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MINISTRY OF HEALTH AND SOCIAL WELFARE
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NATIONAL GUIDELINES

FOR THE MANAGEMENT OF HIV AND AIDS

**NATIONAL AIDS CONTROL
PROGRAMME (NACP)**
Fourth Edition (April 2012)

NATIONAL GUIDELINES

FOR THE MANAGEMENT OF HIV AND AIDS

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Ministry of Health and Social Welfare

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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
ddI	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 Immunisation
EPTB	Extrapulmonary Tuberculosis
ESR	Erythrocytes Sedimentation Rate

FBO	Faith Based Organisation
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	HIV Associated Dementia
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	Intergrated 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 Bednets
KS	Kaposi's Sarcoma
LFT	Liver Function Test
LIP	Lymphocytic Interstitial Pneumonitis
LPV	Lopinavir
LRTI	Lower Respiratory Track 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 Steroida Anti Inflammatory Drugs
NVP	Nevirapine
OI	Opportunistic Infection
OPD	Out-Patient Department
ORS	Oral Rehydration Salts
OST	Oploid Substitution Therapy
PCP	Pneumocystis Jiroveci Pneumonia
PCR	Polymerase Chain Reaction
PEP	Post Exposure Prophylaxis
PGL	Persistent Generalised 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 Organisation

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FOREWORD

During the past 30 years of the HIV epidemic in Tanzania, the country has responded in several ways, 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 (PL HIV). The main focus of the program is to improve access to Care and treatment at facilities and through Home-Based Care (HBC), for as many PLHIV as possible. This is in line with the MKUKUTA, National Health Policy 2007 Primary Health services Development Program (MMAM), Health Sector Strategic Plan 3 (HSSP-3) (2009) and the Health Sector HIV/AIDS Strategic Plan II (HSHSP-II) (2008). The MoHSW in collaboration with the implementing partners, has realized significant achievements in this program, that includes the enrolment for patients for HIV Care and Treatment, giving a cumulative figure of 749,302 cases, whereby, a total of 390,320 eligible patients, have started ARVs. For those who are not eligible, they are closely monitored at 1,100 health facilities, that are providing Care and Treatment services in the whole country.

There is still a need to expand the services to reach out to more PLHIV, and thus, this requires putting in place more efforts; that will ensure there is the availability of adequate infrastructure, trained health staff, laboratories services, counselling services and ARVs. Success in these, will constitute the provision of quality services by a functional health system.

The field of HIV and AIDS, especially Care and treatment is rapidly evolving. Newer and more potent medicines are continuously being developed and used, and knowledge on the existing medicines, in terms of their efficacy, short and long term side effects, is becoming clearer and more experience on Care and treatment is gained. These recent developments and experiences in the field of HIV and AIDS, have made it necessary for the country to come up with revised and updated guidelines, to reflect the changes that have taken place. Thus improve the quality of care and treatment of the patients.

This edition has taken into consideration the new WHO (World Health Organisation) recommendations, that were revised in 2009 and 2010, on ART eligibility and types of ARV regimens, which gives the clinicians and patients, flexibility on the choice of regimen, and thus, provide quality care. Other considerations include, the best practices and key lessons from facilities that are implementing care and treatment programs. It is also being emphasized that, the 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, etc., as collaborative activities, should immediately be considered and implemented.

Like the previous edition, it covers key areas of Adult and Paediatric HIV and AIDS management; Nutrition; Management of Opportunistic Infections; Home Based Care and the Continuum of Care; Counselling 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, 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 and AIDS, contributions from users of these guidelines is vital and 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.



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Chapter 1.

Chapter 1. Overview

CHAPTER 1. OVERVIEW

1.1 Epidemiology of HIV/AIDS

HIV/AIDS is a major health problem globally. UNAIDS estimated that, by end of 2009, a total of 33.3 [31.4 – 35.3] million people worldwide were living with HIV and AIDS. Sub-Saharan Africa is the world's most severely affected region. 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 there are now reports of declining trends in HIV incidence in a number of countries, presumably due to behaviour 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 more recently, the life-prolonging effects of antiretroviral therapy.

Since the first three AIDS cases were reported in Tanzania in 1983, the HIV epidemic has spread rapidly to all districts and communities in the country, and affected all sectors of the society. In 2007 about 2 million persons were estimated to be living with HIV/AIDS, with approximately 600,000 (30%) in need of ART by the criteria used at that time. Recent data based on household surveys estimate the sero prevalence in adults aged between 15 – 49 years in Tanzania to be 5.7%, with a wide variability among regions (THMIS, 2008). Sexual intercourse is the main mode of transmission, which is why sexually active individuals between the ages of 15 and 49 are most severely affected, with women being at a higher risk of infection than men.

Today in Tanzania as in most Sub-Saharan African countries, HIV and AIDS are recognized not only as a major public health concern, but also as a socio-economic and developmental problem.

In response, the government has strengthened efforts to scale up care and treatment services. According to the National AIDS Control

Program Care and Treatment report it is estimated that 21% - 30% of PLHIV in Tanzania have registered at CTC, and 63% - 83% of those eligible for treatment are receiving ARVs. Availability of ART has had great impact in prolonging lives. In analysing 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 unfavourable effect on the overall quality of health care 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 TBB programme established in 1980, the national TB infection rate in Tanzania has increase fivefold, 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. It is therefore important that all HIV infected patients be screened for TB and, if positive, promptly treated for TB; and if negative, started on TB prophylaxis.

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.

Ill health and death due to AIDS are reported to have reduced 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 Tanga.

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 the loss of a family's primary income generator. Studies conducted in the Arusha, Kagera and Mwanza regions show a serious breakdown of the social network, 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 also lack of opportunities for education and health care. 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 have shown that the decline in HIV prevalence rates was a result of a combination of all these factors.

The components of a minimum package for HIV and AIDS response include: blood safety initiatives, STD (sexually transmitted disease) 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 has shifted. Initially, the response focused solely on interventions aimed at prevention; now, it puts emphasis on care and treatment as well.

Since 2004, the Government, in collaboration with partners, initiated a care and treatment programme under the NACP. By December 2010, a total of 740,040 HIV-infected people had been enrolled at 1100 health facilities throughout the country. Scaling up ART remains a challenge. Out of the estimated 440,000 HIV-infected Tanzanians who are eligible, only 335,292 are currently on ART (NACP 2011). 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 the HIV-1 subtype. No infection with HIV-2 has been reported yet. The common HIV-1 subtypes (clades) in Tanzania are A, C, D and their recombinants.

1.4.2 HIV Transmission

HIV infection is acquired from 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, HIV transmission resulting from exposure to saliva, urine or sweat is not likely, if at all.

1.4.3 Pathophysiology of HIV Infection

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 unknown, lead to the rapid depletion of the CD4+ T-lymphocytes. The decline in the CD4+ T-lymphocyte count is a reflection of declining cellular immunity, which eventually 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 over time, 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; particularly if they are tested 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 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.

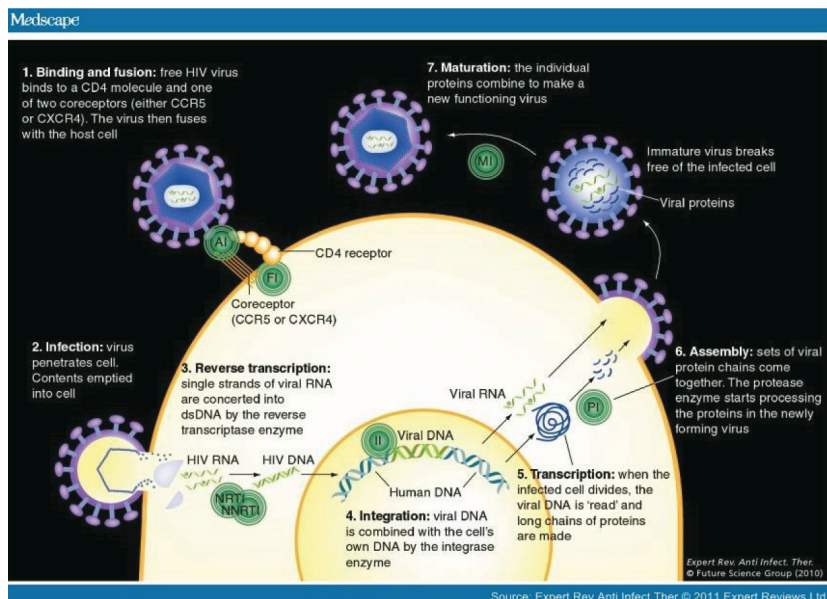
Clinical and biological studies of patients over long periods have demonstrated that measuring viral load (expressed as number of copies/ml) is the most powerful predictive indicator of disease progression. Viral load and number of circulating CD4⁺ T-lymphocytes/mm³ are the two most important laboratory parameters to consider when deciding whether to start treatment. 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 risk of complications like the 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. On average, however, it takes eight to ten years. 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, do minimise the risk of rapid onset of immuno-suppression. Preventive therapies currently used include those for TB, bacterial infections, *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 proviral 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)

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



Antiretroviral 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+ T lymphocytes.

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.

Organisation of HIV and AIDS Care and Treatment



CHAPTER 2. ORGANISATION OF HIV AND AIDS CARE AND TREATMENT

2.1 Introduction

The Health Sector HIV and AIDS Strategic Plan (HSHSP) II 2008-2012 builds on the National HIV and AIDS Care and Treatment Plan for PLHIV, which was developed in 2003, and calls for the provision of quality HIV and AIDS services at all health care facilities across the country, which itself requires the establishment and organisation of effective CTCs. By the end of 2010, a total of 1100 health facilities had began providing care and treatment services. Of those, 220 are hospitals and the remaining 880 are primary health facilities.

The National Program has also developed and operationalized several service delivery quality improvement documents (e.g. National Essential Health Sector HIV and AIDS Intervention Package – NEHSHIP, National Guidelines for Quality Improvement of HIV and AIDS Services, and Comprehensive Supportive Supervision and Mentoring Manual and Tools). NACP has also revised The Patient Monitoring System (PMS) and seven modules of the National Standard Operation Procedures (SOPs) for HIV Care and Treatment to facilitate provision of quality HIV and AIDS services.

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 Plan, an expanded 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. Within the health sector, health services exist within communities for identification of people in need of care and treatment. These services are: HIV Testing and Counselling (HTC), Home Based Care (HBC), PMTCT, Out Patient Department (OPD), In Patient Department (IPD), and TB Clinics. HTC components include Voluntary Counselling and

Testing (VCT) at facilities, as stand-alone sites, or as part of one-time campaigns using any place of gathering, Provider Initiated Testing and Counselling (PITC) in health facilities, and Home Based Testing and Counselling (HBTC). Using all effective communication channels, including interpersonal and peer-led group education, media-led, mobile and electronic communication technologies, people in both urban and rural areas need to be encouraged to come forward for testing and counselling so that those in need of care and treatment can be identified and linked to relevant services as part of the continuum of care.

2.3 Scope of Care and Treatment

The provision of HIV Care and Treatment services, including ARVs, can take place at health care facilities including PHC sites as long as trained staff is available and sites have been assessed and registered. Once enrolled, these CTC services can be provided at a stand alone CTC, or integrated with general services such as at dispensary at the small health centre level, or integrated as a "One Stop Shop" service at TB/HIV clinics or MTCT sites. In case of established need, it is 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 HBC services.

The core elements of HIV prevention, treatment and support that need to be available within CTC services at any level include basic education about the mode of HIV transmission, about disease progression, about management of the disease, and about all elements of PHDP (*see also Chapter 3*). This includes the following:

1. Education about behavioural risks and condom use for infected people
2. Orientation on care and treatment services available in hospital and district

3. Education and regular counselling on life-long disease management, and in particular on treatment adherence
4. Education and counselling on actions that may delay progression of disease and reduce co-morbidities; for example, addressing nutrition, food safety, clean water and use of insecticide treated bed-nets
5. Early identification and management of co-morbidities such as TB
6. Prophylaxis for OIs and cancers including Cotrimoxazole, TB preventive therapy and cervical screening
7. Assessing eligibility for ART (clinical staging, social eligibility and CD4 counts)
8. Effective referrals to essential hospital services such as antenatal clinics for MTCT, family planning advice before and while on ART, STI or other specialized clinics
9. Recording and reporting according to the established electronic and paper based system
10. Registration and appointment systems for effective treatment continuation and preventing missed appointments
11. Referral to community services such as HBC, social welfare and legal support
12. In order to provide effective and quality HIV and AIDS Care and Treatment, service delivery needs to be organized in a manner to ensure efficiency, user friendliness, and regular, standardized follow up. Quality Improvement (QI) initiatives are a helpful tool in this regard.

2.4 Organisation of Care and Treatment Services

2.4.1 Staffing and Team Approach

For CTC services to function well, adequate and trained staff need to have clearly outlined roles and responsibilities. Since HIV and AIDS is now a manageable chronic disease, the principles of chronic disease management must be followed. Team approaches involving a patient,

a family care giver and a healthcare team (consisting of at least a triage nurse, a doctor and a treatment/adherence nurse) will ensure the building of an ongoing relationship between patient and the health care team for life-long care. Regularly scheduled visits minimise drug depletion at home; this is enabled by records that are easy to retrieve, and disciplined observance of appointment schedules. Weekly CTC team meetings to discuss bottlenecks and case studies will help to build team spirit, while quarterly staff meetings between heads of relevant units involved in HIV care such as CTC, TB, VCT, PRCH, STI, HBC, Pharmacy, Laboratory and In-patient units will help to build better internal cooperation and patient referrals.

CHMT (Council Health Management Team) members must conduct regular (at least quarterly) supportive supervision visits to assess efficiency and effectiveness of service delivery, and identify where mentoring by experts from supervising hospitals or health programmes should be put in place.

The National Standard Operating Procedures manual outlines the following services to be provided by available staff within CTC:

- Registration and appointments management; filling of CTC1 and CTC2 basic information; height, weight, Blood Pressure (BP), (Body Mass Index(BMI)), pulse rate and temperature
- Triage: assessment of immediate medical needs, TB screening questionnaire, support and referring the patient to the next relevant unit or staff at the CTC
- Clinical management
- Patient ART preparedness and adherence counselling
- All elements of PHDP
- Data collection and management
- Referral management within the hospital, and with relevant institutions and community organisations

2.4.2 Patient Visits Plan

At the initial clinic visit, a triage nurse will assess patient's needs, register basic information on reliable patient demographics and contact information, issue relevant forms such as CTC1, CTC2 (see Section 2.4.4 for explanation of these forms) and the TB screening tool, weigh the patient, and direct her/him to relevant sites. The nurse will draw blood for a confirmatory HIV test if there is doubt about their status; and for a CD4 cell count, or sputum smear if indicated, before the patient meets a counsellor or clinician. In the case of unavailability of Point of Care or same day laboratory services, the patient will be scheduled for a follow-up visit with a clinician to discuss the test results.

At the follow-up visit, after consultation with a clinician, patients who are recommended for and agree to initiate therapy will meet with a counsellor to discuss adherence, medication dosages and adverse reaction management. The nurse will draw another blood sample for tests that will help inform the treatment protocol and identify baseline values for monitoring toxicity. Patients will be scheduled for a follow-up appointment in two weeks, then monthly for the first six months, depending on assessment by the clinician on the status of a patient on ART. However, after the patient is clinically stable, with good adherence for at least the first six months or more to ART regimen, and no history of drug toxicity or recurrent OI, s/he may be given an appointment of two months hence or more, as agreed between the clinician and the patient.

During these scheduled visits, the patient will see an evaluating clinician, pick up their medication from the pharmacy, and meet with a counsellor (see counselling section below). At six month intervals, nurses will perform CD4 counts and basic blood tests, and patients will see a clinician to evaluate response to therapy.

Those who are not eligible for treatment still require regular monitoring of their status with assessment of clinical stage, and CD4 count every six months for all asymptomatic cases (i.e. WHO stage I)

and all symptomatic cases (i.e. WHO stages II and CD4 above 350). Regardless, all patients are advised to come into the CTC immediately should their condition deteriorate prior to their next scheduled visit.

Experience in Tanzania with QI initiatives over the last few years shows that, when patients at both urban and rural sites are given an appointment with specific time allocation (block appointment) on a given day, patient flow, staff and patient satisfaction greatly improves. In this efficiency approach, patients are asked to opt for time they feel most comfortable coming to the clinic.

2.4.3 Adherence Management and Lifestyle Counselling

Adherence to preventive therapies, TB treatment and ARVs are important factors in ensuring better health outcomes. Patients in long term therapy or prophylaxis, including ARV treatment, are strongly encouraged to identify an adherence/treatment assistant. This can be any person (e.g. a family member, friend, colleague, or community member) to support the patient in complying to prescribed medication.

During the monthly visit to the CTC, each patient will be screened for TB and provided with relevant prophylaxis as indicated. In addition, the nurse will probe for adherence using a checklist to identify possible lapses, and reinforce key practices related to optimal adherence.

Patients also receive information and counselling on various PHDP elements such as transmission risk reduction, nutritional and family planning advice, and adverse event management. Other psychosocial needs such as social or legal support, disclosure of HIV status, mental health, referrals to HBC services and facilitation for joining PLHIV (People Living with AIDS) support groups will also be addressed during the counselling session. In addition, the patient will be screened for TB and other OIs for early identification, treatment or prophylaxis.

Note: The adherence assessment checklist is described in the 2010 CTC2 forms to be kept in the patient file.

2.4.4 Medical Records System

The Patient Identification Card (CTC1), the Patient Record Form (CTC2), the Registers (pre-ART and ART), the Reporting Forms (for Cross-sectional and Cohort analysis), and the referral form have been designed for the purpose of patient identification, patient monitoring and programme monitoring. In addition, an appointment book to facilitate scheduling and follow-up on lost patients is 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 in care and treatment services; the patient will keep it and use it for identification purposes at every visit.

b) Patient Record Form (CTC2) Revision 2010 is a form initiated at the first visit of any HIV positive person attending the CTC for management and monitoring of 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 in a 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 key information on patient management should be filled in by the relevant health provider.

c) Registers

There are two types of registers used at the CTC: the Pre-ART register and ART 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; it also allows cohort analysis. All patients who first enrol 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, s/he 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; again, it 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 CTC2 form facilitates the monitoring of individual patients, and the information collected in the register facilitates the monitoring the whole group of patients.

d) Referral Transfer Out Form

It is important that the patient carries treatment relevant information with her/him whenever s/he sees a new clinician, e.g. when s/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.

2.4.5 Reporting

Reporting at the CTC should be done as follows using the appropriate reporting forms and tools:

a) Quarterly Reports: A quarterly summary of newly enrolled patients 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. A member of the Care and Treatment Team fills out data continuously as the cohort reaches 6, 12, 24 months; the data are 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 information to the Care and Treatment Team and the district, regional and national levels to monitor how well the programme is doing with regard to patients started on ART. That information includes surviving patients, patients still on a first line regimen, and functional status of the patient. It also provides a comparison between patients with six months of ART at the current facility, and other patients with six 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.

A member of the Care and Treatment Team should keep an Appointment Book at the registration unit and fill it 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 whether

the patient has shown up. Information on patient show up is crucial for tracking missing patients who can easily be identified and traced.

Each facility participating in the National Care and Treatment Programme should designate one 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.

2.5 Linkages Across a Continuum of Care

Linkages between a variety of care-related providing units within the facility and with partnering programmes in the community are encouraged at all levels. Partnerships and regular dialogue between the CTC and support programmes in the community must be established within the district in order to ensure a continuum of care. Often members of PLHIV support groups or staff from HBC programmes can assist at CTC service delivery sites to enable effective referrals and follow up.

The expanded CHMT or continuum of care subcommittees should promote the necessary dialogue. 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 (HBC)
- PLHIV 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 comprehensive prevention, support and care

services available within the district, with contact details to enable a prompt referral across the continuum of care. *(For detailed of comprehensive services, see also Chapter 3.)*

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

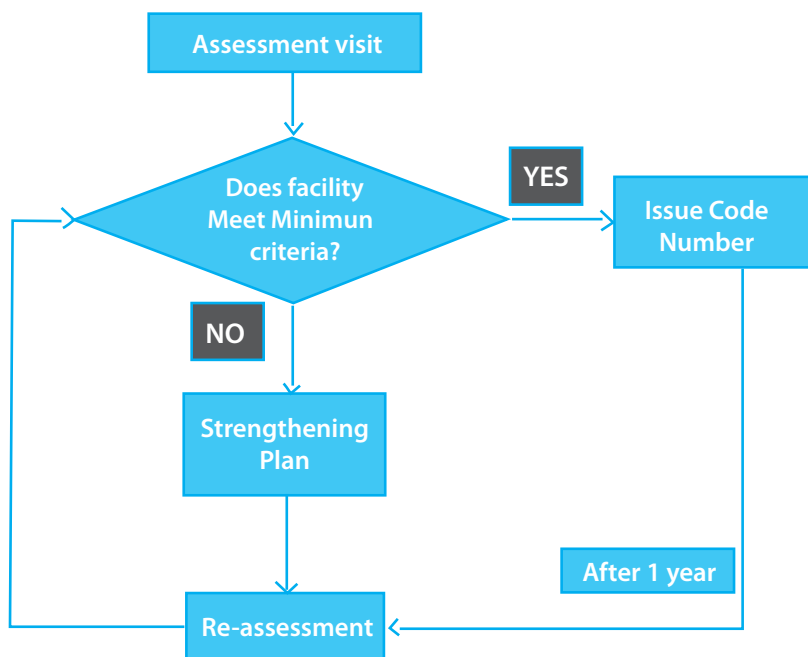
Selection of health facilities for provision of HIV and AIDS services is done by CHMT, and then communicated to the RHMT (Regional Health Management Team) for arrangement of assessment. Having received the request from councils in their jurisdiction, an RHMT-designated person, and implementing partners supporting respective regions, will conduct assessment of the health facility. On these visits, the CHMT focal person, usually the DACC, will form this team.

