survivor is HIV positive, refer the person to CTC for enrolment and further management. Do not offer PEP.
- Rape survivors presenting later than 72 hours after being raped should not be offered PEP.
- If the rape survivor is not psychologically ready, the baseline HIV test can be delayed by up to 3 days after commencement of PEP. If the test result is positive, PEP should be stopped and the patient should be referred to a CTC. It should also be explained to the rape survivor that the HIV infection is not the consequence of the sexual assault but from previous exposure.
- Provide psychosocial support and ensure adherence to PEP regime. The loss rate is high in this group of patients.
- Monitor for ARV drug toxicity and manage the conditions (if present) accordingly.

The recommended treatment regimen is

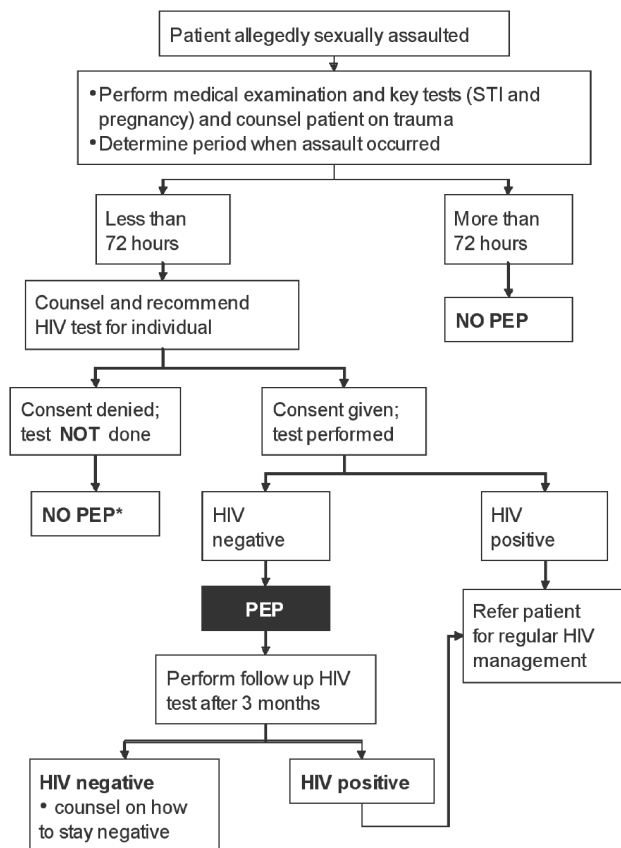
TDF 300mg + 3TC 300mg + EFV 600mg once a day for 4 weeks

The noted contraindications for each of the listed drugs should be considered as per details in appropriate chapters.

v. Patient Monitoring

Three months after the PEP period, the individual should return for a confirmatory set of HIV tests to determine whether the treatment was effective. If treatment was not effective and the individual became infected, s/he should be enrolled in the care program at the CTC and monitored appropriately as all HIV positive individuals.

Figure 5:1 Post Exposure Prophylaxis after Sexual Assault



*Administering PEP on a HIV+ individual could lead to resistance development

More details on PEP can also be found in the current National Guidelines on Post-Exposure Prophylaxis Following Occupational and on-Occupational Exposures to Blood and Other Body Fluids

5.2.6 Blood Safety

Unsafe blood transfusion is a well-documented mode of transmission of HIV and other infections. Even if blood is available, 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 modern health care. The Ministry of Health and Social Welfare has established national blood programmes to ensure the availability of safe blood and blood products through a nationally coordinated blood transfusion service. The National Blood Safety Programme has developed an integrated strategy to promote the provision of safe and adequate supplies of blood to reduce the risks associated with transfusion.

Health managers and providers should therefore:

- Ensure good laboratory practice in all aspects of the provision of safe blood, from donation to testing for transfusion-transmissible infections (HIV, hepatitis viruses, syphilis and other infectious agents) to blood grouping to compatibility testing to the issuing of blood.
- Reduce unnecessary transfusions through the appropriate clinical use of blood including, where possible, the use of intravenous replacement fluids and other simple alternatives to transfusion.

CHAPTER 6: MANAGEMENT OF COMMON SYMPTOMS AND OPPORTUNISTIC INFECTIONS IN HIV AND AIDS IN ADOLESCENTS AND ADULTS

6.1. Introduction

Antiretroviral treatment (ART) does not provide a cure of HIV/AIDS, 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 at a CD4 threshold of less than 500 will therefore prevent occurrence of OIs and other co-morbidities. Provision of prophylaxis, prompt diagnosis and adequate treatment of OIs are crucial in improving the quality of life in PLHIV.

This chapter highlights clinical features and treatment of the common symptoms encountered in persons infected with HIV; prevention of common opportunistic infections; diagnosis and treatment of some opportunistic illnesses seen in persons infected with HIV.

6.2. Clinical Features Commonly Encountered in Patients with HIV and AIDS

6.2.1 Fever

Fever in a patient may be due to a variety of causes. However, the associated clinical features may inform the diagnosis. If no pointing features to a diagnosis are present, as a minimum the following should be done:

Blood slide for malaria parasites

Sputum for microscopy/AFB

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

6.2.2. Cough and Shortness of Breath

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

Pulmonary TB/pleural effusion, commonly due to TB

Bacterial pneumonia

Pneumocystis Jiroveci Pneumonia (PCP)

Pulmonary Kaposi's sarcoma

Viral pneumonia

Disseminated pulmonary strongyloidosis

Cardiac failure, commonly due to dilated cardiomyopathy

Pericardial effusion, commonly due to TB

Sometimes, it may not be possible to determine the underlying cause of cough and dyspnoea on clinical history and physical examination alone. At such times, laboratory tests may be of critical value. The recommended laboratory investigations include:

Sputum for microscopy/AFB x 2 (can be done at all levels)

Sputum for pyogenic culture and sensitivity

Chest x-ray

Bronchoscopy (consultant hospitals)

ElectroCardioGram (ECG) and Echocardiography (where available)

FBP and ESR

Oxygen saturation using pulse oximeter in PCP cases

6.2.3. Oral, Oropharyngeal and Oesophageal Candidiasis

Patients with oropharyngeal and oesophageal candidiasis may complain of pain and/or difficulty in swallowing, which may be due to infection of the oesophagus with *Candida*. On examination white painless plaque ("curd like") on buccal or pharyngeal mucosa or tongue surface that can easily be scrapped off will be seen. Where available, a barium swallow X-ray can be performed. For treatment, any of the following may be used:

Fluconazole orally

Miconazole

Nystatin oral suspension,

Clotrimazole oral

2% sodium benzoate or Gentian violet solution

6.2.4. Candidiasis in the Oesophagus, Trachea, Bronchi or Lungs is Diagnostic of AIDS

The following drugs are recommended for the treatment of Candidiasis:

Miconazole nitrate

Clotrimazole

2% sodium benzoate solution

Nystatin oral suspension

Fluconazole 150mg/day or 200mg/day for 2-3 weeks (for oro-pharyngeal candidiasis and others)

Note: Treatment should be continued until symptoms resolve.

6.2.5. Vaginal Candidiasis

This is one of the common illnesses presenting with itchy (curd-like) discharge. The diagnosis is largely clinical, and it can be managed with:

Clotrimazole pessaries

Miconazole pessaries

Fluconazole taken orally (in case of pessaries failure)

6.2.6. 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 diseases such as cancer

Intractable vomiting

HIV itself

The treatment of weight loss includes:

Provision of Therapeutic foods (e.g. Plumpy Nut or fortified blended flour)

High calorie and protein foods

Treatment of the underlying cause (for further reading see Chapter 13)

6.2.7. Diarrhoea

Diarrhoea in persons with HIV induced illnesses may have a variety of causes including:

Common pathogens such as *Salmonella* or *Shigella*

Amoebiasis

Chronic malabsorption

Cryptosporidiosis

Mycobacterium Avium Complex (MAC) infection

Isosporidiosis.

Clostridium difficile infection

Investigations:

Examine stools for Culture and microscopy for treatable causes e.g. *Salmonella*, *Shigella*, *V.cholerae*, *Amoeba*, *Mycobacterium AviumAomplex (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: However, starting ART as per eligibility criteria is often the best treatment for persistent /resistant diarrhoea (particularly cryptosporidiosis)

6.2.8. Persistent Generalized Lymphadenopathy (PGL)

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

HIV

Mycobacterium tuberculosis infection

Kaposi's sarcoma

Lymphomas

Other causes such as pyogenic bacterial infection with regional lymphadenitis

Investigations may include:

Aspiration of the fluctuant node with a 21G needle and staining the aspirate for acid-fast bacilli (AFB)/Gram stain/cytology (Fine Needle Aspiration)

Lymph node biopsy for histological diagnosis

Chest X-ray

FBP and ESR

Treatment is mainly of the underlying cause.

6.2.9. Skin Rashes, Sores and Generalized Pruritus

General causes for the above conditions include:

Pruritic Papular Eruption (PPE)

Infestation with external parasites e.g. scabies

Fungal skin infections (Dermatomycoses)

Herpes zoster infection

Herpes simplex infection

Kaposi's sarcoma (KS)

Bacterial skin infection e.g. Impetigo

Seborrheic dermatitis and Sebo-psoriasis

Molluscum contagiosum

Investigations:

The diagnoses are mostly based on clinical presentation; however, when necessary the following investigations can be performed from the affected lesions:

Potassium Hydroxide (KOH) preparation microscopy

Skin scrapings (for fungal element &Sarcoptes scabiei) microscopy

Pus swab for culture and sensitivity

Skin biopsy for KS and Molluscum contagiosum

The following are recommended actions for the management of different causes:

Scabies:

Benzyl benzoate Emulsion, or 1% lindane lotion

Cloxacillin or Erythromycin if secondarily infected Dermatomyces

Whitfield's ointment or Griseofulvin tablets for Tinea

Clotrimazole or Miconazole cream for Candidiasis

Impetigo:

Cloxacillin

Erythromycin

Pruritic Papular Eruption (PPE):

Antihistamine, e.g. Cetirizine

Antibiotics, e.g. Cloxacillin or erythromycin

Seborrheic dermatitis:

Antifungal (systemic if severe)

Steroids (careful if concomitant TB is suspected)

3% salicylic acid ointment

Molluscum contagiosum:

Individual lesion may be treated by:

Curettage

Cryotherapy

Electro cauterization

Kaposi's sarcoma:

This depends on the extent and severity and the options include:

Anti-retroviral therapy (preferably PI-based, especially when extensive)

Referral for Chemotherapy and Radiotherapy

It should be noted that cancer conditions in HIV infected clients are managed in the same way as when they occur in patients that are not infected.

6.2.10. Altered Mental Status and Persistent Severe Headache

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

i. Infection Conditions

1. Meningitis

Fungal meningitis, especially cryptococcal

Tuberculous Meningitis

Bacterial Meningitis

2. Cerebral malaria

3. Encephalitis

Toxoplasma encephalitis

(CMV) Cytomegalovirus encephalitis

ii. Metabolic Conditions

1. Severe dehydration

2. Hypoglycemia

iii. Mental Conditions

1. HIV-dementia

2. Depression

3. Psychotic conditions

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

Cryptococcal Antigen test

CT Scan (where available)

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 and sepsis

Pneumocystis Jiroveci Pneumonia (PCP)

Toxoplasmosis

Malaria

6.3.1. Indication for Prophylactic Treatment Using Cotrimoxazole

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

Adults and adolescents

All HIV infected patients, in WHO Stage 2, 3 and 4 (see Chapter 9 for WHO staging criteria)

Asymptomatic HIV infected individuals with CD4 counts of <500 cells/ml.

Pregnancy

All pregnant women throughout their pregnancy

Note:

1. Caution should be exercised when initiating cotrimoxazole Presumptive treatment (CPT) during the first trimester of pregnancy in women who may not have access to good nutrition; and anaemic patients, because cotrimoxazole can cause a deficiency in folic acid.
2. Pregnant women who are receiving CPT do not need sulfadoxine pyrimethamine (SP), an additional medication to prevent malaria

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.

Duration:

If treatment with ARV is not available, CPT for adults who qualify but are not on ARVs should continue for life.

Criteria for stopping:

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

If ART is initiated and CD4 count is above 500 cells/ml in adults

If 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 PLHIVs

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) is given daily for six months as well . IPT provides up to 18 months of protection against TB. (Further details on this are provided in chapter 10.)

6.4. Treatment of Opportunistic Infections

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. Below are recommendations on how to identify and handle treatable causes of morbidity as a result of selected opportunistic infections in HIV infected individuals.

6.4.1. Viral infections

Viruses that are commonly associated with HIV and AIDS include:

Herpes simplex virus

Varicella zoster virus

Human papilloma virus

Herpes simplex virus infection (HSV)

The classical presentation of primary HSV infection includes:

Fever

Lymph node enlargement

Small painful vesicles

Painful ulcers on the mucosa and skin

Pain along gluteal and upper thigh muscles (Sacral radiculomyelitis) may occur with genital/rectal HSV

Lesions that usually resolve within 10-21 days after primary infection. The HSV then becomes latent in trigeminal and sacral nuclei and may reactivate.

The clinical features in patients with HIV and AIDS may also include persistent/

erosive genital/peri-rectal ulcerations which are mainly associated with HSV-2 and more recurrent herpetic lesions.

The diagnosis is usually based on clinical history and physical findings. Laboratory tests include serology, culture, immunofluorescence or immunoassay, but these are not practical in Tanzania.

Treatment:

Acyclovir 400mg orally three times daily for 7 days for mild and moderate cases of HSV

Acyclovir 800mg orally, five (5) times daily for 5 days for severe and recurrent HSV

Antibiotics such as Erythromycin should be used when there is secondary bacterial infection

Analgesics when pain is severe

Varicella-zoster virus (Herpes zoster or shingles)

Clinical features of herpes zoster:

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 including the following:

More lesions

Disseminated disease associated with pneumonitis, hepatitis and hemorrhagic skin lesions

Central Nervous System (CNS) manifestations including encephalitis and cerebellar ataxia

Prolonged healing time

Bacterial super-infection

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.

Treatment:

Analgesics e.g. Paracetamol, Aspirin or Diclofenac to relieve pain even though the pain may sometimes be unmanageable

Acyclovir 800mg 5 times per day for 7-10 days for mild and moderate cases

IV/Oral Acyclovir 10 mg/kg/day 8 hourly for 7 days for disseminated VZV or ophthalmic nerve involvement

Erythromycin or Cloxacillin 500mg three times daily for 7 days for bacterial super-infection

Amitriptylin 25-50mg nocte for post-herpetic pain (neuralgia)

Note: Use of steroids (prednisolone) in herpes zoster is not recommended.

Human papilloma virus (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, with several studies now clearly demonstrating an increased risk of precancerous cervical lesions and a more rapid progression to cancer amongst HIV-infected women. Invasive cervical cancer and its precursor, cervical intraepithelial neoplasia (CIN), are associated with persistent infection with oncogenic, “high- risk” (HR) types of the human papillomavirus (HPV). In women with healthy immune systems, most HPV infections are transient and cleared. Persistent HR-HPV infection, though, significantly increases the risk of cellular change leading to the development of precancerous lesions and eventually invasive cervical cancer.

Primary prevention of cervical cancer involves prevention of infection with HPV. Primary prevention can be achieved through behavioural change approaches and the use of biological mechanisms, including HPV vaccination. However, abstinence from sexual exposure, being mutually faithful and consistent condom use can reduce the risk of HPV transmission.

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.

6.4.2. Bacterial infections

Bacterial infections that occur with increased frequency in persons with HIV and AIDS include:

Respiratory infections: Streptococcus pneumoniae, Haemophilus influenzae

Septicemia: Non typhoid salmonella, Pseudomonas aeruginosa

Cutaneous infections: Staphylococcus aureus

Note: Treatment of bacterial infections is the same as in non- HIV infected individuals.

6.4.3. Fungal infections

Fungal infections commonly found in association with HIV and AIDS include: *Cryptococcus neoformans*, *Pneumocystis jiroveci*, *Candida* species, and *Histoplasma capsulatum*.

Cryptococcus neoformans

This is a major cause of meningitis in HIV infected persons. Contrary to bacterial meningitis, the patient may not suffer from fever in this case. However, severe headache with or without meningism or altered level of consciousness is a common presenting feature. Diagnosis depends on demonstration of positive Cerebral Spinal Fluid (CSF) with Indian Ink preparation.

Treatment:

The preferred regimen is in 3 phases;

Phase 1; Induction phase;

Amphotericin B 0.7mg/kg/day IV + 5 Flucytosine 100mg/kg/day administered orally for 14 days

Phase 2: Consolidation phase

Fluconazole 400mg/ day for 8 weeks or until CSF is sterile.

Phase 3: Suppressive phase

Give patient maintenance therapy with Fluconazole 200mg per day.

Alternatively, give Fluconazole IV 400-1200 mg/day for 10 days or until the drug can be administered orally then continue with the same dose for 10 weeks. Thereafter maintain 200 mg daily on alternate days as secondary chemoprophylaxis.

Serial lumbar puncture to reduce intracranial pressure has been found to reduce mortality. Use manometer, if not available a giving set and graduated ruler can be improvised to measure intracranial pressure.

Pneumocystis jiroveci pneumonia (PCP)

This condition is quite common in Tanzania especially among HIV infected children. Patients with PCP usually present with non-productive cough, fever, chest tightness and shortness of breath that has evolved over 2-4 weeks. Chest signs may be minimal despite severe shortness of breath.

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" although the chest radiograph may appear normal in 10-30% of patients.

Diagnosis:

Usually in clinical circumstances diagnosis is based on clinical presentation and exclusion of other common causes of severe dyspnoea.

Treatment:

Cotrimoxazole 1920 mg 3 times /day 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 + Primaquine 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

For prophylaxis therapy give Trimethoprim-sulphamethoxazole (TMP-SMX) as shown above.

6.4.4. Protozoa

Toxoplasma encephalitis

Clinical features include:

Focal paralysis or motor weakness depending on the brain area affected

Neuro-psychiatric manifestations corresponding to the affected area in the brain

Altered mental status (forgetfulness etc.)

Diagnosis:

Usually is predominantly based on clinical findings after exclusion of other common causes of neurological deficit. If available, a CT scan is very useful for confirmation.

Treatment:

For acute infection Sulphadiazine tabs 1 gm 6 hourly + Pyrimethamine tabs 100mg loading dose, then 50mg /day + Folic acid tabs 10mg /day for 6 weeks.

After six weeks of treatment give prophylaxis therapy with Sulphadiazine tabs 500mg 6 hourly + Pyrimethamine tabs 25-50mg /day + Folic acid tabs 10mg /day.

For those allergic to sulphur replace Sulphadiazine tabs with Clindamycin capsules 450mg 6 hourly.

Discontinue maintenance therapy when CD4 count is >200 cells/ml, initial therapy is completed and patient is asymptomatic.

Primary prophylaxis therapy for toxoplasmosis can be accomplished with Trimethoprim–Sulphamethoxazole (TMP-SMX) tabs 160/800mg administered orally/

day. For those allergic to sulphur, give Dapsone tabs 50mg/day + Pyrimethamine tabs 50mg per week + Folic Acid tabs 10 mg 3 times a week.

Intestinal protozoa

For intestinal protozoa which is a common cause of diarrhoea and difficult to diagnose, the recommended treatment is Albendazole tabs 800mg BD (twice a day) for one week.

CHAPTER 7: PEDIATRIC HIV AND AIDS-RELATED CONDITIONS

7.1 Introduction

The majority of children with HIV acquire the infection from their mothers during pregnancy, labour and delivery or after birth during 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 of infection soon after birth but usually develop features of infection in the early infancy period, although these features may overlap with those of other common childhood diseases. The HIV infection progresses more rapidly in children than in adults.

7.2 Diagnosis of HIV Infection in children

7.2.1 Diagnosis of HIV infection in children below 18 months of age

Infants born to HIV-infected women have passively transferred antibodies that can persist until 9 to 18 months of age. The positive rapid antibody tests may only indicate the presence of passively transferred maternal HIV antibodies. Therefore, virologic tests or DNA PCR, are required in order to confirm HIV infection in children <18 months of age.

PCR tests should be done at 4-6 weeks of age or at any time thereafter when the child is first seen by health care workers:

A single positive PCR test means the infant is presumably infected and should be initiated on ART. At initiation, a second PCR should be taken to confirm the infection. NB: The second test should not delay ART initiation.

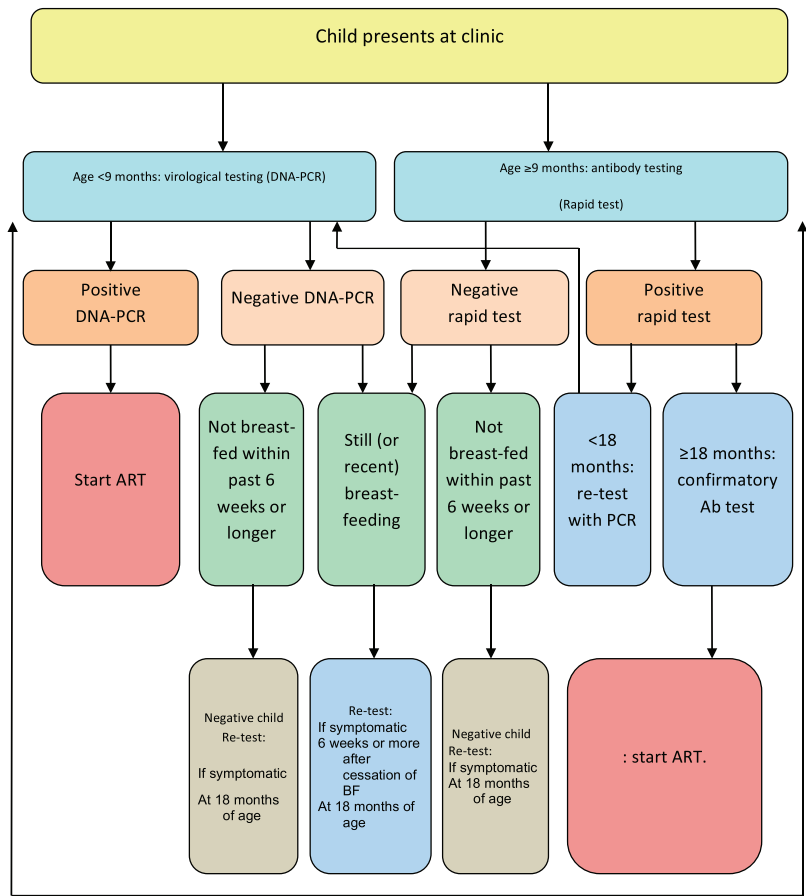
For a child that was **never breastfed**: A single negative PCR test after the age of 4 weeks excludes HIV infection.

For a child that has completely stopped breastfeeding for **more than 6 weeks prior to virologic (DNA PCR) testing**, a negative PCR test excludes HIV infection.

If the child is **being breastfed**, a negative virologic test does not exclude infection. On-going exposure to HIV through breastfeeding continues to put the child at risk of infection. Confirmatory testing should be done 6 weeks after complete cessation of breastfeeding as described above to determine final infection status.

Children between the age of 9 and 18 months *at the first health encounter* or after cessation of breastfeeding should have a rapid HIV antibody test since maternal HIV antibodies diminish rapidly between 9-18 months of age. 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 virological tests are not available but HIV antibodies are present (rapid test is positive), a presumptive diagnosis should be made and ART started.

Figure 7.1: Diagnosis of HIV Infection in infants and young children less than 18 months of age



7.2.2 Diagnosis of HIV infection in children where the mother is not available

Since the mother's HIV status is unknown, the HIV exposure status of the baby will have to be established by performing a rapid HIV antibody test. The guardian/ care taker needs to be counselled for HIV testing of the child. If the antibody test is positive then HIV DNA PCR (if available) should be done, ideally at 4 weeks of age or thereafter. If the age of the infant cannot be established do a PCR immediately. Repeat the PCR for all infants after 6 weeks if the initial PCR was negative. In addition, the child should be started on co-trimoxazole prophylaxis.

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

1. Do rapid test
2. If positive: HIV PCR
3. If age is known: HIV PCR at 4 weeks of age
4. If age is unknown: HIV PCR immediately
5. For all: Repeat HIV PCR to confirm 6-8 weeks later if first result was negative

Notes:

1. 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 neurodevelopment delay might be signs of HIV infection.
2. **Postnatal transmission** of HIV infection is likely to be evident by 6 weeks after breastfeeding has been terminated.

7.3 HIV and AIDS manifestations in children

Clinical signs and symptoms of HIV infection are useful parameters in making an HIV diagnosis, but 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/conditions specific 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/conditions common in HIV-infected children and uncommon in uninfected 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/conditions common in HIV-infected children but also common in uninfected children

- Chronic, recurrent otitis with ear discharge
- Persistent or recurrent diarrhoea
- Severe pneumonia
- Tuberculosis
- Failure to thrive
- Acute and chronic malnutrition including marasmus and being underweight

A presumptive diagnosis of severe HIV disease should be made if the child fits the criteria of Table 7.1:

Table 7. 1: Criteria for presumptive diagnosis of severe HIV disease in infants and children <18 months of age where viral testing is not available

A presumptive diagnosis of severe HIV should be made if:	
<p>1. The child is confirmed as being HIV antibody-positive</p> <p>AND</p>	<p>2a. The infant is symptomatic with two or more of the following:</p> <ul style="list-style-type: none"> • Oral thrush • Severe pneumonia • Severe sepsis <p>OR</p> <p>2b. A diagnosis of any AIDS-indicator condition(s) can be made.</p>
<p>Other findings that support the diagnosis of severe HIV disease in an HIV-seropositive infant include:</p> <p>Recent HIV-related maternal death or advanced HIV disease</p> <p>Child's %cd4 +<20%</p>	
<p>Confirm the diagnosis of HIV infection as soon as possible.</p>	

- AIDS-indicator conditions include some but not all HIV paediatric clinical stage 4 conditions such as Pneumocystis pneumonia, Cryptococcal meningitis, severe wasting or severe malnutrition, Kaposi sarcoma, Extra-pulmonary TB.
- **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 indrawing, 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 indrawing, bulging fontanelle, lethargy, reduced movement, not feeding or sucking breast milk, convulsions.
- The HIV status should be confirmed at 18 months or as soon as possible.

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. (For details see Annex 3)

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

IMCI guidelines are a useful tool at the first level referral facility to screen children with possible HIV infection who need to be referred for HIV testing or that have the test performed and are referred for 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 for further HIV evaluation and management.

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

WHO CLINICAL STAGING OF HIV/ AIDS FOR CHILDREN WITH CONFIRMED HIV INFECTION (refer to the annex 2)

Clinical staging is useful for assessment at baseline (first diagnosis of HIV infection), entry into long-term HIV care and in the follow-up of patients 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.

7.4 Care and support of HIV exposed and infected children

7.4.1 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.
- Baseline laboratory tests should be performed to establish viral and immunological status whenever possible.
- 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 breastfeeding) and timing of HIV diagnosis. HIV-infected children should receive routine paediatric care and be monitored for their HIV disease progression. Children should be seen monthly.
- At each visit, a complete physical examination should be done paying particular attention to signs commonly associated with HIV infection (e.g. adenopathy, hepatomegaly and splenomegaly).
- Visits should also focus on assessment and management of intercurrent illness as well as assessment for development of new WHO stage 3 or 4 clinical conditions, which may indicate treatment failure
- Nutrition, growth and neuro development assessment should be done and charted at all stages of development right through adolescence.
- Doses of prophylactic or treatment medications should be adjusted on the basis of growth and compliance and tolerability should be assessed 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 exposed to 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 and Social Welfare.
- Counselling and psychosocial support should include the children and be provided in an age appropriate fashion

7.4.2 Management of infants born to HIV positive women

The HIV-exposure status of all infants attending RCH services should routinely be established and documented. The counseling of parents on the care of infants born to 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
- Chemoprophylaxis with cotrimoxazole, a fixed dose combination of trimethoprim/sulfamethoxazole (TMP/SMX) even if HIV status is unconfirmed
- Infants of HIV infected mothers should receive prophylactic treatment against PCP and other opportunistic infections using TMP-SMX from 4-6 weeks of age (or at first encounter with the health care system if), and continued until HIV infection is excluded (6 weeks after cessation of breastfeeding). This should be given orally as per required dosing (see annex 5 paediatric dosing chart).
- Mothers should be counseled on the advantages of exclusive breastfeeding, with particular attention to the risk of mixed feeding (refer to the '*Infant Feeding Guidelines in HIV and AIDS*' provided in the PMTCT guidelines). Infants should exclusively breastfeed for the first six months of life and then continue breastfeeding until 1 year. At six months of life, infants can begin taking complementary food.
- 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 through counseling.

7.5 Clinical Manifestations of Pediatric 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 crepitations (crackles), decreased breath sounds or bronchial breathing
- When pulse oximetry is available it may demonstrate hypoxia (O_2 saturation 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 pneumonia.
- 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.
- Where blood cultures can be done they may assist in identifying the causative agent
- Sputum induction and nasopharyngeal aspirate may assist in the diagnosis of TB or PCP.