The first step in the assessment process is to develop a strengthening plan for the health facility by the health care workers supported or guided by the assessment team.

Assessed facilities can be categorized into:

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

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 three months ago (i.e., supervision must occur 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 three 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 two 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
 - Pregnancy tests
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 a three month supply of ARVs and other medicines
5. Proper patient records and reporting system:
 - An established and working medical record system

6. Counselling and testing services:
 - One confidential room for counselling and testing
 - One HCT 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

HIV and AIDS related commodities are relatively expensive and therefore they require proper handling to ensure effective use. Proper management ensures optimal use of quality medicines and other medical supplies to patients when they need them. The process of management involves identification of the medicines and other medical supplies needed, and acquisition of the needed medicines, and supplies from reliable sources e.g. Medical Store Department (MSD) and ensurance of their proper utilization by the user.

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 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 drugs rationally since irrational drug use (especially in the context of ART) may have unwanted consequences at both individual and population levels, including:

- 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

2.7.3 Prescriptions

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

The prescription for ARVs should clearly indicate the name, age, and sex of patient; the medicines and dosage; and should include the name, signature and prescriber's code (where applicable).

2.7.4 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 counselling.

The pharmacist/dispenser should make sure that the patient understands the dosage and drug intake schedule as well as instructions regarding the storage and food requirements. The pharmacist/dispenser should also caution patients about possible side effects, respond to specific questions and problems related to ARV treatment encountered by patients, and advise them on measures to be taken to reduce these side effects, including the option of immediate return to the clinic.

2.7.5 Records

In order 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 Pharmacy Register

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 a pharmacy module/electronic database is available, the patient's information and their prescribed medication should be recorded. Reports on medicine consumption and stocks should be kept by facilities in order to understand their ongoing supply requirements. On an annual basis, these reports should be sent to the Ministry of Health and Social Welfare through the District Medical Officer (DMO) for program monitoring and forecasting.

2.7.7 Patient Identification Cards

Each patient has a patient identification card (CTC1) that includes information on medication. Patients (or appointed adherence assistants) must present the cards to the dispenser every time they collect medicines, and all medications received must be recorded on the card.

2.7.8 Storage

To ensure proper control and security of ARVs and other drugs, the following procedures should be in place at the facility pharmacy:

Stock must be kept in a high security storage area with a single pharmacist/ pharmaceutical technician (at any one time) responsible for receipts and issues.

Normal stock records must be kept for all receipts and issues, along with a running balance, and ledgers maintained for each item. At the end of each month, the pharmacist in charge must check the physical stock against the stock records.

ARVs must be stored at the appropriate temperature. Suspensions such as second line medicine, e.g. Kaletra (Lopinavir/Ritonavir) must be refrigerated.

Commodities must be stored according to the first-to-expire first-out (FEFO) procedure and stock management.

Damaged and expired commodities should be immediately separated from usable ones and disposed using the established procedures.

The pharmacist should maintain adequate stocks of ARVs for all required medications (first line, second line, adults, paediatrics) at all times.

2.7.9 Procurement

The Medical Stores Department is in charge of procurement of ARVs, which they will then distribute to all the care and treatment clinics across the country. Requisition of antiretroviral drugs from the facilities will follow the normal procedure for other drugs, except that a separate requisition form is used.

Upon receipt of the drugs at the facility, the pharmacist shall check the ARVs brought by MSD and sign the delivery note.

An adequate buffer stock of drugs must be kept at all times and closely monitored to avoid stock outs.

2.7.10 Ordering ARVs

The pharmacist will order ARVs using one of the Integrated Logistic System (ILS) forms. This built-in inventory control system is designed to ensure that drugs are ordered on quarterly basis using existing stock levels and not morbidity data.

Relevant data on the consumption of ARV medicines must be kept and sent to the Ministry of Health and Social Welfare every year.

Orders to the MSD should be made well in advance to allow supplies to reach the facilities in time.

2.7.11 Collaborating with Clinical Staff

The pharmacist will need to work with clinical staff to obtain an estimate of the number of patients expected to be enrolled on therapy.

The pharmacist also needs to keep clinical staff informed of the current stock levels of ARVs, particularly of items nearing stock-out. 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.

2.7.12 Monitoring of Adverse Drug Events

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

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

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.

2.7.13 Audit

Procurement, storage, distribution and dispensing procedures, and records and stock in hand will be subject to internal and external audit. Given the cost and complexities of handling ARVs, frequent auditing by facility managers is anticipated.

Chapter 3.

HIV and AIDS Prevention Services in Health Care Settings



CHAPTER 3. HIV AND AIDS PREVENTION SERVICES IN HEALTH CARE SETTINGS

3.1 Introduction

Health facilities play an important role in primary prevention of HIV through various activities initiated by the health sector. Good examples are the facility based VCT sites, PITC activities at all units of the facility using the opt out method, IEC activities as group and individual education and counselling, male circumcision and comprehensive prevention and support programmes for PLHIV such as PHDP activities.

3.2 Male Circumcision

A number of studies in South Africa, Kenya and Uganda, among others, have demonstrated that MC (male circumcision) has a significant protective benefit against HIV infection in female-to-male transmission, with reported reduction in HIV incidences ranging from 50-60% among circumcised men. In 2007, WHO issued guidelines encouraging 13 priority countries, including Tanzania, to develop and scale up male circumcision for HIV prevention programmes, with the goal of reaching 80% or more coverage of MC. The WHO-recommended MC for HIV prevention package includes MC, HIV and sexual health group education, individual counselling, HIV testing on an opt-out basis, conduct of physical exam and STI check, safe surgical practices by trained providers, and two to three post-operative follow up visits. In Tanzania, national MC prevalence is 67%, however there are large regional variations (e.g. 97% in Lindi vs. 21% in Shinyanga). Therefore the GoT (Government of Tanzania) has prioritized eight regions (Iringa, Mbeya, Shinyanga, Rukwa, Kagera, Mwanza, Mara (one district) and Tabora), with lower than average MC rates and relatively high HIV prevalence for the scale up of MC for HIV prevention services. HIV-negative males aged 10 to 34 are given priority for free MC for HIV prevention services. MC

can be carried out in health facilities (static sites) and also in outreach campaigns.

A circumcising team in either setting consists of a surgeon (trained nurse, clinical officer or doctor), a bed nurse for each bed, two runners, a data clerk, a receptionist, two instrument processors, and two counselors.

During implementation of medical MC facilities, managers and providers should ensure that:

- Male circumcision is undertaken by an appropriately trained health provider (nurse, clinical officer or doctor) under local anaesthesia.
- Messages that outline the partial protection benefits of medical MC are clearly explained to clients, and that clients understand the need to continue to use the full range of HIV prevention strategies (abstinence, partner reduction, faithfulness to one partner, and/or condom use) after their healing period is complete.
- Opt-out HIV testing and counselling is offered to all clients (and their partners or guardians if present) seeking medical MC, but is not mandatory. Clients opting out, as well as clients testing HIV-positive, should be further counselled on the lack of HIV prevention benefits for HIV-positive men and the extra importance of adhering to the post-operative abstinence period. After counselling, clients still wishing to be circumcised should be provided with services.
- Counselling should stress that resumption of sexual relations before complete wound healing may increase the risk of acquisition of HIV infection among recently circumcised HIV-negative men. Men who undergo circumcision should abstain from sexual activity for at least six weeks.

There is broad community engagement to introduce or expand access to safe MC services. Such engagement also serves as a means of communicating accurate information about the intervention to both

men and women, and engaging community leaders to promote and facilitate MC for HIV prevention activities.

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

3.2 Positive Health, Dignity and Prevention (PHDP)

Positive Health, Dignity and Prevention focuses on improving and maintaining the health and well-being of people living with HIV, which, in turn, contributes to the health and well-being of partners, families and communities. This is in direct 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 people living with HIV within a human rights frameworks.

PHDP also advocates for programmes 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 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.

2. Health Sector Interventions to Optimize the Health of PLHIV

To date, HIV prevention has largely focused on providing information, counselling and testing to those who are HIV-negative. While this is an important strategy, people living with HIV have often been left out of prevention, and more recently, practitioners have recognized 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 aims 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.

3. Community Interventions

Community involvement in HIV prevention includes community-based programmes such as HBC; community mobilization for participation in HIV related activities such as counselling and testing campaigns; PLHIV support organisations; 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.

3.2.1 Health Facility Interventions

- Changes in the risk behaviours of HIV infected individuals are likely to have greater 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 urinal 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. Integrating prevention strategies into the HIV clinic ensures comprehensive and consistent quality of care. Finally, prevention messages can be reinforced at every visit.

3.2.1.1 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 and establish social norms

3.2.1.2 Messages and Counselling to Support Healthy Behaviours

Sexual Risk Behaviour

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 partners.

Many people find it difficult to change their behaviours, especially around sexual practices. Changes surrounding sexual behaviour 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 their health care providers. The stigmatization of HIV remains a real issue and even admitting sexual activity can be difficult for PLHIV.

Patients may not be ready to adopt new practices immediately, and sustaining safer sexual behaviours 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 delivering prevention messages and counselling at every visit. Specific risk reduction messages providers can promote include partner reduction, condom use, disclosure and knowledge of 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 enrolment in 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 behaviour). 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 partners.

Patients 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 message reinforcement.

Another important benefit of treating HIV is that viral load decreases. This has been shown to decrease patients' likelihood of transmitting HIV. However, even patients on ARVs can still transmit HIV, including drug resistant strains of the virus. So, again, it is important for health care providers to help patients understand that they can still transmit HIV and recommend that they take precautions, even when they are on treatment

Couple Counselling and Partner HIV Testing

Health care providers should encourage patients to bring in their partners for HIV testing and counselling. This provides an opportunity to counsel couples together, and also 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 behaviours, 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 reduced the chances of infecting her/his partner.

In concordant relationships where both partners are HIV-positive, there is a potential consequence of unprotected sex to the HIV-infected patient, which is that s/he may become “re-infected” with a different strain of HIV (including a 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 patients who have unprotected sex with HIV-positive partners.

3.2.1.3 Screening and Treatment of STIs

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 (though 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 passing HIV and/or another STI onto their partner(s). It is also important to treat the STI in both the patient and her/his 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 neurological and developmental effects on the baby. Moreover, current or past STIs in women and men 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.” HCWs 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 counsellors and clinicians should work hand-in-hand in providing support to STI patients in notifying their partner(s) about the need for treatment.

3.2.1.4 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 PLHIV couples have access to contraception and advice about pregnancy is to provide family planning and safer pregnancy counselling within the CTC following an integrated model of service provision. To ensure that PLHIV receive these 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 PLHIV couples' 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. Clinicians should 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 future care for their children,

- in case they become unable to care for them.
- If a pregnant woman is on **ARVs or other medications**, providers should assess her drug regimen and adjust it as needed to ensure that the medications will not harm the foetus. For example, the EFV (Efavirenz) based regimen is not recommended in the first trimester.

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, injectables, 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 PLHIV 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 both pregnancy and HIV and STI transmission.

3.2.1.6 Managing Most at Risk Populations

Most at risk populations (MARPs) are the key group in controlling the HIV epidemic. HCWs need to identify and address the special needs of these individuals whenever they seek health services.

Specific actions should be taken when managing:

a) Injection Drug Users (IDUs):

- Promote voluntary screening for HIV, TB, STI, Hepatitis B and Hepatitis C among IDU and their injecting and sexual partners
- Provide access to treatment for HIV positive IDU and their HIV-infected injecting/sexual partners
- Provide opioid substitution therapy (OST) and other drug dependence treatments in line with the national guidelines
- Provide Naloxone for management of opiate overdoses for IDUs
- Refer IDUs to NGO supported community outreach programmes for IDUs

b) Female Sex Workers

- Promote voluntary screening for HIV, TB, STI, Hepatitis B and Hepatitis C among female sex workers and their sexual partners
- Provide access for HIV positive female sex workers and their sexual partners to treatment (where indicated)

c) Men who have Sex with Men (MSM)

- Promote voluntary screening for HIV, TB, STI, Hepatitis B and Hepatitis C among males who have sex with men (MSM) and their sexual partners
- Provide access to treatment for HIV positive men who have sex with men and their sexual partners (where indicated)

d) Incarcerated Prisoners and Those who Leave Prisons

- Promote voluntary screening for HIV, TB, STI, Hepatitis B and Hepatitis C among those incarcerated in prisons

- Provide access to care and treatment for HIV positive individuals incarcerated in prisons
- Provide access to care and treatment for HIV positive prisoners leaving prisons
- Provide TB/HIV collaborative activities within prisons

3.2.1.7 Identification of Social Needs and Referral for Community-Based Services

We recommend that CTC should have a directory of all services available in the catchment area where PLHIV can read about them. Whenever 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.

3.2.2 Community Interventions

3.2.2.1 Support PLHIV to Voluntarily Disclose Sero Status

- Support HBC and lay 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

3.2.2.2 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

3.2.2.3 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 managed and cope with HIV infection and treatment
- Support community outreach campaigns to fight HIV-related stigma and discrimination against PLHIV and MARPs

3.2.2.4 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 lay 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 destigmatization of HIV in the community

3.2.2.5 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 PLHV 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.

Chapter 4.

HIV and AIDS Prevention Services in Health Care Settings



CHAPTER 4. HIV PREVENTION IN A HEALTH CARE SETTING

4.1 Introduction

Though estimates vary by region, 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. 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. Comprehensive infection control strategies and procedures can dramatically reduce the risk of transmission associated with health care.

4.2 Occupational Exposure

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 injection and other equipment is poorly sterilised, HIV may be passed from an HIV-infected individual to an uninfected patient within the health care setting.

Protecting the occupational health of health workers and ensuring that they know their status and receive HIV treatment as appropriate is an important priority for the health sector. HIV and other BBPs (blood borne pathogens) 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 usually results from contaminated equipment and other materials that have been incorrectly or inadequately processed.

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 minimise 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 that 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

4.3 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 or the use of unscreened blood.

Access to safe blood transfusion is an essential component 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.

4.4 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.

4.5 Prevention of HIV Transmission through Standard Precautions

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

4.5.1 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 equipment 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.

4.5.2 Implementation of Standard Precautions

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

4.5.2.1 Hand Hygiene

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

4.5.2.2 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

4.5.2.3 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 (must 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.

4.5.2.4 Aprons

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

4.5.2.5 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.

4.5.2.6 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.

4.5.2.7 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.
- Minimise 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.

4.5.2.8 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. Mark all sharp containers “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.

4.5.2.9 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 colour-coded. In the absence of colour-coded containers, other containers may be used, but they should be properly and visibly labelled.

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 neighbouring community.

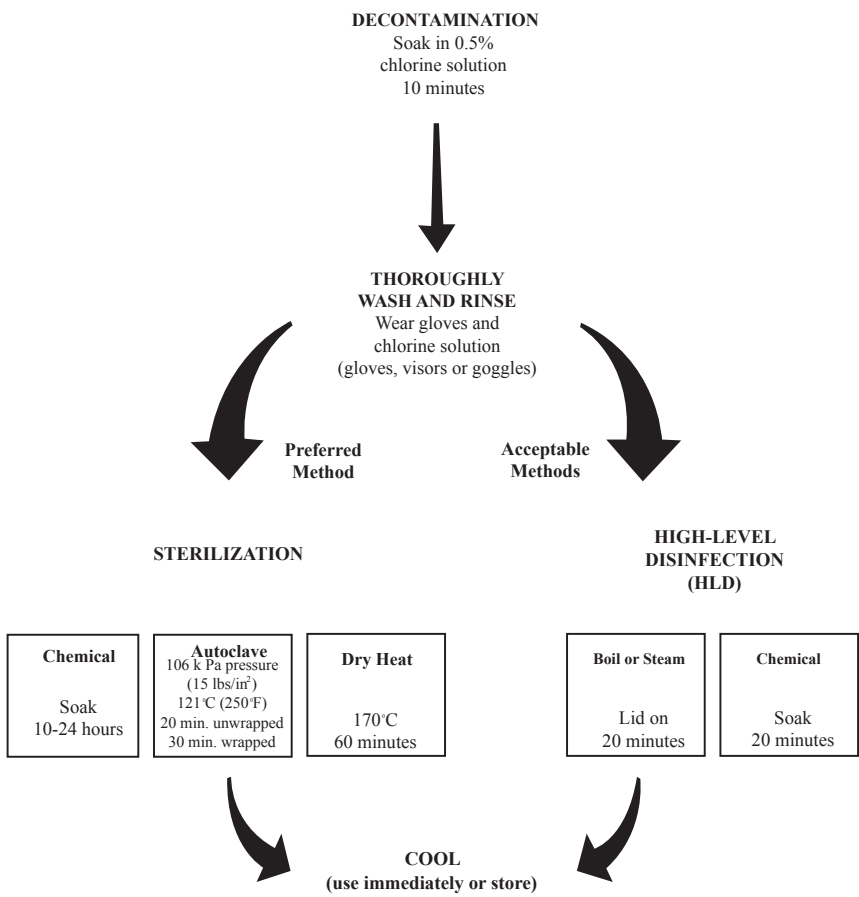
4.5.2.10 Home-based Healthcare Waste Management

Community Health Nurses and other healthcare workers 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 as done in a healthcare setting.

4.5.2.11 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. They 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 physical 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.

4.5.2.12 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 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.

4.5.2.13 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.

4.6 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 minimise 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.

4.6.1 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 infectious. Effective post-exposure management entails the following elements: (1) Management of Exposure Site, (2) Exposure Reporting, (3) Assessment of Infection Risk, (4) Appropriate Treatment, Follow-up and Counselling.

4.6.1.1 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.

4.6.1.2 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 to which the healthcare worker was exposed,
- Details of the exposure source person, and
- Medical documentation that provides details about post exposure management.

4.6.1.3 Risk Assessment for Occupational Exposure

In addition to the type of bodily fluid, 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 in blood exposure to either person involved

Table 4.1: Risk of Transmission after Occupational Exposure

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

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

4.6.1.4 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 two hours after exposure and before testing the exposed person. Thereafter, exposed healthcare workers should be counselled and tested for HIV at baseline in order to establish infection status at the time of exposure. PEP should be discontinued if an exposed healthcare worker refuses to test. To facilitate an effective choice of HIV PEP drugs, the evaluation should include information on the type of medication the exposed person might be taking and any current or underlying medical conditions or circumstances (such as pregnancy, breast feeding, renal or hepatic disease) that might influence drug selection. Vaccination against Hepatitis B should be considered in the case of large volume needle-stick injury.

4.6.1.5 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.

4.6.1.6 Drugs for HIV PEP

For most cases of exposure to HIV a combination of AZT and 3TC should be used. However, for exposure that poses an increased risk of transmission, see the following table.

Table 4.2: Recommended Regimen Following Percutaneous HIV Exposure.

INFECTION STATUS OF THE SOURCE				
Exposure Type	HIV Positive Class 1+	HIV Positive Class 2+	Source of unknown HIV status †	Unknown source
Less severe ¶	Recommend basic 2-drug PEP++	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basis 2- drug PEP** or source with HIV risk factors	Generally, no PEP warranted; however, consider basic 2-drug PEP** in setting where exposure to HIV infected persons is likely
Large volume §§	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors++	Generally, no PEP warranted; however, consider basic 2-drug PEP** in setting where exposure to HIV-infected persons is likely

Legend:

* - HIV positive

Class 1 – asymptomatic HIV infection or known low viral load (i.e. <1,500 RNA copies / mL). Class 2 – symptomatic HIV infection, AIDS, acute sero-conversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of post exposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counselling, resources should be available to provide immediate evaluation and follow-up care for all exposed persons.

† Source of unknown HIV status (e.g. deceased source person with no samples available for HIV testing).

§ Unknown source (e. g. a needle from a sharps disposal container).

¶ Less severe (e. g. solid needle and superficial injury).

** The designation “consider PEP” indicates that PEP is optional and should be based on an individualised decision between the exposed person and the treating clinician. If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

§§ More severe (e.g. large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient’s artery or vein).

Table 4.3: Recommended Regimen Following Mucous Membrane or Non-intact Skin* Exposure.

INFECTION STATUS OF THE SOURCE					
Exposure Type	HIV Positive Class 1+	HIV Positive Class 2+	Source of unknown HIV status †	Unknown source	HIV negative
Small volume**	Consider basic 2-drug PEP++	Recommend Basic 2-drug PEP	Generally, no PEP warranted however, consider basis 2-drug PEP** for source with HIV risk factors	Generally, no PEP warranted; however, consider basic 2-drug PEP** in setting where exposure to HIV infected persons is likely	No PEP warranted
Large volume§§	Recommend Basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors++	Generally, no PEP warranted; however, consider basic 2- drug Ep** in setting where exposure toHIV-infected persons is likely	No PEP warranted

Legend:

- * For skin exposures, follow-up is indicated only if there is evidence of compromised skin integrity (e.g. dermatitis, abrasion, or open wound).
- † HIV- Positive: Class 1 - asymptomatic HIV infection or known low viral load (e. g. <1,500 RNA copies/mL). Class 2 - symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of post-exposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counselling, resources should be available to provide immediate evaluation and follow-up care for all exposures.
- § Source of unknown HIV status (e.g. deceased source person with no samples available for HIV testing).
- ¶ Unknown source (e.g. splash from inappropriately disposed blood).
- ** Small volume (i.e. a few drops).
- †† The designation “consider PEP” indicates that PEP is optional and should be based on an individualised decision between the exposed person and the treating clinician. If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.
- §§ Large volume (i.e. major blood splash).