Management at outpatient level

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

- Oral amoxicillin 40mg/kg/dose BD for 7 days.
- If a child is taking cotrimoxazole prophylaxis (CPT), cotrimoxazole should not be used to treat pneumonia unless PCP is suspected. If PCP is suspected then high dose cotrimoxazole should be used.
- If the child is under one year of age the risk of PCP is very high and the child should be treated with high dose cotrimoxazole in addition to standard antibiotic management.
- 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 saturation 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 de- or over hydration
- Remember to give paracetamol for fever and pain.
- Ensure adequate feeding, if necessary by naso-gastric tube

Specific therapy:

- Use chloramphenicol or ceftriaxone/cefotaxime (3rd generation) if available
- Use ampicillin/cloxacillin and gentamicin as alternatives (especially for newborns or severely malnourished children)
- Antibiotic therapy for HIV-infected children needs to be longer 7-14 days
- If the child is under one year, PCP must be considered as a possible diagnosis and treatment with high dose cotrimoxazole started. Steroids could be prescribed in case of severe respiratory distress
- If an infant presents with severe pneumonia they should be treated for both bacterial pneumonia and PCP and investigated for possible HIV
- 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 cloxacillin, clindamycin or vancomycin.

7.5.1.2 Lymphocytic Interstitial Pneumonitis

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

Clinical signs and symptoms

- Chronic cough
- Cyanosis
- Digital/finger clubbing
- Difficulty in breathing
- 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 evidence the patient has 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 for specialist care if 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. 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 ($paO_2 < 90\%$)
- 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 stain or immunofluorescent stain
- 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 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
- Paracetamol for pain
- Continue therapy for bacterial pneumonia
- Nutrition support

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.
- After five years of age, initiation of cotrimoxazole prophylaxis is recommended for symptomatic children (WHO clinical stages 2, 3 or 4 for HIV disease) or children with a CD4 of ≤ 500 .
- All children who begin cotrimoxazole prophylaxis should continue until the age of five years when they can be reassessed.
- In children older than five years of age, discontinuation can be considered for those with repeat CD4 count above 500/ml and adherent to ART.

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 10.5 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, tends to be more severe and prolonged, and is often associated with other comorbid conditions, including severe acute malnutrition and pneumonia.

Causative organisms are similar to those in otherwise healthy infants. (i.e. Rotavirus, Enterobacter, E.coli, Salmonella species etc.). Persistent diarrhoea (>14 days) is more common among children with more severe immune suppression and might be caused by other AIDS defining conditions (i.e. CMV).

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

Clinical features

- Increased frequency, volume of liquid stools
- Acute watery diarrhea – non-bloody diarrhea lasting <14 days
- Dysentery – diarrhea with visible blood mixed in stools
- Persistent diarrhea – diarrhea lasting more than 14 days
- Dehydration should be assessed according to WHO/IMCI guidelines

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
- Low-osmolality ORS is preferable to standard ORS for treatment of dehydration (intravenous electrolyte solution in cases of severe dehydration) in HIV-infected and -exposed infants and children with diarrhoea.
- 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 are recommended for 2 weeks for all HIV-infected and -exposed infants and children with persistent diarrhoea.
- Persistent diarrhea not responding to standard treatments is a WHO Clinical Stage III condition, and an indication for ART in children

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 and an indication for ART in children.

Management

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

7.5.5 Esophageal candidiasis

Clinical features

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

Management

- Fluconazole 3-6 mg/kg 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
 - Insert tissue or cotton wool in ear
 - Remove and then reinsert new one until last one comes out clean
- Otic drops—use immediately after wicking
- 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 and warts.

- Herpes Zoster

7.5.7.1 Herpes Zoster

Refer to Section 6.4.1 for description of clinical presentation.

Management

- Acyclovir 20mg/kg/dose 4 times per day for 7 days and
- Cloxacillin 25mg/kg/dose 4 times per day for 7 days
- Paracetamol for pain

7.5.7.2 Kaposi sarcoma (KS)

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

- Management
 - Children with severe KS should be referred to specialty centers for chemotherapy
 - ART should also be given as treatment for KS
 - Note: KS patients can develop IRIS while on ART

7.5.8 Malnutrition

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

Clinical presentation of severe malnutrition

Severe malnutrition is characterized by the presence of any of the following: weight/height z score < -3, a MUAC of < 11.5cm in children of 6-59 months of age, visible wasting in infants of < 6 months of age, or bilateral pitting oedema.

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 that may be hard to diagnose, such as TB.

CHAPTER 8: HIV AND AIDS IN PREGNANCY

8.1 Introduction

In Tanzania, recent estimates shows that rural HIV prevalence (4.3%) is lower than that of urban areas (7.2%). HIV prevalence is higher among women (6.2%) than men (3.8%), (THMIS 2012), and is even higher for women attending antenatal clinics (6.9% in 2008). AIDS-related mortality rates among children under five years of age are still unacceptably high. It is estimated that 200,000 children under 15 years of age are living with HIV (UNAIDS 2010), and that 90% of them may have acquired the infection through MTCT. Different parts of the country are disproportionately affected. The prevalence of HIV infection ranges from 1.5% in Manyara region to 14.8% in Njombe region (THMIS 2011-12). Factors that have driven the epidemic include low and inconsistent use of condoms; multiple sex partners; mobility; transactional sex; cross-generational sex; poor quality of transfused blood; lack of male circumcision; mother-to-child transmission; gender inequities accompanied with poverty, and most-at-risk populations (TACAIDS, 2009).

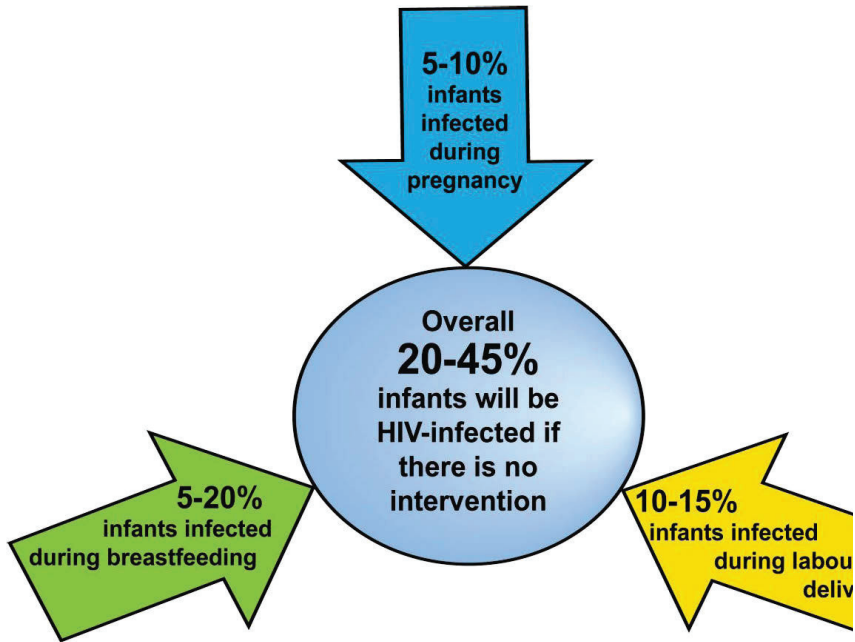
In spite of the challenges, significant progress has been made in the country. The number of men and women testing for HIV and receiving results has doubled from 15% in 2003 to approximately 32% in 2008. The proportion of pregnant women who access PMTCT services has grown from almost none at the pilot of PMTCT services in 2000 to 61% in 2008, and the access to antiretroviral (ARV) medications continues to grow nationwide. The Health Sector HIV/AIDS Strategic Plan (2008–2012) was intended to consolidate interventions to prevent HIV infections and reduce HIV vulnerability among the Tanzanian population. All those who are infected and affected were expected to receive treatment, care and support.

The annual number of new infections exceeds by far the number of individuals enrolled into ARV treatment. The high incidence of new HIV infections in the country indicates that more effort is required in HIV prevention in order to maintain the gains made through roll out of care and treatment programmes. In view of the country's commitment to universal access to HIV prevention, care and treatment and to the Millennium Development Goals (MDGs), reinvigoration of HIV prevention is an absolute necessity.

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

Mother-to-child transmission (MTCT) of HIV refers to the transmission of HIV infection from HIV-infected mothers to their infants. MTCT can occur during pregnancy, labour and delivery, and breastfeeding. 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 infection in children aged below 15 years.

Figure 8.1: Estimated HIV outcomes for infants born to women living with HIV



There are multiple risk factors that increase the chance that a mother will transmit HIV to her child:

1. High maternal viral load and low CD4 count, which occur 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 infection than with HIV-2 infections.
3. Obstetric and neonatal risk factors, as outlined in Table 8.1.

Table 8.1: Viral factors, maternal conditions, and obstetric interventions that may increase the risk of HIV transmission

During Pregnancy	During Labour and delivery	When Breastfeeding
<ul style="list-style-type: none"> • High maternal viral load and low CD4 count (newly infected individuals or advanced AIDS) • Viral, bacterial or parasitic placental infections (e.g., malaria) • Sexually transmitted illnesses (STIs) 	<ul style="list-style-type: none"> • High maternal viral load and low CD4 count (new infection or advanced AIDS) • Chorioamnionitis (from untreated STIs or other infections) • Rupture of membranes for more than 4 hours before delivery 	<ul style="list-style-type: none"> • High maternal viral load and low CD4 count (new infection or advanced AIDS) • Oral disease in the infant (e.g., or mouth sores) • Breast abscesses, nipple fissures, and mastitis • Duration of breastfeeding • Mixed feeding (i.e., breastfeeding combined with other foods or fluids) before 6 months of age

8.3 Goal of Tanzania's PMTCT programme

The goal of the PMTCT programme is to virtually eliminate MTCT of HIV by 2015 and improve care for infected parents and children. The program has the following objectives:

1. Increase the percentage of HIV positive pregnant and breastfeeding women who receive ARVs.
2. Ensure access to care and treatment for mothers and babies living with HIV.
3. Improve child survival among HIV-exposed and infected children.

For more information on the structure and goals of the PMTCT programme, see *Chapter 9 of the PMTCT guideline: PMTCT Programme Management, Monitoring, Evaluation and Supply Chain Management*.

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.

8.4. Four elements of a comprehensive approach to PMTCT

Four elements of a comprehensive approach

A comprehensive approach to PMTCT consists of 4 elements that are discussed in the following chapters of these guidelines:

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

8.4.1. 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

- 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.
- 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 partner.
- Gender concerns and equality should be considered when offering PMTCT services
- All health care providers should emphasize early diagnosis and treatment of STIs in their practice

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 practice. 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. Specific methods to reduce HIV transmission in the workplace are given in *Chapter 8 (PMTCT guideline): Safety and Supportive Care in the Work Setting*.

8.4.2. 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 counseling 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 one or more contraceptive methods 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. For more information on contraceptive devices and methods available nationally, see *Appendix 2-A: Contraceptive Methods in the National PMTCT guideline (2013)*.

Practice Points

- Couples/Women living with HIV should be empowered to make informed decision on the method of choice for family planning.
- Dual protection is the 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 use of contraceptives and become pregnant should be provided with adequate counselling on PMTCT.

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

The PMTCT program offers a range of services and interventions that reduce the risk of MTCT. These include HIV education, testing and counseling for pregnant and breastfeeding women and their partners, antiretroviral treatment (ART) and prophylaxis, safer delivery practices, and counseling on safer infant feeding and care of the HIV-exposed infant. These interventions are discussed in detail in subsequent chapters of these guidelines.

8.4.4. 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 program 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.

Lifelong ART is recommended for all HIV-positive pregnant and breastfeeding women regardless of their CD4 count or WHO clinical stage or gestational age. However, all women diagnosed with HIV infection should have clinical and immunological evaluation to monitor their progress as they start ART. Care and treatment services to pregnant and breastfeeding women living with HIV should be provided in RCH settings or by referral when care and treatment services cannot be provided in RCH clinics. More information on ART can be found in Chapter 9 (Antiretroviral therapy). Infants born to mothers living with HIV will require close follow-up and monitoring of the following: growth and development, immunizations, prophylaxis against HIV infection and opportunistic infections (ARVs and CTX), early testing for HIV and nutritional supplements. All HIV-infected infants should be provided with comprehensive paediatric HIV care and treatment services. These services are discussed further in Chapters 5, 6 and 7.

Table 8.2: Services that contribute to a comprehensive approach to PMTCT

PMTCT services	How these services contribute to a comprehensive approach
Routine HIV testing and counseling	<p>Identifies women/couples living with HIV so that they can receive PMTCT services and HIV care, treatment and support</p> <p>Identifies women who are currently negative but at high risk for acquiring infection during pregnancy / breastfeeding period. Women/couples should be encouraged to continue using protective interventions</p>
Comprehensive antenatal care (ANC)	<p>Monitors pregnancy progress, early recognition and treatment of pregnancy-related complications such as STIs and anaemia, prevention of malaria and TB, counseling mother on optimal nutrition</p> <p>Provision of preventative methods such as cotrimoxazole preventive therapy (CPT) for malaria</p>
Lifelong ART for HIV positive pregnant and breastfeeding women	<p>Improves maternal health, which in turn improves child's survival chances</p> <p>Reduces maternal viral load, which in turn reduces infant exposure to the virus and risk of MTCT</p>
ARV prophylaxis for HIV exposed Infants	Reduces the chances of the HIV-exposed infant from getting infected with HIV from the mother in the postpartum period
Safer delivery practices	Reduces likelihood of labour and delivery complications and infant exposure to HIV during labour and delivery

Counseling 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 mother	Supports mother's health and nutrition status and addresses a woman's family planning needs.
Early infant HIV diagnosis, and treatment	<p>Identifies infants infected with HIV and starts them on ART to improve their survival</p> <p>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 4 weeks of age; ensures infant confirmatory testing after cessation of breastfeeding, facilitates early initiation of ART for HIV infected children</p>
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 counseling to both partners on family planning and dual protection

8.5 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 is the first step in providing appropriate ANC services. This should be provided on a routine basis with proper information to allow the mother to consent. Counseling 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.

8.5.1 Specific Interventions to Prevent MTCT services in the ANC setting

Antenatal care improves the general health and well-being of mothers and their children. The ANC setting is an important source of healthcare for women of childbearing age. Given the high prevalence of HIV infection in Tanzania, all pregnant women should be considered at risk of acquiring HIV infection. By integrating PMTCT services into essential ANC services, national healthcare programmes improve care and pregnancy outcomes for all clients. ANC 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. The essential package of ANC services for women living with HIV infection is shown in Table 8.3. See Chapter 7 (PMTCT guideline): Care and support of HIV-exposed and HIV infected infants and children for additional information about these specific services.

Practice Point

- Pregnant women living with HIV should attend ANC clinic every month to support adherence to medications and to ensure close follow-up and monitoring
- Practice to medications and to ensure close follow-up and monitoring

Table 8.3 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	Include visual and hands-on examination to assess for current signs or symptoms of illness including HIV, TB, malaria, cancer of the cervix and STIs.
Laboratory testing	Conduct routine tests and HIV-specific laboratory tests: <ul style="list-style-type: none"> • Syphilis • Confirmatory HIV testing (if indicated) • Urinalysis

	<ul style="list-style-type: none"> • Full Blood Picture (FBP) • CD4 cell count • Liver and renal function tests
HIV staging	Conduct clinical and immunological staging according to WHO clinical staging system.
Antiretroviral treatment (ART)	Provide life-long ART to all HIV positive pregnant women regardless of CD4 count, WHO clinical stage or gestational age. If ART is not available at the facility, refer to CTC but continue to follow at ANC during pregnancy and the postpartum period.
Tuberculosis (TB)	Screen for signs and symptoms of TB disease at every visit. Evaluate for TB disease if symptomatic.
Opportunistic infection (OI) prophylaxis	Prescribe cotrimoxazole preventative therapy (CPT), regardless of WHO clinical stage or CD4 cell count.
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 national guidelines.
STI prevention and treatment	<p>Assess risk, diagnose and treat STIs according to national guidelines.</p> <p>Counsel on preventing STIs. Always recommend condom use during pregnancy and lactation.</p>

Adherence to ART	<p>Provide counseling and education on healthy pregnancy, HIV care and treatment and PMTCT.</p> <p>Ensure accurate knowledge of maternal ART and infant antiretroviral (ARV) prophylaxis (schedule, dosing etc.).</p> <p>Ensure knowledge and understanding of the rationale for ART and infant ARV prophylaxis and the risks of non-adherence.</p>
Nutrition	<p>Conduct nutritional and dietary assessment and provide counseling.</p> <p>Give iron, foliate, and multivitamin supplements according to national guidelines.</p>
Delivery at a health facility	<p>Explain that interventions for PMTCT — including the provision of ARVs to the mother and infant — are critical during the labour and delivery period.</p> <p>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 are at higher risk of HIV infection.</p> <p>Administer immunization according to national guidelines.</p>
Infant feeding	<p>Support the mother to breastfeed exclusively for the first 6 months, followed by the introduction of complementary feeding with continued breastfeeding until 12 months of age.</p> <p>At 12 months of age, encourage cessation of breast feeding over the course of about one month.</p>

HIV-exposed infant	<p>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.</p> <p>Inform about infant HIV testing and emphasize the importance of early diagnostic testing.</p> <p>All HIV-exposed infants should be tested for HIV infection at 4 – 6 weeks of age and re-tested 6 weeks after complete cessation of breastfeeding.</p>
	<p>HIV testing should also be performed to exposed infants and children six weeks after complete cessation of breast feeding.</p> <p>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 breastfeeding).</p>
Safe Motherhood	<p>Instruct her to return to the clinic/hospital immediately if she experiences symptoms of pregnancy complication such as bleeding, fever, signs and symptoms of pre-eclampsia, severe pallor or abdominal pain.</p>
Signs or symptoms related to HIV	<p>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.</p>

Psychological and social support	<p>Assess and address needs for psychological and social support.</p> <p>Refer to community-based psychosocial support networks or organizations where available.</p> <p>Encourage partners to undergo testing and counsel them on disclosure.</p> <p>Assess need to test other children in the family, even if they are asymptomatic.</p>
Effective family planning and safer sex	<p>Counsel about consistent use of condoms during pregnancy, as well as throughout the breastfeeding period to avoid new HIV infection, re-infection and further transmission.</p> <p>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).</p>

NB: Plan the mode of and place for delivery in good time.

8.5.2. Cervical Cancer Screening

Women living with HIV are at greater risk for developing cervical cancer. Women living with HIV have higher rates of:

- Co-infection with human papillomavirus (HPV)
- Persistent HPV infection
- Larger precancerous lesions that are more difficult to treat
- Recurrence of precancerous lesions following treatment
- Rapidly progressive cervical cancer

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

8.5.3 Care of HIV-infected women during labour and delivery

All labour and delivery services should include interventions to prevent MTCT. These include:

- 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 8.3.

Table 8.3 Safer obstetric practices to reduce MTCT

Safer Obstetrical Practice Description	
Use Standard Precautions (good infection prevention practices) for all patient care.	Use protective gear, safely use and dispose of sharps, sterilize equipment and safely dispose of contaminated materials. See <i>Chapter 8, PMTCT guideline: Safety and Supportive Care in the Work Setting</i> for more details.
Minimize vaginal examinations	Perform vaginal examinations only when necessary, using sterile technique.
Avoid prolonged labour.	<p>Consider use of oxytocic medications to shorten labour when appropriate.</p> <p>Use non-invasive foetal monitoring to assess need for early intervention.</p> <p>Use a partogram to monitor the progress of labour, and record all medications used during labour, including ART.</p>
Avoid artificial rupture of membranes.	Avoid early rupture of membranes (before 7 cm dilation) unless necessary.
Avoid unnecessary trauma during delivery.	<p>Avoid invasive procedures, including scalp electrodes or scalp sampling.</p> <p>Avoid routine episiotomy.</p> <p>Minimise the use of instrumental vaginal delivery such as forceps or vacuum delivery.</p>

Minimize the risk of postpartum haemorrhage	<p>Carefully manage all stages of labour to prevent infection and avoid prolonged labour.</p> <p>Actively manage the third stage of labour by using oxytocin, ergometrine or misoprostal medications and controlled cord traction.</p> <p>Perform uterine massage.</p> <p>Repair genital tract lacerations.</p> <p>Carefully remove all products of conception.</p>
Use safe transfusion practices.	<p>Minimize the use of blood transfusions.</p> <p>Use only blood screened for HIV, hepatitis B and C and, when available, syphilis and malaria.</p>
Provide support and reassurance.	<p>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).</p>

8.5.4 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 after delivery for the infant prophylaxis regimen.

Mode of delivery

Caesarean section performed before the onset of labour or membrane rupture has been associated with reduced MTCT in circumstances where maternal viral load is high. However, in Tanzania, the capacity to perform caesarean sections to reduce MTCT is low; therefore this operation is not regularly performed. With effective use of ART, Caesarean section is not indicated.

Practice Point

Caesarean section is indicated only for obstetric reasons; it is not recommended for the purpose of reducing MTCT in Tanzania.

8.5.5. 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 infection
- Consider the use of antibiotics after uterine evacuation
- Conduct family planning counselling

8.5.6. 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.

Exposed infant discovered post delivery

Administer NVP syrup immediately after birth and continue at appropriate dose until six weeks of age.

- Infant prophylaxis is most effective when given as soon as possible after birth –preferably within 6 to 12 hours.
- However, NVP syrup may be started between birth and four weeks of age for infants who present late. NVP prophylaxis should stop when the infant is six weeks of age, even if started late.

Practice Point

Infants who are diagnosed with HIV infection should initiate ART by a trained clinician at CTC or RCH. See *Chapter 7: Care and support of HIV-exposed and HIV infected infants and children* for additional information.

Safer delivery practices for infants

The goal of safer delivery practices for HIV-exposed infants is to minimize trauma to the newborn and reduce the time that the newborn 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 hand 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 if she is going to breastfeed. 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-breastfed infants, administer vitamin A 50,000 IUs at birth or within 6 months.
- See *Appendix 7-C: Vitamin A Supplementation* for the complete schedule of vitamin A administration.

8.5.7. 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 dispose of blood-stained linens and

pads safely.

Postpartum care for women with unknown HIV status

Women whose status is unknown should receive the same postpartum care as with HIV infection. They should be strongly encouraged to be tested for HIV and to follow the national recommendation to breastfeed exclusively.

HIV testing and counseling:

Women who received HIV testing during labour and delivery should receive additional HIV Post test counseling postpartum. Women of unknown HIV status should receive pre-test information, counseling 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, counseling and HIV testing.

Counseling about safer infant feeding:

All women, regardless of HIV status, should receive infant feeding counseling during postpartum care according to the national guidelines and as outlined in *Chapter 6 in PMTCT guideline: Infant Feeding in the Context of HIV Infection*.

Mothers should receive support to exclusively breastfeed.

- Healthcare workers should encourage and provide counseling 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 of 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.

Counseling about infant HIV testing and CPT:

Women with HIV must be provided with counseling about the importance of infant testing and the schedule for testing prior to discharge. HIV-exposed infants should have an initial HIV test at the age of 4 to 6 weeks. Infants who test HIV-negative will need repeat HIV testing six weeks after complete cessation of breastfeeding.

In addition, all HIV-exposed infants should begin CPT at the age of 4 to 6 weeks.

These essential follow-up services are discussed in *Chapter 7: Comprehensive Care and Support for Mothers and Families with HIV Infection*.

Counseling about postpartum family planning:

Women living with HIV should receive counseling on preventing unintended pregnancy. Use of condom as dual protection should be discussed in order to prevent HIV re-infection. For more information see *Chapter 7: Comprehensive Care and Support for Mothers, Babies and Family Members living with HIV*.

General postpartum education

Regardless of HIV status, the mother will need to be educated before discharge about:

- Accessing help in the event of postpartum haemorrhage and other complications
- How to dispose of potentially infectious materials, such as lochia and blood-stained sanitary pads
- Perineal and breast care
- Care of the infant's umbilicus
- Proper hygiene, including changing diapers and washing the infant
- Recognising signs and symptoms of infant illness and HIV infection (See *Chapter 7 PMTCT guideline :Comprehensive Care and Support for Mothers and Families with HIV Infection*)
- Recognising signs and symptoms of postpartum infection. These include: burning with urination, fever, awareness of heartbeat; foul smelling lochia, redness, pain, pus or any discharge from incision or episiotomy site; cough (dry or producing sputum) or shortness of breath and severe lower abdominal pain.
- Women should have access to the chosen family planning method within 6 weeks after delivery to avoid unintended pregnancy or the risk of new infection. Encourage the use of condoms for dual protection.

Scheduling of comprehensive care visits for the mother and infant

Mothers with HIV and their families will need additional on-going HIV care, treatment and support services. The postpartum period is the time to implement the follow-up plan to connect mothers and their families with medical and support services. Healthcare workers should facilitate referrals and linkages to HIV treatment, care and support services. Healthcare workers are responsible for ensuring that the mother knows the time, location, contact person and purpose of all follow-up appointments.

These essential follow-up services are outlined in *Chapter 7: Comprehensive Care and Support for Mothers and Families with HIV Infection*.

Practice Point

Standard of care, mother-child follow-up in RCH will continue until the child attains the age of 5 years.

All postpartum follow-up appointments for the mother and 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. When 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 immunization cards and should be followed monthly at Under-Five clinics.

Postpartum assessment of healing and routine physical assessment

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

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

8.6. Use of antiretroviral (ARV) drugs during pregnancy and Lactating mothers.

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.

8.6.1. Prevention of Mother to Child Transmission

The pregnant or breast feeding women with HIV should be started with 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)+Lamivudine93TC)+ 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 to others. Available Alternative first line ART regimen includes AZT+3TC+NVP. Also this regimen is recommended to pregnant women in the first trimester and women of child bearing age.

Table 8.4 Infant NVP dosing

Infant age	NVP daily dosing
Birth to 6 weeks <ul style="list-style-type: none"> • Birth weight 2000–2499 g • Birth weight ≥ 2500 g 	10 mg once daily 15 mg once daily

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

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

8.6.2. Monitoring patients on ART

Antiretroviral medicines are known to produce short- and long-term side effects in some people. Clinical follow-up is crucial. HCWs should ask clients about any side effects that they may have experienced and offer information on how to manage them. Clients should be questioned about other medications that may interfere with ARV medications. Patients experiencing intolerable side effects, potential drug interactions should be referred for evaluation at CTC. Successful ART results in decrease in viral load, immune recovery and therefore an increase in the number of CD4 cells. Every six months, the CD4 count is used to monitor the immunologic response to ART. Patients with immunologic failure (falling CD4 count) while on ART should be referred for evaluation at CTC. WHO clinical staging is critical to monitor the effectiveness of treatment in persons on ART and should be performed at every visit. Ideally, the clinical stage should remain stable in an individual on ART.

Practice Point

National guidelines recommend CD4 testing for adults and adolescents at initiation of ART and every six months thereafter. WHO clinical staging should be performed at every visit.

Key Point:

- Every HIV+ pregnant and lactating women should receive baseline CD4 test, but should not delay ART initiation.
- Where viral load is available should be used for monitoring of HIV+ pregnant women and lactating mothers.

CHAPTER 9: ANTIRETROVIRAL THERAPY

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, effective treatment of HIV-infected individuals with ART is highly effective at preventing transmission to sexual partners.

9.1 TYPES OF ANTIRETROVIRAL DRUGS

The currently existing and commercially available antiretroviral drugs in Tanzania fall into the following four main categories:

Nucleoside reverse transcriptase inhibitors (NRTIs)

Non-nucleoside reverse transcriptase inhibitors (NNRTIs)

Nucleotide reverse transcriptase inhibitors (Nucleotide analogues)

Protease inhibitors (PIs)

9.1.1 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 under this class include:

Zidovudine (AZT),

Lamivudine (3TC),

Emtricitabine (FTC)

Abacavir (ABC),

9.1.2 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. Drugs under this class that are available in Tanzania are Nevirapine (NVP) and Efavirenz (EFV).

9.1.3 Nucleotide Reverse Transcriptase Inhibitors (Nucleotide analogues)

Nucleotide analogues resemble NRTIs and an example of this relatively new class of antiretroviral drugs is Tenofovir (TDF).

9.1.4 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. Drugs available in Tanzania that fall under this class are;

Atazanavir (ATV).

Lopinavir (LPV),

Ritonavir (usually used as a booster with above mentioned PIs)

9.2 GOALS OF ANTIRETROVIRAL THERAPY

The principal aim of antiretroviral therapy is to prevent morbidity and mortality in people with HIV/AIDS by suppressing viremia and thereby restoring 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 tissues where they become dormant and stop to replicate. Therefore once patients are initiated on ART, they need to be maintained on ART for life.

The primary goals of antiretroviral therapy are:

- Maximal and durable suppression of viral load to < 50 copies/uL
- Restoration and/or preservation of immunologic function
- Reduction of HIV-related morbidity and mortality
- Improvement of quality of life.

Secondary goals are to decrease the incidence of HIV through;

- Reduce the pool of individual who are infectious and thus reduce the risk of HIV transmission in the community.
- Increased uptake of early voluntary testing and counselling with more people knowing their status and practicing safer sex,
- The reduction of transmission in discordant couples, and
- Reducing the risks of HIV transmission from mother to child

9.3 WHEN TO START ART

Based on available evidence, use of ART improves quality of life and survival for PLHIVs. Early initiation of ART is important for desirable health outcome in terms

of reducing risk of death, disease progression including tuberculosis and other opportunistic infections Eligibility criteria are based on degree of HIV-related disease that is expressed using the WHO clinical staging and Degree of HIV-related immunosuppression which is expressed using CD4 cells count levels.

9.3.1 Evaluation to be done Before Initiating ART

From the moment a patient tests HIV-positive, he/she should be referred to the CTC. In health facilities where ARV is being initiated in RCH and TB clinics, patients can be managed at those clinics.

Before initiating ART in any patient, 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. In addition the TB screening questionnaire should to be administered.

Thereafter, the following baseline laboratory tests are recommended:

- A complete blood count (If not available do Hemoglobin HB)
- Urinalysis
- CD4 T-lymphocytes count (if it was not done in the past 6 months)
- Tests to rule out active TB where indicated (sputum AFB, CXR) in case of indication from the screening questionnaire
- Urine for pregnancy (to women of reproductive age)
- Liver function Tests (Serum Alanine Aminotransferase, ALT) – (if clinically indicated)
- Renal Function Tests (Creatinine, Blood Urea Nitrogen (BUN)) (if clinically indicated)
- Viral load (where available and indicated)
- Rapid test for syphilis

The following could be done if available:

Serum creatinine and lipids

Hepatitis B and C serology

Treatment decisions should be based on the extent of clinical disease progression and readiness of the patient. The gold standard for evaluating immune function remains to be CD4+ T lymphocyte counts.

The tests mentioned above, when available, should be done at baseline and as needed for clinical care (e.g. in cases of toxicity), and at least every six months for patients on treatment.

9.3.2 When to start ART in Adults and Adolescents

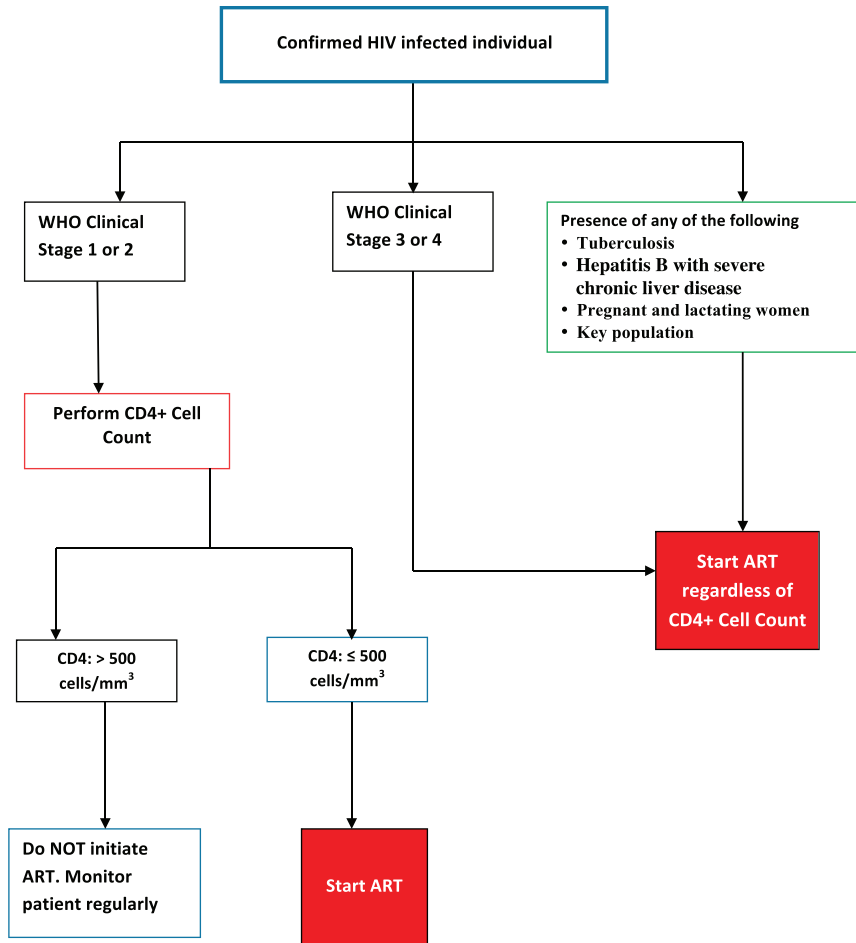
Among adults and adolescents, there are two classes of patients that are eligible to begin treatment:

- All patients in WHO stage 3 and 4 clinical criteria, regardless of CD4 cell count
- All adolescents and adults with CD4 count < 500 cells/mm³, regardless of WHO clinical stage

ART should be initiated in all individuals with HIV regardless of WHO clinical stage or CD4 cell count in the following situations:

- Individuals with TB-HIV co-infection
- Individuals co-infected with HIV and HBV with evidence of severe chronic liver disease
- The following key population people who inject drugs (PWIDs), men who have sex with men (MSM), sex workers, prisoners
- Partners with HIV in serodiscordant couples should be offered ART to reduce HIV transmission to uninfected partners.

Figure 9.1: Criteria for ART in Adults and Adolescents



9.3.3 When to start ART in pregnant and breastfeeding women

Use of antiretroviral drugs has been shown to reduce the risk of transmission of HIV from mother to child. Lifelong ART is recommended for all HIV-positive pregnant and breastfeeding women regardless of their CD4 count or WHO clinical stage or gestational age. However, all women diagnosed with HIV infection should have clinical and immunological evaluation to monitor their progress as they start ART. Care and treatment services to pregnant and breastfeeding women living with HIV should be provided in RCH settings or by referral when care and treatment services cannot be provided in RCH clinics.

9.3.4 Considerations before starting ART

In addition to assessing mere medical eligibility, it is important to assess the capacity to adhere, address a patient's willingness and, readiness to be on ART. Psychosocial considerations (not exclusion criteria) need to be evaluated before initiation of therapy during several (at least more than one) pre-treatment visits, and strengthened in subsequent visits. These include:

Demonstrated reliability, i.e. has attended two or more scheduled visits to an HIV clinic

No evidence of active alcohol or other substance abuse that could affect adherence

No untreated active depression

It is strongly recommended that clients to be initiated on ART should have disclosed their HIV status to at least one friend or family member who will become their adherence assistant (AA) and, if possible, the client should join a support group. Clients need to have accepted their HIV positive status and be clear on the consequences of HIV infection, the role of ART, and the need to strictly adhere to the treatment plan before commencing therapy.

Clients also need to be able to attend the CTC on a regular basis or have access to services that will enable them to maintain the treatment chain. Transport may need to be arranged for patients in rural areas or for those who live far from the treatment site.

The patient and other family members (with patients' consent) should then be educated on HIV/AIDS and the need to adhere to the agreed treatment plan.

General orientation of the patient and family members should include:

Who to call and where to get refills

Who to call and where to go when clinical problems arise

Who to call/where to go for assistance on social, spiritual and legal problems that might interfere with adherence to treatment

9.4 WHAT ART REGIMEN TO START WITH (FIRST-LINE ART)

9.4.1 Introduction

Antiretroviral therapy both in naïve patients and those who have received treatment before involves the use of a combination of drugs. Triple therapy consisting of 2 NRTI + 1 NNRTI or 2 NRTI + 1 PI or 3 NRTI's is recommended. 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. Practitioners should be recommended on the basis of a patient's clinical condition, lifestyle, and ability to tolerate the regimen.

Note: The recommended ARV regimen should be composed of at least 3 drugs. .

9.4.2 First line ARV combination regimen for adults and adolescent ART naïve patients

The MoHSW recommends the following drugs combinations for first line treatment for adults and adolescents. They should be used according to indications and contraindications that govern the use of ARVs to minimize side effects and drug-drug interactions.

TDF+3TC+EFV

TDF+FTC+EFV

AZT+ 3TC+EFV

AZT+3TC+NVP

ABC+3TC+EFV

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

TDF+3TC+EFV

TDF+FTC+EFV

AZT+3TC+NVP

ABC+3TC

The default first line regimen in Tanzania is:

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

Note:

For adolescents, the dose of TDF is 200 mg BD for a body weight of between 20-35 kgs.

For patients with <40kg, the dose of EFV should be <600mg.

CHAPTER 9: ANTIRETROVIRAL THERAPY

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 patients if there is no contraindication.

The regimen is useful in TB/HIV and HIV/HBV co-infection.

Alternative first line regimens can be:

- i) Zidovudine (AZT)+Lamivudine(3TC)+Nevirapine (NVP)

This regimen can be prescribed when Efavirenz is contraindicated, e.g. in Neuropsychiatric complications of Efavirenz.

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 given, and a full dose if there are no side effects such as skin rash or hepatic toxicity. In summary, this means:

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

- ii) Tenofovir (TDF) + Emtricitabine (FTC) + Efavirenz (EFV)

- iii) Abacavir (ABC) + Lamivudine (3TC) + Efavirenz (EFV)

The major concern with Tenofovir-based treatment is renal safety. Tenofovir-associated nephrotoxicity is especially likely in patients with pre-existing renal dysfunction or those receiving other concomitant nephrotoxic medications, low birth weight, advanced age and lower CD4 cell counts. Otherwise the overall rate of discontinuation for renal events is extremely low. Routine renal toxicity monitoring is not required except in patients with the conditions associated with kidney disease such as diabetes, hypertension, obesity, and in patients with co-administered nephrotoxic drugs using creatinine clearance.

In cases where neither Nevirapine nor Efavirenz cannot be used the patient should use boosted PI.

9.4.3 ART in Women of Childbearing Potential or Pregnant Women

All HIV infected pregnant women and lactating mothers are eligible for ART regardless of CD4 count. 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 either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Dual contraception with condoms and contraceptives is therefore recommended

9.4.4 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/AIDS. Given appropriate support, former and active IDUs 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 might be started not earlier than 2 -3 months after starting medical assisted therapy. There is an increased risk of interactions through cytochrome CYP 450 3A between Nevirapine, Efavirenz, Ritonavir and Methadone.

Once daily regimen:

- Tenofovir (TDF) 300mg+Emtricitabine (FTC) 200mg or Efavirenz (EFV) 600mg
- Efavirenz (EFV) 600mg+Abacavir (ABC) 600mg+Lamivudine (3TC) 300mg

Efavirenz decrease Methadone plasma concentration up to 50% constant methadone dose correction is required.

Combination for second line once daily regimen:

- Lopinavir 800mg/Ritonavir 200mg+TDF300mg+FTC200mg or
- Lopinavir800mg/
Ritonavir200mg+Abacavir600mg+Lamivudine300mg. Associated with frequent diarrhoea.
- Atazanavir300mg/Ritonavir100mg+TDF300mg+FTC200mg
- Atazanavir300mg/
Ritonavir100mg+Abacavir600mg+Lamivudine300mg.

Boosted Atazanavir has no interaction with Methadone is well tolerated and has a high genetic barrier to resistance development. It's contraindicated in liver failure.

9.5 CHANGING ANTIRETROVIRAL THERAPY

There are multiple reasons which may prompt the need to change antiretroviral therapy. These can be grouped into two major categories:

Drug adverse events (toxicity)

Treatment failure

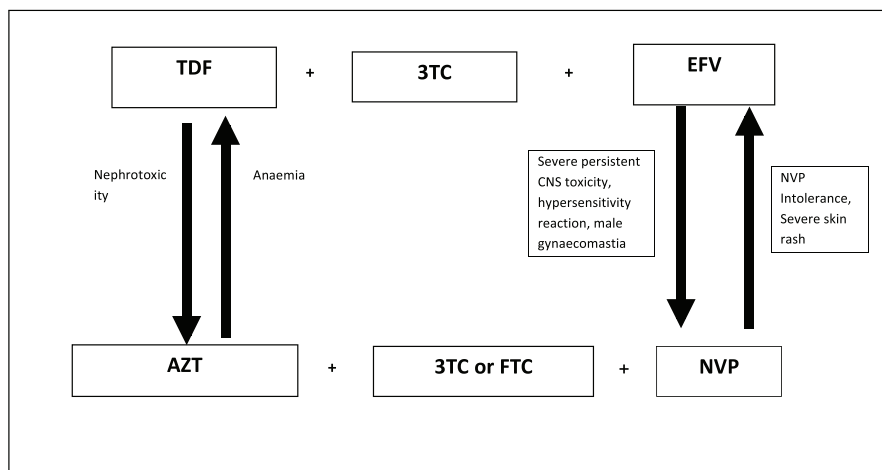
9.5.1 Changing antiretroviral therapy due to toxicity

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, if possible. Table 8.3 below provides guidance on ARV drug combinations with some common toxicity substitution within first line regimens.

Table 9.1: Common toxicity substitution in first line drugs

First Line	Problem	Substitution
TDF + 3TC + EFV	Nephrotoxicity due to TDF	AZT + 3TC + EFV
AZT + 3TC + NVP	Anemia due to AZT	TDF + 3TC + NVP
	Hypersensitivity due to NVP	AZT + 3TC + EFV
AZT + 3TC + EFV	Anemia due to AZT	TDF + 3TC + EFV
	Lipodystrophy due to AZT	TDF + 3TC + EFV
	Both Anaemia and Nephrotoxicity	ABC + 3TC + EFV

Figure 9.2: Substitution within First line Antiretroviral Regimens



9.5.1.1 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 will decrease over time. These 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, neuroleptics (e.g. Amitriptylin) 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 intake in 24 hours or dehydration due to vomiting, severe headache not responsive to non-narcotic analgesics, or fatigue reducing activity by more than 50%. In these situations, one or more ARVs should be replaced by another.

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.

9.5.1.2 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 6-8 weeks of therapy. NVP will be initiated at a lower dose for the first 2 weeks when only one NVP dose 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 at 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 LFTs). If a mild drug-reaction type rash occurs, patients will continue treatment with caution and careful monitoring. LFTs 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 LFTs) LFTs 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 will be started that do not include NVP. The remaining 2 ARVs will be paired with a replacement ARV such as EFV, if not contraindicated.

9.5.1.3 ABC (Abacavir) hypersensitivity

ABC hypersensitivity occurs in up to 5% of patients and can be fatal. Hypersensitivity symptoms include: flu symptoms, shortness of breath, cough, fever, aches and pains, a general ill feeling, fatigue/tiredness, swelling, abdominal pain, diarrhoea, nausea, muscle or joint aches, numbness, sore throat or rash. ABC will be stopped immediately and not re-started if this occurs.

Note: If there is a history of ABC hypersensitivity, then ABC is contraindicated.

9.5.1.4 EFV (Efavirenz) Side effects

EFV can cause CNS side effects such as vivid dreams, nightmares, vertigo, or confusion. These symptoms are often mild and transient. Patients may benefit from assurance that these symptoms are common and will decrease over time.

Table 9.2: 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 <50 kg) Untreated diabetes mellitus Untreated hypertension Concomitant use of nephrotoxic drugs or a boosted PI	If TDF is being used in first-line ART, substitute with AZT or ABC If TDF is being used in second-line ART (AZT use in first line ART), substitute 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	Hypersensitivity reaction	Genetic predisposition (HLA-B * 5701 gene)	If ABC is being used in first-line ART, substitute with TDF or AZT

AZT	Anaemia, neutropaenia, myopathy, lipoatrophy or lipodystrophy	Baseline anaemia or Neutropaenia CD4 count ≤ 200 cells/mm ³	If AZT is being used in first-line ART, substitute with TDF or ABC
	Lactic acidosis or severe hepatomegaly with steatosis	BMI >25 (or body weight >75 kg) Prolonged exposure to nucleoside analogues	If AZT is being used in second-line ART, substitute with ABC
LPV/r	Hepatotoxicity	Underlying hepatic disease HBV and HCV co-infection Concomitant use of hepatotoxic drugs	Replace with ATV/r
	Pancreatitis	Advanced HIV disease	
	Lipoatrophy or metabolic syndrome dyslipidaemia, severe diarrhoea	Risk factors unknown	
ATV/r	Indirect hyperbilirubinaemia (clinical jaundice)	Underlying hepatic disease HBV and HCV co infection Concomitant use of hepatotoxic drugs	ATV/r should be replaced with LPV/r if severe jaundice develops with significantly raised transaminases, otherwise the indirect hyperbilirunemia is usually transient and ATV/r can be continued
	Nephrolithiasis and risk of prematurity	Risk factors unknown	Replace with LPV/r

EFV	Persistent central nervous system toxicity (such as abnormal dreams, depression or mental confusion)	Depression or other mental disorder (previous or at baseline) Daytime dosing	Replace with NVP. If the person cannot tolerate either 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 gynaecomastia		
NVP	Hepatotoxicity	Underlying hepatic disease HBV and HCV co-infection Concomitant use of hepatotoxic drugs CD4 >250 cells/mm3 in women CD4 >400 cells/mm3 for men First month of therapy (if lead-in dose is not used)	EFV. If the person cannot tolerate either NNRTI, use boosted PIs
	Severe skin rash and hypersensitivity reaction (Stevens-Johnson syndrome)	Risk factors unknown	

9.5.2 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 virologic, immunologic and/or clinical. It results from failure to suppress viral replication with the development of viral resistance.

Table 9. 3: WHO definitions of clinical, immunological and virological failure for the decision to switch ART regimens

Failure	Definition	Comments
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
Immunological	CD4 count falls to the baseline (or below) or Persistent CD4 levels below 100 cells/mm ³	Without concomitant or recent infection to cause a transient decline in the CD4 cell count A systematic review found that current WHO clinical and immunological criteria have low sensitivity for identifying individuals with virological failure.
Virological	Plasma viral load above 1000 copies/ ml based on two consecutive viral load measurements after 3 months, with adherence support	The optimal threshold for defining virological failure and the need for switching ART regimen has not been determined An individual must be taking ART for at least 6 months before it can be determined that a regimen has failed.

In Tanzania, immunological and clinical parameters are used to identify treatment failure. However, in light of declining costs of performing viral load measurements, along with the simplification of processes, where available, viral load parameters should also be applied. Where available, Viral Load should be used to confirm immunological failure. Furthermore, clinical failure must be distinguished from the Immune Reconstitution Inflammatory Syndrome (IRIS), in that, while clinical failure is associated with failing CD4 counts, IRIS is associated with improvements in immune response, i.e. CD4 counts. These are late markers of virologic gene. With the need to identify early ART failure and preserve future treatment options, viral load testing is now recommended.

9.6 MONITORING PATIENTS ON ARV THERAPY

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. Appearance or persisting opportunistic infections, or lack of weight gain, can indicate treatment failure hence should require further evaluation to determine fulfillment of criteria for treatment failure. Switching to second line treatment should not be based on clinical criteria alone.

Laboratory Monitoring:

CD4+ T-lymphocyte count is one of the criteria used to determine the eligibility for initiation and define immunological treatment failure. Although initiation of ART in patients with TB, HBV, key populations, pregnant and lactating women and HIV positive partners in discordant relationships, advanced HIV disease (WHO clinical stage 3 and 4) is done irrespective of CD4 count level, it is advised to determine baseline CD4 count in these individuals to monitor immunological response. A rise in CD4 count indicates effective antiretroviral treatment. The CD4+ T-lymphocyte count should be repeated every 6 months, however in cases of suspected IRIS or treatment failure it can be tested at intervals less than six months.

Viral load (VL) monitoring is the preferred approach 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. Where facilities are available, targeted rather than routine VL testing is recommended. Targeted VL testing is only done when treatment failure is suspected. Treatment should be considered effective if the viral load is <50 copies/ml.

CD4 count will be done 6-monthly while patients are on the first line regimen.

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

i) Scheduled visits

Initial 6 months after starting ART:

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

Six months after starting ART:

After the patient is clinically stable, with good adherence for the at least six months or more 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.

Table 9.4: Summary of Adult and Adolescent ART Laboratory Monitoring of Patients on First Line Regimen

Regimens	Monitoring Tests	Frequency	Rationale
I. TDF/3TC/EFV TDF/3TC/NVP	Serum creatinine	Baseline, and 6 monthly	TDF is nephrotoxic
	Serum creatinine	Baseline and once yearly	
II. AZT/3TC/EFV	CD4	Baseline, 6-monthly	ART monitoring
	FBP/Hb	Baseline, week 4 thereafter, 6 monthly	Contains AZT
III. AZT/3TC/NVP	CD4	Baseline, 6-monthly	ART monitoring
	ALT	Baseline, 6 monthly and whenever symptomatic	Contains NVP
	FBP/Hb	Baseline, week 4 thereafter, 6 monthly	Contains AZT

Note: Clinical evaluation will determine more frequent laboratory tests if required.

Baseline = testing for ART eligible patients at initiation of ART

NB: The frequency of CD4 and viral load monitoring may be less than 6 months when IRIS or treatment failure is suspected.

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 whether 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. A good referral mechanism should therefore be established between the clinic and other levels of health care delivery, including home based care teams.

9.7 Immune Reconstitution Inflammatory Syndrome (IRIS)

IRIS is a phenomenon associated with 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 patientsPatients with advanced HIV disease with CD4 count < 50 cells/mm³
- Patients with undiagnosed and untreated opportunistic conditions
- Patients who are started on ART shortly after 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 occurs 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 9.5 below.

Table 9.5: Immune Reconstitution Inflammatory Syndrome

<p>Diagnosis of infectious IRIS would require: Both major (A plus B) criteria or Criterion A plus 2 minor criteria</p>
<p>Major criteria</p> <p>A. A typical presentation of “opportunistic infections or tumours” in patients responding to anti-retroviral therapy (ART) includes:</p> <ul style="list-style-type: none"> • Localized disease e.g. lymph nodes, liver, spleen • Exaggerated inflammatory reaction e.g. Severe fever, with exclusion of other causes 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 e.g. • Development of enlargement or cerebral space occupying lesions after treatment for cerebral <i>Cryptococcus</i> or toxoplasmosis • Progressive pneumonitis or the development of organizing pneumonia after treatment for pulmonary TB or PCP
<ul style="list-style-type: none"> • New onset or worsening of uveitis/vitritis after resolution of CMV retinitis • Fever and cytopenia after treatment for disseminated <i>Mycobacterium avium</i> complex (MAC) disease • Enlargement of Kaposi's sarcoma lesions and subsequent resolution or partial regression without Commencement of radiotherapy, systemic chemotherapy or intralesional therapy.
<p>B. Decrease in plasma HIV-RNA level by > 1 log 10 copies/ml</p>
<p>Minor criteria</p> <ul style="list-style-type: none"> • 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 • 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 infection/malignancy

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: 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.v fluids
- Restart ART when the patient stabilizes

9.8 SECOND-LINE ARV REGIMEN

Before treatment failure is presumed 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 comprise of at least 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.

9.8.1 Second-line antiretroviral therapy in adults and adolescents

Drugs used as the second line drugs in Tanzania include:

NRTIs

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

PIs

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

The second line NRTI choice for adults and adolescents depends on the first line regimen. For patients on TDF in first line, the default second line option is to use is AZT plus 3TC or FTC combined with a ritonavir-boosted PI, either LPV/r or ATV/r. (AZT+3TC or FTC + ATV/r or LPV/r). The preferred PI is ATV/r due to its low toxicity profile and convenient once a day dose.

If patients were started on AZT and had never used TDF regimen, the default second line option will be TDF based regimen.

For patients who were initiated on TDF in first line because of intolerance to AZT, the default second line option is to use ABC plus 3TC combined with a ritonavir-boosted Atazanavir. (ABC + 3TC + ATV/r)

Doses for these drugs are given in Appendix 4.

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

Table 9.6: Second line regimen choices

FIRST LINE	→	SECOND LINE
AZT/3TC+NVP (or EFV)	→	ATV/r or LPV/r +TDF/FTC
TDF/3TC (or FTC)+EFV (or NVP)	→	ATV/r or LPV/r + AZT/3TC
Either of the above	→	ATV/r or LPV/r + ABC+3TC

9.8.2 Laboratory Monitoring of patients on second line drugs

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

- CD4, Baseline, 6-monthly
- FBC, Baseline, then monthly for 3 months, then 6 monthly (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 3 monthly
- Serum creatinine at baseline and once yearly

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 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 that do not have cross-resistance that have no overlapping toxicities or drug-drug interactions.

9.8.2.1 Scheduled visits

Patients started on a second line regimens need to come to the clinic every month for the first 3 months to see the doctor and thereafter bi-monthly when stable. Drugs need to be collected every month.

Staging = initial testing for all patients when being referred for antiretroviral therapy.

Baseline = testing for ART eligible patients at initiation of new ART regimen.

9.8.2.2 Unscheduled visits

Clinical judgment will be used to assess whether additional clinical or laboratory interventions are required.

9.8.3 Treatment failure with second line regimens

Patients on second-line therapy who begin to fail on the basis of clinical, immunological, or virological parameters should receive increased adherence support (refer to chapter 11).

CHAPTER 9: ANTIRETROVIRAL THERAPY

Confirm virological failure by determining viral load/CD4 counts. Assess adherence and intensify adherence support. A multi-disciplinary switch team should decide when to switch.

If they continue to fail virologically, despite demonstrated increased adherence, their ART regimen should be continued until they cease to derive clinical benefit from the treatment. Where adherence is consistently <80%, ongoing education and counselling should be provided.

If the patient experiences an AIDS defining (WHO stage 4) illness while on second-line therapy, refer the patient to a tertiary care clinic (referral hospital).

9.9 Antiretroviral Therapy in Children

9.9.1 Goals of Antiretroviral Therapy in Children

The goals of antiretroviral therapy for children are to:

Prolong the survival of HIV-infected children

Promote optimal growth and development

Preserve, enhance, or reconstitute the immune system and therefore reduce opportunistic infections

Suppress HIV replication and therefore prevent disease progression

Reduce the morbidity of children and improve their quality of life.

NOTE: In most children, CD4 cell counts rise with the initiation of therapy and immune recovery. Generally, CD4 levels 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 levels at the start of ART, the slower the recovery. Persistent failure of CD4 response should alert the clinician to potential adherence problems or non-response to ART. In this case, viral load determination can be useful. Undetectable viral loads of <1000 copies/μL should be achieved and sustained.

In order to achieve these goals the following strategies should be used:

Adequate counselling

Creation of a supportive environment for patients 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.

It is important that prescribers are clear about when to start antiretroviral drugs as described above. 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.

9.9.2 When to start ART in children

9.9.2.1 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: All HIV exposed children aged less than 18 months with a presumptive HIV infection. (have a positive rapid antibody test and meets WHO criteria for severe HIV disease (see Table 7.1 in Chapter 7)

Table 9.7: When to start in

Age	When
Children 0-15	Treat all regardless of WHO clinical stage or CD4 cell count
Children below 18 months who qualify for presumptive diagnosis	Start ART while awaiting virologic confirmation

9.9.2.2 Initiation of ART for Adolescents 15 years or older

Among children 15 years and older, there are 2 categories of patients that are eligible to begin treatment:

All children 15 years and older infected with HIV with severe or advanced symptomatic disease (WHO clinical stage 3 or 4) regardless of age and CD4 cell count.

All children older than 15 years in Stage 1 or 2 with CD4 <500 cell/mm³

9.9.3 First-Line ARV Regimens in Infants and Children

9.9.3.1 ART Treatment for Children less than 3 years

The first line regimen for children less than 3 years is ABC + 3TC + LPV/r. This is best prescribed using FDC pediatric ABC + 3TC tablets and pediatric LPV/r tablets or syrups. Alternative regimen is AZT + 3TC + LPV/r. If LPV/r is not available, NVP may be substituted in pediatric FDC AZT +3TC + NVP.

Table 9.8 Summary of first line ART Regimen for children younger than 3 years

First line Regimen	ABC + 3TC + LPV/r
Alternative Regimen	AZT + 3TC + LPV/r
Alternative Regimen	AZT + 3TC + NVP

9.9.3.2. ART Treatment for Children over 3 year

Table 9.9: The first line regimen for children over 3 years old

	Children 3 years to adolescents < 35 kg	Adolescents > 35 kg
First Line	ABC + 3TC + EFV	TDF + 3TC + EFV
Alternative Regimen	AZT + 3TC + EFV	AZT + 3TC + EFV
Alternative Regimen	ABC + 3TC + NVP	AZT + 3TC + NVP

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

9.9.3.3 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 malaria¹⁰

9.9.4 Reasons for Changing ARV Therapy in Infants and Children

The principles on which to base changes in therapy and the management of 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 can be replaced with another drug that does not have the same side effects.

9.9.4.1 Clinical criteria for treatment failure

Clinical conditions indicating that a change to second-line therapy is warranted include:

¹⁰ Achan J et al. antiretroviral agents and prevention of malaria in HIV infected Ugandan Children. New England Journal of Medicine 2012, 367:2110-2118.

- Poor growth (failure to gain weight, declining or stationary weight) over a 6-months period, after excluding other causes, such as TB, food insecurity
- No improvement of neuro-developmental milestones
- Development of HIV encephalopathy
- Recurrent infections, such as oral candidiasis, persistent diarrhoea, recurrent severe bacterial pneumonia, etc. (see annex 2 Paediatric WHO Clinical Staging).
- 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 intercurrent episodes of pneumonia, LRTI and gastroenteritis should not be regarded as clinical failure. Pulmonary or lymph node TB, which are clinical stage 3 conditions, may not be an indication 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.

9.9.4.2 Immunological Criteria for treatment failure

If adherence is good, immunological criteria indicating that a change to second-line therapy is warranted includes:

Table 9.10: CD4 criteria suggesting immunological failure ^a

Immunological failure is recognized as developing or returning to the following age-related immunological thresholds after at least 24 weeks on ART, in a treatment-adherent child:	
≥ 2years to <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 atleast two CD4 measurements should be available. Use of %CD4+ in children <5 years and absolute CD4 counts in those ≥5 years of age is preferred. If serial CD4 values are available, the rate of decline should be taken into consideration	

Note: CD4 percent should not be measured during an intercurrent infection but can be determined when the child has recovered

If there is a modest decline in CD4 count or percent (< 5%) and if there is no failure to thrive, do not change medication, instead maintain close monitoring.