Table 4.4 ARV Regimens According to Level of Risk.

Risk category	ARV regimen	Drug regime
Low risk	Dual therapy (two drugs)	Zidovudine (ZDV)+Lamivudine (3TC)
High risk	Triple therapy (three drugs)	ZDV+3TC+Efavirenz (EFV), or Lopinavir

4.6.1.7 Timing of Post Exposure Prophylaxis (PEP)

PEP should be initiated as soon as possible, preferably within two 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.

4.6.1.8 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 six months post-exposure (i.e. at six weeks, twelve weeks and six months). 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 two weeks after starting PEP. It should include, at the least, 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, s/he should be referred to a CTC for proper HIV care and management.

4.6.2 HIV PEP in Sexual Exposure

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

4.6.2.1 *Appropriate Management of Exposed Persons*

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

Healthcare providers are responsible for providing 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/minimise 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 organisations (police/legal services), according to local laws and regulations.

4.6.2.2 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 4.5: 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 higher 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

4.6.2.3 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 the potentially exposed person and HIV status of 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 behaviour 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.

4.6.2.4 Basic Steps to be Taken after Sexual Exposure

- Perform counselling 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 first dose of PEP as early as possible. The efficacy of PEP decreases with the length of time. Offer PEP promptly, preferably within two 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 after 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

AZT 300 mg 12 hourly+150mg 3TC 12 hourly daily for 4 week

A third drug, EFV or Lopinavir/r should be added if:

- There have been multiple perpetrators
- Anal penetration occurred
- There is obvious trauma to the genital areas
- One of the perpetrators is known to be HIV positive

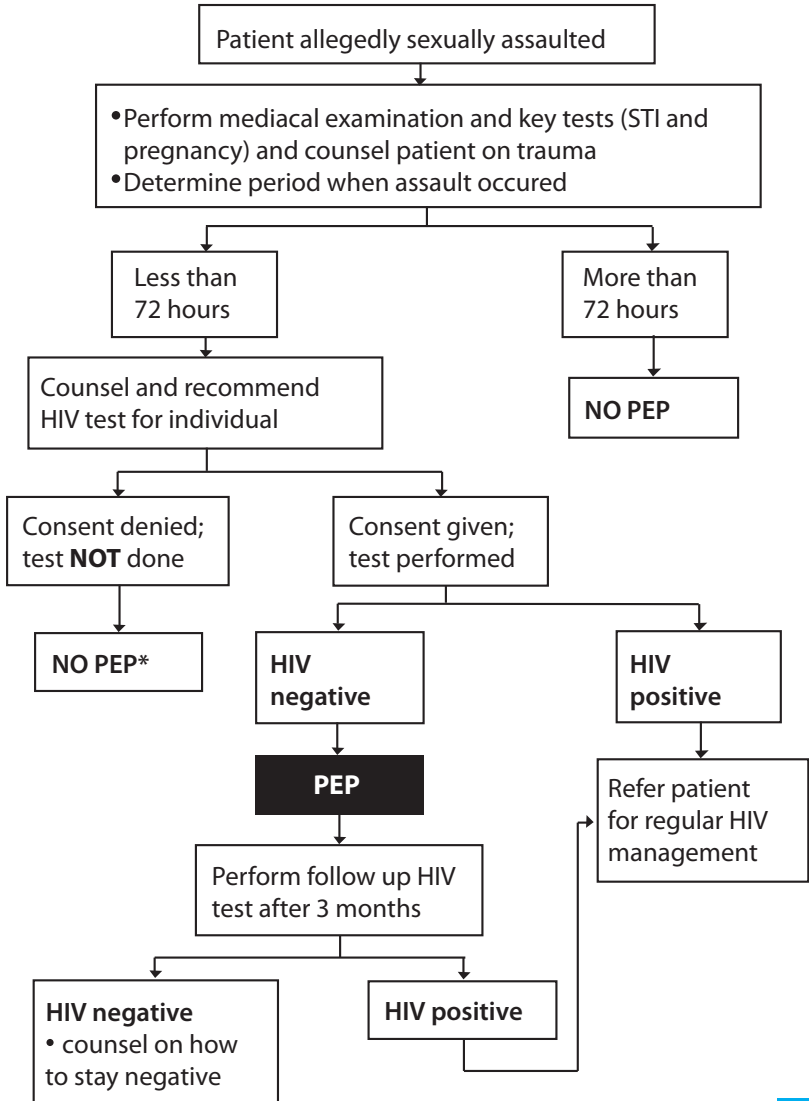
The noted contraindications for each of the listed drugs should be considered as per details in appropriate chapters.

4.6.2.5 Patient Monitoring

Routine testing with a full blood count and liver enzymes for patients on AZT and 3TC is not recommended due to short duration of therapy. Any blood tests to be performed should be based on patient's condition.

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 4.2: Post Exposure Prophylaxis after Sexual Assault.



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

Chapter 5.

Laboratory Tests for HIV and AIDS



CHAPTER 5. LABORATORY TESTS FOR HIV AND AIDS

5.1 Introduction

Laboratory testing is an integral part of HIV and AIDS care and treatment. These tests provide additional information on an individual's HIV status, the level of disease progress, treatment eligibility and response to treatment, and drug adverse reactions.

5.2 Tests for HIV Diagnosis

5.2.1 HIV Testing in Adults and Children over 18 Months

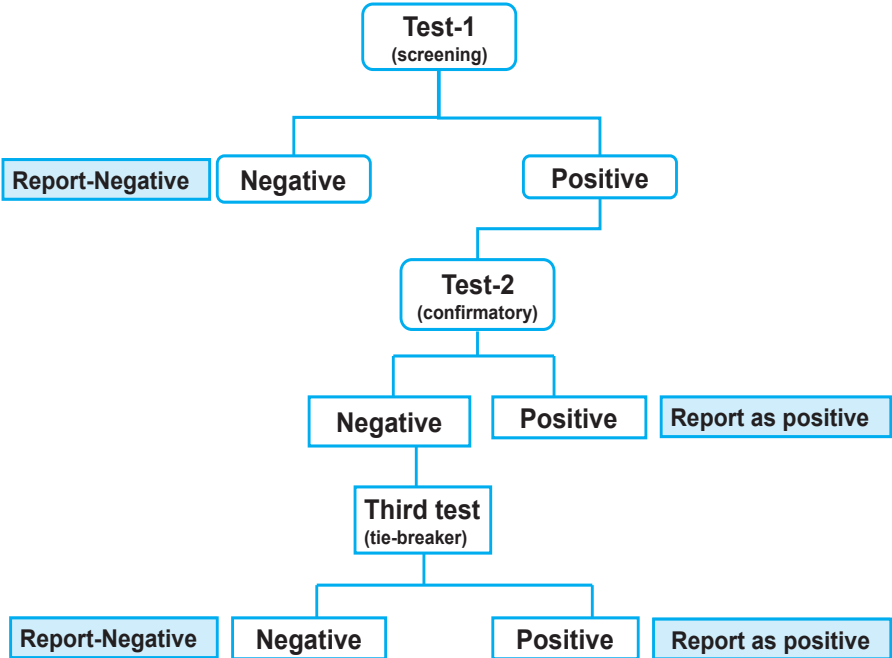
Diagnosis of HIV infection in adults and children older than 18 months is commonly done by detection of antibodies to HIV using rapid tests or Enzyme Immunoassays (EIA).

The national HIV rapid testing algorithm is made up of the following rapid tests.

1. Determine HIV 1/2
2. Uni-Gold HIV

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 the non-laboratory hospital, clinic or community settings by HCWs trained to perform 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 5.1 The National HIV Rapid Test Algorithm.



5.2.2 Diagnosing HIV Infection in Children Under 18 Months

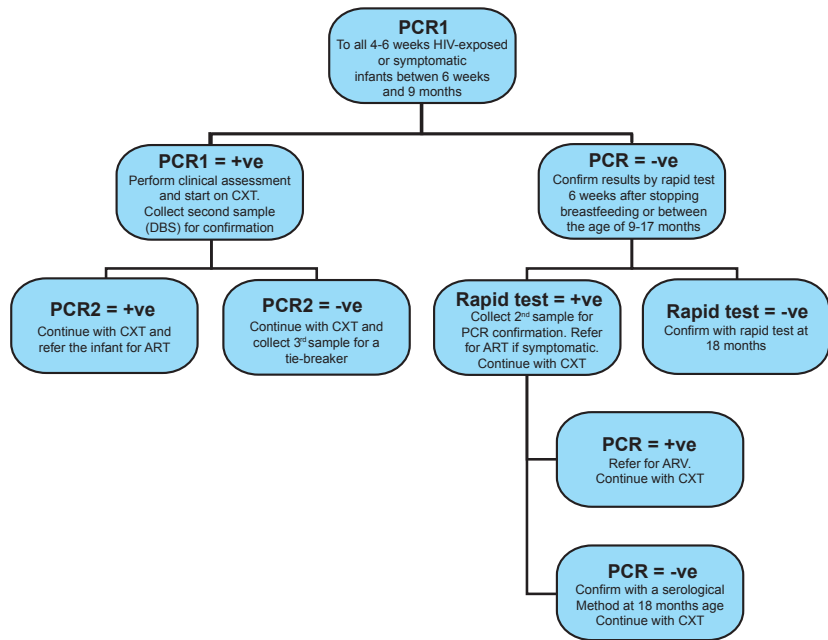
A positive antibody test (rapid test or EIA) in infants under 18 months of age does not confirm HIV infection, but rather mere exposure to HIV (for details see Chapter 7). The laboratory diagnosis of HIV infection in infants and children aged < 18 months is done by detection of viral nucleic acid (RNA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

The method of HIV DNA polymerase chain reaction (PCR) 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 four weeks. Capacity for PCR testing has been developed at the four zonal consultant hospitals in Tanzania. Samples for PCR testing can be whole blood or dried blood spots (DBS) on special filter paper cards that must be transported to the zonal hospital laboratories.

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

Figure 5.2. HIV Testing Algorithm for Children



5.3 Tests for HIV Disease Stage

CD4 cells progressively decrease as HIV disease advances and immune status deteriorates. Measurements of CD4 counts are important immunologic markers of disease progression; as such, they assist in making decisions 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 six years, CD4 are reported as well in %. (For details see Chapter 9, Figure 9.1).

Capacities for measuring CD4 counts have been established at all zonal, regional and district hospital laboratories. However, equipment to measure CD4 % is currently only available at all zonal and some regional hospital laboratories.

5.4 Tests for Monitoring Responses to Antiretroviral Treatment

Successful antiretroviral therapy results in decrease of viral load, immune recovery and therefore increase in number of CD4 cells. Every six months the CD4 count is used to monitor the immunologic response to antiretroviral therapy. When available, viral load may be considered in addition to clinical and immunologic measurements to diagnose treatment failure earlier, or to access discordant clinical and immunologic findings in patients in whom it is suspected ART has failed. However, capacity for viral load measurements is currently limited to zonal consultant hospitals.

5.4.1 Tests for Monitoring Disease Progress and

Treatment Safety

Guiding principles are:

1. Laboratory monitoring is not a prerequisite for the initiation of ART.
2. Viral load testing is not essential for routine monitoring patients on ART.

3. Symptom-directed laboratory monitoring for safety and toxicity is recommended for those on ART.
4. If resources permit, use viral load in a targeted approach to confirm suspected treatment failure based on immunologic and/or clinical criteria.
5. If resources permit, use viral load in a routine approach, measured every six months, with the objective of detecting failure earlier than would be the case if immunologic and/or clinical criteria were used to define failure.

**Table 5.1 Laboratory Monitoring Before, During and After
Initiating ART.**

Phase of HIV management	Recommended test	Desirable test
At HIV diagnosis	CD4	HBsAg
Pre-ART	CD4	
At start of ART	CD4	Hb for AZT ¹ Creatinine clearance for TDF ² ALT for NVP ³
On ART	CD4	Hb for AZT ¹ Creatinine clearance for TDF ² ALT for NVP ³
At clinical failure	CD4	Viral load
At immunologic failure	Viral load	
Women exposed to PMTCT interventions with sd-NVP with a tail within 12 months and without a tail within six months of initiating ART	Viral load six months after initiation of ART	

¹*Recommended test in patients with high risk of adverse events associated with AZT (low CD4 or low BMI, or body-mass index).*

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 coinfection).*

Patients who are not yet eligible for ART should have CD4 counts taken 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 coinfection and who, therefore, should initiate TDF-containing ART.

5.4.2 Viral Load (Virological Assessment)

Plasma viral load (HIVRNA) measurement is not required before the initiation of ART. However, expanded access to viral load (VL) testing is necessary to improve the accuracy of diagnosing treatment failure; VL measurement is considered a more sensitive indicator of treatment failure as compared to clinical or immunologic indicators. VL may be used in a targeted or routine strategy. The objective of the targeted strategy is to confirm suspected clinical or immunologic failure, maximizing the clinical benefits of first-line therapy and reducing unnecessary switching to second-line therapy. Earlier detection of virological failure allows for targeted adherence interventions and better preservation of the efficacy of second-line regimens.

5.4.3 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, supported by laboratory investigations, is crucial. Capacity for testing haematology indices and clinical biochemistry has been developed at the laboratories of all hospitals with a CTC in the country. The frequency of monitoring depends on the ART regimen used (see table 8.5 in Chapter 8).

Furthermore, the toxicity of ART drugs 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 for adults and children.

Table 5.2 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 x upper normal limit	>2.5-5 x upper normal limit	>5.0-10 x upper normal limit	>10 x 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 upper normal limit	>1.3-1.6 upper normal limit	>1.6-2.0 upper normal limit	>2.0 upper normal limit
Management	Continue ART. Repeat test two weeks after the initial test and re-assess.	Continue ART. Repeat test one week after initial test and reassess; if ALT still grade 3, consult expert about stopping ART.		Consult expert immediately before stopping ART.

Table 5.3: 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 mo. – < 2 y. o.	9.0-9.9 g/dL	7.0-8.9 g/dL	<7.0 g/dL	Cardiac failure secondary to anaemia
Haemoglobin □ 2 y.o.	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 × 10 ⁹ /L	0.4-0.749 × 10 ⁹ /L	0.25-0.399 × 10 ⁹ /L	<0.25 × 10 ⁹ /L
ALT (SGPT)	1.1-4.9 µg/l upper normal limit	5.0-9.9 µg/l upper normal limit	10.0-15.0µ/l upper normal limit	>15 µg/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

5.5 Tests for Diagnosing Opportunistic Infections

Common OIs and the laboratory investigations to confirm the diagnosis of OIs are discussed in Chapter 6. For laboratory diagnosis of common OIs such as TB, upper respiratory tract infections, meningitis, diarrhoeas and septicemia, diagnostic protocols are available and should be used as standard operating procedures. Laboratory capacity for TB Acid fast bacilli (AFB) and general microscopy exists at all hospitals and health centres. Cultures to test for bacterial infections can be performed at all zonal and regional hospitals.

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

5.6 Laboratory Safety Procedures

Adherence to safety precautions in the laboratory is required at all steps, including specimen collection, storage, transportation and disposal of biohazard wastes, so as to minimise occupational risks such as the risk of transmission of HIV, hepatitis B virus (HBV) and other blood-borne disease agents. All specimens should be treated as infectious. For more details, see Chapter 4.

5.6.1 Sample Storage Procedures

All samples should be stored in tightly closed, labelled tubes and kept in an upright position in racks. Workers must observe temperature requirements during specimen storage, keep a record of all samples, and always dispose used or old specimens in a timely fashion by autoclaving and incineration.

5.6.2 Sample Transportation Procedure

Whenever the capacity for a particular test does not exist in the laboratory on-site, the laboratory staff should make efforts to prepare samples for transportation to the nearest facility with such capacity.

When transporting samples from the clinic to laboratory, or from one laboratory to another, the following should be observed:

- Specimens should be packaged 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.
- (DBS) samples 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 procedures and timing.
- A specimen delivery checklist should be used to verify that there is a requisition form for all samples transported.
- Dispatch and receipt records of transported samples should be maintained.

Chapter 6.

Management of Common Symptoms and Opportunistic Infections in HIV and AIDS in Adolescents and Adults

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

6.1 Introduction

Despite the availability of ART, it is important to bear in mind that there is still no cure for HIV or AIDS. It is also important to remember that HIV infected patients do not die from HIV infection per se, but rather from the various complications resulting from the HIV induced immune deterioration. A sizeable proportion of HIV infected patients yield to opportunistic illnesses. Fortunately, most of these illnesses are amenable to therapy, and their early recognition and prompt treatment can significantly reduce HIV associated morbidity and mortality. Even where such illnesses cannot be cured, a lot can be done to substantially improve the duration and quality of an HIV infected patient's life.

This chapter highlights the following: clinical features and treatment of the common symptoms encountered in persons infected with HIV, prevention of common opportunistic infections and guidance as to their management, and 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, and hemogram (Full Blood Picture (FBP), Erythrocytes Sedimentation Rate (ESR).

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

Urine cultures, sputum culture for MTB, blood culture for TB and other organisms, and blood for the Extended Widal test.

6.2.2 Cough and Dyspnoea

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

- Pulmonary TB
- Bacterial pneumonia
- PCP
- Pleural effusion, commonly due to TB
- Pulmonary Kaposi's sarcoma
- Viral pneumonia
- 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 the basis of 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)

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*. Upon examination, white plaque (“curd like”) on buccal or pharyngeal mucosa or tongue surface can be easily seen and scraped off. 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 including AIDS 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:

- Therapeutic foods (e.g. Plumpy Nut or fortified blended flour)
- High calorie and protein feeds
- Treatment of the underlying cause (for further reading see Chapter 15)

6.2.7 Diarrhoea

Diarrhoea in persons with HIV induced illnesses including AIDS may be 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 treatable causes, e.g. Salmonella, Shigella,

V.cholerae, Amoeba, Mycobacterium Avium Aomplex (MAC) and Isospora.

Diarrhoea can be treated immediately by rehydration with Oral Rehydration Salts (ORS) or intravenous (IV) fluids. Treatments of underlying causes include:

- Nutritional therapy (see details in Chapter 15)
- Anti-diarrhoeal drugs such as Loperamide (in persistent diarrhoea among adults with no obvious treatable causes)

Note: 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 itself
- 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
- 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 Pruritis

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

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 (Kaposi's Sarcoma) 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
- Dermatomycoses:
- 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
- Moluscum contagiosum (individual lesions):
- Curettage
- Cryotherapy
- Electro cauterization
- Kaposi's sarcoma (depends on the extent and severity):
- Anti-retroviral therapy (preferably PI-based, especially when extensive)
- Referral for Chemotherapy
- Radiotherapy

It should be noted that cancer conditions in HIV infected patients 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

- 4 Septicemia
- ii Metabolic Conditions
 - Severe dehydration
 - Hypoglycemia
- iii Mental conditions
 - HIV-dementia
 - Depression
 - Psychotic conditions

Recommended investigations include:

- Blood sugar
- Blood slide for malaria parasites
- Lumbar puncture for CSF examination [including]?
- 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

For adults and adolescents prophylactic treatment using cotrimoxazole should be provided if any of the following criteria applies:

- All HIV infected patients in WHO Stage 2-4 (see Chapter 8 for WHO staging criteria)
- Asymptomatic HIV infected individuals with CD4 counts of <350 cells/ml
- Pregnancy

Note: Caution should be exercised when initiating Cotrimoxazole Preventive Therapy (CPT) during the first trimester of pregnancy in women who may not have access to good nutrition; and also anaemic patients, because cotrimoxazole can cause a deficiency in folic acid. 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 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 350 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 Preventive Therapy Against TB in PLHIV

There is sufficient evidence on the benefits of 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) should be offered at a dosage of 300 mg daily for at least six months for adults. IPT provides up to 18 months of protection against TB. (Further details are provided in Chapter 10.)

6.4 Treatment of Opportunistic Infections

It is very important that all efforts be made to deal with such treatable conditions in people with HIV and AIDS, particularly because they are managed at various levels of care 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 OIs in HIV infected individuals.

6.4.1 Viral Infections

Viruses that are commonly associated with HIV and AIDS include herpes simplex virus (HSV), varicella zoster virus, and 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 options are:

- Acyclovir 400mg orally three times daily for 7 days for mild and moderate cases of HSV
- Acyclovir 800mg orally, five times daily for five days for severe and recurrent HSV
- Antibiotics such as Cloxacillin or 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
- CNS (central nervous system) manifestations including encephalitis and cerebellar ataxia
- Prolonged healing time
- Bacterial super-infection

The diagnosis of herpes zoster is usually based on findings of characteristic painful skin lesions at different stages of evolution (e.g. erythema, papule, vesicles, and crusts) in a dermatomal distribution.

Treatment involves:

- Analgesics to relieve pain even though the pain may sometimes be unmanageable
- Acyclovir 800mg 5 times per day for 7-10 days
- 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 seven days for bacterial super-infection
- Paracetamol/Aspirin or Diclofenac, also Amitriptylin 25-50mg nocte for post-herpetic pain (neuralgia)

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

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 is a major cause of meningitis in HIV infected persons. Unlike the case of 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 CSF Indian Ink preparation.

The preferred regimen of treatment is Amphotericin B 0.7mg/kg/day IV + 5 Flucytosine 100mg/kg/day administered orally for 14 days (induction phase), followed by Fluconazole 400mg/day for eight weeks or until CSF is sterile (consolidation phase). Thereafter the patient is given maintenance therapy with Fluconazole 200mg per day (suppressive phase).