9.9.4.3 Virological Criteria for treatment failure

Virological failure is recognized if the child is adherent to their (first line) ART regimen, more than 6 months from ART initiation and has a two consecutive viral load measurements over 1000copies/ml after 3 months.

The WHO recommends the use of routine viral load monitoring to decide on treatment failure where there is regular access and where affordable. Viral load is the most sensitive method to detect viral replication.

Table 9.11: Laboratory parameters for monitoring infants and children at baseline, before and during ART

Laboratory tests for diagnosis and monitoring	Baseline (at entry into care)	At initiation of first-line or second-line ART regimen	Every six months	As required or symptom-directed
HIV diagnostic testing	√			√
Haemoglobin ^a	√	√		√
WBC and differential count				√
%CD4+ or absolute CD4 cell count	√	√	√	√
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				√
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				

9.9.5 Clinical 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
- Clinical staging
- Immunization status
- Other medical conditions
- Screening for malaria and TB
- Deworming

9.9.6 Recommended Second-Line ARV Therapy for Infants and Children

- After failure of a first-line NRTI-based regimen, a boosted PI plus two NRTIs are recommended for second line ART; LPV/r is the preferred boosted PI.
- 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 undertaken.
- After failure of a first line LPV/r based regimen, children 3 years or older 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 + 3TC 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 + 3TC or TDF + 3TC.

Table 9.12: Summary of recommended first- and second-line ART regimens in children < 15 years

	Children	First Line Regimen	Second Line Regimen
LPV/r – based first line regimen	<3 years	ABC+3TC + LPV/r	No change ^a
		AZT +3TC+ LPV/r	
	≥ 3 years	ABC+3TC + LPV/r	AZT + 3TC + EFV
		AZT +3TC+ LPV/r	ABC or TDF ^b + 3TC + EFV
NNRTI based first line regimen	All ages	ABC+3TC + EFV (or NVP)	AZT + 3TC + LPV/r ^c
		TDF ^b + 3TC + EFV (or NVP)	
		AZT +3TC+ EFV (or NVP)	ABC or TDF ^b + 3TC + LPV/r ^c

^a No change is recommended unless in the presence of advanced clinical disease progression or lack of adherence specifically because of poor palatability of LPV/r. In this case, switching to a second line NVP-based regimen should be considered. Based on the recent approval of the use of EFV in children less than 3 years, an EFV-based regimen could be considered as an alternative.

^b TDF may only be given to children > 2 years

^c ATV/r can be used as an alternative to LPV/r in children older than 6 years

9.9.7 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 or more of treatment).

Adverse reactions can vary in severity from mild to severe to life-threatening and may be specific to the drug or generic 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 and neutropenia. Measuring hemoglobin is recommended before initiating ART among children with low body weight, low CD4 counts and advanced HIV disease. Patients with severe anemia at baseline (haemoglobin < 7.5 g/dL) should avoid AZT as first line therapy.

TDF

TDF is associated with nephrotoxicity. Nephrotoxicity is more common in elderly patients, those with long term diabetes or uncontrolled hypertension or also taking PI based therapy. Monitoring of creatinine clearance is recommended for these high risk individuals.

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 not 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 etiology in a child on NVP requires careful consideration of whether NVP should be continued.

LPV/r

LPV/r's major toxicity include hepatotoxicity, pancreatitis, diarrhea 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; discussed above.

Principles in the management of ARV drug toxicity

1. Determine the seriousness of the toxicity
2. Evaluate concurrent medications and establish whether the toxicity may be attributable to an ARV drug or drugs, or to a non-ARV medication taken at the same time.
3. Consider other disease processes (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 reaction according to its severity (**see Annex 8**).
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 feasible. If the patient does not improve on symptomatic therapy, consider single-drug substitution.
 - d. *Mild reactions:* Reassure child and caregiver that while the reaction may be bothersome, it does not require a change in therapy; Provide counseling and support to mitigate adverse reactions.

Emphasize on the maintenance of adherence despite mild and moderate reactions.

Table 9.13: 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 NNRTI, 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 younger than 3 years and EFV for children 3 years and older)
Severe anaemia or neutropenia	AZT	ATV/r can be used for children older than 6 years
Severe gastrointestinal intolerance		Substitute with ABC if < 35 kg Substitute with TDF if ≥ 35 kg
Persistent and severe central nervous system toxicity	EFV	NVP
Tubular renal dysfunction	TDF	If TDF is being used in first line ART, substitute with AZT or ABC If TDF is being used in second line ART, substitute with ABC

CHAPTER 10: TB AND HIV CO-INFECTION

10.1. Introduction

TB and HIV are overlapping epidemics. Both have been declared global emergencies demanding global attention. HIV is the strongest risk factor for the development of TB. It increases the 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-%¹¹. HIV also increases the risk of TB reactivation. On the other hand, TB increases the risk of progression from HIV to AIDS disease; TB is the most common opportunistic infection; and the major cause of death among AIDS patients.

HIV is fuelling the TB epidemic in many countries especially in Sub-Saharan Africa. Globally there were 9.0 million cases of TB in 2013 and Africa accounted for about 80% of HIV positive TB cases and TB deaths among HIV positives.

Tanzania is one of the 22 high-TB burden countries in the world. The prevalence rate for TB is estimated at 172 per 100,000 populations¹².

TB cases notification has decreased over time: there were 64,267 cases in 2009, 63,453 in 2010, 61,838 in 2011, 61,126 in 2012. HIV infection among TB patients was 37% in 2013 compared to 39% in 2012 and TB mortality rates have decreased: 6.1 per 100,000 population (HIV +ve TB cases only) and 6 per 100,000 populations (excluding HIV +ve TB cases) in 2013 compared to 15 per 100,000 population and 13 per 100,000 populations respectively. Rate of ART among TBHIV co-infected individuals increased from 54% in 2012 up to 73% in 2013.

10.2.0 TB Management in HIV and AIDS Patients

10.2.1. Pattern of HIV-related TB

HIV not only increases the number of TB cases, but also influences the clinical course of TB disease. As HIV infection progresses, CD4+ T-Lymphocytes that play an important role in the body's defense against tubercle bacilli decline 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. The most common type of TB in HIV is extra pulmonary TB.

10.2.2. Pulmonary TB

According to NTLR Report 2012 among the 61,126 notified TB cases in 2012, 25,138 were new smear-positive PTB cases, 21,393 were new smear-negative PTB cases, 14,595 were EPTB cases, 1,052 were relapses and 1,828 were retreatment cases, excluding relapses.

The WHO defines smear-positive pulmonary tuberculosis as a patient with one sputum smear examination positive for acid-fast bacilli (AFB). Smear-negative pulmonary tuberculosis is defined as the presence of at least two sputum specimens negative for AFB, radiographical abnormalities consistent with active tuberculosis.

¹¹ Manual for the Management of Tuberculosis and Leprosy, sixth edition, 2013

¹² WHO Global TB Report 2014

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*.

10.2.3. Extra-pulmonary tuberculosis (EPTB)

About 24% of new TB patients in Tanzania present as EPTB¹³. The most common forms of extra pulmonary TB are pleural effusion, lymphadenopathy, pericardial disease, millary disease, meningitis, spinal TB (Pott's disease) and disseminate TB. 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.

Table 10.1: Severe and less severe extra pulmonary TB cases

Severe extra-pulmonary TB	Less severe extra-pulmonary TB
<ul style="list-style-type: none"> • Meningitis • Millary • Pericarditis • Bilateral or extensive unilateral effusion • Spinal • Intestinal • Genito-urinary tract 	<ul style="list-style-type: none"> • Lymph node • Unilateral pleural effusion • Bone (other than spine) • Peripheral joint • Adrenal gland • Skin

10.2.4 Tuberculosis diagnostic approaches

There are 2 approaches for TB diagnostic: Clinical and laboratory

i. Clinical diagnosis

Clinical diagnosis of TB involves:

- A careful and extensive history-taking, which includes asking the patient questions relative to:
 - Symptoms suggestive of TB disease: cough for two weeks or more, night sweats, fever, and weight loss.
 - If coughing, the sputum colour and quantity.
 - History of TB disease and the outcome of treatment.
 - The presence of other medical conditions such as HIV/AIDS and diabetes mellitus.
 - History of TB contact(s).
 - Tobacco-smoking, including amount and duration of smoking.
 - History of substance abuse (drugs and alcohol).

- Alcohol ingestion, including amount and duration.
- Occupational history that may suggest exposure to silica dust, especially among miners.
- Physical examination. Although no physical sign is sensitive or specific enough for TB, it is critical to assess patients for fever, look for anaemia, exclude lymphadenopathy, and confirm the presence or absence of chest and neurological abnormalities and hepato-splenomegaly in order to screen for co-morbidities and rule out EPTB in all patients, including those with suspected PTB.

Note: Nearly a quarter of all TB patients may not have the classical five symptoms of TB, including cough, and they are diagnosed based on an abnormal chest x-ray suggestive of TB.

ii. Laboratory diagnosis

Early identification of TB cases and putting them on effective treatment is important in TB care and control. Diagnosis of PTB depends on the identification of tubercle bacilli either by sputum smear microscopy or culture and identification of bacterial DNA using molecular techniques.

a) Sputum smear microscopy

Sputum smear examination has been the cornerstone of TB diagnosis for more than a century. It remains the only available test in most low-income settings such as Tanzania. The test is relatively quick, easy to perform, and inexpensive. The purpose of sputum microscopy is to:

- Diagnose people with infectious TB.
- Monitor the progress of treatment.
- Confirm that cure has been achieved.

Note: For details for sputum smear microscopy please refer to the NTLP Manual

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. In Tanzania, GeneXpert® is used as a follow-up test for smear-negative HIV-positive TB suspects and in children as an initial test. It will also be performed on contacts of MDR TB and previously treated patients who are likely to have drug-resistant TB.

Drug Susceptibility Testing (DST)

In Tanzania, DST is done primarily for routine surveillance of drug resistance, using 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 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
- Erythrocyte sedimentation rate

Note: For more details of TB diagnosis please refer to the NTLF Manual

10.2.5 Standard regimen for new adult TB patients

- New adult TB patients should receive a six-month regimen containing rifampicin: 2RHZE/4RH. The regimen requires daily 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), where available, and culture and DST. All patients who are rifampicin resistant should receive MDR TB treatment in a designated health facility.
- Patients who are rifampicin negative 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 who are failures 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 at three and 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.

10.3. Collaborative TB/HIV activities

The MOHSW commits itself to the endeavor 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; Establish and strengthen the mechanisms for delivering integrated TB and HIV services; reduce the burden of HIV in patients with presumptive and diagnosed TB; and reduce the burden of TB in PLHIV (3Is Strategy) and initiate early antiretroviral therapy. The following collaborative TB/HIV activities are recommended to be implemented in the country both by the HIV/AIDS and TB programs:

- i. Establish and strengthen the mechanisms for delivering integrated TB and HIV services
 - Set up and strengthen a coordinating body for collaborative TB/HIV activities functional at all levels
 - Determine HIV prevalence among TB patients and TB prevalence among people living with HIV
 - Carry out joint TB/HIV planning to integrate the delivery of TB and HIV services
 - Monitor and evaluate collaborative TB/HIV activities
- ii. Reduce the burden of HIV in patients with presumptive and diagnosed TB
 - Provide HIV testing and counselling to patients with presumptive and diagnosed TB
 - Provide HIV prevention interventions for patients with presumptive and diagnosed TB
 - Provide co-trimoxazole preventive therapy for TB patients living with HIV
 - Ensure HIV prevention interventions, treatment and care for TB patients living with HIV
 - Provide antiretroviral therapy for TB patients living with HIV

- iii. Reduce the burden of TB in PLHIV (3Is Strategy) and initiate early antiretroviral therapy
 - Intensify TB case-finding and ensure high quality anti TB treatment
 - Initiate TB prevention with Isoniazid preventive therapy and early antiretroviral therapy
 - Ensure control of TB Infection in health-care facilities and congregate settings

Since TB is the leading opportunistic infection in HIV, all people living with HIV should: be screened for TB on every visit in order to reduce morbidity and mortality; be provided with IPT to prevent them from developing active TB depending on eligibility; and observe principles of TB infection control. According to the WHO 2004 the interim policy on collaborative TB/HIV activities, strategies for controlling TB in persons with HIV infection should include:

10.3.1 Intensify TB case-finding and ensure high quality anti TB treatment

Intensified TB case finding involves screening for symptoms and signs of in settings where HIV-infected people are concentrated. (Annex 10 TB screening tool) TB screening promote early identification TB among people living with HIV/AIDS, and increases access to TB treatment, improve survival, quality of life and reduces transmission of TB in the community. Children below 5 years should also be screened to exclude active TB using a special screen tool. People with presumptive TB should undergo diagnostic follow up using the TB diagnostic flow chart for children older than 6 years and adults (Annex 11 diagnostic flow chart) and the algorithm for diagnosing pulmonary TB in children below 6 years old (Annex 12). Furthermore, the diagnosis of childhood TB may be done clinically in the absence of bacteriological confirmation by using the score chart for diagnosis of TB in children.

NOTE: Smear microscopy will continue to be used as a gold standard for testing all patients with presumptive TB.

GeneXpert® will be used as a follow-up test for smear-negative HIV-positive patients with presumptive TB and in children as an initial test. It will also be performed on MDR TB contacts and patients with history of TB drug resistance.

10.3.2 Isoniazid Preventive Therapy (IPT) and early Antiretroviral Therapy (ART)

10.3.2.1 Isoniazid Preventive Therapy (IPT)

Isoniazid preventive therapy (IPT) is an intervention that should be part of the package of care for people living with HIV. IPT involves giving Isoniazid (INH) tablets to eligible individuals with latent infection of *M. tuberculosis* in order to prevent progression to active disease. In individuals with HIV, the risk of developing tuberculosis is reduced by about 60% and their survival is also prolonged. The protective effect is expected to last for about 18 months from the last dose of INH. It is however, important to exclude active TB before starting IPT. 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 repeated after two years from the first dose of the last IPT cycle. This therapy requires several steps to be taken, including identification

of HIV-positive clients, screening to exclude active TB, assessing eligibility for IPT and monitoring of client' adherence to treatment. In case of neuropathy due to INH, Pyridoxine should be used.

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.
- A tuberculin skin test should be offered to all HIV infected individuals where possible.

For patients with history of TB treatment:

- Patients who had active tuberculosis in the past 2 years should not be considered for preventive therapy.
- Patients who were treated for tuberculosis more than 2 years earlier may be considered because they may have already been re-infected with TB.
- Patients who receive IPT and who are eligible for antiretroviral therapy can complete their TB preventive therapy even if ART is started as there is no interaction between Isoniazid and the current ART regimen used.

Other exclusion criteria for IPT include:

- Alcohol abuse
- Non-adherence to long term treatment
- Current/ past history of hepatitis
- Medical contra- indication to INH
- Terminal AIDS (WHO clinical stage 4)

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 be repeated after two years from the last IPT cycle)
- Pyridoxine: 25mg daily until neuropathy subsides

Isoniazid Preventive Therapy in children

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

- All newborns with no symptoms of active TB disease that are born to mothers with active TB disease.
- All HIV-infected children less than 12 months with no symptoms of active TB disease and with a known TB contact.
- All HIV-infected children who are 12 months or older with no symptoms of active TB disease.

Note: IPT should be initiated only after TB disease has been ruled out

Explain to the child (if age appropriate) and parent/caregiver that treatment with the medicine isoniazid is essential to prevent the child from becoming very sick with TB disease. Describe the potential side effects and that they should return to the clinic if 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 repeated after two years from the last IPT cycle).
- 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
- Pyridoxine: 1-2 mg/kg daily until neuropathy subsides

10.3.2.2 Early Antiretroviral Therapy (ART) Add regimes of TB treatment

ART has been reported to reduce TB rates by up to 90% at the individual level, 60% at the population level, and also reduces TB recurrence rates by 50%. Initiation of ART for all those with HIV/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.

ART in TB/HIV co-infected individuals:

ART should be initiated for *all* people living with HIV with active TB disease irrespective of CD4 cell count. TB treatment should be started first, followed by ART as soon as possible, within the first 2 weeks of starting TB treatment. Refer to chapter 9 on ART.

NB: Rifampicin and Nevirapine should not be used together due to drug interactions and hence regimens which contain Nevirapine should not be used.

When using Nevirapine based regimen, the patient should be started on a normal dose (200mg bd). A loading dose is not required.

In individuals who need TB treatment and who require an ART regimen containing a boosted protease inhibitor (PI), it is recommended to use Rifampicin and a boosted antiretroviral regimen containing Lopinavir with additional Ritonavir dosing (LPV/r 400mg/ 100mg BID). i.e 2 tabs. This regimen is associated with high levels of toxicity, and requires close 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 or 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 in the ART regimen.

Consideration 2:

When TB is diagnosed in PLHIV who are already on ART and Medically Assisted Therapy using Methadone, the level of Methadone should be increased by 50% when used along with Rifampicin due to drug-drug interactions.

10.3.2.3 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).

10.3.3 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 generally are aimed at reducing exposure to *M tuberculosis* among health care workers, prison staff, police and their clients, and other persons in the congregate settings.

10.3.3.1 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 includes

- **Infection control plan**

All clients should be screened for TB as soon as they arrival at the facility to identify those with a cough of any duration. 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 counseling; refer them to CTC at the end 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 their risk of developing TB and they should avoid escorting TB suspects/patients.¹⁴

- **Clinic operating procedure:**

Patients who report at CTC to register should be observed and probed about coughing and if so sent immediately to laboratory to provide sputum sample and return to CTC for registration and care.

10.3.3.2 Environmental control measures

Environmental protection should include maximizing natural ventilation and direct sunlight. This is the second line of defense 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 spread of TB. The common control measures include:

- Open doors and windows to bring in air from the outside
- Waiting areas and examination rooms designed in a manner that they have maximum natural ventilation. Fans may also assist in the process of air distribution.

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

- Collection of sputum for TB outside (in an open environment) and away from other people, not in small rooms or other enclosed areas.

10.3.3.3 Personal protective measures

Personal protective measures protect healthcare workers, patient and family members in areas where the concentration of droplet nuclei cannot be adequately reduced by administrative and environmental control measures. These measures prevent 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 that have been expelled 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 **ONLY** 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 drugs 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 have an HIV test. If they test positive, they should avoid contact with presumptive TB and TB patients.
- Normal masks do not protect medical staff against inhaling infected droplets and are therefore not recommended as a preventive measure for health staff.

10.4 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 infection. During early stages of HIV infection when immunity is good, the signs 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 tuberculosis meningitis, miliary TB, and widespread tuberculosis lymphadenopathy occur.

10.4.1 The Diagnosis of Tuberculosis in Children

The diagnosis of TB in children can be very difficult due to the wide range of symptoms. Sputum cannot often be obtained from children and is often negative even on culture. Symptoms 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 smear microscopy as the “gold standard”.

10.4.2 Treatment of TB in children

In principle, TB treatment in children does not differ from that in adults. TB cases in children are usually sputum smear negative or extra-pulmonary and thus fall into category III. In most cases smear is not done due to difficulties of sputum collection in children, severe forms of TB such as meningitis, miliary TB or TB of the spine should be defined as category I. The three tables below show the recommended regimen and dosage for children.

Table 10.2 Recommended treatment regimens for children.

TB disease group	Intensive phase	Continuation phase
All forms of PTB and EPTB except TB meningitis and TB of the spine/bone/joints	2 RHZE	4 RH
TB meningitis, miliary TB, TB of the spine/bone/joints	2 RHZE	10 RH
Previously treated smear-positive PTB (relapse, return after default, treatment failure)	3 RHZE	5 RHE

Table 10.3 Weight-based dosing of anti-TB drugs for children (2-20 kg body weight)

Weight	Intensive phase* (2 months)		Continuation phase (4 months)
	RHZ 60/30/150 mg	Ethambutol 100 mg	RH 60/30 mg
2–2.9 kg	½ tablet	½ tablet	½ tablet
3–3.9 kg	1 tablet	½ tablet	1 tablet
4–5.9 kg	1 tablet	1 tablet	1 tablet
6–7.9 kg	1.5 tablets	1.5 tablets	1.5 tablets
8–10.9 kg	2 tablets	2 tablets	2 tablets
11–13.9 kg	3 tablets	2 tablets	3 tablets
14–19.9 kg	4 tablets	3 tablets	4 tablets

Table 10.4 Weight-based dosing for children using adult anti-TB drug formulations

Weight	Intensive phase (2 months)	Continuation phase (4 months)
	RHZE 150/75/400/275 mg	RH 150/75 mg
5–9.9 kg	½ tablet	½ tablet adult
10–14.9 kg	1 tablet	1 tablet adult
15–19.9 kg	1½ tablets	1½ tablets adult
20–24.9 kg	2 tablets	2 tablets
25–29.9 kg	2½ tablets	2½ tablets
30–40 kg	3 tablets	3 tablets
>40 kg	4 tablets	4 tablets

For children with severe forms of TB, Ethambutol is recommended at a dose of 15 mg/kg (2RHZE/4RH). The feared side effect of retro-bulbar neuritis is rarely seen in children taking higher dosages exceeding 20 mg/kg for a long period of time. Nevertheless, if there is any doubt, an alternative regimen (2RHZ/4RH) for young children can be applied.

For HIV infected infants and children younger than three years old:

ABC + 3TC + AZT is recommended regimen as an option for children who develop TB while on an ART regimen containing NVP or LPV/r. Once TB therapy has been completed, this regimen should be stopped and the initial regimen should be restarted.

10.4.3 BCG vaccination

BCG (Bacille Calmette-Guerin) is a live attenuated vaccine derived from *M. bovis*. In Tanzania, the BCG vaccination is included in the Expanded Programme of Immunization (EPI). The vaccine is given intra-dermally in the upper part of the right arm at a dose of 0.05 ml to all neonates shortly after birth. The dose increases to 0.1 ml if the vaccine is given to children older than one year.

BCG protects young children against disseminated and severe forms of tuberculosis, e.g. TB meningitis and miliary TB. BCG protection may last up to the first fifteen years of life and has no protection against the development of TB in adults. However, it gives some protection against the development of leprosy.

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 with a high prevalence of tuberculosis like Tanzania, 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.

CHAPTER 11: ADHERENCE TO ART AND RETENTION ACROSS THE CONTINUUM OF CARE

11.1 Introduction

Adherence to ART means sticking firmly to treatment regimen by taking HIV medicines every day and exactly as agreed between health care provider, client and treatment supporter (in case of minors). Adherence has been correlated strongly with HIV viral suppression, reduced rates of resistance, an increase in survival, improved quality of life and prevent the spread of HIV to partners and offspring.

Adherence to ART is an essential component of treatment success. Adherence rates of >95% are needed to maximize the benefits of ART. Achieving such high rates over a long period of time is a challenge; therefore different approaches to improving adherence should be sought and tailored to the patient's lifestyle through proper counseling and health education.

11.1.1 Factors that influence adherence

The following have been identified as predictors of good adherence to HIV medications:

- Availability of emotional and practical life support, including assigning treatment assistant at home
- Patients' ability to fit the medications into their daily routine
- Patients' understanding that poor adherence leads to resistance development and may limit future treatment options
- The recognition that taking all medication doses is important
- Patients feeling comfortable to take their medication in a variety of settings including in public
- Availability of a clinic capable of monitoring treatment
- Keeping clinic appointments
- Tolerability of ARVs.

11.1.2 Strategies that enhance adherence

There are three main categories of strategies that those caring for HIV patients must be aware of in order to facilitate improvement and sustain adherence to treatment with ARVs. Below are the different strategies and their applicability:

(i) *Patient related strategies*

- Disclosure of HIV status
- Health care workers should negotiate a treatment plan that the patient understands and to which he/she commits.
- A client's "readiness" to be on life-long medication should be clearly established.

- Client must understand that the first line ART regimen has the best chance of long-term success.
- Family members should be recruited to become participants in the treatment plan.
- Couple/Family counseling.

(ii) Clinician and health team related strategies should include:

- Building a trusting relationship with patients
- Cultivating among health providers attitudes and behaviours that are supportive and non-judgmental to encourage patients to be honest about their adherence and challenges they face.
- Monitoring and encouraging adherence at every clinical encounter.
- Explaining possible side effects associated with treatment initiation
- Linkages to community support.

(iii) Regimen-related strategies

- Regimens should be simplified by using fixed drug combination and reducing frequency of taking drugs
- Drug interactions and side effects should be minimized through rational drug selection.
- Differences between medication requirements (e.g. with food, without food, etc.) should be minimized

11.2 Adherence Monitoring and Evaluation

11.2.1 The role of the Care and treatment team

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 home based care and support activities to ensure a strong client tracking system that will help to understand reasons for missed visits, loss to follow up for both clients on ARV drugs and those that are not yet eligible to start ARV drugs.

The following are important considerations for care and treatment team members:

- All care and treatment team members shall provide ongoing adherence monitoring and timely response to adverse events or interim illnesses.
- Adherence support must be intensified when some negative changes are noted, realized by investigating new barriers, scheduling frequent visits, home care programs, enlisting the support of family/friends, reviewing teaching or increasing the frequency of home visits.
- Health care providers should work in a multi disciplinary team approach to ensure all team members provide consistent messages related to adherence to clients and their adherence assistants.
- Clients and/or treatment assistants or care providers 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
- There shall be in place systems to adequately document indicators for levels of ARV drug adherence for individual clients as well as using collected information to assess performance at site level

Note: Client who takes < 80% of their pill doses are unlikely to have any durable viral suppression and should be targeted urgently for adherence improvement, and 6 month follow up.

All health care team members should adhere to the following strategies:

- Spend time and have multiple encounters to explain goals of therapy and need for adherence.
- Consider monitoring of medications such as Cotrimoxazole or other surrogate medicines prior to ART initiation.
- Negotiate a treatment plan that clients can understand
- Encourage disclosure to identified adherence assistant(s) among family or friends who can support the treatment plan.
- Inform the client before hand of potential side effects including their severity, duration and coping mechanisms.
- Establish “readiness” to take medications before ART initiation.
- Encourage use of alarms, radio, treatment supporters, and family members to remind on the use of ART medication or other available mechanical aids for adherence.
- Prevent adverse drug interactions by advising clients against over the counter drugs and traditional medicines.
- Anticipate, monitor and treat side effects.
- Include adherence discussions in support groups.
- Develop links with community-based and home-based care organizations to support adherence.
- Encourage participation in peer adherence support groups.

11.3 ART Adherence Counselling

When clients test positive for HIV they are referred for care and treatment services. Due to the special characteristics of HIV and AIDS care and treatment, access to care and treatment services signifies the start of a life-long relationship between the client and the care and treatment staff.

Depending on eligibility criteria, the provision of care and treatment services will involve lifelong ARV medication. It is important for client to strictly adhere to ARV medication.

Adherence to care is defined as a patient's ability to follow a care and treatment plan in the long term, attend follow up appointments as scheduled, take medications at prescribed times and frequencies, recognize side effects, seek treatment and follow

instructions regarding food and other medications, as well as avoid risk behaviors and practices such as drinking alcohol, having unprotected sex etc.

Emphasis is on a strict need for 95% or greater adherence to prescribed ARV drugs, for life. There is also more emphasis on viral suppression rather than on curing AIDS. As such, attaining the required level of ARV drug adherence is important because viral suppression cannot be achieved when ARV drugs are not used as prescribed, and for life. This is because viral replication results in the rapid development of mutations of the virus which then becomes resistant to the ARV drug. The consequences of this include a lack of response to treatment by the client; transmission of a drug resistant HIV virus to the client's (sexual) contacts and consequently, the presence of a larger number of people with drug resistant HIV in the community. The resulting programmatic implication of this is the loss of effectiveness of the first line regimen that will have wide public health implications for the entire country. Adherence is therefore a major requirement for successful care and treatment of HIV and AIDS.

11.3.1 First Visit

The client needs to be informed about what to expect when they visit the facility, including whom they will see and when, and if possible the average time they will spend at each visit. This will allow them to adequately prepare for clinic appointments.

During these visits the triage nurse should review the CTC1 card with the client and ensure that the client's information is filled out completely and accurately.

Counseling for treatment adherence

Formal treatment adherence support can be either clinic based or community home based.

a) Formal Clinic Adherence Support

This kind of support entails:

- The provision of consistent messages to client regarding ARV drug adherence. This is done by triage nurses, counselors, clinicians and pharmacy staff.
- Repeating messages regarding adherence at every clinic visit.
- Working in partnership with clients to develop plans for using ARV drugs as prescribed that fit in their lifestyle and a system to monitor the implementation of these plans
- Working with clients and their treatment assistants by supporting a process of disclosure and identifying a treatment assistant if one has not been identified. It should be noted that the presence of an identified treatment assistant is not a criteria for initiating ARV drugs. This means that clients with no treatment assistant who have been assessed and are ready to start should be provided access to ARV drugs
- Learning from clients about the potential drug, clinical, environmental and individual barriers to adherence and using problem solving approaches

either help clients to overcome the barriers or advocate for changes that will remove external barriers that are not under the client's control.

- Adherence monitoring systems at facility level using assessment of the level of adherence at every visit, (self report method is recommended) and objective evaluation of adherence such as unannounced pill counts.

b) Formal Community Home-based Support

Formal community home based support requires:

- The presence of an active home-based care programme.
- Active linkages with community-based programmes for the care and support of persons living with HIV and AIDS. These services include referral to and from HIV and AIDS counseling and testing services, PMTCT services, mental health services, as well as psychosocial support services. This may be in the form of post test clubs, adherence support groups, legal aid, nutrition counseling and income generating support.

All CTC staff providing direct services to clients (clinicians/prescriber, nurses, counselors, pharmacy staff, phlebotomists, laboratory technicians, and home based care providers) should receive treatment adherence related training using approved national curricula.

Specific guidance for adherence counselors organized to address issues that should be done at each of the visits prior to the initiation of ARV drugs and at each subsequent follow up visit are listed below;.

During the first visit the counselor should:

- Review client's basic knowledge on HIV infection and development of AIDS and correction of misconceptions.
- Review if client understands of how HIV is transmitted and how ARV drugs affect HIV transmission risk and provision of information where gaps in understanding are evident.
- Provide information on the monitoring of the HIV disease with particular focus on the implication of CD4 lymphocyte counts and viral load levels, to make sure that these are well understood by the client. Adherence counseling aids/brochures should be used for demonstration.
- Discuss ART as a lifelong treatment.
- Provide information on the strictness of treatment adherence in ART while emphasizing that adherence to recommended treatment regimens should be greater than 95%. Review with client their previous adherence practices to medical recommendations and provide practical examples of what adherence greater than 95% would mean for the client.
- Establish whether client has identified a treatment assistant; document such information in the counselling log book, and encouraging the client to attend his or her next clinic session with the identified treatment assistant.
- Explore with client the advantages and disadvantages of sharing their test results; addressing barriers to disclosure and develop with the client a disclosure plan that should be documented for supportive follow up visits.

- Discuss HIV transmission risks and helping the clients to assess their own risk and develop risk reduction strategies which should be documented for supportive follow up visits.
- Discuss other aspects of the client's lifestyle focusing on how this might influence current and continued lifelong use of ARV drugs.
- Provide brief counseling interventions for clients that use alcohol.
- Encourage clients to consider the viability of abstinence from alcohol and using a similar approach for other substances of abuse.
- Provide time for questions from the client and responding accordingly.

11.3.2 Second Visit

This adherence counseling session prepares the client for the assessment of readiness to start ART. This visit will also be a rapid start initiation visit for adult clients clinically assessed to be at WHO AIDS Stage 3 and 4 or who have a CD4 count <350 cells/mm³ at baseline regardless of HIV clinical staging.. For rapid start clients follow the bulleted steps to complete preparedness and initiation of ARV drugs outlined at the end of this section.

During the second visit, the adherence counselor should:

- Review risk reduction and life style change plans and their implementation. Address barriers to implementation and help the client to revise their plan if necessary and document the process.
- Assess the mood state of the client, document it and alert a physician if depression or anxiety disorder is suspected. Document and provide supportive counseling.
- Review the client's implementation of disclosure strategy and plans for the identification of a treatment assistant. If a client has not yet disclosed his or her HIV serostatus, identified a treatment assistant, review the plans and address barriers accordingly.
- Review client's knowledge on how ARV drugs work to prevent HIV transmission and correct misconceptions
- Provide information on first line ARV drugs and their potential positive and negative effects, criteria used to initiate clients on ARVs; discuss that ARV drugs are lifelong treatment and not a cure for AIDS. Provide education on reasons for the need to take every dose as prescribed and counsel on medicine adherence; use pamphlets where available to illustrate the relationship between missing doses and the development of ARV drug resistance.
- Work with the client to develop a treatment adherence plan that explores potential barriers and enablers of adherence to ART including potential solutions to identified barriers. For details see the NACP Adherence Toolkit, section 2.1,
- Set enough time for questions from the client and respond accordingly.

11.3.3 Third Visit

For the third CTC visit, confirm readiness to start ARV medicines and initiate the client with medicine when the baseline CD4 counts are ≤ 500 copies/ μ l in adults

and children below two years with confirmed HIV diagnosis, or children 24-60 months old with CD4 cell per count below 700 copies/ μ l ($\leq 25\%$);

In all visits the counselor should:

- Review the implementation of risk reduction and lifestyle change plans with the client, and document successes, barriers and revisions in plans where these occur.
- Assess the client's mood state, document it and alert a physician if depression or anxiety disorder is suspected, and document and provide supportive counseling if any abnormal mental condition is identified.
- Review the client's knowledge on ART and ARV first line drugs, potential positive and negative effects; the criteria used to initiate clients on ARVs as in the first and second visits.
- Review the client's implementation of disclosure and treatment assistant identification plans, revising where necessary and document successes, barriers and revisions to plans
- Review the outcome of implementing solutions previously agreed on the barriers to regular use of ARV medicine that the client identified (to be done only for regular start up clients); to review with the client their treatment adherence plan and explore potential solutions for accessing ARV drugs when unexpected travel occurs, and to document any changes in adherence plans in the counseling log book.
- Discuss with the client results of the readiness to start assessment and confirm readiness to start ART.
- Provide time for questions from the client and respond accordingly.

Guidelines under this section will address follow up visits after initiating ARV drugs. The nurse counselor will:

- Review and document the client's knowledge on the ARV medicine prescribed and their dosage. Some tips to assess adherence from self report include:
 - Using a model (of all ARV drugs available at a clinic) to help the care provider or adolescent client to identify types of drugs used, number of ARV tablets used in each time and timing of use rather than referring to the last prescription.
 - Checking prescribed medication to see if it matches the client's reported drug use.
 - Discussing and correcting any misunderstanding of how drugs should be taken, the timing, the number of pills and whether they should be taken with or without meals.
- Explore missed doses with the care provider or adolescent client and document the number of missed doses since the last visit.
 - Explore the number of missed doses on each drug in the past week and the past month. Establish % of total medicine prescribed and that taken for the past month and document if level of adherence is at $>95\%$ or not.
 - Review the client's knowledge on ART, tell him/her that medicines

are of lifelong treatment and is not a cure for AIDS.

- Review knowledge of reasons for the need to take every dose as prescribed. Use pamphlets where available to illustrate the relationship between missing doses and the development of ARV drug resistance.
- Explore and document the potential and negative effects from ARVs and other medicines.
 - Review information on first line ART regimen and explore experiences with positive effects and side effects.
 - Discuss with the care provider or adolescent client strategies to minimize drug side effects.
- Explore factors that may prevent and those that may facilitate correct use of drugs in the care provider or adolescent client's environment tool and discuss on possible solutions of the barriers.
 - Discuss drug storage at home.
 - Using the care provider or adolescent client tool, review and plan with client on how to take their ARV drugs as prescribed. Document if any changes occur to previously agreed plan.
 - Discuss what the clients will do to ensure they have sufficient drugs in the event of unexpected travel before their next clinic visit.
- Explore disclosure and treatment assistance. Document the items as follows
 - The outcome of the disclosure plan while encouraging or formulating a new plan if disclosure has not occurred.
- Presence of a treatment supporter, if none encourage the client to identify one Preventive counseling including risk reduction and lifestyle modification counseling.
 - Review implementation of risk reduction strategies and encourage change or help treatment supporter or client to plan new strategies.
 - Review implementation of agreed lifestyle modification and encourage change or help treatment supporter or a client to plan new strategies for a change.
 - Assess the mood state of a client.
- Provide time for questions from treatment supporter or client and respond accordingly.

Checklists should be used in the CTCs to structure adherence counseling sessions and for documentation of counseling sessions. Using checklists and documenting counseling sessions helps to improve the quality of counseling delivered as it informs areas that need to be strengthened through supportive supervision and continued in service training. Counseling checklists for children with their care supporter and for adolescents' counseling visit is found in NACP Adherence Toolkit, section 1.2.

11.3.4 Management of previously ARV exposed patients

Treatment for patients who have been previously exposed to antiretroviral therapy should be discussed by the CTC team touching on issues such as adherence levels and intensify adherence. Generally:

- Patients that are controlled on their antiretroviral medication at appropriate doses should continue on the same regimen if possible.
- Those who stopped for reasons other than treatment failure and for whom failure is not suspected, can restart the original regimen.
- Those known or suspected to have failed a previous regimen should be started on drugs they have not been exposed to before as appropriate.

11.4 Adherence Management and Lifestyle Counseling

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 for clients on long term therapy or prophylaxis including ARV treatment.

During monthly visit to the CTC, each client will be screened for TB and provided with relevant prophylaxis as indicated. 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 (positive prevention), 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 PLHA support groups will also be addressed during the counselling session. In addition, clients will be screened for other OIs for early identification, treatment or prophylaxis.

Note: Adherence assessment checklist is described in specific codes within the 2010 CTC2 card that is kept by the patient file.

11.5 Adherence Issues in Adolescents and Youths

HIV infected adolescents and youths are subjected 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:

1. Dedicated adolescents and youth friendly services/clinics
2. Adequate support from caregiver, family, and friends.
3. Stability in one's life so that they are able to obtain basic needs as well as play and attend school like other children
4. Beneficial and early disclosure leads to increased participation in their treatment
5. Change in health status or laboratory parameters, encourages continuation of treatment
6. 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.
7. 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 he will adhere to the regimen.

8. Access to a supportive clinician may also provide discussing options. Adolescents are curious and should be given as much information by the HCP.
9. Supportive community that do not stigmatize HIV clients

Factors affecting drug adherence among adolescents

1. Unstable living conditions where s/he moves from one guardian to another or if living in the streets
2. Lack of support from guardian, family and friends. Lack of readiness and refusal
3. Depression: Individuals who are depressed lack the motivation to carry on with life's activities
4. Drug abuse - Substance use makes it difficult for individuals to adhere to treatment. Alcohol use increases the risk of ARV drug toxicity.
5. Death ideology
6. Mental health issues

Strategies for enhancing ARV drug adherence among adolescents

1. Consider practicing drug adherence with vitamin pills, IPT and Cotrimoxazole-prophylaxis.
2. Involve adolescent when discussing treatment options
3. 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
4. The health care provider (HCP) should develop a good relationship with the adolescent so that they regard them as their partners in health.
5. The members of the counseling and testing team with the best relation to the adolescent should take the lead in the counseling and support of adolescent
6. Regimens should fit into the adolescent's life as much as possible. Remind adolescent that they need to continue taking the drugs even when they are feeling unwell or feeling well.
7. Use of simplified regimens, preferably ARV taken at once; this is likely to work best
8. Positive approach to treatment that nurtures the adolescent's belief in their success. This task should be taken by the adolescent themselves as well as their family, friends and the HCP
9. Information should be given proactively, in appropriate simple and understandable language and in writing as adolescents may not ask questions on their own.
10. Use real life examples to illustrate issues as adolescents often think in concrete terms
11. Explain to adolescents what to expect while on therapy and how to manage potential positive and negative side effects and adherence problems.
12. 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

1. Encourage adolescent to establish a schedule for taking drugs

2. They should keep the drugs where they can see them in the morning and evening.
3. They must take the ARV drugs at the same time every morning/evening.
4. They can 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
5. They should 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
6. They should plan ahead to take ART when they are away from home.
7. They should plan for sudden events that change their normal schedule and therefore always have a few tablets with them.
8. The adolescent should 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.

11.6 Adherence Issues in Children

- Adherence in children is a special challenge because of the interrelationship of factors relating to children, caregivers, medications.
- Good adherence means that children must take their medications every day as they are prescribed without missing doses.
- Adherence in children is more challenging as children rely on a responsible parent/caregiver for medication. Mothers of HIV-infected children are often HIV-infected themselves; therefore the care of the child may be affected by the mother's compromised health. It is preferable that a secondary (back-up) informed caregiver be involved in the care of an HIV-infected child.
- Psychological support is critical for caregivers as well as children, and peer support groups may be particularly beneficial for mothers with young children on ART.
- Appropriate disclosure can improve adherence. An older HIV-infected child who understands about his/her infection can be actively involved in ARV treatment.
- Adolescents have specific challenges to adherence which need to be addressed (see Adolescent Adherence section).
- For adherence success it requires commitment and knowledge on the part of the child/adolescent and primary caregiver.
- Changes in paediatric dosages as the child grows can also affect adherence
- A good relationship between healthcare providers and the caregiver helps optimise adherence.

11.6.1 Factors That Influence Adherence in children

The care provider should inquire to find out the factors that are likely to affect child's adherence:

a) Child related factors

Child related factors include the living environment of the child, the child's age, the complexity of the drug regimen, and the health status of the child, including other medications the child is also taking.

b) Family/caretaker related factors

Family/caregiver related factors include the 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.

c) System related factors

System related factors include the relationship between the caregiver and the clinician, medication stock outs and contradicting information from different health providers regarding medication regimen.

11.6.2 How to prepare for adherence in children

The healthcare provider should:

- Establish parent/caregiver readiness to start ARVS
- Disclose child's status and need for lifelong treatment to responsible parents/caregiver
- Identify responsible person for daily drug administration
- Family centered approach is recommended which should include testing of other family members, including all children, and enrollment of the mother in ART Conduct joint session with parent/caregiver, drug dispenser and the child (depending on age and disclosure status).
- Conduct demonstration sessions on drug dosages and administration
- 11.6.3 Considerations for readiness to start treatment for children
- Before starting medications, the healthcare provider should consider the following:
 - Parent/caregiver understands importance of clinic visits and maintaining CTC 1 card.
 - Understand roles of different household members in drug administration
 - Relevant household members trained
 - Criteria for readiness to start are met
 - If caregiver is ready to start, ART may be initiated on the same clinic day

11.6.4 Strategies for Successful Adherence among children

- Before ANY medications are started, every patient must be assessed for treatment READINESS with all potential barriers identified and addressed.
- Strategies for adherence MUST be household or family oriented
- Adherence counseling is ongoing process and takes time and commitment.
- Ensure use of relevant checklist and SOPs
- Adherence must be addressed at EVERY patient visit.
- Review strategies regularly: to meet the changing needs of the growing child.
- Work as a team – doctors, nurses, pharmacists, counselors all reinforce adherence.
- Identify one household caregiver who gives medication to child and should attend clinic as well

11.6.5 Common challenges and strategies to improve adherence in children

CHALLENGE	STRATEGIES
1. Child not taking medications Parents/caregiver reports that the child not taking his/her medications.	<ul style="list-style-type: none"> ➤ 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 child sick Caregiver/parent reports the child becoming nauseous and vomiting after taking medications	<ul style="list-style-type: none"> ➤ Administer medications with food ➤ Administer medications with liquid to help reduce gastric irritation ➤ Reassure caregiver/parent that most nausea and vomiting will resolve ➤ If symptoms are severe, consider expert advice on regimen change and timing of medication.
3. Fear of medicines harming the child A caregiver/parent reports the child is clinically deteriorating but that the child has good adherence. The caregiver/parent is worried that the antiretroviral medications will harm the child	<ul style="list-style-type: none"> ➤ Ensure that the child is taking the correct dose ➤ Evaluate the child for other opportunistic infections ➤ Evaluate 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 ask for expert advice about changing the regimen. ➤ Utilize visiting nurse/HBC provider services to assist with adherence assessments and follow up home visits.

<p>4. Regimen dosing confusion</p> <p>A caregiver/parent becomes confused about the medication regimen</p>	<ul style="list-style-type: none"> ➤ Provide 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.
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11.6.6 Consequences of poor adherence in children

Consequences of poor ARV adherence in children include treatment failure, growth and developmental faltering and risk of development of opportunistic infections.

11.7 What Happens to Adherence Over Time?

Adherence declines over time, which is an important phenomenon of treatment fatigue. That is why the real challenge to treatment success is not initial adherence, rather long term adherence. In this regard, the regimen to be chosen should be one that patients can adhere to for life.

11.8 What Needs to Happen to Ensure ART Success?

- Continual adherence support to overcome adherence decline overtime
- Proactive follow up of clients to reduce loss to follow up and increase retention rates.
- Continual quality improvement of ART services.

CHAPTER 12: MANAGEMENT OF MENTAL HEALTH CONDITIONS/DISORDERS IN HIV AND AIDS

12.1. Introduction

Mental disorders are more common in HIV infected than in non-infected people. In some instances, this is due to mental conditions existing prior to the HIV infection (which increases the risk of infection) while in other instances HIV could result in mental health condition as psychological consequence of the infection or because presence of the HIV virus on the brain. There is a strong evidence of the relationship of substances use disorders and mental illness with HIV infection. [Chandra et al 2005] Therefore there are two groups of people who develop mental health conditions and HIV infection

- Those with pre-existing mental illnesses who become secondarily infected with HIV
- Those who are HIV positive and present with mental health conditions (either directly or indirectly)

There are five common groups of mental health conditions among people with HIV/AIDS are:

- Mood Disorders (i.e. Depression and Mania)mania, adjustment Disorders, post-traumatic stress disorders,
- Organic Disorders (Delirium and Dementia)
- 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 etc)
- 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. They include delirium with or without focal neurological signs or with signs of meningeal irritation and HIV associated dementia. Preexisting mental disorders are associated with increased risk of acquiring HIV infection. This group of patients often comes to ART services with special management needs.

12.2. Primary Neurological Complications that have Secondary Mental health Manifestations

12.2.1 Delirium

Definition

Delirium is a state of altered consciousness marked by anxiety, incoherent or disorganized speech, disorientation and hallucinations. The distinguishing features include drowsiness, lethargy and a changing level of alertness. The person has difficulties with attention, focus and judgment, and there may be perceptual disturbance such as seeing things that are not there. Children and adolescents may present with disruptive or altered behaviours and may be less able to describe their experiences. All these symptoms usually develop over hours or days and the presentation fluctuates. Delirium is generally a direct physiologic consequence of a medical condition.

Importance

The diagnosis of delirium should be considered first when one meets with acute onset of disturbed consciousness. Delirium may be life threatening and requires immediate medical attention. It often occurs in patients with severe medical illness, pre existing dementia, substance intoxication/withdrawal and acute head injury. Delayed diagnosis and management of delirium can be fatal. When assessing children and adolescents, family members can be very helpful in alerting the clinical staff to the unusual nature of their child's behaviours.

Epidemiology

As many as 30% to 40% of hospitalized AIDS patients develop delirium and up to 80% of patients with terminal illnesses including AIDS patients develop delirium near death. The rate is higher in elderly persons with AIDS. Most critically, the mortality rate of patients with delirium can be high.

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

Among children and adolescents, delirium caused by medications may be more common, especially when there is a lack of pediatric formulations of medications.

Diagnostic Features

Onset is usually acute, over hours or days. The patient appears disoriented and struggles to understand surroundings because of clouded thinking and diminished awareness. The disturbance tends to fluctuate during the course of the day. Delirium in HIV infected patients can present with a spectrum that includes: labile affect; impairments of memory, attention, and orientation; difficulty with logical thinking; and impaired judgment. Thinking and language may be affected by decreased verbal fluency. Patients may also be over talkative. Characteristic perceptual disturbances are visual hallucinations and illusions (misinterpretation of visual cues, such as mistaking shadows for people). The HIV infected patient may present with impaired psychomotor functions, which may be in the form of decreased activity, increased activity or a mixture of both. The patient may show daytime lethargy and night time agitation with an altered sleep cycle. When delusions are present they are often paranoid and episodic. Neurological abnormalities that have been reported in these patients include tremors, ataxia, myoclonus, cranial nerve palsies, asterixis, cerebellar signs and nystagmus.

Differential Diagnosis

Delirium is often misdiagnosed as a primary psychiatric disorder. When patients appear hypoactive, depression is a frequent misdiagnosis for delirium. Clinicians should maintain a high level of suspicion for delirium related to CNS infections, substance including alcohol use, and among HIV infected patients, multiple medication interactions and/or toxicity.

Acute Management

The appropriate treatment of delirium involves interventions to search for and correct underlying causes of delirium, as well as relieve current symptoms. Joint and coordinated management of the patient with delirium by the doctor, medical assistants, other primary care or specialty clinicians will frequently help ensure appropriate comprehensive evaluation and care.

Identifying the Aetiology

An essential principle in the management of delirium is the identification and correction of the aetiological factors. Careful review of the patient's medical history and interview of family members or others close to the patient may provide some direction.

Appropriate laboratory and radiological investigations may be necessary to determine the underlying cause(s) of delirium. The choice of specific tests to be undertaken will depend on the results of the clinical evaluation. Common differentials for new onset seizures include cryptococcal meningitis, toxoplasmosis, and a cerebral lymphoma. Central nervous system causes include space occupying lesions, cerebral tuberculosis, brain abscess, Cryptococcal infection, toxoplasmosis, bacterial and fungal meningitis. If excessive alcohol use with features suggestive of dependence on alcohol has been reported to be a problem, the possibility of alcohol withdrawal syndrome due to relative or total reduction in alcohol use should also be ruled out.

12.2.2. 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 often affected with behavioral and personality changes that significantly affect the individuals quality of life. There is no clouding of consciousness in HAD.

Epidemiology

In the United States, before highly active antiretroviral therapy (HAART) came into existence, 40 to 60 percent of HIV infected people used to develop HAD. Now, it is estimated that only 27% of people infected with HIV develop HAD. However, cognitive impairment is still the most common CNS complication of HIV infection. Contrary to earlier beliefs, recent reports indicate that HAART does not seem to decrease the prevalence of HAD, however when viral suppression occurs, cognitive performance improves. HAD is also said to be more serious in people above 60 years of age and takes a more fluctuating course in older people than in younger age groups.

Risk Factors

It is well known that not all patients infected with HIV develop HAD. Older age and increased level of immunodeficiency are known risk factors for the development of HAD. In the pre HAART era, HAD almost always occurred in cases whose CD4 count was less than 200 cells/ μ l, where viral load was significantly elevated. However, recent observations indicate that cases with low CD4 count and very low viral load also develop HAD. There seems to be growing evidence that HAART does not prevent neuropsychological impairment but may alter the type of impairment experienced and delay the onset of dementia.

Diagnosis of HAD

HAD can produce different combinations of progressive cognitive decline, motor dysfunction, affective changes and behavioral abnormalities. Generally, cognitive and motor symptoms occur early and include word finding difficulty, forgetfulness, psychomotor slowing and diminished writing or visual/motor skills. But, HAD shows a highly variable clinical course and spectrum of signs and symptoms, ranging from subtle cognitive, affective behavioral and motor impairments to profound dementia. Seizures, global cognitive deterioration, mutism, incontinence, and severe confusion are other common clinical features of late stage HAD.

Clinical Manifestations of HIV-associated Dementia (HAD)

Affective impairment is usually in the form of apathy, irritability and sometimes manic symptoms (new onset psychosis). Behavioural changes include psychomotor retardation (slowed speech and response time), personality change and social withdrawal. Common cognitive changes include lack of visual spatial memory (misplacing things), poor visual- motor coordination, and difficulty with complex

sequencing (difficulty in performing previously learned complex tasks), impaired verbal memory (word finding ability), impaired concentration and attention. Patients will often show motor changes such as unsteady steps, loss of balance due to leg weakness, dropping things, tremors, poor handwriting and decline in motor skills.

Differential Diagnosis

The early stage of HAD may be subtle in its presentation causing difficulty to distinguish it from other primary psychiatric disorders including substance use disorders, intoxication and alcohol withdrawal. In contrast to Alzheimer's disease, which is a cortical dementia, HAD is a sub cortical dementia. Clinicians should exclude other treatable, reversible causes of change in mental status such as CNS opportunistic infections and malignancies before a diagnosis of HAD can be made. Cognitive impairment may occur as an accompanying feature of a depressive episode. The term pseudo dementia is used to describe this clinical presentation, which resolves with appropriate treatment of the depressive disorder.

Investigations

Take a thorough history, inquiring about medications, time of onset and course of symptoms, drug and alcohol use, opportunistic infection symptoms, HIV history, including duration, opportunistic infections, and CD4 levels. Physical/neurological examination should include checking temperature and other vital signs, thorough physical and neurological examination to determine potential reversible causes such as opportunistic infections. MRI/CT scans can exclude other CNS disorders (where available).

Diagnostic Tests

Commonly requested tests are: FBC with differential, serum analysis, serological tests for syphilis, serum B12 and folate (where available), and CD4 count. A lumbar puncture may be necessary to rule out acute infection, such as bacterial meningitis, Cryptococcal meningitis, and toxoplasmosis.

Acute Treatment

ARV medication should be continued. In addition to treatment of the existing opportunistic infections, use antipsychotic medications to treat agitation and hallucinations. Because patients with HAD are sensitive to anticholinergic side effects and extrapyramidal symptoms, antipsychotic medications should be given in low dose and increased slowly while carefully monitoring side effects and treatment response. Giving haloperidol 1.5 mg per day with slow increase in the dosage depending on the response would control agitation and some delusional beliefs. If available, atypical antipsychotic agents such as olanzapine and risperidone can be used starting with low doses. For patients on PIs like ritonavir and NNRTIs, use with caution as increased or decreased levels of Psychotropics may occur because they are metabolized by the same enzyme in the liver. Avoid benzodiazepines, which tend to increase confusion and decrease concentration.

Long-term Treatment

Involve family members/treatment assistants in both medication management and

attending clinics and educate them about HAD. Assess independent functioning in the home and refer to home based care when assistance in care is indicated. Advance attention should be paid to living wills, health care proxies and durable power of attorney to allow patients to make decisions about their treatment and lives before they become too ill to do so.

12.2.3. HIV-Related Mania

Definition and Characteristic Features

AIDS related mania is thought to be secondary to HIV CNS involvement and affects about 4% of clinic patients. It is characterized by loss of the ability to control mood, and presents with elated or irritable moods (either occurring acutely or sub acutely), increased activity and energy regardless of physical status, decreased need for sleep and an exaggerated sense of self importance. Behavioral changes centre on increased activity, perceived increased energy, intrusiveness and uninhibition. The condition occurs with more advanced immunosuppression and is often associated with HIV related cognitive impairments.

Management

ART treatment relieves the symptoms of AIDS related mania. In the Tanzanian context, mood stabilizing drugs such as sodium valporate (used at doses for treatment of epilepsy) have been noted to be useful for the control of acute symptoms in patients that are on ARV. Other antiepileptic drugs such as carbamazepine and lamotrigine are also powerful mood stabilizers. When carbamazepine is prescribed, drug doses should be adjusted within one-two weeks of treatment as carbamazepine induces liver enzymes and increases its own metabolism as well as that of other drugs metabolized in the liver such as ART drugs. If possible, they should be avoided in patients on ART.

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. A syndromal diagnosis should be made for all these conditions.

Adjustment Disorder

This condition occurs predominantly at the time of HIVD (HIV disease) diagnosis and the disorder includes acute and chronic adaptation responses to HIVD diagnosis. These responses include fear of discrimination and imminent death, guilt over infecting others, exacerbation of existing mental health conditions and acute suicidal ideation. With HIVD progression, patients also need to adapt to changes in their lives brought about by each new symptom and loss event such as death of an intimate partner or child as a result of an AIDS related condition. The nature of the adaptation response will influence the patient's ability to:

- Disclose his or her sero-status to others.
- HIV-related self stigmatization

Adjustment disorder has been noted to be a major barrier to sharing test results and hence prohibiting access to social support that may protect patients from many other mental health consequences of HIVD.

- Adopt safer sexual practices
- Adopt safer infant feeding options for postnatal mothers
- Access medical and mental health care
- Define those involved in his or her care.

Management

Supportive medical/clinical counseling is the mainstay of more positive adaptive responses to HIVD diagnosis. Issues to consider during counseling following loss and crisis are noted below.

12.3. Addressing Loss and Crisis amongst PLHIV

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 has experienced. There are six stages of bereavement. These are: shock, denial, anger, bargaining, depression and acceptance. Among PLHIVs 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 may be generated by a person's response to rapid disruption of personal affairs. Examples can include the breakup of an intimate relationship, the aftermath of an earthquake, rape or other forms of assault. A crisis situation is a critical 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, and in the case of HIV and AIDS, the triggers that lead to crisis might be death of another PLHIV, emergence of a new symptom, treatment failure or anything that is perceived by the patient as a severe life event.

Management

Management is through bereavement counseling. This is a form of supportive counseling with the objective of identifying with the patient, loss events and responses to these events as well as aiding the process of acceptance and constructive adaptation. A crisis situation takes the form of a blow, withdrawal and acceptance, and as with loss events, is best managed through counseling.

Note: Health care workers are encouraged to refer to a manual on HIV and AIDS counseling for issues related to different aspects of counseling.

12.4. Anxiety Disorders

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. The initial fear accompanying an HIV diagnosis tends to subside and then persist at a lower level. Symptoms of anxiety disorders are both psychological and physical due to physiological arousal. The wide range of physiological manifestations include: shortness of breath, chest pain, racing/pounding heart, dizziness and gastrointestinal disturbances, which may overlap with symptoms of other common medical disorders. In addition, patients present with fear, worry, insomnia, impaired concentration and memory, diminished appetite, compulsive rituals and avoidance of situations that make them anxious.

Diagnosis

An anxiety disorder occurs when symptoms interfere with a patient's daily functions, personal relationships and cause marked subjective distress. Even brief episodes of anxiety, such as those occurring during a panic attack may interfere markedly with a patient's life and warrant diagnosis of an anxiety disorder. Other Anxiety disorders are differentiated from adjustment disorders by the lack of a clear precipitant, and from major depression by the absence of somatic features of depression. CNS pathologies, metabolic illnesses (e.g., hypoxia), endocrinopathies, and respiratory and cardiovascular conditions may also mimic (resemble) anxiety disorders and should be ruled out.