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

Pneumocystis jiroveci pneumonia (PCP) 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 two to four 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 appearance” although the chest radiograph may appear normal in 10-30% of patients. Usually in clinical circumstances diagnosis is based on clinical presentation and exclusion of other common causes of severe dyspnoea.

Treatment of PCP consists of cotrimoxazole 1920 mg three times / day for 21 days, and in severe cases, IV cotrimoxazole 15–20mg TMP/75-100mg SMX/kg/day IV, administered 6 or 8 hourly, with the possibility of switching 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 one to five, then 40mg once daily for days six to ten, 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

The clinical features of **toxoplasma encephalitis** 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 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.

For acute infection, treatment includes Sulphadiazine tabs 1 gm 6 hourly + Pyrimethamine tabs 100mg loading dose, then 50mg /day + Folinic acid tabs 10mg /day for six weeks. After six weeks of treatment give prophylaxis therapy with Sulphadiazine tabs 500mg 6 hourly + Pyrimethamine tabs 25-50mg /day + Folinic 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/daily. For those allergic to sulphur, give Dapsone tabs 50mg/day + Pyrimethamine tabs 50mg per week + Folinic Acid tabs 10 mg three times a week.

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.

Paediatric HIV and AIDS-related Conditions



CHAPTER 7. PAEDIATRIC 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 (vertical transmission). The absolute risk of transmission without any intervention is between 5-10% during pregnancy; 10-20% during labour and delivery, and 10-20% during breast feeding. The risk of getting infected is highest for infants whose mother's CD4 count is below 350cells/ml. The child of an HIV infected mother acquires HIV antibodies from her/his mother during pregnancy.

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 passively acquired maternal antibodies may persist in the infant for 9–18 months of age even if the child is not HIV infected. The correct terminology used to describe the infant of an HIV infected mother is 'HIV- exposed infant' unless proven to be HIV infected. In that case it would be referred to as HIV-infected. Children under 18 months of age with a positive antibody test (rapid test or EIA) whose mother's HIV status is unknown and/or children born to HIV-infected mothers are also referred to as 'HIV-exposed infants'. Exposure to HIV continues as long as a child of an HIV-infected mother is breastfeeding.

The natural history of perinatal HIV infection in infants falls under one of the following three categories:

- Rapid progressors who are likely to have acquired the infection in utero or during early perinatal period. These usually die within the first year of life (unless treated early)and constitute between 25-30%;
- Children who develop symptoms early in life then deteriorate and die at the age of between 3-5 years. These constitute about 50-60%;

- Slow progressors who live beyond 8 years who constitute between 5-25%.

There are age-specific differences in immunologic markers of disease, virological patterns and clinical manifestations of HIV infection in children. The HIV viral load (VL) is relatively higher in children than in adults, most likely because of the inability of the infant's immature immune system to contain viral replication as well as the presence of a greater number of HIV susceptible cells in the expanding lymphoid tissue during infancy. In this regard, the prognosis of HIV infection in children is worse than in adults.

Unlike in adults, in children there are age-specific differences in the immunologic markers of disease, virological pattern and clinical manifestation of HIV infection. The basic effect of HIV on the immune system is CD4 cell depletion and dysfunction. Absolute CD4 count is higher in healthy young children than in adults and the CD4 count varies with age and slowly declines to adult levels by the age of six years. The proportion of T-lymphocytes that are CD4 cells (CD4%) changes less with age. Therefore measurement of the CD4 % is the preferred immunologic marker for monitoring disease progression in younger children, rather than absolute CD4 count.

7.2 Diagnosis of HIV Infection in Infants and Children

Below 18 Months of Age - Early Infant Diagnosis (EID)

All infants born of HIV-infected women have passively transferred antibodies that can persist until 9 to 18 months of age. Serological tests might react positive, but might only indicate the presence of passively transferred maternal HIV antibodies. Therefore interpretation of positive antibody tests is difficult in children below 18 months of age. Assays that detect the virus or its components (i.e. virologic tests) are required in order to confirm HIV infection in children <18 months of age. The two most commonly used tests for such a diagnosis are DNA

PCR or RNA PCR. However, DNA PCR is the preferred method of choice.

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

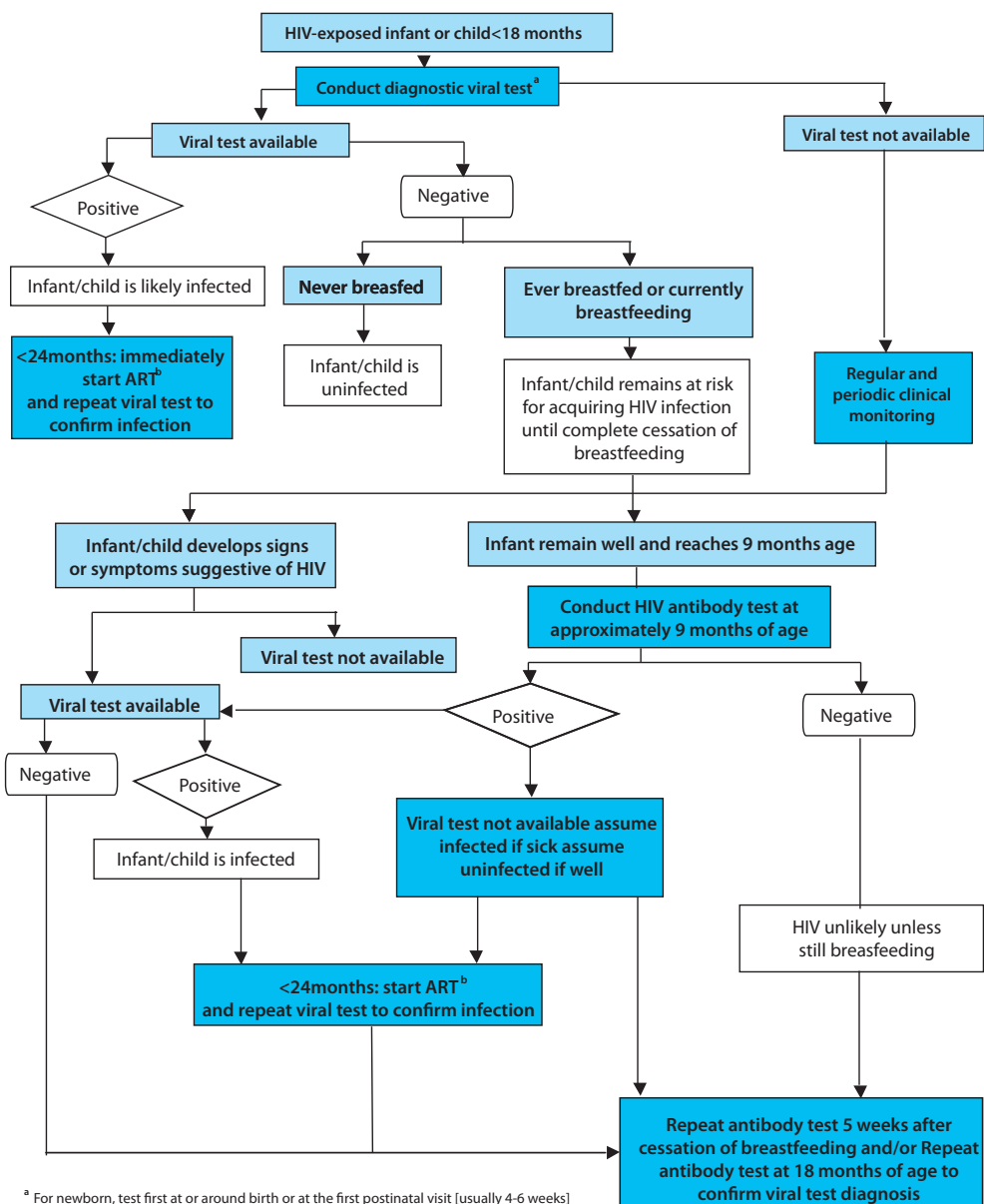
- A single positive PCR test means the infant is presumably infected and should be initiated on ART. At initiation a second PCR should be taken to confirm the infection but the second test should not delay ART initiation.
- For a child that was never breastfed: A single negative PCR test after the age of four weeks excludes HIV infection.
- For a child that has completely stopped breastfeeding for more than six 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 six weeks after complete cessation of breastfeeding as described above to determine final infection status.

Children between the ages of 9-18 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. If the antibody test is negative and the infant is still breastfeeding, the antibody test should be repeated at least six weeks after complete cessation of breastfeeding. (For further details, see National HIV Early Infant Diagnosis Guideline.)

However if the child is symptomatic is HIV antibody positive, and fulfills criteria for presumptive diagnosis (see table seven below) then the child should be started on ART until HIV infection is executed (by a negative antibody test at 18 moths or a negative PCR if available at an earlier age).

Fig 7.1 Establishing the Presence of HIV Infection in HIV Exposed Infants and Children Less than 18 Months of Age in Resource-Limited Settings.

Children less than 18 Months of Age in Resources-Limited Setting.



^a For newborn, test first at or around birth or at the first postnatal visit [usually 4-6 weeks]

^b Start ART, if indicated, without delay. At the same time retest to confirm infection

^c The risk of HIV transmission remains as long as breastfeeding continues

A presumptive diagnosis of severe HIV disease should be made if:

Table 7: Criteria for Presumptive diagnosis of Severe HIV disease in infants and children <18month of age where viral testing is not available

A Presumptive Diagnosis of Severe HIV disease should be made if:	
1. The child is confirmed as being HIV antibody-positive	2a. The infant is symptomatic with two or more of the following: <ul style="list-style-type: none"> • oral thrush • severe pneumonia • severe sepsis
AND	OR
	2b. A diagnosis of any AIDS- indicator condition(s) can be made
Other findings that support the diagnosis of severe HIV disease in an HIV-seropositive infant include: <ul style="list-style-type: none"> - Recent HIV-related maternal death or advanced HIV disease - Child's %CD4+ <20% 	
Confirm the diagnosis of HIV infection as soon as possible	

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, extrapulmonary TB

As per IMCI definition:

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

Severe pneumonia:Cough or difficult in 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 a young infant with any severe sign e.g fast breathing, chest indrawing, budging fontanele, lethargy, reduced movement, not feeding or sucking breast milk, convulsions,

- The HIV status should be confirmed at 18 months.
- Presumptive diagnosis should NOT be done in children older than 18 months of age. In these children HIV infection must be confirmed or excluded using widely available antibody tests.
- For details see Appendix 3.

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 include:

- 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 include:

- 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 include:

- Chronic, recurrent otitis with ear discharge

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

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

WHO Paediatric Clinical Staging (see Appendix 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. It should be used to guide decisions on when to start cotrimoxazole prophylaxis and other HIV-related interventions, including when to start antiretroviral therapy. If HIV infected individuals are not treated with ART, the clinical stages have been shown to be related to survival, prognosis and progression of clinical disease.

7.4 Management of Infants Born to HIV Positive Women

The HIV-exposure status of all infants attending RCH services should be established and documented. The counselling 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), and continued until HIV infection is excluded (six weeks after cessation of breastfeeding). This should be given orally as per required dosing (see Appendix 5 paediatric dosing chart)
- Mothers should be counselled on the advantages of exclusive breastfeeding, with particular attention to the risk of mixed feeding as it increases the risk of transmission. (Refer to the Infant Feeding Guidelines in HIV and AIDS provided in the PMTCT guidelines of the Ministry of Health and Social Welfare)
- Care for the mothers 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 counselling

7.5 HIV Diagnostic Protocol for Infants Where a Mother is Not Available

When the mother's HIV status is unknown, the HIV exposure status of the baby must be established by performing a rapid HIV antibody test. The guardian/caretaker needs to be counselled on HIV testing of the child. If the antibody test is positive, then a HIV DNA PCR (if available) should be done, ideally at four weeks of age or thereafter. If the age of the infant cannot be established, PCR must be done immediately, and repeated for all infants after six weeks if the initial PCR was negative. In addition, the child should be started on cotrimoxazole prophylaxis.

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

Notes:

1. A clinical examination to assess for signs and symptoms of HIV infection should be performed during all visits. Exposed children should be seen monthly for the first year of life. The infant should be followed up as per recommendations for all children. But failure to thrive and neurodevelopmental delay might especially be signs of HIV infection.
2. Postnatal transmission of HIV infection is likely to be evident by six weeks after breastfeeding has been terminated. If PCR is unavailable, clinical monitoring and prophylaxis should continue until presumptive diagnosis of HIV can be done, upon which ART should be started.

7.6 Care of HIV-Infected Children

- All children should be assessed for symptoms related to HIV and for the need for treatment and prophylaxis for OIs and other HIV related conditions.
- Baseline laboratory tests should be performed to establish viral and immunologic 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. Family members who are aware of the diagnosis should also be identified.
- HIV-infected children should receive routine paediatric care and be monitored for their HIV disease status. Children under the age of one year should be seen monthly and thereafter every three months with special attention to nutritional status and neuro development. 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).
- Growth and development should be evaluated and charted at all stages of development through adolescence.
- The need for medication should be reviewed based on history, physical examination and laboratory findings.
- Doses of prophylactic or treatment medications should be adjusted on the basis of growth and compliance, and tolerability should be reassessed 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 be 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). 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.

Disclosure:

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 year 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 s/he is taking, or when acting in a way that suggests that s/he 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 counselled. 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 disclosure counselling to prepare and enable them to support disclosure in their children. Health care workers should be equipped with knowledge and skill on disclosure counselling.

7.7 Clinical Manifestation of Paediatric HIV Infection

7.7.1 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 compromised children. The most common respiratory conditions include:

7.7.2 Bacterial Pneumonias

The common causes of pneumonia include *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Staphylococcus aureus*, and gram negative bacteria such as *Klebsiella pneumoniae*. Usually recurrent bacterial pneumonia suggests immunodeficiency. Further investigations should be done to exclude TB, Lymphocytic Interstitial Pneumonitis (LIP), fungal infection.

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 will demonstrate hypoxia (O₂ saturation less than 92%).

Diagnosis

Diagnosis of pneumonia is mainly made by medical history and physical examination. However, some laboratory and other 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 might 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 PCP or TB.

Management at Outpatient Level

Management should follow national/ IMCI guidelines. The following can be used:

- Oral amoxicillin or penicillin.
- Where the child is already on Cotrimoxazole prophylaxis, CPT should not be used to treat pneumonia unless PCP is suspected. If PCP is suspected, then high dose CPT should be used.
- If the child is under one year of age the risk of PCP is very high and should be considered.
- Give Paracetamol for fever.
- Cough syrups have no added value and hence 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 oximeter is critical for the assessment of O₂ saturation; 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 and steroids prescribed.
- If an infant presents with severe pneumonia, s/he should be treated for both bacterial pneumonia and PCP and investigated for possible HIV.
- Children treated for PCP should continue on PCP prophylaxis until the diagnosis of HIV exposure or infection has been excluded.
- 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) will show pneumatoceles (very small cavities). For such children, treatment should also include Cloxacillin or Vancomycin.

7.7.3 Lymphocytic Interstitial Pneumonitis (LIP)

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, include the following.
- Antiretroviral therapy as specific therapy
- Steroids are needed when children with LIP having respiratory distress
- Prednisone 2 mg/kg/day - initially for four weeks daily and then alternate day maintenance for two to three months, then review
- Oxygen therapy during episodes of hypoxia
- Bronchodilators like salbutamol where there is wheezing
- Antibiotics are needed during episodes of concurrent super infection with pneumonia
- Chest physiotherapy and postural drainage if there is secondary Bronchiectasis

- Supportive care includes correction of anaemia, especially iron supplementation
- Consult or refer for specialist care if child shows poor response to treatment.

7.7.3 *Pneumocystis Jiroveci* Pneumonia (PCP)

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 three to six months of age. Infants are usually in a good nutrition state and may have no clinical features that indicate the presence of HIV. However, it may be the first AIDS defining illness.

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 ($\text{paO}_2 < 90\%$)
- 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 (CPT) IV 20mg/kg TMP / and 80mg/kg SMX /day divide in 4 doses given every 6 hours for 21 days
- Oral cotrimoxazole 100mg/kg/day divided into 2-4 doses may also be used if IV not available
- Prednisone at 2mg/kg/day for 7-14 day (taper if more than 7 days)
- 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 one year of age living with HIV should receive cotrimoxazole prophylaxis regardless of symptoms or CD4 percentage.
- After one year 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 <25%.
- All children who begin cotrimoxazole prophylaxis (irrespective of whether cotrimoxazole was initiated in the first year of life or afterwards) 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 350/ml and adherent to ART.

7.7.4. TB in Children

HIV-infected children should be evaluated for TB disease at the time of their HIV diagnosis, and at any time they present with symptoms suggestive of TB, or have a history of new contact with an adult with TB. But 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 these guidelines.

7.7.5 Diarrhoea

Diarrhoea is one of the most common causes of under-5 mortality worldwide. Diarrhoeal 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 counselled about the management and hygiene (hand washing, safe water). In case of persistent diarrhoea other causes should be excluded.

- Clinical features
 - o Increased frequency, volume of liquid stools
 - o Acute watery diarrhoea – non-bloody diarrhoea lasting <14 days
 - o Dysentery – diarrhoea with visible blood mixed in stools
 - o Persistent diarrhoea – diarrhoea lasting more than 14 days

- o Dehydration should be assessed according to WHO/IMCI guidelines
- Investigations
 - o Stool microscopy
 - o Stool culture/sensitivities if available
 - o May be particularly useful for persistent diarrhoea
- Management
 - o Management of diarrhoea in HIV-exposed and HIV-infected children should generally be the same as for HIV-uninfected children.
 - o 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.
 - o 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 six months of age, 20 mg per day for infants and children over six months).
 - o Emphasize continued or increased feeding during and after the diarrhoeal episode.
 - o Ciprofloxacin is recommended for three days at an oral dose of 15 mg/kg for treating bloody diarrhoea.
 - o Daily micronutrients are recommended for two weeks for all HIV-infected and -exposed infants and children with persistent diarrhoea.
 - o Persistent diarrhoea not responding to standard treatments is a WHO Clinical Stage III condition, and an indication for ART in children.

7.5.6 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
 - o Nystatin suspension
 - o Infants –100,000 units every six hours
 - o Children – 400,000 – 600,000 units every six hours
 - o Clotrimazole oral drops
 - o Miconazole oral gel
 - o Gentian violet

7.5.7 Oesophageal Candidiasis

- Clinical features
 - o Usually associated with extensive oral thrush
 - o Infants and young children - refusal to feed and crying during feeds
 - o Older children – pain with swallowing
 - o Vomiting
- Management
 - o Fluconazole 3-6 mg/kg once daily

7.5.8 Suppurative Otitis Media (Draining Ears)

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

- Management
 - o Wicking
 - o Insert tissue or cotton wool in ear

- o Remove and then reinsert new one until last one comes out clean
- o Otic drops—use immediately after wicking
- o Keep ear upright for 15 minutes after drops

7.5.9 Skin Manifestations

Rashes and other skin problems are a very common manifestation of HIV in children, so being familiar with these conditions and their treatment is important.

- Papular pruritic eruption (PPE)
- Tinea corporis
- Warts

7.5.10 Kaposi Sarcoma (KS)

Though not as common as in adults, children do get Kaposi sarcoma. The presentation is generally the same as in adults, and includes purple plaques on the skin and mucous membranes, especially the palate, nodular skin disease, lymphatic involvement with “woody” oedema, and less commonly visceral and pulmonary presentations.

- Management
 - o ART is the cornerstone of management
 - o KS may respond better to PI-based ART rather than NNRTI-based ART, though this is controversial
 - o Other
 - o Chemotherapy
 - o Radiotherapy
 - o Treatment options for KS are available, including chemotherapy, and children with KS not responding ART alone need referral to specialty centres for evaluation for other potential treatments

7.5.11 Malnutrition

Childhood acute malnutrition is high among HIV-infected children. Severe wasting is a common clinical presentation of HIV infection in children. Generally, despite their HIV status, children with severe malnutrition are at risk for a number of life-threatening problems and urgently require 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.

Immediate initiation of ART is indicated in HIV-infected infants and children with unexplained severe malnutrition that is not caused by an untreated OI, and who do not respond to standard nutritional therapy (i.e. WHO Stage 4 disease).

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 < 11.5 cm 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 the 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.

Antiretroviral Therapy in Adults and Adolescents

CHAPTER 8. ANTIRETROVIRAL THERAPY IN ADULTS AND ADOLESCENTS

8.1 Introduction

Since 1996, when more extensive use of potent antiretroviral therapy for HIV started globally, there has been a significant improvement in the safety and tolerability of regimens used for initial treatment. The pill burden and dosing frequency have been reduced, and short-term and long-term adverse events minimised; all of which have contributed to the success rates in initial treatment.

The last decade has seen dramatic advances in the development of ARVs, which now offer extended patient survival and improved quality of life. Combined ART medications have confirmed their potential to reduce HIV replication. Therapeutic regimens may be directed at one or several of the replication sites in the life cycle of the virus. Recently, new evidence has emerged on when to initiate ART, optimal ART regimens, management of HIV co-infection with tuberculosis and chronic viral hepatitis and management of ART failure.

8.2 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)

8.2.1 Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

This was the first group of drugs to be used, and is still the mainstay of antiretroviral therapy in the country. The primary mechanism of action of this class of drugs 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)
- Abacavir (ABC)
- Emtricitabine (FTC)
- Stavudine (d4T)

8.2.2 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).

8.2.3 Nucleotide Reverse Transcriptase Inhibitors (Nucleotide

Analogue)

Nucleotide analogues resemble monophosphorylated nucleosides, and therefore require only two additional phosphorylations to become active inhibitors of DNA synthesis. An example of this relatively new class of antiretroviral drugs is Tenofovir (TDF).

8.2.4 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:

- Lopinavir (LPV)
- Atazanavir (ATV)

8.3 Treatment using ARV Drugs in Adults and Adolescents

From the moment a patient tests HIV-positive, s/he should be referred to the CTC. The initial management requires a complete assessment of the patient, starting with in depth medical history and a thorough physical examination, including WHO clinical staging. Thereafter the following tests should be done:

- Complete blood count/Hgb
- Urinalysis
- Urine for pregnancy test (in women of reproductive age)
- CD4 T-lymphocytes count
- Liver function (if clinically indicated)
- Renal function (if clinically indicated)
- Viral load (where available and indicated)

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 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.

8.3.1 Criteria of Initiation of ART in Adults and Adolescents

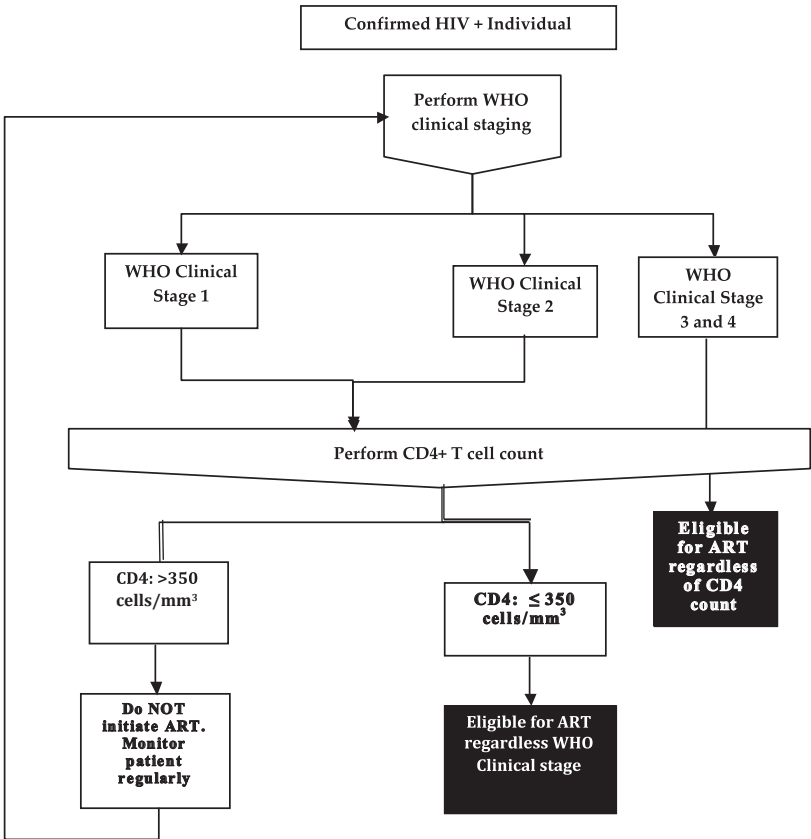
Patients

Based on experience and available evidence, use of ART improves quality of life and survival for PLHIVs. Optimal time of ART initiation is important for desirable health outcome in terms of reducing risk of death, disease progression including tuberculosis, and occurrence of serious adverse events. WHO recommends that HIV infected patients be initiated based on WHO clinical stage and CD4 cells count level.

There are therefore 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 adolescences and adults including pregnant women with a CD4 count $< 350\text{cells/mm}^3$, regardless of clinical symptoms

Figure 8.1. Criteria for ART in Adults and Adolescents.



From the moment a patient tests HIV-positive, s/he 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. The initial management requires a complete assessment of the patient, starting with in depth medical history and proper physical examination including WHO clinical staging.

In addition to assessing mere medical eligibility, it is important to assess the patient’s capacity to adhere, 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:

- o Demonstrated reliability, i.e. has attended two or more scheduled visits to an HIV clinic
- o No evidence of active alcohol or other substance abuse that could affect adherence
- o No untreated active depression

It is strongly recommended that clients who are 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, 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.

8.3.2 Evaluation to be Done Before Initiating Therapy

Before initiating therapy in any patient, a good history of the patient must be taken and a top-to-toe physical examination conducted. In addition the TB screening questionnaire should to be administered. Thereafter, the following baseline laboratory tests are recommended:

- Urinalysis
- Renal Function Tests (Creatinine, Blood Urea Nitrogen (BUN))
- A complete blood count (if not available, do Hgb)
- Chemistry profile for liver (serum alanine aminotransferase, ALT)

- Tests to rule out active TB where indicated (sputum AFB, CXR) in case of indication from the screening questionnaire
- CD 4 count (if not done in the past 6 months)
- Urine for pregnancy (to women of reproductive age)
- VDRL (when necessary)

The following could be done if available:

- Serum creatinine and lipids
- Hepatitis B and C serology
- Viral load

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

8.3.3 Goals of 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.

The eradication of HIV in an infected individual cannot be achieved with currently available antiretroviral regimens. This is due to the establishment of a pool of latently infected CD4⁺ T-lymphocyte cells during the very early stages of acute HIV infection, which persists with an extremely long half-life, even with prolonged suppression of plasma viremia to <50 copies/mL. 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
- Restoration and/or preservation of immunologic function
- Improvement of quality of life
- Reduction of HIV-related morbidity and mortality

Secondary goals are to decrease the incidence of HIV through:

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

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.

8.4 Recommended ARV drugs in Tanzania

8.4.1 Introduction

Antiretroviral therapy both in naïve patients and in those who have previously received treatment involves the use of a combination of drugs. We recommend triple therapy consisting of 2 NRTI + 1 NNRTI, 2 NRTI + 1 PI, or 3 NRTI's. 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 recommend regimens on the basis of a patient's clinical condition, lifestyle, and ability to tolerate the regimen.

Note: The use of monotherapy in the treatment of HIV infection is prohibited.

8.4.2 First Line ARV Combination Regimen for Adults and Adolescent ART Naïve Patients

The MoHSW recommends the following drugs for first line treatment:

- Zidovudine (AZT)
- Lamivudine (3TC)
- Tenofovir (TDF)
- Emtricitabine (FTC)
- Nevirapine (NVP)
- Efavirenz (EFV)
- Stavudine (d4T)

The following drug combinations can be made out of these drugs for adults and adolescents, and should be used according to indications and contraindications that govern the use of ARVs to minimise side effects and drug-drug interactions.

- AZT+ 3TC+EFV
- AZT+3TC+NVP

- TDF+FTC+EFV
- TDF+FTC +NVP
- TDF+3TC+EFV
- TDF+3TC+NVP
- d4T+3TC+NVP
- d4T+3TC+EFV

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

- AZT+3TC
- AZT+3TC+NVP
- TDF+3TC+EFV
- TDF+FTC+EFV
- TDF + 3TC
- TDF+FTC
- d4T+3TC+NVP

The default first line regimen in Tanzania is:

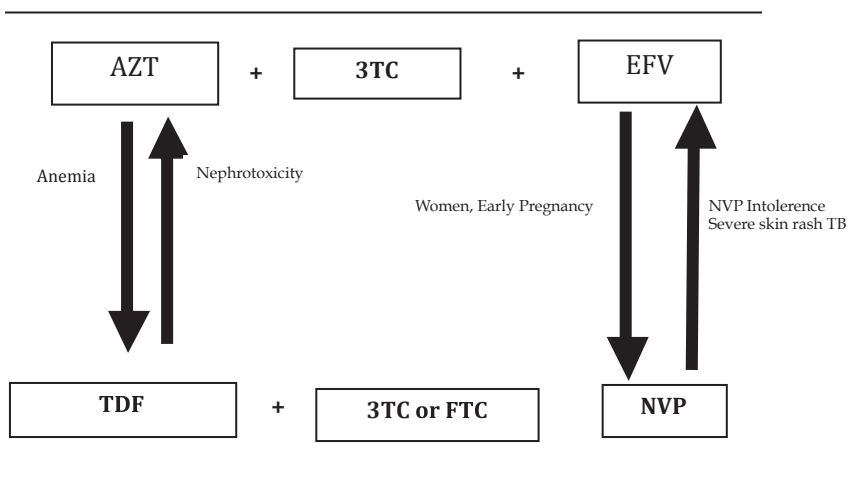
- Zidovudine (AZT) 300 mg/Lamivudine (3TC) 150 mg twice daily and Efavirenz (EFV) 600 mg once daily at night.
- For women of child bearing age, Nevirapine (NVP) 200mg twice a day is given instead of Efavirenz.

Note:

- For adolescents, the dose of AZT is 200 mg BD for a body weight of between 20-40 kgs.
- For patients with <40kg, the dose of EFV should be <600mg.
- Efavirenz has been reported to be associated with teratogenicity in early pregnancy. In this case, Nevirapine should be prescribed instead.
- In women for whom effective contraception can be assured, EFV remains a viable option for the NNRTI component of the regimen.

The AZT+3TC+EFV combination is the default combination to be prescribed to all patients if there is no contraindication.

Figure 8.2. Recommended First Line Drug Regimen in Tanzania



Under certain circumstances, however, the following regimens can be used as first line:

- Zidovudine (AZT)+Lamivudine(3TC)+Nevirapine (NVP)
- This regimen can be prescribed when Efavirenz is contraindicated, e.g. in neuropsychiatric complications of Efavirenz and pregnancy.

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 two weeks. And

if there are no problems, THEN Zidovudine 300 mg/
Lamivudine 150 mg/Nevirapine 200 mg twice daily).

- Tenofovir (TDF) 300mg / Lamivudine (3TC) 300mg / Efavirenz (EFV) 600mg

A triple FDC is available with use (potential for one pill once daily) and the treatment of HIV/HBV coinfection.

- Tenofovir (TDF) + Lamivudine (3TC) + Nevirapine (NVP)
- Tenofovir (TDF) + Emtricitabine (FTC) + Efavirenz (EFV)
- Tenofovir (TDF) + Emtricitabine (FTC) + Nevirapine (NVP)

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, or who have low birth weight, advanced age or lower CD4 cell counts. Otherwise the overall rate of discontinuation for renal events is extremely low. Renal function should be monitored through routine urine testing for the occurrence of proteinuria and, if available, serum creatinine.

NOTE : Stavudine based Regimen

- Stavudine (d4T)+Lamivudine (3TC)+Efavirenz (EFV)
- Stavudine (d4T) +Lamivudine (3TC) + Nevirapine (NVP)

Initiation

- New patients should not be started on Stavudine based regimen.
- Stavudine can only be used when Zidovudine or Tenofovir is contraindicated

Continuation

- Stavudine can also be used for the continuing patient who is stable on stavudine regimen without any sign of side effect.

In cases where Nevirapine or Efavirenz cannot be used as a first line drug, a single drug from the second line drugs can be used; for example LPV/r or ABC.

8.4.3 ART in Women of Childbearing Potential or Pregnant Women

The guiding principle for the treatment of women of childbearing potential or pregnant women is that therapeutic decisions should be based solely on their need and eligibility for ART. The recommended first-line regimen for this patient subgroup is AZT + 3TC + NVP. However, special circumstances of pregnancy or breast-feeding raise additional issues concerning toxicity to mothers and children, the choice of ARV drugs, and the prevention of HIV transmission from mothers to infants.

Women who are receiving ART and become pregnant should continue their treatment unless they are in the first trimester of pregnancy and EFV has been part of the regimen, in which case, EFV should be discontinued and replaced by NVP.

Note: ARV drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms must be recommended for preventing HIV transmission. This may also compensate for any possible reduction in the effectiveness of the hormonal contraceptive.

8.4.4 Antiretroviral Drugs for Non-ART Naïve Patients

Treatment for patients who have been previously exposed to antiretroviral therapy should be discussed with an antiretroviral expert before they are enrolled in the CTC and (re)started on treatment. 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.

8.4.5 Antiretroviral Drugs for Intravenous Drug Users (IDU) on Methadone Assisted Therapy

Drug use and addiction do not preclude successful ARV treatment. HAART is as effective for HIV positive IDUs 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 HAART. Special attention should be paid to the particular needs of former and active IDUs when administering ART, including those related to substance dependence, co-morbidities and co-infections. ART might be started not earlier than two to three months after starting methadone assisted therapy. There is an increased risk of interactions through cytochrome CYP 450 3A between Nevirapine, Efavirenz, Ritonavir and methadone.

Once daily regimen:

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

Efavirenz decreases methadone plasma concentration up to 50%; it [?] requires constant methadone dose correction.

- i. Nevirapine(NVP)400mg+TDF300mg+FTC300mg.
- ii. Nevirapine400mg+ABC600mg+Lamivudine300mg.

Nevirapine decreases methadone plasma concentration by up to 80%, and increases propensity to liver toxicity and skin rash.

Combination for second line, once daily regimen:

- i. Lopinavir 800mg/Ritonavir 200mg+TDF300mg+FTC200mg or
- ii. Lopinavir 800mg / Ritonavir 200mg+Abacavir 600mg + Lamivudine 300mg. Associated with frequent diarrhoea
- iii. Atazanavir 300 mg/Ritonavir 100mg +TDF 300mg + FTC2 00mg
- iv. Atazanavir 300 mg / Ritonavir 100 mg + Abacavir 600 mg + Lamivudine 300mg

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

8.5 Adherence to Antiretroviral Therapy

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 counselling and health education. (See Chapter 12 on adherence counselling)

8.5.1 Factors that Influence Adherence

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

- 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

8.5.2 Strategies that Enhance Adherence

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

(i) Patient related strategies

- Health care workers should negotiate a treatment plan that the patient understands and to which s/he commits.
- A patient's "readiness" to be on life-long medication should be clearly established.
- Patients must understand that the first ART regimen has the best chance of long-term success.
- Family members should be recruited to become participants in the treatment plan.

(ii) Clinician and health team related strategies should include

- Building a trusting relationship with patients.
- Adopting provider attitudes and behaviours that are supportive and non-judgmental to encourage patients to

be honest about their adherence and about problems they have with adherence.

- Monitoring and encouraging adherence at every clinical encounter.
- Explaining possible side effects when initiating treatment.

(iii) Regimen-related strategies

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

8.5.6 Adherence Issues in Adolescence

HIV infected adolescents many have the stigma related to chronic illness, challenge of parental authority and wish of more direct involvement in their own care and treatment. Adolescents are more likely than anyone else to discontinue a regimen if they encounter any difficulties.

Favourable Circumstances for Adherence

1. Adequate support from caregiver, family, and friends.
2. Stability such that they are able obtain basic needs as well as play and attend school like other children.
3. Beneficial and early disclosure leads to increased participation in their treatment.
4. In case of change in health status or lab parameters, encourage continuation of treatment
5. 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.

6. Familiarity with someone who is sick or who died recently who may have died due to non drug adherence encourages the adolescent to avoid a similar fate, so s/he will adhere to the regimen.
7. Access to a supportive, non-judgmental clinician who will also discuss options. Adolescents are curious and should be given as much information by the HCW as possible.
8. Community that is supportive and not stigmatising against HIV.

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; refusal.
3. Depression. 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. Fatalistic attitude towards death.
6. Mental health issues.

Strategies for Enhancing ARV Drug Adherence Among Adolescents

1. Consider practicing drug adherence with vitamin pills and Cotrimoxazole-prophylaxis.

2. Involve the adolescent when discussing treatment options.
 3. Explore with the adolescents the 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 see them as their partners in health.
 5. The members of the Counselling and Testing team with the best relation to the adolescent should take the lead in the counselling and support of adolescent.
 6. Regimens should fit into the adolescent's life as much as possible. Remind the adolescent that they need to continue taking the drugs both when they are feeling unwell and when they are feeling well.
 7. Use of simple regimens – a once or twice daily regimens 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 family, friends and the HCP.
1. Information should be given proactively, in appropriate language and in writing, as adolescents might not ask questions on their own.
 2. Use real life examples to illustrate as adolescents often think in concrete terms.
 3. Explain to adolescents what to expect while on therapy and how to manage side effects and adherence problems.
 4. Adolescents should be encouraged to discuss their problems with their care provider or person they trust.

How to Help the Adolescent Develop an Individual Strategy for Drug Adherence

1. Encourage adolescent to establish a routine 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 changes in the body.
6. They should plan ahead to take ART with them when they are away from home.
7. They should plan for sudden events that change the normal routine, 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 partner.

8.6 Changing Antiretroviral Therapy

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

1. Drug Adverse Events or Toxicities

- Intolerable side effects
- Drug interactions
- Pregnancy if the patient is on EFV

2. Treatment Failure

- Clinical failure – occurrence or persistence of HIV related OIs
- Immunologic failure
- Virological failure

There are no studies or reliable estimates of the number of days, weeks, or months that represent a clinically important interruption of one or more components of a therapeutic regimen that would increase the likelihood of drug resistance. If there is a need to discontinue any antiretroviral medication for an extended period, clinicians and patients should be advised of the theoretical advantage of stopping all antiretroviral agents simultaneously, rather than continuing one or two agents, to minimise the emergence of resistant viral strains. However, with regimens containing Nevirapine, dual therapy should continue for a week after stopping Nevirapine.

8.6.2 Changing Antiretroviral Therapy Due to Toxicity

From a clinical perspective, it is generally recommended that when changing a patient'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 switches. It is based on the first line drugs recommended -Tanzania.

Table 8.3: Common Toxicity Switches for First Line drugs.

First Line	Problem	Substitution
AZT + 3TC + EFV	Anaemia due to AZT	TDF*** + 3TC + EFV TDF*** + FTC + EFV d4T + 3TC + NVP or EFV*
AZT + 3TC + NVP	Anaemia due to AZT	TDF*** + 3TC + NVP TDF*** + FTC + NVP d4T + 3TC + NVP or EFV*
	Hypersensitivity due to NVP	AZT + 3TC + EFV TDF*** + 3TC + EFV d4T + 3TC + EFV*
TDF + 3TC + EFV or NVP (TDF containing regimen)	Nephrotoxicity due to TDF	AZT + 3TC + NVP or EFV* d4T + 3TC + NVP or EFV*
d4t + 3TC + NVP or EFV*	Peripheral neuropathy due to d4T	AZT + 3TC + NVP or EFV* TDF*** + 3TC + NVP or EFV TDF*** + FTC + NVP or EFV
	Lipodystrophy due to d4T	TDF*** + 3TC + NVP or EFV TDF*** + FTC + NVP or EFV

*Only if the patient is older than three years of age and weight $\geq 10\text{kg}$, or in a woman in reproductive age.

** Follow liver function tests (LFTs) closely.

***Follow renal functions closely

8.6.3 Severity of Adverse Events Due to ARVs

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 seldom 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 three 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.

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 two 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 two 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, three ARV drugs will be started that do not include NVP. The remaining two ARVs will be paired with a replacement ARV such as EFV, if not contraindicated.

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.

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.

d4T (Stavudine) Side Effects

Peripheral neuropathy is a common side effect with the use of Stavudine. Occurrence of lactic acidosis has also been reported. Cumulative exposure to d4T has the potential to cause disfiguring, painful and life-threatening side effects such as lipodystrophy and lactic acidosis. For patients who are still on d4T, prescribe 30 mg BID for all individuals, irrespective of body weight. New patients should be started on an AZT or TDF based regimen.

8.6.4 Changing Antiretroviral Therapy Due to Treatment Failure

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

Virological Failure is defined if:

- There a less than 10 fold drop in viral load after 6-8 weeks of therapy, or when the viral load is detectable after six months of therapy, or when the viral load (VL) is persistently above 5,000 copies/ml.

Immunologic Failure is defined as a:

- 50% drop in CD4 count from peak value, or
- return to pre-ART baseline CD4 count or lower.

Clinical Failure results in disease progression which presents as the development of opportunistic infections, or malignancy occurring three months or more after initiation of ART.

In Tanzania, immunological and clinical parameters are used to identify treatment failure. However, in light of declining costs of performing VL measurements, along with the simplification of processes, where available, VL parameters should also be applied. Where available, VL 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.

8.7 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 due to side effects or any other patient or system related reason
- Evidence of malabsorption

Each of the above scenarios could result in sub-therapeutic drug levels and poor clinical response. In such cases, the regimen in question should be salvaged with additional palliative medication and/or patient education. If clinical assessment indicates the presence of treatment failure due to confirmed drug resistance, the best approach is to switch to an entirely new regimen, choosing two or more drugs to which the patient is naïve as the second line drug regimen. Before changing to the second line drug regimen, the patient needs to go through the treatment readiness and education process again. As some patients might hide their non-adherence, this process must be carefully monitored,

8.7.1 Second-line Antiretroviral Therapy in Adults and Adolescents

Drugs used as the second line drugs in Tanzania include:

NRTIs

- Tenofovir (TDF)
- Abacavir (ABC)

PIs:

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

The second line NRTI choice for adults and adolescents depends on the first line regimen. For patients on AZT or d4T in first line, the default second line option is to use is TDF plus 3TC or FTC combined with a ritonavir-boosted PI, either LPV/r or ATV/r. (TDF+3TC or FTC +LPV/r or ATV/r)

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

For patients who were initiated on TDF in first line because of intolerance to AZT and d4T, the default second line option is to use ABC plus 3TC combined with a ritonavir-boosted PI, either LPV/r or ATV/r. (ABC + 3TC + LPV/r or 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.