Management

General measures that help in the treatment of persons with anxiety disorders include reassurance, psycho education and supportive counseling when the level of anxiety does not interfere significantly with social or occupational functioning.

Medications are used when anxiety interferes significantly with sleep or daily functioning. In such cases, the patient's fears should be discussed in an empathic manner in subsequent sessions and the patient informed that medication will be provided for a short time to help decrease the intensity of symptoms until they can cope better. Patients are going to benefit with low doses of antidepressants like TCAs and SSRIs (e.g. Amitriptyline and fluoxetine respectively) e.g. low doses of Amitriptyline one may start with 12.5 mg daily may alleviate the symptoms. Short acting benzodiazepines can be used but there is a risk of dependence.

Persons with anxiety disorders should be encouraged to join psychosocial support groups i.e., support groups where people with common concerns and needs can share their experiences and help each other through difficult periods and therefore achieve better health and well being.

12.5. Major Depressive Disorder

Definition and Importance

Depression is a common mood disorder characterized by low or sad mood, loss of interest or pleasure, feelings of guilt, suicidal thoughts, disturbed sleep, appetite and weight changes, poor attention and concentration, changes in energy level/

fatigue and psychomotor disturbances. Behavioral changes may alert a physician about possible depression including; change in treatment adherence, inability to make life/medical care choices, preoccupation with minor problems, change in functioning, social isolation, interpersonal problems, difficult behaviours in the medical setting, or initiation/return to substance use. Patients may be reluctant or unable to recognize their depressed mood that should be recognized by the attending health care provider and reflected back to the patient.

Importance

Major depression is a mental disorder that affects the mind and body and therefore presents with both psychological and physical symptoms. If untreated depression undermines adherence to medical recommendations and physical survival. About 15% of people that are depressed for more than a year commit suicide. Suicide risk must be assessed and if moderate or high it should be addressed accordingly.

Epidemiology

About 20% to 40% of PLHIVs accessing medical services suffer from depression. Prevalences for major depression among patients with HIV infection only and patients with AIDS have been estimated to be between 15% and 40%, far above the prevalence for the general population {Angelino et al } PLHIVs have at least twice the rate of depression in the general population. Depression is associated with more rapid progression of HIV and AIDS disease and is generally more common among women compared to men.

Risk Factors

Risk factors of depression include:

- Past/Family history of depression
- Female gender
- Adverse life events
- Chronic medical illness including HIV/AIDS
- Lack of social support

Note: An adverse social environment is damaging while positive social support is protective.

Diagnosis

Depressed mood and/or loss of the ability to experience pleasure or interest in normal activities (anhedonia) must be present for more than two weeks and cause significant difficulties in normal functioning (inability to attend to schooling, work or household chores).

Any four of the following also need to be present for a diagnosis of depression:

- Excessive worry, with or without physiological symptoms of anxiety
- Fatigue or loss of energy experienced more on waking up in the morning;

psychomotor retardation (taking a longer time than usual to accomplish tasks or make decisions)

- Unexplained pain (headaches, backache, chest tightness or pain when swallowing, generalized body malaise/aches and pains often reported as “homa”)
- Sleep disturbances characterized by being unable to maintain sleep or a terminal insomnia and/or disturbing dreams
- Decrease in sexual desire
- Decrease in attention and concentration
- Constipation and decreased appetite and weight loss Psychotic symptoms (hallucinations and delusions) may occur with more severe forms of depression.

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 abuse (may be associated with depression)

Management

Antidepressants should be started in low doses, about 50% of dosage for healthy individual of similar profile. PLHIVs tend to be more sensitive to the side effects of psychotropic medicines.

Always initiate treatment with low doses to minimize risk of serious side effects. Tricyclic antidepressants (TCAs) like amitriptyline and imipramine can be used, but selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, fluvoxamine and escitalopram that have fewer side effects are recommended. (PIs interact with SSRIs and TCAs). It is important to ensure adequate doses and for adequate duration (maintenance drug treatment provided at therapeutic dose for 6 months after resolution of symptoms), combined with supportive counseling.

Referral to mental health services is advisable should depressive symptoms not resolve within four weeks of initiating drug treatment. Antidepressants do not treat psychotic symptoms and when present they should be treated with an antipsychotic drug. Care should be taken for possible interactions between antidepressants and ARVs as shown in the following table 12.1.

Table 12:1 Antidepressant dosage and possible ART interactions (there is need to incorporate more medications in drug interactions like antipsychotics, anxiolytics and mood stabilizer).

Drug groups of antidepressants (AD)	Specific drugs/ registered Tanzania	Dose range (mg)	Interactions with ARVs
1. Tricyclics	Amitriptyline Imipramine	25–75 per day	Lopinavir/r & ritonavir increase antidepressant (AD) levels in serum
2. SSRIs (serotonin specific re-uptake inhibitors) (Recommended in patients on ART)	Fluoxetine	10–20 per day	Nevirapine decreases AD level; AD increases levels of Amprenavir, Delavirdine, Efavirenz, Indinavir, LPV/r, Ritonavir, Saquinavir

12.6. Alcohol and Substance Use Disorders

Definition and Importance (*binge drinking, alcohol abuse, and dependence*)

The term “alcoholism” refers to a disease known as alcohol dependence syndrome, the most severe stage of a group of drinking problems which begins with social drinking, binge drinking and alcohol misuse (hazardous use). Alcohol problems occur at different levels of severity, from mild and annoying to life threatening. Although alcohol dependence (alcoholism) is the most severe stage, less severe drinking problems can also be dangerous.

Social drinking refers to casual collateral drinking, usually without the intent to get drunk. It is variable depending on the social or cultural group in question. Binge drinking means having five or more drinks in one session for men and four or more for women, or simply drinking to get drunk. This turns into alcohol misuse when someone’s regular drinking begins to cause problems and the drinking becomes habitual. In spite of continued social, interpersonal or legal difficulties the person continues to drink.

12.6.1 Alcohol Dependence

Alcohol misuse becomes alcohol dependence when drinkers begin to experience a craving for alcohol, a loss of control of their drinking, an increased tolerance to alcohol so that they have to drink more to achieve the same effect and withdrawal symptoms when they are not drinking. Alcohol dependence is a chronic and often progressive disease that includes a strong need to drink despite repeated problems.

12.6.2 Alcohol, Substance Use and HIV

Drug abusers have special clinical needs which require mental health skills and sensitivity in terms of assessing patients' risk behaviours and preparedness of HIV counseling and testing.

People who misuse alcohol or any other type of substance abuse are more likely to engage in HIV transmission sexual and drug use risk behaviours. For example, rates of injection drug use are high among alcoholics in treatment, and increasing levels of alcohol use are associated with greater injection drug-related risk behaviours, including needle sharing and unsafe sexual practices. A history of heavy alcohol use has been correlated with a lifetime tendency toward high risk sexual behaviours, including multiple sex partners, unprotected intercourse, sex with high-risk partners (e.g., injection drug users, prostitutes), and exchanging sex for money to finance addiction. . Alcohol misuse and other substance use occur frequently among people whose lifestyle or personality predisposes them to high risk behaviours in general.

Studies show that decreasing alcohol use among HIV patients not only reduces the medical and psychiatric consequences associated with alcohol consumption but also decreases other drug use/abuse and HIV transmission. Thus, alcohol and other drug abuse treatment can also be considered primary HIV prevention.

12.6.2.1 Diagnosis

Look for signs of alcohol dependence (alcoholism or addiction). Does the patient's pattern of alcohol use lead to distress to self? to others? Are there evidences of tolerance (reports of needing to use larger amounts to become intoxicated) to alcohol and/or avoidance of withdrawal symptoms by drinking in the mornings? If yes to two of any of these questions, establish signs of strong desire or compulsion to use alcohol and difficulty controlling alcohol use.

Do you see withdrawal features? There is a history of recently stopping or decreasing alcohol use after prolonged heavy drinking, with two or more of the following a few hours or days after stopping heavy use: tremor, sweating, increased pulse rate (<100), insomnia, nausea and vomiting, anxiety, transient visual or auditory hallucinations, psychomotor agitation and grand mal seizures.

The above symptoms create distress and impair general functioning. Make sure the changes are not due to a physical illness or another mental disorder.

Do you see hazardous alcohol use patterns and complications? Hazardous alcohol use means repeated binge drinking or regular alcohol abuse that leads to physical, psychological and social complications.

12.6.2.2 Physical complications

They include peptic ulcer, gastritis, pancreatitis, liver disease, ascites, hypertension, cancer, skin changes, seizures, CNS degeneration, neuropathy, and malnutrition, proximal muscle wasting, impaired sexual functioning, and lowered immunity, thrombosis, anaemia and cardiac complications. Alcohol abusers are prone to accidents or injuries. Dangerous drinking during pregnancy can lead to foetal alcohol syndrome (babies are born with characteristic facial and brain abnormalities).

12.6.2.3 Psychological complications

Look for signs of blackouts (retrograde amnesia inability to recall actions that occurred when intoxicated), sleep fragmentation, personality change, poor memory or concentration, delirium, Wernicke-Korsakoff syndrome, evidence of self neglect (e.g., poor hygiene), failed treatment for depressed mood, nervousness and insomnia. Sometimes hazardous use of alcohol can lead to psychosis. Signs of alcohol withdrawal are often overshadowed by psychological symptoms such as sweating, tremors, and morning sickness coupled with intense agitation and hallucinations.

12.6.2.4 Social complications

These include marital problems, domestic violence, child abuse or neglect, missed work, various forms of irresponsibility.

12.6.2.5. Differential Diagnosis

Symptoms of anxiety or depression may occur with heavy alcohol use. Re assess and manage symptoms of depression or anxiety if symptoms continue after patient stops drinking. This means the anxiety/depression could be a primary disorder.

Lowered immunity and other physical complications of HIV can be associated with alcohol use. Alcohol increases susceptibility to some infections that can occur as complications of AIDS. Infections associated with both alcohol and AIDS include tuberculosis; pneumonia caused by the bacterium *Streptococcus pneumoniae*; and the viral disease Hepatitis C, a leading cause of death among people with HIV. Alcohol may also increase the severity of AIDS related brain damage, which is characterized in its severest form by profound dementia (see AIDS associated dementia).

12.6.2.6 Management

Information for patient and family:

Alcohol dependence is an illness with serious consequences. It complicates the management of HIV and AIDS. In assessing readiness to start ARV drugs the risk of non adherence related to alcohol use has to be discussed with all patients. Stopping alcohol use will bring mental and physical benefits, and make one eligible for ART but since abrupt stopping when a patient is dependent can cause withdrawal symptoms, medical supervision is necessary. Despite this, patients with HIV disease must be discouraged from regular or heavy alcohol use and must be screened for alcohol use disorders. Regular consumption of low doses of alcohol uniquely affects HIV-infected patients by escalating the risk of liver disease progression in patients co-infected with hepatitis C and by decreasing adherence to medication in a temporal and dose-dependent fashion

Treatment of alcohol withdrawal symptoms and dependence:

Thiamine (150 mg per day in divided doses) should be given, if available, orally for one month. Use diazepam for three days (day one 20mg, day two 10 mg, day three 5 mg) in case of severe withdrawal symptoms.

When stable

- Alcoholics Anonymous
- Psychosocial intervention
- Psycho-pharmacotherapy

Other Drugs

Needs to start with commonly abused drugs and address them in relation to HIV/AIDS management .e.g. Reports from Zanzibar and Dar es Salaam show HIV rates of around 30% among injection drug users. Rates among cannabis and alcohol abusers are also above national average. Overall there are more male drug users than females (about 4:1 respectively). Even though this fact is less well appreciated, drug using behaviors may be a significant HIV transmission risk factor for many men who do not inject drugs.

A study of homosexual men revealed that up to 16% may have drug use as a risk factor for acquiring HIV. There is a high degree of association between drug use and HIV transmission where the prevalence of HIV among PWIDs ranges from 42% to 51.9% while that of PWUDs is 22.4%. Therefore it is important for the primary care providers' being able to diagnose drug using behaviors. Diagnosing drug dependence or addiction is not an easy task.

Table 12.2: Diagnosis Criteria for Drug Dependence and Drug Abuse

DEPENDENCE (≥3 IN 12 MONTH PERIOD)	
1.	Tolerance
2.	Withdraw
3.	The substance is often in larger amounts for a longer period than intended
4.	Unsuccessful efforts or a persistent desire to cut down or to control substance use
5.	A great deal of time is spent in activities necessary to obtain the substance or to recover from its effects
6.	Important social, occupational, or recreational activities given up or reduced because of substance use.
7.	Continued substance use despite knowledge of having has persistent or recurrent physical or psychological problems that are likely to be caused or exacerbated by the substance.

ABUSE (≥1 IN A 12-MONTH PERIOD)

1. Recurrent substance use resulting in failure to fulfill major role obligations at work, school, or home
2. Recurrent substance use in situations in which it is physically hazardous
3. Recurrent substance-related legal problems
4. Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance
and
5. Never met criteria for dependence

Adopted from American Psychiatric Association: Goldman's Cecil Medicine by Lee Goldman and Andrew I. Schafer 24th edition published by Els.

Many people who are addicted to drugs attempt to conceal or deny that they have an addiction. In addition, diagnostic tests for drug dependence and addiction lack specificity and sensitivity.

Although blood and urine tests are usually quite reliable at detecting recent drug use, individuals can be adept at avoiding being tested or at manipulating test results.

Medically Assisted Treatment (MAT)

Medically Assisted Treatment (MAT) is the most useful and cost-effective intervention for managing opioid dependence and reducing the harms associated with it. MAT has proven to be effective in the treatment of opioid dependence and improves retention in treatment programmes. It is also effective in improving treatment with antiretroviral therapy (ART) and the reduction in illicit opioid use, criminal activities, deaths due to overdose, and behaviours at high risk of HIV transmission and other infectious diseases such as Hepatitis B and C. MAT medications prevent withdrawal symptoms from heroin and other short acting opioids, without causing euphoria or sedation. This means that with once daily dosing a client can be free from the constant fluctuations between intoxication and withdrawal and can make moves towards normalizing and stabilizing their lives.

12.7 Primary Psychosis

Psychosis can be a manifestation of delirium, affective disorders, or schizophrenia, but it can occur in the absence of these conditions. Estimates of the prevalence of new onset psychosis in patients with HIV range from 0.5% to 15%, which is higher than in the general population. New onset psychosis may also be a manifestation of HIV associated encephalopathy and a history of substance abuse is also more common among patients with psychosis.

Treatment for HIV infected patients with psychosis follows the same basic principles as for any other patient with schizophrenia, namely, control of symptoms with medications and psychosocial support and rehabilitation. Quite often, patients

require long-term treatment and require various antipsychotic medications to control the delusions, hallucinations, and overall level of disorganization. Because of the high sensitivity to antipsychotic side effects, always start with low doses and if possible maintain patients on half the required dosage for age and weight.

Counseling for HIV testing should be avoided when persons with mental illness are acutely ill and too disorganized to take in what they are being told. Given the importance of the partnership required for risk reduction and other preventive interventions in persons with HIVD, issues related to screening for HIV and AIDS should be postponed until the person is mentally stable. For persons with previous mental illness that are currently in remission of acute symptoms, as with other clients seen at clinics, risk reduction counseling strategies should be addressed at each counseling session. Monitoring drug treatments for schizophrenia and bipolar disorder should prevent or decrease relapse of episodes. When episodes do occur they should be treated. Working with HIV-infected patients brings you in contact with individuals vulnerable to psychiatric illness.

The education and treatment of mentally ill patients is needed to lower their risk of HIV infection. Likewise, the effective treatment of patients with HIV infection often requires the educated use of psychotropics. Although the potential for drug interactions is present when combining psychotropics and antiretrovirals, the possibility of an improved quality of life and better HAART adherence makes the risk worthwhile (Refer to Management of Mental Health Conditions in Primary Care Settings (MEHATA publications) for treatment guidelines. Referral to mental health services at the district level should be made and a case management approach used with such services.

CHAPTER 13: NUTRITION IN HIV AND AIDS

13.1 Introduction

Malnutrition and HIV are related and aggravates one another in a vicious cycle. HIV infection can lead to under nutrition and malnutrition affects HIV transmission and disease progression.

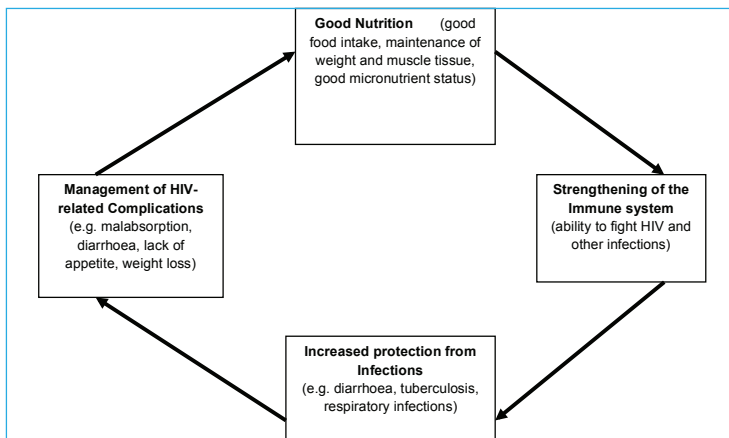
HIV infection impairs the body immune system and thereby increasing vulnerability to infections. Infections lead to increased loss of nutrients which, if **not** replenished, may lead to malnutrition. Malnutrition, on the other hand leads to immune impairment. . Further, when a malnourished person acquires HIV, the progression to AIDS is rapid as the immune system is already too weak to fight off infection. 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 disease progression.

13.2 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 the figure below.

Figure 13:1. The Cycle of Good Nutrition and protection from infections in Context of HIV/AIDS



Nutritional consideration at different stages of HIV infection

At different stages of HIV infection, some health problems may be experienced such as mouth sores (ulcerations), sore throat and diarrhoea. Infections increase the body requirements for energy and may cause deficiency of nutrients and further burdens the already weakened immune system. Table 14.1 Shows Nutrition, Care and Support Priorities by Stage

Table 13.1 Nutritional, care and support priorities by WHO HIV stages

HIV stage	Features	Nutritional Advise
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	<ul style="list-style-type: none"> • 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 moderately or severely malnourished

Late stage (stage 4 of WHO clinical staging)	<ul style="list-style-type: none"> • Weight loss • Symptomatic 	<ul style="list-style-type: none"> • 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 moderately or severely malnourished
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13.3 Nutrient requirements for People Living with HIV (PLHIV)

Energy requirements: The HIV infected person has additional energy needs because of:

- Increased and altered metabolism
- Nutrient malabsorption

In the absence of symptoms (WHO Stage 1), HIV-infected persons should increase energy intake by 10% to 20% percent over the level of energy intake recommended for HIV uninfected persons of the same age, sex and physical activity level.

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.

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.

Micronutrient requirements:

HIV infected individuals are encouraged to include a variety of foods in the diet to prevent deficiency. There is 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).

13.4 Healthy eating for people living with HIV

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 obesity 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 termite (*locally known 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:

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) 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.

Tips for health and nutritious lifestyle for PLHIV

- Eat **variety** of foods emphasizing on nutrient dense foods
- Eat **small** meals frequently (especially for a very sick person)
- Drink clean and safe water
- Be physically active
- Avoid alcohol, avoid smoking
- Add nutrient-dense foods (nuts, oil, fat, milk, oil seeds)
- Use **spices** for appetite and absorption: ginger, garlic, cardamom, lemon
- Germination and sprouting; fermentation (increases nutrient content and improves digestions and absorption)
- Manage stress
- Observe food safety, improve cooking methods and hygiene principles
- Manage specific disease symptoms promptly (e.g., nausea, vomiting, diarrhoea and constipation).

13.5 Nutritional issues associated with ARVs and other medications

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 13.2: 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) →	UNHEALTHY SIDE EFFECTS

Relationship between medication and feeding/dietary patterns

Medications have to be managed correctly in order to ensure that the prescribed drug combination improves drug efficacy, decrease side effects, and does not affect the nutritional status.

Annex 9 lists some of the medications used in Tanzania. The table shows their purpose, potential side effects and nutritional recommendation (more details are found in annex 9)

Proper dietary management can help to manage some side effects. The following are examples:

- **Changes in taste:** The protease inhibitors Saquinavir and 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 flavor enhancers such as salt, sugar, spices, vinegar, or lemon to stimulate the taste buds, increase taste acuity, and mask any unpleasant flavor. Adding spices like onions to soup will boost flavor and can help to improve intake.
- **Anorexia:** Several medications, such as isoniazid and the ARVs lamivudine and stavudine, may cause anorexia and lead to reduced food intake. The dietary management of anorexia requires eating small and frequent meals and favorite 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, yogurt, 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.

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 during meals. 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 50 mg 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 favorite foods.
	Diarrhea	Drink plenty of fluids and eat energy- and nutrient rich food. Avoid fried foods.

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 persons' 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 and increase intake through soft, minced texture, boiled form 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 counseling plan.

Biochemical assessment

Biochemical assessment of nutritional status is done in the laboratory where nutrient deficiencies are detected. Where available test for blood protein (e.g. Serum albumin), micronutrients (e.g. iron) and Lipid (e.g. Cholesterol), can be used to monitor nutritional status of PLHIV. Hemoglobin level is one of the indicators used to monitor anemia

Anthropometry assessment

Anthropometry assessment includes recording of age, sex and anthropometric measurements (Mid Upper Arm Circumference, height, weight).

Patients who have a weight and height measured are plotted on a growth curve and designated low/high weight for height Z score (for children) or BMI Z score (older children), or BMI (adults). MUAC tapes are also used

One can monitor weight loss by using body mass index (BMI) calculated as = Weight (Kg) divided by height (m²). A normal BMI is 18.5 – 24.9 kg/m². A BMI <18.5 denotes underweight; that between 25.0 and 29.9 kg/m² is overweight, and > 30.0 kg/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, an intended weight loss of between 6-7 kg 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.

Therapeutic foods for Moderate and Severe Acute Malnutrition

After the assessment of nutritional status, those who will be categorized as severely or moderately malnourished, and have no medical complication (i.e. no other disease), will be given nutrition education and supplied with the 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.

For Prescription criteria refer national guidelines for management of acute malnutrition

Table 13:4. Indicators for acute malnutrition

Age category	Mild	Moderate	Severe
Children 6 -59 months old,			
		MUAC: 11.5 to < 12.5 cm	MUAC: < 11.5 cm
		W/H -3 Z-scores to -2 Z-scores	W/H < -3 Z-scores
		W/H -3 Z-scores to < -2 SD	
Pregnant women and women within the period of 6 months after delivery		MUAC: 19 to <23.0cm	MUAC <19.0cm
Children 5 - 9 years	MUAC	MUAC 13.5 – 14.4 cm	MUAC < 13.5 cm
	W/H -2 Z-scores to < +1 Z-scores	W/H -3 Z-scores to < -2 SD	W/H < -3 Z-scores
Children 10 - 14 years	MUAC	MUAC 16 –18.4cm	MUAC < 16.0 cm
	W/H -2 Z-scores to < +1 Z-scores	W/H -3 Z-scores to < -2 Z-scores	W/H < -3 Z-scores
Adolescents (15 years and above) and adults	MUAC	MUAC 19 cm –21.9 cm	BMI < 16.0
	BMI ≥ 17 – 18.4	BMI ≥ 16 – 17	MUAC < 19.0 cm

Note:

- 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 14: COMMUNITY BASED HIV AND AIDS SERVICES

14.1 Background

The Health Sector HIV and AIDS Strategic Plan III (HSHSP) 2013 - 2017 calls for comprehensive quality HIV care services at three levels, namely: facility, community and household. Patients should have access to care at all three levels, and an effective referral system needs to be put in place to link all the levels with each other. The availability and use of antiretroviral treatment has reinforced and added new perspectives to this concept of across a **comprehensive continuum of care**. The importance of compliance with treatment regimens and adherence to treatment has resulted in new roles for Community Based HIV and AIDS services.

PLHIVs 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 community Based HIV and AIDS services that cater for these needs of PLHIVs and the community surrounding them.

In Tanzania, Community Based HIV and AIDS Services was formally introduced by the 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. Up to the end of December, 2012, these services expanded to reach 134 councils where a total of 275,547 clients benefitted from these services. The coordination of HBC services in regions and districts has improved significantly following the introduction of regional and Districts HBC coordinators respectively. With increased partner support, 9719 HBC service providers were trained and resulted to increased coverage of services. However, the coverage of Community Based HIV and AIDS services (CBHS) is still partial. In 134 out of 167 councils that have been reached, only 4,707 (35%) health facilities have CBHS in their catchment areas.

14.2 Overall Goal

People living with HIV in all councils have access to quality comprehensive Community Based HIV Services integrated with other services.

14.3 Scope of CBHS

Community based HIV and AIDS services are the holistic approach within the community that focuses to PLHIV and the community surrounding him/hertowards their health improvement. It involves prevention, care and support provided beyond the health institution that aims at meeting the overall needs of people suffering from chronic illnesses and their family members, including those taking lifelong medications such as ARV drugs. Families are the central focus and form the basis of CBHS.

Community Based HIV and AIDS Services ensure 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 programs are developed as a response to these psychological, social, nutritional, economic, legal, clinical, and nursing-care needs and demands.

In Tanzania and other countries in sub-Saharan Africa, clinical and psychosocial interventions have been shown to be more effective and sustainable if they are built upon a foundation of mutual trust between programs and facilities and then followed up by community care programs. The fulfilment of these conditions constitutes the continuum of care for PLHIV.

14.3.1 Contribution of CBHS in Treatment support

The establishment of Community Based HIV and AIDS Services programs by the Ministry of Health and Social Welfare is among the Ministry's strategies to compliment the initiatives of the government to combat HIV and AIDS in ART era. The following are the key areas that the CBHS are contributing in the treatment support:

i. Early case identification and enrollment

The ultimate purpose of Care and Treatment program is to make sure that all HIV positive clients are enrolled into care and those eligible for treatment are started on ARV as early as possible. In order to achieve that, CBHS have strategized to ensure that those who develop symptoms have access to HIV testing and counselling and those who test positive in the community have access to care and treatment services respectively. The CBHS providers in the community will refer people who have symptoms for HIV counselling and testing in the nearest health facility while those who test HIV positive will be enrolled into CBHS for further follow up.

After enrolment to CBHS, the CBHS provider will ensure that the client reach their first referral point (CTC/PMTCT/Paediatric HIV Clinics/TB Clinics etc.). Using the enrolled CBHS clients as an entry point to the household, CBHS providers will provide pre-test information to the clients to facilitate HIV counselling and testing at home by the trained counsellors. Furthermore, at the community level, efforts are being made by CBHS to ensure that all pregnant women, mothers and their exposed children return to the health facility for follow up. Also, CBHS have special attention in the identification and enrolment of Injective Drug users and Commercial sex workers as they are among the key population groups that have a very high risk of contracting HIV infection.

ii. Retention of clients to treatment

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 Ministry of Health and Social Welfare.

Among those, CBHS uses CBHS providers through home visits to provide adherence counselling and health education to the clients who are on treatment to stay on treatment. Also, The CBHS providers are trained to assist the client in choosing a primary care giver who is a relative of a client to help the client in taking medication by reminding or assisting in taking medication.

CBHS providers will link clients who are HIV positive and 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 long time hence helps them with adherence and acceptance of HIV status which will eventually help them in status disclosure.

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 loss to follow up clients by the health facilities, CBHS providers of the catchment areas will be given the names of the clients lost for tracking them. The status of the clients who happen to be enrolled in the CBHS will be provided to the facilities, while those who are not enrolled in CBHS will be tracked manually and provide the 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 return 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 is 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 enhance this system, service providers ensures that the national CBHS referral forms are used in all referrals. The provider receiving the referral form also ensures that the feedback portion is filled in and returned to the referring provider.

Referrals 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. These support services should be known at all levels and form part of a networking mechanism. A service directory and referral network is developed by service providers to enhance this referral system.

14.4 Target group

Community Based HIV and AIDS services targets all HIV positive clients including HIV positive Adults, paediatrics, exposed children, pregnant women, IDUs, CSWs as primary target groups and chronically ill clients as secondary target groups.

14.5 Key service provider in CBHS

For many years, community Based HIV services providers have been given different names by different HIV implementers, these included: HBC providers, Expert patients, Peer educators, Liaison person, Client tracking person, volunteers, Community Based Distributor 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.

14.6 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

14.7 Training

All CBHS Providers are trained using the CBHS training curriculum, developed by the MoHSW through the NACP.

14.8 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 identify and refer all pregnant women to RCH clinics/Health facilities of the catchment areas and make follow up.
- ii. To provide health education to all pregnant women on HIV infection.
- iii. To provide adherence counseling of ART to HIV positive pregnant women and adults who are enrolled in care and treatment/PMTCT.
- iv. 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.
- v. To identify and refer all Injective Drug users, MSM and Commercial sex workers to health facilities for further management.
- vi. 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

Chapter 15. SUPPLY CHAIN MANAGEMENT AND RATIONAL USE OF HIV AND AIDS COMMONIDITIES AND RELATED SUPPLIES

15.1. Introduction

A comprehensive HIV and AIDS program 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 and related supplies is critical to ensure adequate and continuous availability of quality and affordable essential medicines, diagnostics and other consumables at service delivery sites. These commodities are relatively expensive and therefore they require proper handling to ensure effective use.