8.8 Monitoring Patients on ARV Therapy

In Tanzania, CD4+ T-lymphocyte count is the gold standard method used to determine the time for initiation and change of therapy. Each patient should have had a baseline CD4+ T-lymphocyte count done

before initiating treatment, and a count repeated at least every six months during treatment. In most cases, treatment will be associated with weight gain, reduced morbidity from opportunistic infections, and improvement in the quality of life. Appearance or persisting opportunistic infections, or lack of weight gain, may indicate poor adherence or treatment failure and the need to consider changing regimens.

In Tanzania, treatment should be considered successful if the viral load is <1000 after six months. However, in most cases, CD4 count will be used instead of viral load, and so a rise in CD4+ T-lymphocyte count will indicate treatment success.

8.8.1 Clinical and Laboratory Monitoring of Patients on First Line Drug Regimen

i) Scheduled Visits

Patients will attend the clinic monthly to collect medication and be seen by a professional nurse, Clinical Officer or Assistant Medical Officer to monitor drug tolerance, adverse events and adherence. Ideally, the clinic nurse, doctor, pharmacist or therapeutic counsellor should count drugs at each scheduled visit. All patients should be seen by a physician at two weeks after initiation of ART to check for adverse events, perform more blood tests (ALT or FBC), and escalate the NVP dose. Patients should be seen by a doctor at four, eight and twelve weeks, and every three months thereafter if well. If not well, patients will need to be seen more frequently as determined by the treating doctor or nurse. Safety bloods are to be taken as per schedule. CD4 count will be done every six months while patients are on the first line regimen.

Assessment	Week 0 (baseline)	2 nd Week	4 th Week	8 th Week	12 th Week	Every month	Every 3 months	Every 6 months
Education/therapeutic counsellor visit	N, C		N, C	N, C	N, C	N, C	N, C	
Treatment readiness assessment	Whole team							
History	D							
Physical exam	D		D	D	D	N	N	N
Weight	N		N	N	N			N
Complete registers	N, C					N, C	N, C	N, C
Safety blood tests (regimen I and II with NVP ^a)	N		N ^a	N ^a				N ^a
Safety blood tests (regimen II and IV with AZT ^a)	N		N	N	N ^b			N ^b
CD4 count	N							N
Adverse events		N, P	D, P	D, P	D, P	N, P		
Adherence check ^c	N, C	P, N, C	P, N, C, D	P, N, C, D	P, N, C, D	P, N, C, D		

Table 8.4 Events Schedule.

N= Nurse, C=Counsellor, D=Doctor, P=Pharmacist

- For patients on NVP containing regimens, ALT will be taken at baseline, at six months, and whenever symptomatic.
- For patients on AZT containing regimens, FBC will be done at 4 weeks, then once every six months.

Table 8.5: Summary of Adult ART Laboratory Monitoring of Patients on First Line Regimen.

Regimens	Monitoring Tests	Frequency	Rationale
I. AZT/3TC/EFV	CD4	Baseline, 6-monthly	ART monitoring
	FBP/Hb	Baseline, week 4 thereafter, 6-monthly	Contains AZT
II. 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
III. TDF/3TC/EFV TDF/3TC/NVP (TDF containing regimen)	Urinalysis	Baseline, and 3-monthly	TDF could be nephrotoxic
	Serum Creatinine	Baseline and once yearly	
IV. d4T/3TC/NVP	CD4	Baseline, 6-monthly	ART monitoring
	ALT	Baseline, 6-monthly, and whenever symptomatic	Contains NVP
V. d4T/3TC/EFV	CD4	Baseline, 6-monthly	ART monitoring

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

Baseline = testing for ART eligible patients at initiation of ART

ii) **Unscheduled Visits**

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

8.8.2 Immune Reconstitution Inflammatory Syndrome (IRIS)

For many opportunistic infections including TB, there can be a transient worsening of the symptoms of infection at two to three weeks, and sometimes up to eight weeks after commencement of ART. This is referred to as the immune reconstitution inflammatory syndrome. The risk is high in those with advanced HIV disease whose CD4 count is <50 cells/mm³.

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 interrupted for immune reconstitution syndromes. 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 8.6 below.

Table 8.6. Immune Reconstitution Inflammatory Syndrome.

<p>Diagnosis of infectious IRIS would require: Both major (A plus B) Criteria, or Criterion A plus two minor criteria</p>
<p>Major criteria</p> <p>A. A typical presentation of “opportunistic infections or tumours” in patients responding to antiretroviral therapy (ART) includes:</p> <p>Localised disease, e.g. lymph nodes, liver, spleen</p> <p>Exaggerated inflammatory reaction, e.g. severe fever, with the exclusion of other causes of painful lesions</p> <p>Atypical inflammatory response in affected tissues, e.g. granulomas, suppuration, necrosis, or perivascular lymphocytic inflammatory cell infiltrate</p> <p>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</p> <p>Development of enlargement of cerebral space occupying lesions after treatment for cerebral <i>Cryptococcus</i> or toxoplasmosis</p> <p>Progressive pneumonitis or the development of organising pneumonia after treatment for pulmonary TB or PCP</p> <p>New onset or worsening of uveitis/vitritis after resolution of CMV retinitis</p> <p>Fever and cytopenia after treatment for disseminated <i>Mycobacterium avium</i> complex (MAC) disease</p> <p>Enlargement of Kaposi’s sarcoma lesions and subsequent resolution or partial regression without commencement of radiotherapy, systemic chemotherapy or intralesional therapy</p> <p>B. Decrease in plasma HIV-RNA level by $> 1 \log 10$ copies/ml</p>

Minor criteria

Increased blood CD4+ cell count after HAART

Increased 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

8.8.3 Laboratory Monitoring of Patients on Second Line Drugs

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, and preferably all three drugs.
- If changing due to toxicity, change only the drug suspected of causing the problem.
- Never change to monotherapy (i.e. single drug).
- When selecting drugs, choose drugs that have not been used before, that do not have cross-resistance, and that have no overlapping toxicities or drug-drug interactions.

8.8.4 Scheduled Visits

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

Table 8.7. Summary of Adult ART Second Line Regimen and Routine Monitoring.

Regimen	Drugs	Monitoring Tests/ Frequency
2nd Line	ABC /Lopinavir/ ritonavir	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
	Atazanavir	Liver function tests, (ALT) 6 monthly Fasting glucose, Every 12 months
	Tenofovir	Urinalysis at baseline and 3 monthly Serum creatinine at baseline and once yearly

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

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

8.8.5 Unscheduled Visits

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

8.8.6 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 12).

However, 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).

8.9 In Case of Loss to Follow Up

Aggressive 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.

8.10 Contraindications (Relative) for Initiation of ART

Antiretroviral drugs should be avoided or delayed in the following conditions:

- If compliance is not assured
- If the patient refuses to give consent
- In the first trimester of pregnancy
- If liver or renal failure occurs

8.11 Discontinuation of ART

ART should only be discontinued only on advice from specialists/ experienced ART clinicians. The only exceptions are cases where:

- The patient is dying and can no longer comply
- There is repeated failure to comply with treatment
- Severe toxicity occurs

8.12 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.

Chapter 9.
ARV Therapy in Infants
and Children



CHAPTER 9. ARV THERAPY IN INFANTS AND CHILDREN

9.1 Antiretroviral Regimens for HIV Infected Infants and Children

Most antiretroviral drugs approved for treatment of HIV infection can be used for children. However, there may be limitations for young children requiring syrup or liquid formulations, as some ARV drugs that are not available in these forms. Moreover, pharmacokinetic parameters in children vary with age and therefore are more complicated than in adults.

There are some Paediatric FDCs now available; see Appendix 6. The use of tablets that require cutting in order to use a portion of the drug should be discouraged, as it can lead to under dosing or overdosing of the drug. This in turn can lead to an increased risk of resistance or toxicity.

Dosing in children is usually based on either body surface area or weight. Drug doses must be adjusted as the child grows in order to avoid risk of under dosage, resistance to drugs or suboptimal response. Standardization is also important so that non-expert personnel can safely dispense correct doses. It is therefore preferred to provide health care workers with job aids such as dosing charts or a dosing wheel. This allows ARV drugs to be administered according to weight bands (see Annexes 5 and 6). Weight banded dosing is safe, accurate and the preferred method for dosing ART in children.

9.2 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

9.3 Selection of Patients for Antiretroviral Therapy

9.3.1 Criteria for Initiating Antiretroviral Therapy in Children (Eligibility for ART)

(See Appendix 2 for WHO clinical staging of HIV/AIDS.)

9.3.1.1 Initiation of ART for Infants and Children Under 24 Months

Initiation of ART is recommended for all children below 24 months of age who have a confirmed diagnosis of HIV irrespective of WHO Paediatric Staging and irrespective of CD4 percentage or CD4 count.

For children less than 18 months old, HIV–infection needs to be virologically proven (using HIV DNA PCR or HIV RNA PCR). For children 18 months of age or older, a positive antibody test (as per natural testup algorithm) confirm HIV infection.

HIV exposed and serological test positive children aged less than 18 months with neither virological confirmation nor CD4 count/% available but who meet WHO criteria for severe HIV disease (see presumptive diagnosis of HIV, refer to page 97) should be initiated on ART. In such cases, HIV antibody testing must be repeated at age 18 months to confirm that the child is definitely HIV infected. Only children with confirmed infection should continue with ARV therapy.

9.3.1.2 Initiation of ART for Children 24 Months or Older

For children over 18 months of age, a positive antibody test is an indication of HIV infection since any acquired antibodies from the mother would have degenerated; but this needs to be confirmed by a second serological test. All children older than two years in WHO Paediatric Stage 3 or 4 HIV diseases should start ART irrespective of CD4 % or count. Initiate ART to children in Stage 1 or 2 if CD4 is below age-adjusted threshold (see Table 9.1)

Table 9.1: Criteria for ART initiation in HIV Infected Children.

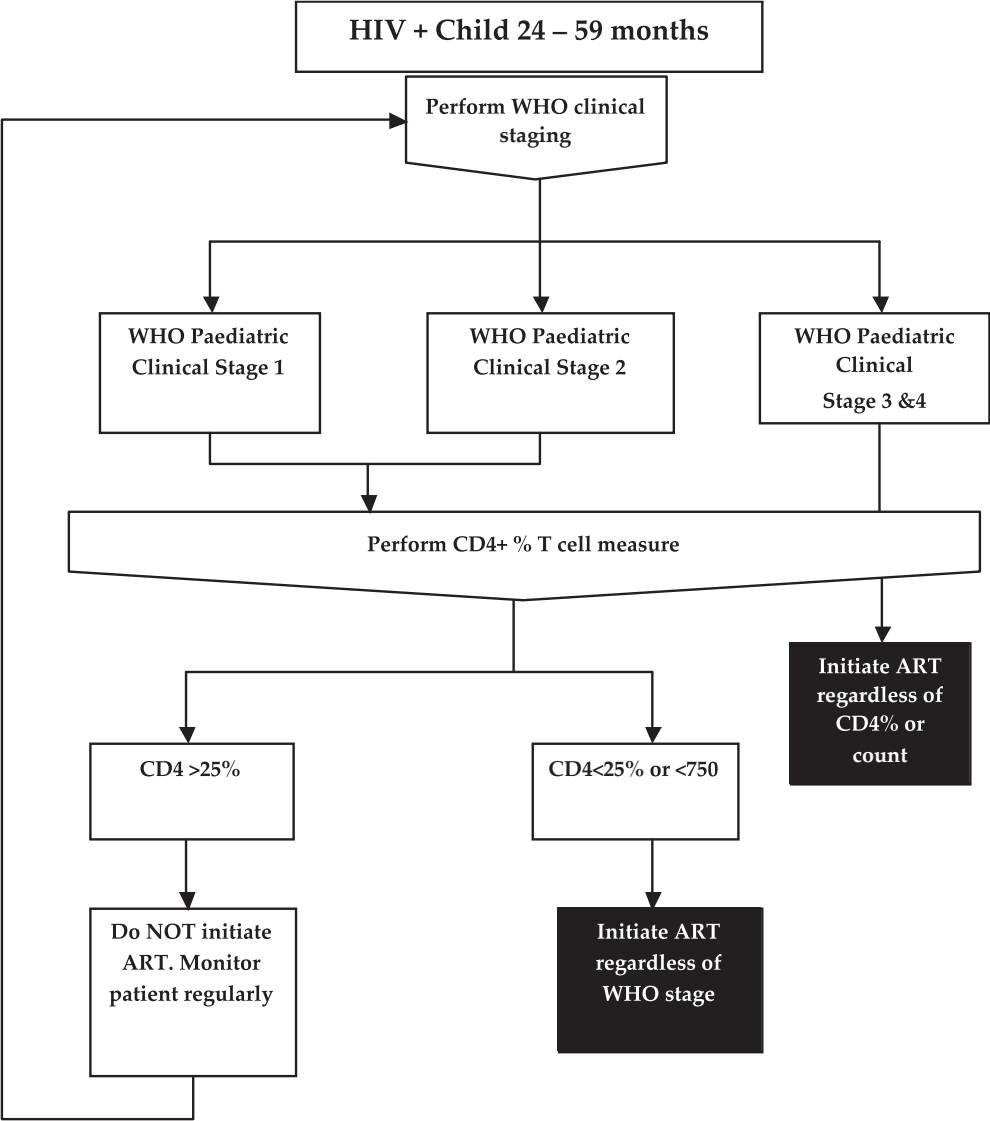
a) CD4 Age-adjusted thresholds for ART initiation in children

Age	Infants < 24 months	24 – 59 months	5 years or over
CD4 percentage	All	□ 25%	N/A
Absolute CD4		□ 750 cells/mm ³	□ 350 cells/mm ³

b) **Age and Clinical Staging Criteria for ART initiation in children with confirmed HIV infection.**

Age	Clinical stage	Immunological status
< 24 months	<i>Treat all</i>	
> 24 months	Stage 4*	<i>Treat all</i>
	Stage 3*	<i>Treat all</i>
	Stage 2*	Treat if CD4 is below age-adjusted threshold (see figure below) Don't treat if no CD4 test is available
	Stage 1*	

Figure 9.1. Clinical Eligibility Criteria for ART in 24 to 59 Months.



9.3.2 Breastfeeding and ART

The penetration of ARVs into human breast milk in lactating women has not been quantified for most ARVs. Although some ARVs, such as Nevirapine, are known to be present in breast milk, the concentration and quantity of drug that would be ingested by the infant would be less than needed to achieve therapeutic levels. In fact, infected breastfeeding infants whose mothers are receiving ARV therapy may end up with sub-therapeutic levels of some ARVs, and this could lead to development of drug resistance in the infant's virus. Thus, if a breastfeeding infant requires ARV treatment, ARVs at standard paediatric doses should be initiated regardless of whether the mother is receiving ARV therapy or not. There is no risk of ARV overdose or toxicity in a breast feeding baby with a mother who is on ART.

Evaluation to be done Before Initiating Therapy in Children

A good history of the patient should be taken together with a thorough physical examination.

The following baseline clinical assessment should be done:

- Weight, height, head circumference and other measures of growth
- Clinical staging of HIV disease
- Developmental status
- Screening for malaria, TB disease, and exposure to TB
- Identification of concomitant medical conditions (e.g. hepatitis B or C infection, TB, other co-infections or OIs, pregnancy in adolescent girls)
- Details of concomitant medications, including cotrimoxazole and traditional or herbal therapies
- Nutritional status, including assessment of the quality and quantity of intake
- For those eligible for ART, assessment of the child's and caregiver's preparedness for therapy

Baseline Laboratory Tests

Laboratory tests that should be done are shown in Table 12, in the next few pages.

9.4 Recommended First-Line ARV Regimens in Infants and Children

The guiding principles for antiretroviral treatment apply for children and adolescents as they apply for adults. For general explanation of ARVs refer to Chapter 8.

9.4.1 Treatment Using ARV Drugs in Children

Any child, irrespective of the age, diagnosed to be HIV infected should immediately be referred to CTC. The initial management should include a complete physical assessment and staging using the WHO staging system (see Appendix 2), as well as complete history including possible exposure to ARV (i.e. for PMTCT or treatment). Another objective is evaluation for presence of active opportunistic infections.

Children under two years of age should be initiated on ART as soon as possible. Waiting for results of laboratory tests should not delay treatment initiation.

List of drugs available in paediatric formulations:

- Zidovudine (AZT)
- Lamivudine (3TC)
- Nevirapine (NVP)
- Abacavir (ABC)
- Efavirenz (EFV)
- Stavudine (d4T)
- Lopinavir/r

Available paediatric FDC:

1. AZT+3TC+NVP
2. NVP+d4T+3TC
3. 3TC+AZT

The first line treatment options for children are as follows in preferential order:

Less than 36 months of age:

- Zidovudine (AZT)+Lamivudine (3TC)+Nevirapine (NVP)
- Abacavir (ABC)+Lamivudine (3TC)+ Niverapine (NVP)
- Stavudine (d4T) + Lamuvudine (3TC) + Nevirapine (NVP)

36 months or older and bodyweight 10kg or higher:

- Zidovudine (AZT)+Lamivudine (3TC)+ Efavirenz (EFV) or Nevirapine (NVP)
- Abacavir (ABC)+Lamivudine (3TC)+Efavirenz (EFV)or Niverapine (NVP).
- Stavudine (d4T) + Lamuvudine (3TC) + Nevirapine (NVP)

Stavudine (d4T) is an alternative to AZT in cases of anaemia (i.e. haemoglobin of <7.5g/dl). However, it should be noted that d4T in liquid formulation needs refrigeration. Side effects of Stavudine, such as peripheral neuropathy, are less common than in adults but they are difficult to recognise in children. From age of 12 years onwards Tenofovir (TDF) is the alternative drug for AZT and d4T.

9.4.2 Antiretroviral treatment for HIV-infected children with previous ARV exposure.

If the mother received ARVs during pregnancy, either for her own treatment and/or to prevent mother to child HIV transmission (PMTCT) , there is a possibility that she may transmit a resistant virus

to her baby. Resistance could also develop in the infant who has used ARV for prophylaxis. This is particularly the case if NVP was used, either alone or as a component of a two-drug regimen for PMTCT.

Children who require ARV therapy and who have previously received either single-dose NVP or 3TC or daily NVP while breastfeeding, as MTCT prophylaxis, should be given a PI based regimen. If a PI based regime is unavailable these children should be given the first line regimen available. For dosing of ARV regimens see Appendix 5, Paediatric Antiretroviral Dosing.

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 in children who are failing to grow; improvement in neurological symptoms and development in children who are demonstrating delay in developmental milestones or encephalopathy; and/or decreased frequency of infections (bacterial infections, oral thrush, and/or other opportunistic infections). In addition to clinical assessments/monitoring recommended in adults, the clinical monitoring of ARV treatment in children should also include:

Feeding practice (Nutrition)-Nutritional status (mid upper arm circumference [MUAC], weight, height, head circumference for children under 3 years old.

- Developmental milestones
- Neurologic symptoms
- Continuation of CPT
- Clinical staging
- Concomitant medical condition
- Screening for malaria and TB

Laboratory Assessments/Monitoring

The table below (Table 9.2) shows the laboratory tests that should be done when monitoring in children on ARV therapy.

Tab. 9.2 *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 ^b	√	√	√	√
Pregnancy testing in adolescent girls		√ ^c		√ ^d
Full chemistry (including but not restricted to, liver enzymes, renal function, glucose, lipids, amylase, lipase and serum electrolytes) ^e				√
HIV VL measurement ^{f,g}				√
OI screening (where possible)	√			√

- a Haemoglobin monitoring at week 8 after initiation of ART is recommended if AZT is used
- b HIV infected children not yet eligible for ART should be monitored with CD4 count every six months. For infants and children who develop new or recurrent WHO stage 2 or 3 events or whose CD4 count approaches threshold values, the frequency of CD4 measurement can be increased. % CD4+ is preferred in children <5 years
- c Pregnancy testing may be needed for adolescent girls prior to initiation a regimen containing EFV
- d For pregnant adolescent girls provide prophylaxis or combined ART for those in need of it for their own health and/or to prevent vertical transmission (see WHO PMTCT Guidelines, 2010)
- e Routine monitoring (every six months) of full chemistry, particular lipid levels, liver enzyme and renal function should be considered for infants and children on second-line drugs
- f At present, VL measurement is not a prerequisite for initiation or regular monitoring of ART in resource-limited settings. VL can be used to diagnosis HIV infection and confirm clinical or immunological failure prior to switching treatment regimen
- g VL should be assessed in infants on NNRTI-based regimens who are known to have been exposed to NNRTIs intrapartum or through breastfeeding.

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 for 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 (<50 - 400)copies/mL should be achieved and sustained. Note that different machines have different cut-off points/values for undetectable viral load. Many machines only have an undetectable value of <400 copies/mL.

9.6 Adherence Monitoring

Adherence in children is a special challenge because of factors relating to children, caregivers, medications, and the interrelationships of these factors.

Achieving greater than 95% adherence to the drug regimen will ensure a good virological response and prevent the emergence of viral resistance. For a child taking medication twice daily, omitting more than one dose in 10 days implies <95%, or suboptimal, adherence.

Adherence in children is more challenging, as children rely on a responsible parent/caregiver for medication. Some children may depend on many and different individuals such as granny, housemaids, siblings, peers and friends who sometimes do not know the child's status, as well as having other responsibilities of interest. Motivation of children/adolescents to take medications daily fluctuates over time. It may also fluctuate when a child does not know her/his status and/or is not actively involved in their care. For adolescents, their needs are diverse, which can affect adherence. Furthermore, paediatric formulation and dosages changes over time depending on drug type, age, weight, etc.

The limited number of paediatric formulations, poor palatability, high pill burden or liquid volume, frequent dosing requirements, dietary restrictions and side-effects may hamper the regular intake of required medications. The successful treatment of a child requires the commitment and involvement of a responsible caregiver. Mothers of HIV-infected children are often HIV-infected themselves; therefore

the care of the child may be less than optimal because of 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; children and peer support groups may be particularly beneficial for mothers with young children on ART.

Adherence success requires commitment and knowledge on the part of the child/adolescent and primary caregiver. Involving the caregiver and the child/adolescent in decision-making in relation to their care, supporting the relationship between them, their family network and HCWs improves adherence. An older HIV-infected child who understands her/his infection can be actively involved in ARV treatment.

A good relationship between the healthcare providers (i.e., counsellors, nurses, and doctors) and the caregiver helps optimise adherence. Ideally, the same primary healthcare provider should continue to treat the patient so that a long-term relationship can develop with the family. Regular education and support during each clinic visit can enhance and maintain good adherence. Adherence can be monitored using diary cards, medication checks, and other improvised measures.

Health workers should look only for children at risk of poor adherence, for example:-

- Children with multiple caregivers
- Adolescents
- Children in boarding schools.

9.6.1 Factors That Influence Adherence

Child Related Factors

- Living environment--homelessness, accessibility to the health facility.
- Age--dependency on guardian/parent, poor understanding of the regimen, schooling. Peer pressure, sports.

- Drug regimen--pill burden, administration, pill sizes, volume of suspensions, frequency of administration, food or fasting requirement, tolerance, taste.
- Health status of child
 - o Common childhood illnesses--child may be on other medications such as antibiotics or antiTB, which might interfere with ARV drugs administration and mood
 - o Developmental milestones--if they are delayed, they may lead to increased dependency, low levels of understanding and child neglect.

Family/Caregiver Related Factors

- State of the caregiver--stigma, unexpected travel, cultural beliefs, education level, various caregivers over time, mothers employed.
- Family socio-economic status--availability of storage for medicine including fridge when necessary.
- Family problems--differences in opinions regarding ARV.
- Parents/ caretaker HIV/AIDS status.
- Relationship between the parent/caregiver and the child.

Non-involvement of the actual medication administrators in the adherence counselling, e.g. house maids/girls.

System Related Factors

- Patient-care giver--clinician relationship:
 - o Unfriendly clinic environment for kids
 - o Poor communication and understanding
- Contradicting information from health providers (doctors, nurses, pharmacists) regarding medications regimens, reactions and effects
- Lack of adolescent - specific HIV-service
- Medication stock out and irregular supply

9.6.2 How to Prepare for Adherence

The service provider should:

- Establish parent/caregiver readiness to start ARVs.
- Disclose child's status and need for lifelong treatment to responsible parents/guardian.
- Identify responsible person for daily drug administration.
- Conduct joint session with parent, family drug dispenser and the child (depending on age and disclosure status).
- Conduct demonstration sessions on drug dosages and administration.

9.6.3 Considerations for Readiness to Start Treatment

Before starting medications the service provider should consider the following:

- Parent/caregiver understands importance of clinic visits and maintaining CTC 1 card
- Child takes cotrimoxazole and multivitamins properly
- Roles of different household members in drug administration
- Relevant household members trained
- Household conditions for drug storage are met
- Criteria for readiness to start are met

Challenges of Adherence for HIV Infected Children up to 8 Years

1. Traditionally, children do not take part in making decisions. Children have no right whether to refuse or to take medications.
2. Educating children needs extra effort and skill. There is limited experience counselling for life time medications in children.

3. A child is growing and developing; needs, relationships, environment and priorities are changing.
4. Drugs – pill/volume burden, taste, colour, frequency, smell, eating schedule - drugs that have requirements to be given with or without food
5. Age of the child (changes in dosing, developmental changes).

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.
- Never rush to treat, always assess carefully.
- Strategies for adherence MUST be household or family oriented.
- Adherence counselling is an 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, counsellors all reinforce adherence.
- For children, identify one household caregiver who gives medication to child and also attends the clinic.

Table 9.3 Common Challenges and Strategies to Improve Adherence in Children.

CHALLENGE	STRATEGIES
<p>1. Child not taking medications</p> <p>Parents/caregiver reports that the child not taking her/his medications.</p>	<p>Obtain a detailed history aimed at identification of the specific causes of her/his broad complaint</p> <p>Explore with the guardian ways to convince the child to take the medications. Insist the importance of adherence for the child's survival</p> <p>Make available information in the primary caretaker's language</p>
<p>2. Medicines make child sick</p> <p>A parental report of the child becoming nauseous and vomiting after taking medications</p>	<p>Administer medications with food if not contraindicated.</p> <p>Administer medications with liquid to help reduce gastric irritation.</p> <p>Reschedule time of taking medications.</p> <p>Request assistance from the school nurse if nausea and vomiting primarily occur in the morning before school. This may only be done with the family's permission.</p>
<p>3. Fear of medicines harming the child</p> <p>A parental report of adherence in the face of deteriorating clinical and immunological status in the child; parental anxiety that the antiretroviral medications will harm the child.</p>	<p>Obtain refill history from primary pharmacy to check the dose.</p> <p>Discuss with the guardian the common side effects of the regimen, encourage continuing with treatment if no severe side effect.</p> <p>Utilize visiting nurse/HBC provider services to assist with adherence assessments.</p> <p>Utilize directly observed antiretroviral therapy (visiting nurse, HBC provider)</p>

<p>4.Regimen/dosing confusion</p> <p>A parent becomes confused about which medications are being given due to multiple names for medications.</p>	<p>Provide parent with a written schedule/ illustration of medications. This should include both brand and generic names and some description of the medications in a language that the child and caregiver can understand.</p> <p>Utilize colour-coded labels with a matched colour-coded calendar.</p> <p>Where possible elicit additional support from another family member or other community resource person.</p>
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Consequences of Poor Adherence

The following are the consequences of poor ARV adherence in children:

(Refer to Chapter 8.)

1. Growth and developmental faltering.

9.7 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 in 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.

9.7.1 Treatment Failure

9.7.1.1 Clinical Criteria for Treatment Failure

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

- Lack of growth response or decline in growth over a six-month period, after excluding other causes, such as TB, lack of food
- No improvement of neuro developmental milestones
- Development of HIV encephalopathy in a child with no previous manifestations
- Recurrence of infections, such as oral candidiasis, those are refractory to treatment
- Advancement from one clinical stage to another or new evidence of stage 3 disease

Note: Short intercurrent episodes of pneumonia, Lower Respiratory Tract Infections (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 six months.

9.7.1.2 Immunological Criteria for Treatment Failure

Immunological criteria indicating that a change to second-line therapy is warranted if adherence is good include:

Fig. 9.2 CD4 criteria suggesting immunological failure

Immunological failure is recognized as developing or returning to the following age-related immunological threshold after at least 24 weeks on ART, in a treatment-adherent child:	
≥ 2 years to <5 years of age	CD4 count of <200 cells/mm3 or %CD4+ <10
≥ 2.5 years of age	CD4 count of <100 cells/mm3

Preferably at least two CD4 measurements should be available

Use of %CD4+ in children <5 years and absolute CD4 count 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; rather, it should be determined one month (or more) post-resolution. If there is a modest decline in CD4 percent (< 5%) and if there is no failure to thrive, do not change medication, instead maintain close monitoring.

9.7.2 Virological Criteria for Treatment Failure

Virological failure is recognized if the child is adherent to their (first line) ART regimen, more than 24 weeks from ART initiation, and still has a persistent viral load over 5000copies/ml.

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

9.8 Recommended Second-Line ARV Therapy for Infants and Children

The recommended second line regimen for infants and children are as follows:

1. After failure on a first-line NNRTI-based regimen, a boosted PI(LPV/r) plus 2 NRTIs are recommended for second-line ART
2. After a failure of first line of LPV/r + 2 NRTIs ; NNRTI + 2 NRTIs is the recommended choice
3. After failure on a first-line regimen of AZT or d4T + 3TC then ABC + 3TC is the preferred NRTI backbone option for second-line ART.

9.9 Laboratory Monitoring of Paediatric Patients on ART

Table 9.4: Paediatric ART Regimens and Routine Monitoring.

Regimen	Test	Frequency
d4T / 3TC / ritonavir	CD4	Staging, 6-monthly
	Fasting cholesterol	Baseline, 6-monthly
	Fasting glucose	Baseline, 6-monthly
d4T / 3TC / nevirapine	CD4	Staging, 6-monthly
	ALT	Baseline, week 2, 4 and 8, thereafter 6 monthly
AZT / 3TC / ritonavir	CD4	Staging, 6-monthly
	FBC	Baseline, then monthly for 3 months, then 6 monthly (with CD4) thereafter
	Fasting cholesterol	Baseline, 6 monthly
	Fasting glucose	Baseline, 6-monthly
AZT / 3TC / nevirapine	CD4	Staging, 6-monthly
	FBC	Baseline, then monthly for 3 months, then 6 monthly (with CD4) thereafter
	ALT	Baseline, week 2, 4 and 8, thereafter 6 monthly
d4T / 3TC/ Lopinavir/ritonavir	CD4	Staging, 6-monthly
	Fasting cholesterol	Baseline, 6-monthly
	Fasting glucose	Baseline, 6-monthly
d4T / 3TC/ EFV	CD4	Staging, 6-monthly
AZT / 3TC / Lopinavir/ ritonavir	CD4	Staging, 6-monthly
	FBC	Baseline, then monthly for 3 months, then 6 monthly (with CD4) thereafter
	Fasting cholesterol	Baseline, 6-monthly
	Fasting glucose	Baseline, 6-monthly

9.9.1 Adverse Reactions

Drug-related adverse reactions while on ART can occur immediately (soon after a drug has been administered), early (within the first days or weeks of treatment) or late (after months of treatment).

Adverse reactions can vary in severity from mild to severe to life-threatening and may be specific to the drug or generic to the class of drugs in use.

9.9.2 Toxicities

The most common toxicities in children include the following:

- Haematological: drug-induced bone-marrow suppression, most commonly seen with AZT (anaemia, neutropenia and, more rarely, thrombocytopenia).
- Mitochondrial dysfunction: primarily seen with the NRTI drugs; include lactic acidosis, hepatic toxicity, pancreatitis and peripheral neuropathy. The NRTIs differ in their ability to affect mitochondrial function: d4T and ddI are worse than AZT; 3TC and ABC have the least toxicity of all.
- Lipodystrophy and other metabolic abnormalities: primarily seen with d4T and the PI class, and to a lesser degree with other NRTI drugs. Abnormalities include fat maldistribution and body habitus changes, hyperlipidaemia, hyperglycaemia, insulin resistance, diabetes mellitus, osteopaenia, osteoporosis and osteonecrosis.
- Allergic reactions: including skin rashes and hypersensitivity reactions. These are more common with the NNRTI drugs, but also seen with certain NRTI drugs, such as ABC.

Because of the risk of potentially life-threatening hepatotoxicity associated with NVP, hepatic dysfunction of any aetiology in a child on NVP requires careful consideration of whether NVP should be continued.

9.93 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 Table 9.5).
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 counselling and support to mitigate adverse reactions. Emphasize the maintenance of adherence despite mild and moderate reactions.

Table 9.5: Severe toxicities of ARVs in infants and children, and potential drug substitutions

Toxicity Event	Responsible ARV	Suggested first line ARV drug substitution
Acute symptomatic hepatitis	NVP	Preferred substitution of NVP to: a third NRTI(disadvantage: may be less potent) or PI(disadvantage: premature start of class usually reserved for second-line)
Hypersensitivity reaction		
Severe or life-threatening rash (Stevens-Johnson syndrome)		
Lactic acidosis	d4T	ABC
Peripheral neuropathy	d4T	AZT or ABC
Lipodystrophy/metabolic syndrome	LPV/r / d4T	ABC
Severe anaemia or neutropaenia	AZT	d4T or ABC
Severe gastrointerstitial intolerance		d4T or ABC
Persistent and severe central nervous system toxicity	EFV	NVP
Potential teratogenicity (adolescent girl in first trimester of pregnancy, or of childbearing potential and not receiving adequate contraception)	EFV	NVP
Hypersensitivity reaction	ABC	AZT

Chapter 10.

TB and HIV Co-infection



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. While the lifetime risk of developing TB in an individual who is HIV negative is 5-10%, for those who are HIV positive, the risk is 30-50%. HIV also increases the risk of TB reactivation. On the other hand, TB increases the risk of progression from HIV to AIDS and is the most common opportunistic infection and the major cause of death among AIDS patients.

HIV fuels the TB epidemic in many countries, especially in Sub-Saharan Africa. In Tanzania, TB cases have increased six-fold from 11,843 in 1983 to 64,267 in 2009, mainly due to HIV/AIDS. About 37% of TB patients in Tanzania are co-infected with HIV, accounting for 60-70% of the increase in the number of TB patients.

10.2 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 alters the clinical course of TB disease. As HIV infection progresses, CD4+ T-lymphocytes that play an important role in the body's defence against tubercle bacilli decline in number and function. Thus, the immune system becomes less able to prevent the growth and local spread of *M. tuberculosis*. The most common types of TB in HIV are disseminated and extra pulmonary TB.

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10.2.2 Pulmonary TB

Even in HIV-infected patients, pulmonary TB (PTB) is still the most common presenting feature. In Tanzania, about 41.5% of new TB patients present with smear positive pulmonary tuberculosis (PTB+) and 36.2% with smear negative pulmonary tuberculosis (PTB-) and 22.3% presented with extrapulmonary TB in 2009.

The WHO defines smear-positive pulmonary tuberculosis as a patient with one sputum smear examination positive for acid-fast bacilli (AFB), **and** laboratory confirmation of HIV infection.

Smear-negative pulmonary tuberculosis is defined as the presence of at least two sputum specimens negative for AFB, radiographical abnormalities consistent with active tuberculosis, **and** laboratory confirmation of HIV infection. 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 that is culture-positive for *Mycobacterium tuberculosis*.

10.2.3 Extra-Pulmonary Tuberculosis (EPTB)

About 22% of new TB patients in Tanzania present as EPTB. The most common forms of extra-pulmonary TB are pleural effusion, lymphadenopathy, pericardial disease, miliary 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 **and** laboratory confirmation of HIV infection **and** a decision by a clinician to treat with a full course of anti-tuberculosis chemotherapy.

Table 10.1 Severe and Less Severe Extrapulmonary TB Cases.

Severe extra-pulmonary TB	Less severe extra-pulmonary TB
Meningitis	Lymph node
Miliary	Unilateral pleural effusion
Pericarditis	Bone (other than spine)
Bilateral or extensive unilateral effusion	Peripheral joint
Spinal	Adrenal gland
Intestinal	Skin
Genito-urinary tract	

10.2.4 Combined Treatment for Patient with TB/HIV Co-infection

ART has been reported to reduce TB rates by up to 90% at the individual level and by approximately 60% at the population level, and to reduce 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 Eligibility for Patient with TB/HIV Co-infection

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, the patient can tolerate ART, preferably within the first two weeks of starting TB treatment.

The recommended first-line ART regimens for TB patients are those that contain Efavirenz (EFV), since interactions with anti-TB drugs are minimal.

For those who are unable to tolerate or have contraindications to an EFV-based regimen, AZT + 3TC + NVP or TDF + 3TC or FTC + NVP or a triple NRTI regimen, e.g. AZT+3TC+TDF, is recommended.

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 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/400mg BID). This regimen is associated with high levels of toxicity, and requires close clinical and laboratory monitoring.

Considerations When TB is Diagnosed in PLHIV Who are Already on ART

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 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.

10.2.5 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).

10.2.6 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. 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.

Children co-infected with TB and HIV have higher case fatality than slightly infected

10.2.6.1 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 not typical. The diagnosis should therefore be based on clinical findings (especially failure to thrive or weight loss), family history of contact with a smear positive case, X-ray examination and tuberculin testing, culture (if available), 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.”

10.2.6.2 Treatment of TB in Children

In principle, TB treatment in children does not differ from that in adults. Nearly all pulmonary TB in children is sputum smear negative (in most cases smear is not done) or is extra-pulmonary tuberculosis and thus falls into Category III. However, severe forms of TB such as meningitis, miliary TB or TB of the spine should be defined as Category I. Treatment can be provided with adult formulation following the dose-body weight relationship presented in Tables 4 and 5.

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.

10.2.6.3 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 has little or 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*, but 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.

10.3 Collaborative TB/HIV Interventions

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

The measures being implemented include; establishing mechanism for collaboration between TB and HIV/AIDS programmes, reducing the burden of HIV in TB patients and decrease the burden of TB in PLHIVs.

The following collaborative TB/HIV activities are recommended to be implemented in the country:

10.3.1 Establish Mechanisms for Collaboration Between TB and HIV/AIDS Programmes

- o Set up effective coordinating bodies for TB/HIV activities at all levels
- o Establish position of National TB/HIV Coordinator and officers
- o Conduct surveillance of HIV prevalence among TB patients
- o Carry out joint TB/HIV planning between NTLP and NACP
- o Resource mobilisation for TB/HIV
- o TB/HIV capacity building
- o Patient empowerment and community involvement
- o Monitoring and evaluation of collaborative TB/HIV activities
- o Operational research to enhance collaborative TB/HIV activities
- o Partnership development and collaboration

10.3.2 Decrease the Burden of HIV in TB Patients

o **HIV Counselling and Testing**

HIV counselling and testing for TB patients offers an entry point for a continuum of prevention, care, support, and treatment for HIV/AIDS patients as well. Diagnostic HIV counselling and testing should be provided in all TB clinics as part of provider-initiated testing and counselling (PITC) services.

o **HIV Prevention Methods**

The close association between TB and HIV infection necessitates that specific policies will be needed to guide the nation in introducing and implementing HIV preventive services for all TB patients.

o **Provision of Cotrimoxazole Preventive Therapy**

TB patients who are co-infected with HIV are eligible to receive cotrimoxazole prevention therapy. Cotrimoxazole therapy is effective in preventing secondary bacterial and parasitic infections.

o **HIV/AIDS Care and Support**

Home-based care is an integral approach to involving the community in the prevention, care, and support of TB/HIV co-infected patients. It is necessary, therefore, to create a comfortable environment in which communities will be fully involved in the care and support of TB/HIV patients.

o **Provision of Antiretroviral Therapy**

Antiretroviral therapy improves the quality of life and greatly improves survival rates for PLHA. High levels of adherence are required in order to achieve long-term benefits and minimise the risk of developing drug resistance.

10.3.3 Reduce the Burden of TB in PLHIVs (3Is Strategies)

Since TB is a leading opportunistic infection in HIV, regular TB screening for all people living with HIV is crucial for success in reducing morbidity and mortality of those living with HIV. According to the WHO (2004) the interim policy on collaborative TB/HIV activities should include:

10.3.3.1 Establish Intensified TB Case Finding

Intensified TB case finding involves screening for symptoms and signs of TB (Annex 9 TB screening tool) in settings where HIV-infected people are concentrated. Early identification of signs and symptoms of TB, followed by diagnosis and prompt treatment in people living with HIV/AIDS, their household contacts, groups at high risk for HIV, and those in congregate settings (e.g., prisons, police quarters, military barracks, refugee camps, mining camps, schools, and living quarters for workers, especially labour-intensive agricultural areas), increases the chances of survival, improves quality of life, and reduces transmission of TB in the community.

10.3.3.2 Isoniazid Preventive Therapy (IPT)

TB disease develops in only 10% of all the individuals infected with *M. tuberculosis*. However, in HIV infected individuals this can be up

to 50%. TB preventive therapy is an intervention that is part of the package of care for people living with HIV. IPT is given to individuals with latent infection of *M. tuberculosis* in order to prevent progression to active disease. In these patients, the risk of developing tuberculosis is reduced by about 60%, and their survival is also prolonged. The protective effect is expected to last for 18 months. It is, however, important to exclude active TB before starting IPT.

Isoniazid is given to individuals who have latent infection with *M. tuberculosis* in order to prevent progression to active disease. Exclusion of active TB is critically important before this preventive therapy is started. Isoniazid is given daily for six to nine months. This therapy requires several steps to be taken, including identification of HIV-positive clients, screening to exclude active TB, and monitoring of client adherence to treatment.

Eligibility for TB Preventive Therapy among PLHIV

For patients with no history of TB treatment:

- All HIV positive individuals with no signs or symptoms suggestive of active TB are eligible for TB preventive therapy.
- 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 two years should not be considered for preventive therapy.
- Patients who were treated for tuberculosis more than two years earlier may be considered because they may have already been re-infected with TB.
- Patients who receive TB preventive therapy and who are eligible for antiretroviral therapy should complete their TB preventive therapy even if ART is started, as there is no interaction between Isoniazid and the current ART regimen used.

IPT should be offered in the following situations:

- Where quality supportive counselling is available
- After effective screening for active TB (annex 5)
- 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

10.3.3.3. Ensuring TB Infection Control in Health Care and Congregate Settings

TB infection control will be concentrated in health care and congregate settings where people with TB and HIV are frequently confined in crowded conditions. Measures to reduce TB transmission include administrative, environmental, and personal protection measures, which are generally aimed at reducing exposure to *M. tuberculosis* among health care workers, prison staff, police and their clients, and other persons in the congregate settings. 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. Environmental protection should include maximising natural ventilation and direct sunlight. Personal protection should include shielding of HIV-positive persons from possible exposure to TB infection.

The control plan should include:

- Screening of all clients to identify persons with a cough of two weeks or more as soon as possible after arrival at the facility.
- In outpatient departments, coughing patients should wait outside or in well-ventilated areas.
- TB suspects need to be examined in a well-ventilated room. Avoid contact between TB patients and HIV positive patients, though this can be difficult as the two patient groups have a large overlap.
- Have patients turn their heads and cover their mouths when they cough.