The key components of procurement and supply management cycle includes product selection, forecasting and supply planning, procurement, storage and distribution, Logistics Management Information System (LMIS), Use or Serving customers, Quality monitoring, financing and 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.

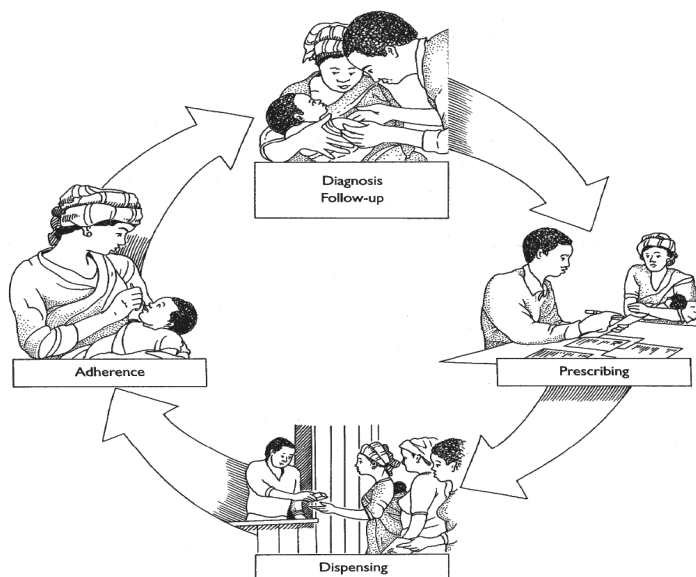
15.2. Rational Use of Medicines

Rational use of medicines requires that medications are 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 individual and population levels. These may include:

- Treatment failure
- Rapid development of drug resistance
- An increase in the risk of toxicity
- Increased cost for treatment of patients due to the need to use expensive medication as a result of irrational use and treatment failure.

Figure15. 1. Medicines Use Process



Aspects of Irrational Use of Medicines

Diagnosis:

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

Prescribing

- Irrational prescribing is observed when there is
 - ✓ Incorrect prescribing
 - ✓ Diagnosis is inadequate,
 - ✓ Inappropriate medicines are prescribed.
- Under prescribing:
 - ✓ Needed medications are not prescribed
 - ✓ Dosage is inadequate
 - ✓ Inadequate duration of treatment.

- Over prescribing:
 - ✓ Prescribing inappropriate length of course
 - ✓ Prescribing very high dose
- Extravagant prescribing:
 - ✓ Prescribing a more expensive branded medicines when there is a less expensive generic medicines
 - ✓ Treating symptoms instead of treating the disease.
- Multiple prescribing:
 - ✓ Two or more medications are prescribed when fewer would achieve the same effect

Dispensing:

- Incorrect interpretation of the prescription.
- Inadequate treatment monitoring: The dispenser does not pick up errors or the dispenser sees the error but does nothing about it
- Incorrect calculation of dosage
- Retrieval of wrong medicines
- Inaccurate counting
- Inadequate labelling.
- Unsanitary procedures.
- Inability to effectively communicate with patients on how to use the prescribed medicines and adherence to dose schedules.

Patient aspects of Irrational Use of Medicines

This occurs when-

- Patient demand more medicines to be prescribed than required
- Not following given instructions.
- Sharing Medicines with others
- Medicine misinformation
- Lack of patient readiness
- Stigma
- Conflict between cultural values and therapy
- Misleading beliefs about HIV/AIDS
- Patients' misunderstandings about the medicines and their uses
- Patient concerns about side effects and ADRs.

15.2.1. 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, age, sex of patient, medicines and dose, and should include the name, signature and prescriber's code (where applicable).

15.2.2. 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 issuing the drugs. ARVs should only be given to the named patient or appointed adherence assistant. Adequate time should be scheduled for antiretroviral dispensing and counseling.

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 respond to specific questions and problems related to ARV treatment encountered by patients. It is also imperative for the dispenser to advise patients on measures to be taken to reduce the side effects, including immediate return to the clinic when they experience unwanted effects.

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.

15.3. Supply Chain Management

15.3.1 Serving the customers

The ultimate purpose of public health supply chain systems is to serve the customers with appropriate commodities in the right quantity, time, place and cost. In the context of HIV and AIDS programs, this purpose means ensuring an uninterrupted supply of quality antiretroviral (ARV) drugs to eligible people living with HIV/AIDS (PLWHA) that are optimal for their condition 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 MOHSW through NACP has designed supply chain systems and procedures and prioritize interventions around the concept of uninterrupted availability of the ARV drugs.

15.3.2 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 programs in resource-limited settings and to ensure that treatment programs using ARV drugs are 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 MOHSW through NACP has updated 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. STGs for ART should provide clear criteria for first- and second-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.

15.3.4 Forecasting and Supply planning (Quantification)

Program managers must prepare medium term forecasts to be able to coordinate funding and procurement among multiple donors and to ensure uninterrupted supplies of HIV/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 on number of new patients being initiated 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 (every after 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 programs to keep up with rapidly changing demands and requirements for ARVs

15.3.5. Procurement

The procurement of HIV/AIDS commodities shall be done by the Medical Stores Department which is also responsible for storage and distribution of the medicines to all health facilities across the country.

A uniform and harmonized national procurement system is required for efficiently procuring quality-assured affordable ARV drugs and diagnostics. Procurement should be based on appropriate selection of products and need-based forecasting, considering consumption, expanding services, phasing in and phasing out formulations and implementing new recommendations. Transparent procedures should be adopted to achieve best-value procurement and a quality assurance system implemented to procure, store and distribute high-quality pharmaceuticals,

diagnostics and other health products.

Procurement systems should:

- Procure the most effective, heat-stable, fixed-dose quality-assured ARV drug formulations in the right quantities at the lowest possible cost and in a timely manner.
- Request that the partners supporting the national HIV programme consolidate and harmonize ARV drugs and diagnostics procurement and supply management systems and pool demands for ARV drugs and diagnostics, exploring options for pooling under a common tender system.
- Use a publicly accessible database to facilitate access to information about prices and support competition .
- Follow the principles described in the United Nations interagency guidelines for donated drugs.

15.3.6. Inventory Management

15.3.5.1 Ordering and Receiving HIV/AIDS commodities

Orders to the Medical Stores Department (MSD) should be timely and made well in advance to allow commodities to reach the facilities in time. The original copies of the completed and signed Report and Request (R & R) form, form A2 and Lab forms should be submitted to MSD before the 14th day of the first Month of the quarter after the reporting period. The R&R forms must be filled completely and accurately including filling-in actual quantities of available commodities after conducting physical inventory at the end of the quarter and correctly estimating requirements for new patients to be initiated on treatment.

Upon receipt of HIV/AIDS commodities at the facility, the receiving officer will ensure that the following particulars of commodities and related supplies on the delivery note and invoice match with the delivered items in the following areas:

- Strength and dosage form;
- Pack size(s)
- Batch numbers
- Expiry dates (Remaining shelf life should at least be 8 months)
- Specifications
- Quantities delivered
- Condition of the commodities (Not damaged)

After ensuring that all the areas are satisfied, 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 copied to the facility for records.

15.3.5.2. 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 a single pharmacist / pharmaceutical technician / Lab 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 store Ledger/bin cards-paper based and Pharmacy database. 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 and disposed using the laid out procedures. Adequate stock levels of Max-Min of 6/3 (For ordering site) and 2/1 (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).

15.3.5.3. Record keeping

In order to facilitate efficient administration and management of ARVs, all information regarding ARV dispensing should be recorded in a dedicated register book (Dispensing registers/ or in the pharmacy database-module) and ART patient card. At the store, all HIV commodity transactions should be recorded in the paper based ledger or in the Pharmacy Module data base.

The Pharmacist/Dispenser should record and sign all the dispensed ARVs in the dedicated register book located in the dispensing unit at the pharmacy. In the facilities where pharmacy module/database (electronic database) is available, then patient's information and their medication prescribed should be recorded. Reports on medicines consumption and stocks of medicines should be kept and tracked by facilities for facilities to understand their requirements. On quarterly basis, these reports should be sent to the Ministry of Health and Social Welfare through the DMO for program monitoring and forecasting.

15.3.6. Logistics Management Information System (LMIS)

A logistics management information system (LMIS) collects, processes, and reports supply chain information. A well-functioning LMIS provides decision makers throughout a supply chain with accurate, timely, and appropriate data. The LMIS can be manual (paper-based), or electronic (pharmacy data base). There are three essential LMIS data which are;

CHAPTER 15: Supply Chain Management And Rational Use Of Hiv And Aids Commonities And Related Supplies

1. Stock on hand
2. Losses and adjustment
3. Consumption data

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.

15.3.7. Supply Chain Monitoring

Monitoring and evaluation is a cross-cutting function that is needed for all programs and functions to ensure commodity security. National programs and their constituent functions must be capable of measuring progress and outcomes if they are to ensure that targets are being met and to determine the corrective actions to be taken.

M & E of logistics activities should be done regularly to assess progress, identify and solve problems. This will ensure:

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

Supply chain monitoring is mostly done through Regular supportive supervision. On The Job Training and Mentoring then follows to Health Facilities observed with problems in some areas of logistics activities.

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.

15.4. Pharmacovigilance

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 that 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 anaemia should be switched to TDF based regimens and those experiencing NVP induced severe rash should be switched to EFV.

15.5. Collaborating with Clinical Staff

The pharmacist shall work closely with clinical staff to ensure appropriate prescribing especially on doses and appropriate ARV combinations. Good collaboration will ensure correct estimates of the number of new patients to be initiated treatment for proper ordering of their medicines.

The pharmacist also needs to keep clinical staff informed of the current stock levels of ARVs, particularly of items nearing stock-out and those in excess and at risk of expiry. In the event of nation-wide supply shortage, the pharmacist

should communicate this information to clinical staff so that they can pursue the best course of action. In addition to logistics related collaborative activities, the pharmacist is expected to keep abreast of new information and changes in ARV regimens and act as a resource to clinicians and other 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.

CHAPTER 16: MONITORING AND EVALUATION

16.1 Introduction

Monitoring is routine follow-up of HIV/AIDS program interventions through collecting, analyzing, and reporting of data to track progress against set plans. Monitoring helps to identify trends and patterns, adapt strategies and inform decisions for programme management. Evaluation, on the other hand, deals with assessment of an ongoing or completed project, programme or policy, its design, implementation and results. The aim of Evaluating HIV/AIDS programs is to determine the relevance and fulfillment of objectives, developmental efficiency, effectiveness, impact and sustainability. A set of indicators and milestones have been identified to help track changes in HIV/AIDS control in Tanzania. Monitoring and evaluation generates information needed for decision-making at different levels of care and management.

16.2 Key components of monitoring and evaluation

16.2.1 Recording

Data collection on HIV/AIDS interventions is done by health workers and community workers at the health facility and community levels using standardized tools coordinated by DACCs and RACCs. Reporting is done from the facility level to district and higher levels through standardized forms on a quarterly basis. The national level through the NACP compiles facility/district data, which are then reported to other stakeholders within and outside the country.

Patient Identification Card (CTC 1), Patient Record Form (CTC 2), Registers (pre-ART ART and cohort), Reporting Forms (for Cross-sectional and Cohort analysis) and referral form have been designed for the purpose of patient identification, patient monitoring and programme monitoring respectively. In addition, an appointment book to facilitate booking appointments and follow-up on patients who are no is also included in the patient monitoring system.

a) Patient Identification Card (CTC1) is a card with a unique patient identification number issued at the registration section of the facility during the first visit. The Card is for all patients enrolled on care and treatment services and it will be kept by the patient and used for identification purposes at every visit.

b) Patient Record Form (CTC2) Revision 2013 is a form initiated at the first visit of any HIV positive person attending the CTC for management and monitoring of patients' clinical outcome. The form has a unique ID number, as in the Patient Identification Card. It is kept in a file and retained in the facility registry or dedicated HIV/AIDS care and treatment cabinet. In case of CTC services integrated in other services such as the TB/HIV and RCH/PMTCT within the same facility, CTC2 forms should be made available at relevant unit and information to be entered in the data management system of the CTC. Key information on patient management is filled in by the relevant health provider.

c) Registers

There are three types of registers used at the CTC: the Pre-ART register, ART register and Cohort Analysis Register

The Pre-ART register is a tool for tracking and monitoring the progress of patients that are enrolled in HIV care as they become eligible for ART and allows cohort analysis. **All** patients who first enroll for HIV care, whether they are on ART or not, are initially listed in the pre-ART register and counted as enrolled in HIV care. This includes patients who transfer in with or without records who were previously in care at another facility but are not yet on ART. The only patients who will **NOT** be entered into the pre-ART register are patients on ART who transfer in with records.

Once the patient begins ART, he/she is transferred to the ART register and is no longer tracked through the pre-ART register.

The ART register is a tool used for patient and program monitoring and allows cohort analysis. However, it is used **ONLY** after a patient has started ART. The purpose of the register is to collect the same information (transferred from their individual CTC 2s) about an entire group of patients in a single location (the register).

Note: The information on the CTC 2 form facilitates the monitoring of individual patients and that collected in the register facilitates the monitoring the whole group of patients.

The Cohort Analysis register

Cohort Analysis Register uses ART register to compile it. In turn the Cohort register is used to compile the cohort analysis report.

Twelve months of baseline ART monthly cohorts (start-up groups) and outcome data at 6, 12 24,36,48,60 and 72 months are included on one side of cohort analysis register. This can be gradually filled out by someone on the Care and Treatment Team or produced from the CTC 2 database, then transferred to cohort analysis report form. Data from the cohort analysis report form can be used for programme monitoring at the facility-level as well as higher up in the system. The same report can generate Early Warning Indicator for HIV Drug resistance (EWI – HIVDR). This is why the Care and Treatment Team at each facility should fill out a cohort analysis report form gradually as results become available and it should also send a copy of the cohort analysis report to their District Coordinator/Supervisor every reporting quarter.

d) Patient Referral Form

It is important that the patient carries treatment relevant information with him/her whenever he sees a new clinician, e.g. when he transfers to another facility. The same initial identification number will be retained to avoid loss of follow up and double recording of the patient.

16.2.2 Reporting

Reporting at the CTC should be done as follows using the appropriate reporting forms and tools:

a) Quarterly Reports

A summary of newly enrolled patients is reported quarterly using a cross-sectional summary of all patients ever enrolled and currently in care and on ART.

The cross-sectional report form is filled using data from the pre-ART and ART registers. It provides the following important information:

- New patients enrolled and eligible for ART but not yet started on ART
- New patients on ART (in the last reporting period; not transfer in)
- Cumulative patients enrolled in HIV care (including transfer in)
- Cumulative patients ever started on ART
- Patients currently on ART and currently in care (non-ART plus ART)
- Patients currently on ART and what proportion are on first line and second line regimens
- Subset of patients on treatment for OIs

b) Programme Monitoring

Programme monitoring is done at the facility-level as well as higher up in the system using a **cohort analysis reporting form** which comprises a collection of indicators for ART start-up groups (monthly cohort) with their status at 6 months, 12 months, and 24 months. Data is gradually filled out by a member of the Care and Treatment Team as cohort reaches 6, 12, 24 months then transferred to an identical cohort analysis report form by the District Coordinator/Supervisor, for submission to higher levels in the system. The Cohort analysis reporting form provides the following information to the Care and Treatment Team and district, regional and national levels to monitor how well the programme is doing with regard to patients started on ART. It contains information on the following:

- Surviving patients
- Patients still on a first line regimen
- Functional status of the patient

It also provides a comparison between patients with 6 months of ART and other patients with 6 months of ART elsewhere.

Because the data from the cohort analyses are of critical importance, it is essential for the District AIDS Control Coordinator (DACC) to fully verify them and provide technical support.

An **Appointment Book** should be kept by a member of the Care and Treatment Team at the registration unit and filled after the patient has received the date for the next visit. It should contain the patient's name, date, unique CTC ID number, the reason for visit and a column for the patient's show up. Information on patient show up is crucial for tracking missing patients who can easily be identified and traced if the patient show up column is properly filled out.

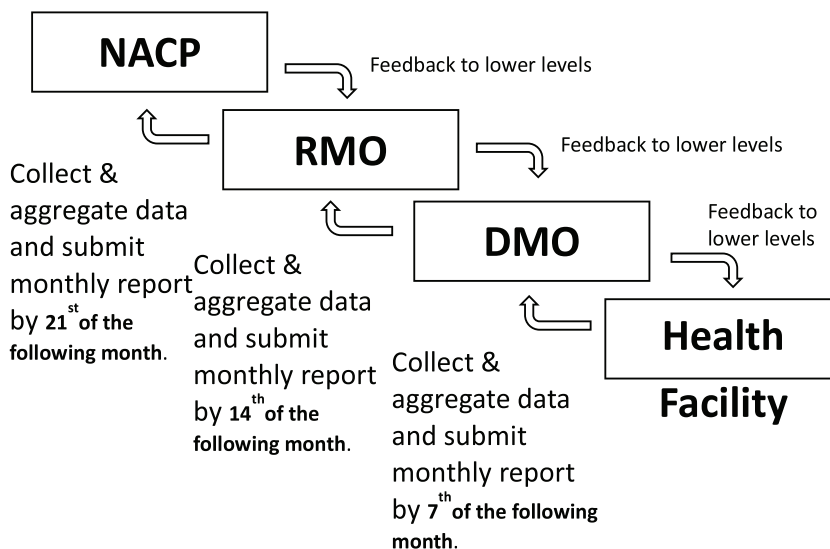
Each facility participating in the National Care and Treatment Programme should identify a specific person to be responsible for care and Treatment data handling and reporting. At each health facility the CTC in charge is responsible for timely and correct collection and submission of reports.

In case of no show, the missed client should be transferred to **HBC Register for Tracking Missing Appointments** so as to facilitate Home Based Care Providers tracking responsibility.

c. CTC 2 database

The CTC2 database is a database designed for HIV/AIDS Care and Treatment clinics in Tanzania. It is designed according to the NACP standard CTC2 card and report formats. The Pharmacy Module of the CTC2 database is a tool to help managing stocks of ARV drugs and matching dispensing records with prescription records, and follows the standard NACP dispensing registers and report and request forms. The CTC3 macro database is a database for multi-clinic analysis designed for use by the NACP, regions, districts and development partners.

Figure 16. 1: Data Flow from Health Facility to National Level



16.2.3 Data analysis and presentation

Analysis of HIV/AIDS data is done at all levels, from the health facility to the national level. Presentation of HIV/AIDS data is done in the form of notes, tables, graphs, maps, and reports depending on the needs to be communicated and the intended audience. This information is used to assess the performance of the different levels in HIV/AIDS control.

16.2.4 Data quality

High quality data are needed to inform, monitor, and manage HIV/AIDS programs. High quality data ensures program's effectiveness. Data are considered to be of high quality when they are accurate, comprehensive, consistent, relevant, and timely. Data Quality Assurance (DQA) should be conducted routinely at all levels by using standardized DQA tools developed by NACP.

16.2.5 Data utilization

Routinely collected HIV/AIDS data provides information on demographic

characteristics of the disease (i.e., sex, age and geographical location), transmission category (mode of exposure), immune status and viral load. Furthermore, routine data allow the program to monitor disease progression and utilization of services. Reports can also be used for program evaluation, planning, and budgeting purposes. Data generated at all level should be analyzed and disseminated to relevant stakeholders for making evidence-based decisions for HIV/AIDS control. RACCs and DACCs should analyze, interpret, and facilitate utilization of data in their respective regions and districts.

16.3 Roles and Responsibilities

In Tanzania, HIV/AIDS M&E activities are carried out at the national and decentralized levels. M&E units for HIV at national level are based at Tanzania Commission for AIDS (TACAIDS) and at the Ministry of Health and Social Welfare (MOHSW). Furthermore, there are directorates or M&E focal persons in all organizations that implement HIV activities and HMIS focal persons at decentralized levels. These officers at these various levels fulfill the following roles¹⁵:

16.3.1 TACAIDS

- Chair the M&E Technical Working Group (TWG), and coordinate its work
- Manage the M&E system for HIV (i.e. provide technical oversight)
- Coordinate M&E plan costing and annual reviews
- Play a key role in coordinating the planning, implementation and dissemination of findings of all surveys and surveillance
- Advocate for and communicate about HIV M&E in all sectors at decision making level to build strong M&E partnerships
- Develop and oversee M&E capacity building strategy, accompanying activities and play a key role in mobilizing resources for the same

16.3.2 National AIDS Control Programme (NACP)

- Implement scheduled and/or agree activities in the annual M&E work plan [roadmap];
- Ensure availability of recording and reporting tools for HIV monitoring
- Coordinate supportive supervision and data quality audits of HIV monitoring data
- Coordinate and act on supervision and data auditing report results
- Create and manage a national CTC 2 database in line with national M&E needs
- Install HIV database at decentralized levels and oversee its operation
- Train decentralized structures on CTC 2 database use.
- Trouble-shoot CTC 2 database problems with decentralized structures
- Coordinate dissemination of output level data
- Advocate for the use of output monitoring data.

15 UNAIDS/The World Bank, 2006 HIV/AIDS M&E – Getting Results: Eleven components of a fully functional HIV M&E System

- Create information products (annual HIV report, etc.)
- Oversee all data dissemination and feedback processes

16.3.3 Regional/District levels

- Coordinate HIV recording and reporting systems at regional/district level
- Manage HIV data export to NACP
- Coordinate HIV M&E capacity building (e.g. training and mentorship) at the regional/district level
- Coordinate HIV data quality audits at regional/district level
- Liaise with stakeholders concerning implementation of program monitoring system
- Manage program monitoring data dissemination
- Support, in collaboration with the HIV Research Officer, the coordination of surveys at regional/district level
- Advise on HIV M&E issues at regional/district level
- Analyze and present HIV M&E data as requested at regional/district level
- Disseminate HIV information products at regional/district level
- Promote HIV data use during decision making and planning of HIV interventions and use data for decision making at regional/district level
- Liaise with NACP on all HIV M&E issues at regional/district level

16.3.4 Health Facility level

- Ensure proper recording and reporting tools are used for HIV care and treatment services
- Ensure completeness of all reporting forms, registers and CTC2 database at facility level
- Ensure timely reporting as per agreed reporting deadline during reporting month/quarter
- Liaise with HMIS focal person or DACC at district level on all HIV M&E issues at facility level
- Ensure quality of recorded and reported collected data

16.3.5 HIV implementing partners

- Ensure compliance with the national HIV program monitoring system
- Support regional/district M&E efforts for HIV implementation
- Keep daily records of implementation of HIV activities
- Promote the use of program monitoring system data when planning HIV interventions.

16.4 Supportive supervision

The MOHSW supportive supervision guidelines describe supportive supervision as a “process which promotes quality outcomes by strengthening communication, identifying and solving problems, facilitating team work, and providing leadership and support to empower health care workers to monitor and improve their own

performance.” The scope of supervision methods is expanded by incorporating self-assessment, peer assessment, and community input.

Mentorship is described as a process conducted by a person or team (mentor[s]) for another person or groups (mentee[s]) in order to help that other person or group do a job more effectively. Mentoring can be done for all professions, but when applied in the clinical setting to improve delivery of health care, it is referred to as “clinical” mentoring.

16.4.1 Purpose of supervision and mentorship in TB and leprosy care and control

The purpose of supervision at the regional, district, and health facility levels is to:

- Provide leadership and guidance to staff through mentorship.
- Monitor implementation of planned activities against defined program goals and targets.
- Monitor that all necessary tasks are properly performed.
- Ensure that resources including training and supplies are properly used and are available to staff to carry out their duties.
- Ensure accountability and responsibility.
- Ensure adherence to the set standards of HIV/AIDS care.
- Identify/Address barriers to service delivery to improve health services on a daily basis.

16.4.2 Stages of supportive supervision and mentorship in HIV/AIDS control activities

The following are the steps that NACP staff, Regional and Council Health Management Teams should follow when conducting supportive supervision and mentorship visits.

Stage 1, before supervision

Preparation for supervision:

- Plan in advance to allow preparation and coordination of all partners and stakeholders.
- Communicate with regional, district, and health facility authorities.
- Review previous supervision reports.
- Identify priority areas for supervision or follow-up.
- Set supervision objectives.
- Prepare supervision schedule.

Stage 2, during supervision

- Establish rapport with staff.
- Review agreed action plan from previous supervision.

- Review objectives together with the supervisee.
- Demonstrate behavior that promotes cooperation and a warm climate (treat the problem as our problem, respect and value the staff, and do not judge or accuse).
- Use supervision tool/checklist to ensure that all key areas/sections are covered.
- Observe and document what the staff do and identify gaps.
- Provide constructive immediate feedback on identified gaps.
- Meet with the team for mentorship and set an action plan for identified gaps, including responsible persons
- Identify strengths, gaps, and areas for improvement.
- Supervisors and mentors meet together/share information and compile report for debriefing.
- Meet with community representatives where possible for feedback.

Stage 3, after supervision

- Provide verbal feedback to authority.
- Return detailed written feedback to the authority and copy to the supervisee.
- Disseminate supervision report to key stakeholders.
- Follow up what was agreed upon before the next visit.
- Report back to management on the findings and plan of action for follow-up.

16.4.3 Composition of supervision team

The supervision team includes members from the MOHSW and partners supported by the regional and district teams. The NACP team is composed of the following officers: medical, laboratory, data management, logistics, drugs and other supplies, financial management and general administration.

The regional supervision team comprises the RACC, Regional Laboratory Technician, RTLC, and regional pharmacist, while the district team comprises of DACC, District Laboratory Technician, DTLC, and district pharmacist.

16.4.4 Frequency of supervision and mentorship visits

Supervision is conducted using a cascade approach as shown below.

Supervision of the region by national level: The national level should visit each region at least once per year. Regions with specific problems should be visited more frequently. Visits should be accompanied by the regional teams to the districts.

Supervision of the district by the regional level: The regional team should visit each district at least once per quarter. The district team should accompany the regional team to health facilities. Districts with specific problems should be visited more frequently.

Supervision of health facilities by the district level: The district team should visit each CTC at least once per quarter. Health facilities with specific problems should be visited more frequently.

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the 1990s, the number of people in the world who are undernourished has increased from 600 million to 800 million (FAO 2000).

There are a number of reasons for this increase. First, the world population has increased from 5 billion in 1987 to 6 billion in 1999, and is projected to reach 8 billion by 2025 (UNEP 1999). Second, the world population is ageing, and the elderly are more vulnerable to malnutrition (WHO 1999).

Third, the world population is becoming more urban, and urban populations are more vulnerable to malnutrition (WHO 1999). Fourth, the world population is becoming more mobile, and mobile populations are more vulnerable to malnutrition (WHO 1999).

Fifth, the world population is becoming more educated, and educated populations are more vulnerable to malnutrition (WHO 1999). Sixth, the world population is becoming more affluent, and affluent populations are more vulnerable to malnutrition (WHO 1999).

Seventh, the world population is becoming more diverse, and diverse populations are more vulnerable to malnutrition (WHO 1999). Eighth, the world population is becoming more mobile, and mobile populations are more vulnerable to malnutrition (WHO 1999).

Ninth, the world population is becoming more educated, and educated populations are more vulnerable to malnutrition (WHO 1999). Tenth, the world population is becoming more affluent, and affluent populations are more vulnerable to malnutrition (WHO 1999).

Eleventh, the world population is becoming more diverse, and diverse populations are more vulnerable to malnutrition (WHO 1999). Twelfth, the world population is becoming more mobile, and mobile populations are more vulnerable to malnutrition (WHO 1999).

Thirteenth, the world population is becoming more educated, and educated populations are more vulnerable to malnutrition (WHO 1999). Fourteenth, the world population is becoming more affluent, and affluent populations are more vulnerable to malnutrition (WHO 1999).

Fifteenth, the world population is becoming more diverse, and diverse populations are more vulnerable to malnutrition (WHO 1999). Sixteenth, the world population is becoming more mobile, and mobile populations are more vulnerable to malnutrition (WHO 1999).

Seventeenth, the world population is becoming more educated, and educated populations are more vulnerable to malnutrition (WHO 1999). Eighteenth, the world population is becoming more affluent, and affluent populations are more vulnerable to malnutrition (WHO 1999).

Nineteenth, the world population is becoming more diverse, and diverse populations are more vulnerable to malnutrition (WHO 1999). Twentieth, the world population is becoming more mobile, and mobile populations are more vulnerable to malnutrition (WHO 1999).

Twenty-first, the world population is becoming more educated, and educated populations are more vulnerable to malnutrition (WHO 1999). Twenty-second, the world population is becoming more affluent, and affluent populations are more vulnerable to malnutrition (WHO 1999).

Twenty-third, the world population is becoming more diverse, and diverse populations are more vulnerable to malnutrition (WHO 1999). Twenty-fourth, the world population is becoming more mobile, and mobile populations are more vulnerable to malnutrition (WHO 1999).

Twenty-fifth, the world population is becoming more educated, and educated populations are more vulnerable to malnutrition (WHO 1999). Twenty-sixth, the world population is becoming more affluent, and affluent populations are more vulnerable to malnutrition (WHO 1999).

Twenty-seventh, the world population is becoming more diverse, and diverse populations are more vulnerable to malnutrition (WHO 1999). Twenty-eighth, the world population is becoming more mobile, and mobile populations are more vulnerable to malnutrition (WHO 1999).

Twenty-ninth, the world population is becoming more educated, and educated populations are more vulnerable to malnutrition (WHO 1999). Thirtieth, the world population is becoming more affluent, and affluent populations are more vulnerable to malnutrition (WHO 1999).

Thirty-first, the world population is becoming more diverse, and diverse populations are more vulnerable to malnutrition (WHO 1999). Thirty-second, the world population is becoming more mobile, and mobile populations are more vulnerable to malnutrition (WHO 1999).

Thirty-third, the world population is becoming more educated, and educated populations are more vulnerable to malnutrition (WHO 1999). Thirty-fourth, the world population is becoming more affluent, and affluent populations are more vulnerable to malnutrition (WHO 1999).

ANNEX 1: WHO CLINICAL STAGING OF HIV DISEASE IN ADULTS AND ADOLESCENTS

CLINICAL STAGE 1	
Asymptomatic	
Persistent generalized lymphadenopathy	
CLINICAL STAGE 2	
	<ul style="list-style-type: none"> • Moderate unexplained weight loss (<10% of presumed or measured body weight) • Recurrent respiratory tract infections: sinusitis, tonsillitis, otitis media and pharyngitis) • Herpes zoster • Angular cheilitis • Recurrent oral ulceration (two or more episodes in last 6 months) • Papular pruritic eruptions • Seborrhoeic dermatitis • Fungal nail infections
CLINICAL STAGE 3	
	<ul style="list-style-type: none"> • Severe Unexplained severe weight loss (>10% of presumed or measured body weight) • Unexplained chronic diarrhoea for longer than one month • Unexplained persistent fever (above 37.6°C intermittent or constant, for longer than one month) • Persistent oral candidiasis • Oral hairy leukoplakia • Pulmonary tuberculosis (current) • Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis or bacteraemia) • Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis • Unexplained anaemia (<8 g/dl), neutropaenia (<0.5 × 10⁹ per litre) or chronic thrombocytopaenia (<50 × 10⁹ per litre)

CLINICAL STAGE 4

- HIV wasting syndrome Pneumocystis pneumonia
- Recurrent bacterial pneumonia (This episode plus one or more episodes in last 6 months)
- Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration or visceral at any site or any duration)
- Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)
- Extrapulmonary tuberculosis
- Kaposi's sarcoma
- Cytomegalovirus infection (retinitis or infection of other organs excluding liver, spleen and lymph nodes)
- Central nervous system toxoplasmosis
- HIV encephalopathy
- Extrapulmonary cryptococcosis including meningitis
- Disseminated non-tuberculous mycobacterial infection
- Progressive multifocal leukoencephalopathy
- Cryptosporidiosis (with diarrhoea lasting more than 1 month)
- Chronic isosporiasis
- Disseminated mycosis (coccidiomycosis or histoplasmosis)
- Recurrent septicemia (including non-typhoidal Salmonella)
- Lymphoma (cerebral or B-cell non-Hodgkin) or other solid HIV-associated tumours

- a. Assessment of body weight in pregnant woman needs to consider the expected weight gain of pregnancy.
- b. Unexplained refers to where the condition is not explained by other causes.
- c. Some additional specific conditions can also be included in regional classifications (such as reactivation of American trypanosomiasis [meningoencephalitis and/or myocarditis]) in the WHO Region of the Americas and disseminated penicilliosis in Asia).

Source: Revised WHO2007 Case Definitions of HIV for Surveillance and Revised Clinical Staging available online <http://www.who.int/hiv/pub/>

ANNEX 2: WHO CLINICAL STAGING OF HIV/ AIDS FOR CHILDREN WITH CONFIRMED HIV INFECTION

STAGE 1
Asymptomatic Persistent generalized lymphadenopathy
STAGE 2
<ul style="list-style-type: none"> • Unexplained persistent hepatosplenomegaly • Papular pruritic eruptions • Lineal gingival erythema • Extensive wart virus infection • Extensive molluscum contagiosum • Recurrent oral ulcerations • Unexplained persistent parotid enlargement • Herpes zoster • Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis or tonsillitis) • Fungal nail infection

STAGE 3	<ul style="list-style-type: none"> • Unexplained moderate malnutrition or wasting not adequately responding to standard therapy • Unexplained persistent diarrhoea (14 days or more) • Unexplained persistent fever (above 37.5°C intermittent or constant, for longer than one month) • Persistent oral candidiasis (after first 6 weeks of life) Oral hairy leukoplakia • Acute necrotizing ulcerative gingivitis or periodontitis • Lymph node tuberculosis • Pulmonary tuberculosis • Severe recurrent bacterial pneumonia • Symptomatic lymphoid interstitial pneumonitis • Chronic HIV-associated lung disease including bronchiectasis Unexplained anaemia (<8 g/dl), neutropaenia ($<0.5 \times 10^9$ per litre) and or chronic thrombocytopaenia ($<50 \times 10^9$ per litre)
STAGE 4	<ul style="list-style-type: none"> • Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy • Pneumocystis pneumonia • Recurrent severe bacterial infections (such as sepsis, pyomyositis, bone or joint infection or meningitis but excluding pneumonia) • Chronic herpes simplex infection (orolabial or cutaneous of more than one month's duration or visceral at any site) • Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) • Extrapulmonary tuberculosis • Kaposi sarcoma • Cytomegalovirus infection: retinitis or cytomegalovirus infection affecting another organ, with onset at age older than one month • Central nervous system toxoplasmosis (after one month of life) Extrapulmonary cryptococcosis (including meningitis) • HIV encephalopathy

- Disseminated endemic mycosis (coccidioidomycosis, penicilliosis extra pulmonary histoplasmosis)
- Disseminated non-tuberculous mycobacterial infection
- Chronic cryptosporidiosis (with diarrhoe)
- Chronic isosporiasis
- Cerebral or B-cell non-Hodgkin lymphoma
- Progressive multifocal leukoencephalopathy
- HIV-associated nephropathy or cardiomyopathy

Source: <http://www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf>

ANNEX 3: PRESUMPTIVE AND DEFINITIVE CRITERIA FOR RECOGNIZING HIV-RELATED CLINICAL EVENTS IN INFANTS AND CHILDREN WITH ESTABLISHED HIV INFECTION

CLINICAL EVENT	CLINICAL DIAGNOSIS	DEFINITIVE DIAGNOSIS
Clinical Stage 1		
Asymptomatic	No HIV related symptoms reported and no clinical signs on examination	Not applicable
Persistent generalized Lymphadenopathy (PGL)	Persistent swollen or enlarged lymph nodes > 1 cm at two or more non-contiguous sites, excluding inguinal, without known cause.	Clinical diagnosis

Clinical event	Clinical diagnosis	Definitive diagnosis
Clinical stage 2 (cont'd)		
Unexplained persistent hepatosplenomegaly	Enlarged liver and spleen without obvious cause	Clinical diagnosis
Papular pruritic eruptions	Papular pruritic vesicular lesion.	Clinical diagnosis
Fungal nail infections	Fungal paronychia (painful, red and swollen nailbed) or onycholysis (painless separation of the nail from the nail bed). Proximal white subungual onychomycosis is uncommon without immune deficiency.	Clinical diagnosis
Angular cheilitis	Splits or cracks on lips at the angle of the mouth with depigmentation, usually respond to antifungal treatment but may recur.	Clinical diagnosis
Lineal gingival Erythema (LGE)	Erythematous band that follows the contour or the free gingival line; may be associated with spontaneous bleeding.	Clinical diagnosis
Extensive wart virus Characteristic	Characteristic warty skin lesions; small fleshy grainy bumps, often rough, flat on sole of feet (plantar warts); facial, more than 5% or body area or disfiguring.	Clinical diagnosis

Extensive molluscum contagiosum infection	Characteristic skin lesions: small flesh- coloured, pearly or pink, dome-shaped or umbilicated growths, may be inflamed or red; facial, more than 5% body area or disfiguring. Giant molluscum may indicate advanced immunodeficiency	Clinical diagnosis
Recurrent oral ulcerations (two or more in six months)	Aphthous ulceration, typical with a halo or inflammation& yellow-grey pseudo membrane.	Clinical diagnosis
Unexplained parotid enlargement	Asymptomatic bilateral swelling that may spontaneously resolve and recur; in absence of other known cause, usually painless.	Clinical diagnosis
Herpes zoster	Painful rash with fluid-filled blisters, dermatomal distribution, can be haemorrhagic on erythematous background, and become large and confluent. Does not cross the midlines.	Clinical diagnosis
Recurrent upper respiratory tract infection (URTI)	Current event with at least one episode in past 6 months. Symptom complex; fever with unilateral face pain and nasal discharge (sinusitis) or painful swollen eardrum (otitis media), sore throat with productive cough (bronchitis), sore throat, (pharyngitis), and barking croup like cough (Laryngo-tracheal bronchitis [LTB]). Persistent or recurrent ear discharge.	Clinical diagnosis

Clinical stage 3		
Unexplained moderate malnutrition	Weight loss: low Weight-for-age, up to -2 standard deviations (SDs) not explained by poor or inadequate feeding and/or other infections, and not adequately responding to standard management.	Documented loss of body weight of -2SD, failure to gain weight on standard management and no other cause identified during investigation.
Unexplained diarrhea	Unexplained persistent (14 days or more) diarrhea (loose or watery stool, three or more times daily), not responding to standard management.	Stools observed and documented as unformed. Culture and microscopy reveal no pathogens.
Lymph node TB Non-acute, painless, "cold" enlargement of lymph nodes usually matted, localized in one region. May have draining sinuses. Response to standard anti-TB treatment in one month. Histology or isolation of <i>M. tuberculosis</i> from fine needle aspirate Pulmonary TB Non-specific symptoms, e.g. chronic cough, fever night sweats, anorexia and weight loss. In older child, productive cough and haemoptysis as well. Abnormal CXR. Isolation of <i>M. tuberculosis</i> on sputum culture Severe recurrent presumed bacterial pneumonia	Reports of fever or night sweat for longer than one month, either intermittent or constant, with reported lack of response to antibiotics or antimalarials. No other obvious foci of disease reported or found on examination. Malaria must be excluded in malarious areas.	Documented fever of $> 37.5^{\circ}\text{C}$ with negative blood culture, negative malaria slide and normal or unchanged CXR, and other obvious foci of disease

		<p>Cough with fast breathing, chest drawing, nasal flaring, wheezing, and grunting. Crackles or consolidation on auscultation. Responds to course of antibiotics. Current episode plus one or more in previous 6 months.</p> <p>Isolation of bacteria from appropriate clinical specimens (induced sputum, bronchoalveolar lavage [BAL], lung aspirate).</p> <p>Acute necrotizing ulcerative gingivitis or stomatitis, or acute necrotizing ulcerative periodontitis</p> <p>Severe pain, ulcerated gingival papillae, sening of teeth, spontaneous bleeding, bad odour, and rapid loss of bone and/or soft tissue.</p> <p>Clinical diagnosis</p> <p>Symptomatic lymphoid</p> <p>interstitial pneumonitis [LIP]</p> <p>No presumptive clinical diagnosis. CXR: bilateral reticulonodular interstitial pulmonary infiltrates present for more than two months with no response to antibiotic treatment and no other pathogen found. Oxygen saturation persistently <90%. May present with cor pulmonale and may have increased exercise-induced fatigue. Characteristic histology.</p> <p>Unexplained persistent fever (intermittent or constant, for longer than one month)</p>
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Oral candidiasis (outside first 6 weeks of life)	Persistent or recurring creamy white, soft, soft small plaques which can be scrapped off (psedomembranous), or red patches on tongue, palate or lining of mouth, usually painful or tender (erythematous form).	Microscopy or Culture
Oral hairy leukoplakia	Fine small, linear patches on lateral borders of tongue, generally bilateral, which do not scrape off.	Clinical diagnosis
Chronic HIV-associated lung disease (including bronchiectasis)	History of cough productive with copious amounts of purulent sputum (bronchiectasis only), with or without clubbing, halitosis, and crepitations and/ or wheezes on auscultations.	CXR: may show honey comb appearance (small cysts) and/or persistent areas of opacification and/or widespread lung destruction, with fibrosis and loss of volume.
Unexplained anaemia ($<8\text{g/dl}$), or neutropenia ($<0.5 \times 10^9/\text{L}$) or chronic thrombocytopenia ($<50 \times 10^9/\text{L}$)	No presumptive diagnosis.	Laboratory testing, not explained by other non-HIV conditions, or not responding to standard therapy with harmininics, antimalarials or anthelmintics as outlined in IMCI.
Clinical stage 4		
Unexplained severe wasting, stunting or severe malnutrition not adequately responding to standard therapy	Persistent weight loss not explained by poor or inadequate feeding, other infections and not adequately responding in two weeks to standard therapy. Characterized by: visible severe wasting of muscles, with or without oedema of both feet, and/ or weight-for-height of -3SDs , as defined by WHO IMCI Guidelines.	Confirmed by documented weight loss of $>3\text{SD}$ +/- oedema

Pneumocystis pneumonia (PCP)	Dry cough progressive Difficulty in breathing, cyanosis, tachypnoea and fever; chest indrawing or stridor. (Severe or very severe pneumonia asin IMCI). Usually of rapid onset especially in infants under six months of age. Response to high-dose co-trimoxazole +/- prednisolone.	Confirmed by: CXR typical bilateral perihilar diffuse infiltrates; microscopy of induced sputum or BAL or nasopharyngeal aspirate (NPA)
Recurrent severe presumed bacterial infection, eg. empyema, pyomyositis, bone or joint infection, meningitis but excluding pneumonia	Fever accompanied by specific symptoms or signs that localize infection. Responds to antibiotics. Current episode plus one or more in previous 6 months.	Confirmed by culture of appropriate clinical specimen
Chronic herpes simplex infection; (orolabial or cutaneous of more than one month duration or visceral at any site)	Severe and progressive painful orolabial, genital, or anorectal lesions caused by HSV infection present for more than one month.	Confirmed by culture and/or Histology

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Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)	Chest pain and dysphagia (difficulty in swallowing), odynophagia (pain on swallowing food and fluids), or retrosternal pain worse on swallowing (food and fluids)	Confirmed by macroscopic appearance at endoscopy, microscopy of specimen from tissue or macroscopic appearance at bronchoscopy or histology.
	responds to specific treatment. In young children, suspect particularly if oral candida observed and food refusal occurs and/or difficulties/ crying when feeding.	
Extra-pulmonary/ Disseminated TB	Systemic illness usually with prolonged fever, night sweats, weight loss. Clinical features of organs involved, e.g. sterile pyuria, pericarditis, ascites, pleural effusion, meningitis, arthritis, orchitis	Positive microscopy showing AFB or culture of Mycobacterium TB from blood or other relevant specimen except sputum or BAL. Biopsy and histology.
Kaposi's sarcoma	Typical appearance in skin or oropharynx of persistent, initially flat, patches with a pink or blood-bruise color; skin lesions that usually develop into nodules.	Macroscopic appearance or by histology: typical red-purple lesions seen on bronchoscopy or endoscopy; Dense masses in lymph nodes, viscera or lungs by palpation or radiology; Histology

CMV retinitis or CMV infection affecting another organ, with onset at age over 1 month	Retinitis only. CMV retinitis may be diagnosed by experienced clinicians: progressive floaters in field of vision, light flashes and scotoma; typical eye lesions on serial fundoscopic examination; discrete patches of retinal whitening with distinct borders, spreading centrifugally, often following blood vessels, associated with retinal vasculitis, haemorrhage and necrosis.	Definitive diagnosis required for other sites. Histology or CMV demonstrated in CSF by culture or DNA - PCR
CNS toxoplasmosis with onset at age over 1 month	Fever, headache, focal neurological signs, convulsions. Usually responds within 10 days to specific therapy.	Positive serum Toxoplasma antibody and available, neuroimaging showing single/multiple intracranial mass lesions
Extra-pulmonary Cryptococcus including meningitis	Meningitis: usually sub acute, fever with increasing severe headache, meningitis, confusion, behavioral changes that responds to cryptococcal therapy.	Isolation of Cryptococcus neoformans from extra pulmonary site or positive cryptococcal antigen test (CRAG) in CSF or blood.
HIV encephalopathy	At least one of the following, progressing over at least two months in the absence of another illness: failure to attain, or loss of, developmental milestones, loss of intellectual ability;	
	or progressive impaired brain growth demonstrated by stagnation of head circumference; or Acquired symmetric motor deficit accompanied by two or more of the following: paresis, pathological reflexes, ataxia, gait disturbances.	

ANNEX 4. DOSAGES OF ANTIRETROVIRAL DRUGS FOR ADULTS AND ADOLESCENTS

Generic Name	Strength and Dose
NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS	
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 mg twice daily or 300mg once daily
NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS	
Tenofovir (TDF)	300 mg once daily
NON – NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS	
Efavirenz (EFV)	600 mg once daily
Nevirapine (NVP)	200 mg once daily for 14 days, followed by 200 mg twice daily
PROTEASES INHIBITORS	
Atazanavir + ritonavir (ATV/r)	300 mg + 100 mg once daily

Lopinavir/ritonavir (LPV/r)	<p>Treatment-naïve patients</p> <p>Two tablets twice daily irrespective of co administration with EFV or NVP(200/50 mg twice daily i.e. 2 tabs twice a day)</p> <p>Tablets (heat-stable formulation) Lopinavir 200 mg /ritonavir 50 mg</p>
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ANNEX 5: PAEDIATRIC ANTIRETROVIRAL DOSING

Simplified table giving number of tablets of child-friendly solid formulations for morning and evening dosing

Drug	Strength of paediatric tab (mg)	Children 6weeks of age and above										Strength of adult tb(mg)	Number of tablets by weight-band	
		Number of tablets by weight-band morning and evening											25-34.9	
		3-5.9kg		6-9.9kg		10-13.9		14-19.9		20-24.9			am	pm
		am	pm	am	pm	am	pm	am	pm	am	pm			
SINGLE DRUGS														
AZT	60	1	2	1.5	1.5	2	2	2.5	2.5	3	3	300	1	1
ABC	60	1	2	1.5	1.5	2	2	2.5	2.5	3	3	300	1	1
NVP	50	1	2	1.5	1.5	2	2	2.5	2.5	3	3	200	1	1
COMBINATIONS														
AZT/3TC	60/30	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300/150	1	1
AZT/3TC/NVP	60/30/50	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300/150/200	1	1
ABC/AZT/3TC	60/60/30	1	2	1.5	1.5	2	2	2.5	2.5	3	3	300/150/150	1	1
ABC/3TC	60/30	1	1	1.5	1.5	2	2	2.5	2.5	3	3	600/300	1	
LPV/r ^c	100/25	NR	NR	2	1	2	2	2	2	2	2	100/25	3	3

A See ABC/3TC FDC closing table.

B Higher doses of LPV/r may be required when co-administered with enzymes-inducing drugs such as NVP, EFV, Los-amprenavir (FPV), Rifampicin.

Simplified table giving ml of liquid formulation and number of tablets or capsules of adult solid formulation for morning and evening dosing

Drug	Strength of pediatric syrup tab (mg)	Children 6 weeks of age and above									
		Number of tablets by weight-band morning and evening									
		3-5.9 kg		6-9.9 kg		10-13.9 kg		14-19.9 kg		20-24.9 kg	
		am	Pm	am	Pm	am	Pm	am	pm	am	Pm
AZT	10 mg/ml 300 mg	6 ml	6 ml	9 ml	9 ml	12 ml	12 ml	0.5	0.5	1	0.5
ABC	20 mg/ml 300 mg	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	0.5	0.5	1	0.5
3TC	10 mg/ml 150 mg	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	0.5	0.5	1	0.5
NVP	10 mg/ml; 15 mg or 20 mg	5 ml	5 ml	8 ml	8 ml	10 ml	10 ml	1	0.5	1	0.5
LPV/r	80/20 mg/ml	1 or 1.5 ml ^b	1 or 1.5 ml ^b	1.5 ml	1.5 ml	2 ml	2 ml	2.5 ml	2.5 ml	3 ml	3 ml

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b. LPV/r liquid for 3-3.9 kg, use 1 ml a.m and 1 ml p.m; for 4-5.59 kg use 1.5 ml p.m. In addition, higher doses of LPV/r may be required when co-administered with enzymes- inducing drugs such as NVP, EFV, FPV or rifampicin.

Drug	Strength	Number of tablets or capsules by weight-band once daily					Strength of tab. cap (mg)	Number of tab/cap by wt band once daily
		3-5.9kg	6-9.9kg	10-13.9	14-19.9	20-24.9		
		Once daily	Once daily	Once daily	Once daily	Once daily		Once daily
SINGLE DRUGS								
EFV ^a	200mg	NR	NR	1	1.5	1.5	200	2
a. EFV is not recommended for children below 4 years and weighing less than 10kg								
NR=not recommended EC=enteric coated								

ANNEX 6. NEW WHO DOSING RECOMMENDATIONS FOR EXISTING PEDIATRICS FDCS

Dosing Schedules: NVP/AZT/3TC (50/60/30mg) | AZT/3TC (60/30mg)

Weight range (kg)	< 5.9 kg	6-9.9 kg	10-13.9 kg	14-19.9 kg	20-24.9 kg	25 kg and Above
INDUCTION DOSE NVP/AZT/3TC(50/60/30mg) Tablet AZT/3TC(60/30mg) Tablet	1A.M	1.5A.M	2A.M	2.5 A.M	3A.M	4A.M or 1 tab OD of 200/300/150mg (Adult formulation)
	1P.M	1.5P.M	2P.M	2.5 P.M	3 P.M	4 P.M or 1 tab OD of 300/150mg (Adult formulation)
MAINTANANCE DOSE NVP/ AZT/3TC(50/60/30mg) Tablet	1 BD	1.5 BD	2 BD	2.5 BD	3 BD	4 BD or 1 tab BD of 200/300/150mg (Adult formulation)
	0.5 P.M	0.5 P.M	1 P.M	1 P.M	1.5 P.M	2 P.M or 1 tab OD of 30/150mg (Adult formulation)

ANNEX 7. THE ROLE AND SOURCES OF SELECTED MICRONUTRIENTS

Micronutrient	Role	Food sources
Vitamin A	Growth and function of T and B cells for immunity, maintenance of mucosal epithelial cells, including the lining of the respiratory, gastrointestinal and gastro-urinary tracts; vitamin A deficiency is associated with increased adult mortality, higher infant mortality and child growth failure.	Liver and dairy products, kidney, egg, some fish, yellow sweet potato, pumpkin, palm oil, carrot, dark green leafy, vegetables, fruits, such as papaya and mango

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Thiamine Vitamin B1	Important for energy metabolism; supports appetite and nervous system functions.	Whole-grain cereals, beans, meat, fish, chicken, egg
Riboflavin Vitamin B2	Important for energy metabolism; support normal vision, health, and integrity of skin.	Milk, egg, liver, yoghurt, meat, dark green leafy vegetables, whole grain cereals, fish and beans
Niacin Vitamin B3	Essential for energy metabolism, support health and integrity of the skin and nervous and digestive systems.	Milk, egg, meat, poultry, peanuts, groundnuts, wholegrain cereals, fish
Pyridoxine Vitamin B6	Facilitates metabolism and absorption of fats and protein; helps make red blood cells	Sweet potato, white beans, avocado, Cabbage, broccoli, meat, fish, green leafy vegetables.
Cobalamin Vitamin B12	Important for new cell development and maintenance of the nerve cells	Red meat, fish, chicken, shellfish, cheese, eggs, milk, fermented products.
Ascorbic Acid Vitamin C	Important for protein metabolism, immune function and iron absorption; Increases resistance to infections	Citrus fruits, such as orange, lemon, tangerine, guava, baobab, tomato
Micronutrient	Role	Food sources
Vitamin E	Protects cell structures and facilitates resistance against diseases	Leafy vegetables, vegetable oils, peanut, egg yolk, vegetables, nuts, seeds, and liver
Calcium	Builds strong bones and teeth; important for functioning of heart and muscle functions, blood clotting and pressure and immune defenses.	Milk, dark green leafy vegetables, shrimp, dried fish, beans, lentils, peas, whole grain millet, oil seeds, okra

Iodine	Ensures the development and proper functioning of the brain and the nervous system; important for growth development and metabolism.	Fish and other seafood, salt with iodine
Iron	Transports oxygen to the blood, eliminates old red blood cells and builds new cells; required for utilization of energy and metabolism by cells.	Red meat, poultry, shell fish egg, peanut, groundnuts, leafy vegetables, lentils, beans, some cereals, dried fruits
Magnesium	Strengthens the muscles; important for nervous system function, involved in bone development, maintenance of teeth.	Cereals, dark green vegetables, seafood, nuts, legumes, groundnuts
Selenium	Prevents impairment of the heart muscle; enhances the body's antibacterial and antiviral defenses.	Seafood, liver, meat, nuts, unrefined grains, brown rice, wheat germ, whole grain cereals, carrot, onion, milk, egg

ANNEX 8: MODERN MEDICATIONS AND RECOMMENDED FOOD INTAKES AND SIDE EFFECTS

Medication	Purpose	Nutrition Recommendations	Foods/averages/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

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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 thrush	With food		Nausea, vomiting, diarrhoea; can be used during breastfeeding
Nystatin ®	Treatment of thrush	With food		Infrequent occurrence of diarrhoea, vomiting, nausea

Antiretroviral drugs				
Abacavir (ABC) NNRTI	Antiretroviral	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	Antiretroviral	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	Antiretroviral	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	Antiretroviral	Can be taken with food, but do not take with a high fat meal	Alcohol	Elevated blood cholesterol levels, elevated triglycerides levels, rash, dizziness, anorexia, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence

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Nevirapine (NVP) NRTI	Antiretroviral	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	Antiretroviral	Can be taken without regard to food	St John's wort	Abdominal pain, diarrhoea, headaches, headache, weakness, nausea; may increase the risk of lipodystrophy and or diabetes
Nelfinavir PI	Antiretroviral	Take with meal or light snack	St John's wort	Diarrhoea, flatulence, nausea, abdominal pain, rash; may increase the risk of lipodystrophy
Ritonavir PI	Antiretroviral	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 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 Thrush	With food		Nausea, vomiting, diarrhea; can be used during breastfeeding
Nystatin ®	Treatment of thrush	With food		Infrequent occurrence of diarrhea, vomiting, nausea
Antiretroviral drugs				
Abacavir (ABC) NNRTI	Antiretroviral	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	Antiretroviral	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

Stavudine (d4T) NNRTI	Antiretroviral	Can be taken without regard to food	Limit alcohol	Nausea, vomiting, diarrhea, peripheral neuropathy, chills and fever, anorexia, stomatitis, diarrhoea, anaemia, headaches, rash, bone marrow, and pancreatitis
Zidovudine (AZT) NNRTI	Antiretroviral	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	Antiretroviral	Can be taken with food, but do not take with a high fat meal	Alcohol	Elevated blood cholesterol levels, elevated triglycerides levels, rash, dizziness, anorexia, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence
Tenofovir (TDF)	Antiretroviral	Can be taken without regard to food		Low rate of renal toxicity especially among people with pre-existing or risk factors for renal disease.
Nevirapine (NVP) NRTI	Antiretroviral	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

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Lopinavir PI	Antiretroviral	Can be taken without regard to food	St John's wort	Abdominal pain, diarrhoea, headaches, headache, weakness, nausea; may increase the risk of lipodystrophy and or diabetes
Nelfinavir PI	Antiretroviral	Take with meal or light snack	St John's wort	Diarrhea, flatulence, nausea, abdominal pain, rash; may increase the risk of lipodystrophy
Ritonavir PI	Antiretroviral	Take with meal if possible	St John's wort	Nausea, vomiting, diarrhoea, hepatitis, jaundice, weakness, anorexia, abdominal pain, fever, diabetes, headache, dizziness; may increase the risk of lipodystrophy
Saquinavir PI	Antiretroviral	Take with meal or light snack; take within two hours of a high fat meal and high calcium meal Garlic supplements	St John's wort	Mouth ulceration, taste changes, nausea, vomiting, abdominal pain, diarrhoea, constipation, flatulence, weakness rash, headache; may increase the risk of lipodystrophy

ANNEX 10: TB SCREENING TOOLS FOR HIV/AIDS PATIENTS**Chat for Diagnosis of TB in Children**

Chat for the Diagnosis of TB in Children						
	0	1	2	3	4	Score
General Features						
Duration of Illness	Less than 2weeks	2-4 weeks		More than4 weeks		
Failure to thrive or weight loss	Weight gain		No weight gain		Weight loss	
TB contact	None	Report not proven		Proven smear +/EP	Proven smear+	
Tuberculin test				Positive		
Malnutrition				Not improved after 4weeks		
Chronic infant disease				Not improved after 4 weeks		
Duration of Illness		Recurrent		No response To antibiotic		

Chat for the Diagnosis of TB In Children						
	0	1	2	3	4	score
Local Features						
Chest X-ray				TB suggestive features likeinfiltration,cavity orhilar lymph nodes		
Lymphnodes				Cervical, sub-mandible		
Swelling of bones or joints				Suggestive feature on X-ray		
Ascitis			Without Abdominal mass	With abdominal mass		
Meningitis				Chronic C.N.S sign		
Angle deformity of the spine					X-ray	
TOTAL SCORE						