Suggested Clinic Operating Procedure:

Patients who report at CTC to register should be observed and probed about coughing; if they've been coughing for more than two weeks, they should be sent immediately to laboratory to provide sputum sample and return to CTC for registration and care.

Environmental Control Measures

Environmental control is the second line of defence for preventing the spread of TB in HIV care settings. If the work practice controls are inadequate, environmental control will not eliminate the risk of 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.
- Collection of sputum for TB outside (in an open environment) and away from other people, not in small rooms or other enclosed areas.

Protection of Health Care Workers

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 TB suspects and patients.
- Normal masks do not protect medical staff against inhaling infected droplets and are therefore not recommended as a preventive measure for health staff.

Chapter 11.

Chapter 11. HIV and AIDS in Pregnancy

CHAPTER 11. HIV AND AIDS IN PREGNANCY

11.1 Introduction

In Tanzania HIV prevalence is higher among women (6.6%) compared to men (4.6%). Also, HIV prevalence is significant higher in urban areas (8.7%) than in rural areas (4.7%¹). The majority (56%) of people living with HIV are women. Mother to child transmission (MTCT) is the most common mode of HIV infection among children. Worldwide, it is estimated that 200,000 children under 15 years of age are living with HIV. According to MOHSW, 18% of all HIV new infections in Tanzania are due to MTCT. With more than 1.8 million births and 6.8% HIV prevalence at antenatal clinics, approximately 100,000 HIV-positive women deliver HIV-exposed infants annually. Mother to child transmission is responsible for over 90% of new infections in infants and young children.

PMTCT Scale-up is based on the UN recommendation of a comprehensive four-element strategy to prevent HIV in infants and young children which includes:

- Primary prevention of HIV among women of reproductive age
- Prevention of unintended pregnancies among women living with HIV
- Prevention of HIV transmission during pregnancy, delivery and breastfeeding
- Treatment, care and support for women living with HIV, their children and families

11.2 Primary Prevention of HIV Among Women and Their Partners

Since there is no cure for HIV infection, primary prevention of infection is the most effective means of controlling the spread of HIV and its impact on individuals, families and communities. Preventing

HIV infection in women of childbearing age is the best way to prevent MTCT. The following should be taken into consideration:

- Encouraging sexually active women and men to adopt safer sex including the use of barrier methods (condoms) for prevention of HIV infection.
- All national healthcare services should emphasize early diagnosis and treatment of STIs.
- Providing young people with information and services to keep them free of HIV infection, and encouraging them to abstain from sex until they can make responsible decisions.
- Encouraging sexually active women and men to be faithful to their regular sexual partners.
- Encouraging and supporting women of childbearing age and their partners to know their HIV status.
- Prevention measures to include the counselling of HIV negative women on safer sexual practices and getting their partners tested.
- Using similar criteria for sero-negative and sero-positive women and following practices for universal precautions for blood transfusions during pregnancy and labour when indicated. (See Chapter 4).

11.3 Prevention of Unintended Pregnancies Among Women Infected with HIV

Although family planning (FP) is part of a comprehensive public health strategy to prevent MTCT, it has been neglected in most programmes. Having children or not is every woman's or couple's right. The use of FP should respect and *respond to reproductive rights of woman and her partner*. HIV-infected women should receive information about preventing unintended pregnancies, the risks of MTCT of HIV infection and consequences thereof, thus enabling them to make informed decisions.

All HIV-infected women and their partners (HIV-infected and uninfected) should be counselled on family planning to enable them choose appropriate and effective contraceptive methods. This should start during the antenatal period. Programmes should take advantage of the high attendance of women at child welfare clinics to both counsel and provide them with effective contraception during the post partum period. Another major opportunity for providing FP services is through the care and treatment centres. The provision of family planning services during this period will greatly reduce the number of unintended and unplanned pregnancies, thus reducing MTCT. Health facilities providing care and treatment services also offer a major opportunity for providing or referring to family planning services.

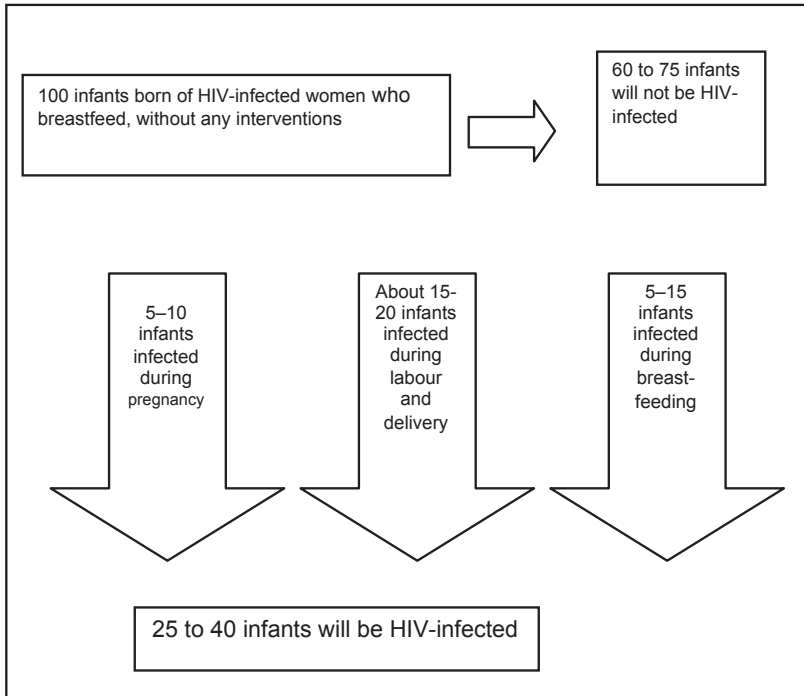
Note: A woman's/couple's choice of contraceptive methods should be based on the woman's health status and personal preference. However, dual protection is recommended for HIV-infected women. Condoms along with a second contraceptive method can prevent both pregnancy and STIs, including HIV.

11.4 Prevention of HIV Transmission During Pregnancy, Delivery and Breastfeeding

11.4.1 Mother to Child Transmission of HIV (MTCT)

The risk of MTCT is estimated at 15 – 40% in the developing world. Transmission of HIV from mother to child accounts for over 90% of all HIV infection in children aged below 15 years.

Figure 11.1 HIV Outcomes for Infants Born of Women Infected with HIV.



There are multiple risk factors that increase the chance MTCT of HIV. These include viral, maternal, obstetric and neonatal factors:

Viral Factors

- **Viral load:** High maternal viral load and low CD4 count occurs in new infection with HIV or advanced AIDS
- **Viral strain:** Transmission rates are higher with HIV-1 than HIV-2. Different strains have different rates of transmission, e.g., higher with C and E subgroup
- **Viral resistance:** Pre-existing resistance to available ARV drugs used for prophylaxis

Factors During Pregnancy

- High maternal viral load and low CD4 count (new infection or advanced AIDS)
- Viral, bacterial or parasitic placental infections (e.g., malaria)
- Febrile illnesses
- Genital tract infections
- Behavioural factors (e.g., cigarette smoking, use of hard drugs and unprotected sex)
- Micronutrients and vitamin deficiency
- Antepartum Haemorrhage
- Premature rupture of foetal membranes
- Chorioamnionitis

Factors During Labour and Delivery

- High maternal viral load and low CD4 count (new infection or advanced AIDS)
- Prolonged labour for more than 4 hours before delivery
- Invasive delivery procedures that increase contact with mother's infected blood or body fluids (e.g., episiotomy, artificial rupture of membranes, vacuum extraction delivery)
- Complicated deliveries (e.g., breech delivery because of the likelihood of manipulation in breech delivery)
- Chorioamnionitis (from untreated STI or other infections)
- Preterm delivery
- Low birth weight
- Intrapartum haemorrhage

Breastfeeding Factors

- High maternal viral load and low CD4 count (new infection or advanced AIDS)
- Duration of breastfeeding
- Mixed feeding (i.e., breastfeeding combined with other foods or fluids)
- Oral disease in the baby (e.g., thrush or mouth sores)

- Poor maternal nutrition status (e.g., micronutrient and vitamin deficiencies)
- Breast disease (abscesses, nipple fissures and mastitis)

11.5 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. Counselling about the test result is essential to improve maternal health and prevent MTCT of HIV. The second step is to provide more efficacious ARV prophylaxis to HIV positive women who get pregnant at the appropriate times during the pregnancy and labour period. Adoption of safer ANC, delivery and breastfeeding practices will contribute greatly to the prevention MTCT. See the following discussion.

11.5.1 Comprehensive Antenatal Care for Women with HIV and AIDS

ANC for HIV-infected pregnant women includes the same basic services provided for all pregnant women. However, obstetric and medical care should be expanded to address the specific needs of HIV-infected women including:

- Provision of prophylactic ARV
- ART for the eligible mother (CD4 below 350)
- Provision of appropriate obstetric care
- Infant feeding counselling and support
- Promotion to establish spouse's partner(s') HIV status

Specific Actions to be Taken:

- Antenatal care for HIV-infected women should take into account the health of the mother as well as the need to reduce the risk of HIV transmission to the infant. Antenatal examinations should therefore focus on HIV-related symptoms and opportunistic infections, including TB, and follow national guidelines for prophylaxis and treatment. Where prenatal diagnostic investigations are indicated, non-invasive screening tests should be considered first, to reduce the risk of MTCT.
- In accordance with national guidelines, routine tests including anaemia, syphilis, urine analysis and full blood picture (FBP) should be done. Where there are integrated care and treatment services, assess for ART eligibility, do a CD4+ T-cell count and initiate ART according to national guidelines. If there are no integrated services, refer to CTC.
- Assess for signs and symptoms of common infections in pregnancy, e.g. urinary tract and respiratory infections and genital tract infections. Treat promptly according to national guidelines, and administer tetanus toxoid immunisations when appropriate.
- Health care workers providing care for HIV-infected pregnant women should pay special attention to signs and symptoms of common opportunistic infections such as PCP and TB, and follow national guidelines for prophylaxis and treatment.
- Provide counselling on adequate and nutritious food, and give routine iron, folate, and multivitamin supplements according to national guidelines.
- CPT should be provided for all HIV infected pregnant women (see criteria Chapter 6) throughout pregnancy.
- As malaria is a major cause of high maternal and infant morbidity and mortality, administer sulfadoxine pyrimethamine (SP) as prophylaxis at 20-24 weeks and again at 28-32 weeks (always one month apart). For all women who are on CPT, malaria prevention with SP is not required.

- All HIV infected women require infant-feeding counselling and support. Promote and support exclusive breastfeeding for women who do not know their HIV status. Consider replacement feeding for HIV-infected women if it is acceptable, feasible, affordable, sustainable and safe (AFASS); otherwise encourage them to practice exclusive breastfeeding for the first six months.
- Identify unmet family planning needs and counsel the patient about the various family planning methods, relating them to the patient's particular situation and needs.
- Provide appropriate contraceptives to prevent unintended pregnancy among HIV infected women.
- Counsel about consistent use of condoms during pregnancy, as well as throughout postpartum and breastfeeding periods to avoid STIs and HIV re-infection. Discuss family planning options and future fertility involving the partner when possible. Advise dual protection methods.
- Assess pregnant women's families and social support networks and refer those in need to AIDS support organisations, faith-based organisations and clubs.
- Provide psychological counselling and social support with referrals where indicated.
- Emphasize the importance of keeping all ANC appointments as well as all postpartum and ongoing follow-up care appointments for both mother and infant/child. Plan the delivery options and place with the patient, and involve the spouse or another key member of the family after a thorough assessment of the patient, including review of the obstetric and medical history.
- Note : The care of women with HIV in the antenatal period should take into account the health of the mother as well as the need to reduce the risk of HIV transmission to the infant, and antenatal examinations should therefore include a focus on HIV-related symptoms and illnesses. Maternal nutritional status is important for the mother,

as well as the risk of MTCT. Finally, where prenatal diagnostic investigations are indicated, non-invasive screening tests should be considered first, to reduce the risk of MTCT. Screening for and prevention of factors may increase MTCT of HIV infection.

- Counsel the woman on potential problems in the course of pregnancy, how she can avoid them, and how she can seek medical advice as soon as she notices one.
- Plan the mode of and place for delivery in good time.
- Counsel on infant care, including non-breastfeeding and its risks, future fertility and reproductive behaviour.

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 as part of PHDP efforts. Screening should be initiated at HIV diagnosis, regardless of age, once sexually active. 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.

11.5.2 Care During Labour and Delivery

Determine Women's HIV Status

- Women with unknown HIV status should be offered routine pre-test education and rapid HIV testing so

that ARV prophylaxis can be administered before delivery. Women who receive HIV testing during labour and delivery should receive additional HIV post-test counselling during postnatal period.

- If testing during labour is not possible, women should receive HIV counselling and testing and infant feeding counselling during the immediate postpartum period, but before hospital discharge so that the infant can start ARV prophylaxis immediately.

Administer ARV Prophylaxis During Labour and Delivery

- Continue ARV treatment or implement ARV prophylaxis during labour to reduce maternal viral load and provide protection to the infant
- Women on ARV treatment should receive all ARV drugs according to their regular dosing schedule
- All infants born of HIV-infected women should receive ARV prophylaxis regardless of whether the mother has received ARV

Modify Routine Labour and Delivery Care

Labour management should follow normal obstetric guidelines.

HCWs should implement the modified safe obstetric practices to reduce MTCT. These should be individualised as much as possible to avoid increasing risk of maternal and neonatal morbidity and mortality.

Pregnant women with HIV should be treated with respect and dignity during all phases of obstetric care. Antenatal, obstetric and postpartum services provided for women with HIV often need to be strengthened and/or modified.

Note: Women in labour should be treated with empathy. They do not need to be isolated, but their confidentiality must be maintained. . Some other routine obstetric procedures should be avoided in HIV-infected women (if not otherwise indicated), including artificial rupture of membranes and episiotomy. Observance of infection control is critical, for health workers and mothers. When the life of the mother

and child is at risk, proper emergency obstetric care measures such as episiotomy and rupture of membranes should be taken.

11.5.3 Postpartum Care

Comprehensive postpartum follow-up for HIV-infected women and their infants is particularly important, in part because postpartum complications are encountered more frequently. In addition, HIV-infected women have special postpartum needs that include, for example, support and education for infant feeding choices; follow-up and HIV testing for the baby and advice on home-based care; and management of common HIV-related illnesses. Finally, the needs for comprehensive care for HIV-infected women extend beyond the traditional six-week postpartum period. This extended period should be used to provide effective counselling and contraception to the women, especially when women bring their children for immunizations and other welfare services.

Safer Obstetrical Practices to Reduce MTCT Include:

Use Standard Precautions (Good Infection Prevention Practices) for All Patient Care:

Use protective gear, safely use and dispose of sharps, sterilise equipment and safely dispose of contaminated materials.

Perform vaginal examinations according to protocol and avoid unnecessary vaginal examination.

Avoid Unnecessary Premature Rupture of Membranes:

Use a partogram to measure the progress of labour and indicate medications used during labour including ARV prophylaxis.

Avoid Unnecessary Trauma During Delivery:

Avoid routine episiotomy.

Minimise the use of instrumental vaginal delivery (vacuum extraction with caution to prevent prolonged second stage; use of vacuum extraction is indicated for prolonged labour).

Do episiotomy on indication.

Minimise the Risk of Postpartum Haemorrhage:

Carefully manage all stages of labour to prevent infection and avoid prolonged labour.

Actively manage the third stage of labour by using oxytocic drugs and controlled cord traction.

Perform uterine massage.

Repair genital track lacerations promptly.

Carefully remove all products of conception.

Considerations Regarding Mode of Delivery:

Caesarean section, when performed before the onset of labour or membrane rupture, has been associated with reduced MTCT. However, post partum infection risks are higher among seropositive women after caesarean section. In Tanzania, caesarean section is indicated for life saving obstetric reasons for all pregnant women independent of serostatus.

11.5.4 Home Birth Attendants (HBA)

To prevent infection during labour and delivery, HBAs should receive information on:

- Mechanisms by which HIV is transmitted from mother to child

- Their own risk of infection and how to protect themselves
- Basic skills to deliver PMTCT interventions, including safer delivery practices
- Standard precautions to prevent infections
- Immediately after delivery they should escort mother and the babies to health facilities for immediate post partum care and initiation of prophylaxis for the baby

11.5.5 Care After a Spontaneous Abortion (Miscarriage)

HCWs should do the following for women who have a spontaneous abortion:

- Provide HIV counselling and testing
- Assess for signs and symptoms of HIV infection/AIDS
- Post abortal care including:
 - o Consider using antibiotics after uterine evacuation
 - o Counsel on family-planning

11.6 Management of Infants During the Early Postpartum Period

The immediate care of a newly born HIV-exposed infant should follow standard practice. Regardless of the mother's HIV status, all infants should be kept warm after birth and handled with gloved hands until maternal blood and secretions have been washed off.

Safer Delivery Practices for Infants

Other practices to ensure the safety of infants born of HIV-infected women, which can help to minimise trauma to the infant and reduce the infant's exposure to infected blood and maternal secretions, include:

Clamping the cord immediately after birth, and avoiding squeezing the umbilical cord towards the infant. Covering the cord with a gloved hand or gauze before cutting it to avoid splashing of blood from the cord.

Using suction method only when the baby shows signs of distress or aspiration, and preferably mechanical suction at less than 100 mm Hg pressure or bulb suction.

Wiping/drying the infant with a towel.

The baby should be bathed as soon as possible to remove any blood and maternal secretions.

Determining the mother's feeding choice. If replacement feeding is used, place the infant on mother's body for skin-to-skin contact and provide help with the first feeding. If breastfeeding, place the infant on mother's breast.

Administering BCG vaccine according to national guidelines.

For non-breastfed infants, administering vitamin A 50,000 IUs within six months, while administering Vitamin A to breastfed infants starting at nine months according to national guidelines.

11.7 Follow-up Care for HIV-infected Mothers

The postpartum period should provide continuing treatment, care, and support. It is also the final opportunity to connect mothers and their children with follow-up care, treatment and support. HCWs should facilitate referrals and linkages to HIV treatment, care and support programmes to ensure that the mother receives ongoing care.

The patient's first postpartum appointment should be within one week (seven days) after delivery. Additional appointments should take place at 28 days and 42 days after birth.

Refer the mother-baby pair back to CTCs at the woman's 42-day postpartum visit to ensure that she accesses ongoing care and treatment for herself and her family. However if ART has already been integrated into MNCH, this practice should be followed.

The required postpartum services include the following:

- Physical assessment
- Infant-feeding support
- Sexual and reproductive health care, including family planning
- Screening for cervical and breast cancer
- HIV treatment care and support
- Prevention and treatment of opportunistic infections, including tuberculosis malaria, and immunisations
- Nutritional counselling and support
- Social and psychosocial support and home-based care as needed

11.8 Use of Antiretroviral (ARV) Drugs

During Pregnancy

Use of antiretroviral drugs has been shown to reduce the risk of transmission from mother to child.

11.8.1 Prevention of Mother to Child Transmission

The choice of ARV medications to be used to prevent MTCT is based on the resources and expertise available to administer the regimen at the facility level and according to the national policy/programme. PMTCT programmes should deliver combination regimens for PMTCT that include AZT, 3TC and NVP.

Table 11.2: Antiretroviral Prophylaxis to Prevent MTCT for Women not in Need of Treatment for their own Health and their Infants.

WOMAN ON ARV PROPHYLAXIS FOR 4 WEEKS OR LONGER AT TIME OF LABOUR

Antepartum	Intrapartum	Postpartum
AZT 300 mg twice a day from as early as 14 weeks of gestation	AZT (300 mg) 12hrly from start of labour*	None — ARV prophylaxis is completed at delivery

WOMAN ON ARV PROPHYLAXIS FOR LESS THAN 4 WEEKS AT TIME OF LABOUR

Antepartum	Intrapartum	Postpartum
AZT 300 mg twice a day from as early as 14 weeks of gestation	sd-NVP (200 mg) and AZT (300 mg) + 3TC (150 mg) 12hrly from start of labour*	Continue AZT (300 mg) + 3TC (150 mg) for 7 days after administration of sd-NVP

INFANT ARV PROPHYLAXIS REGIMEN*

Feeding method	Regimen
Breastfed infant	NVP from birth until 1 week after all exposure to breast milk has ended, or for 6 weeks if breastfeeding ceases before 6 weeks
Exclusively replacement fed infant	NVP from birth until 6 weeks of age

PREGNANT WOMEN WHO TEST POSITIVE RIGHT AFTER DELIVERY

Antenatal (ANC)	Intrapartum (During Labour)	Postpartum (Mother)	Infants (Newborn)
Not applicable	Not applicable	Refer to CTC	NVP SYRUP daily for 12 months of age and for one week after exposure to breast milk hand ended

PREGNANT WOMEN WHO ARE ON ART FOR HER OWN HEALTH

Antenatal (ANC)	Intrapartum (During Labour)	Postpartum (Mother)	Infants (Newborn)
Instruct her to continue with her regimen	Instruct her to continue with her regimen	Instruct her to continue with her regimen	Give Infant NVP SYRUP Daily for 6 weeks ONLY

Table 11.3: Infant NVP Dosing^a.

Infant NVP dosing recommendations*	
Infant age	NVP daily dosing
Birth ^b to 6 weeks	
Birth weight 2000–2499 g	10 mg once daily
Birth weight ≥ 2500 g	15 mg once daily
> 6 weeks to 6 months	20 mg once daily
> 6 months to 9 months	30 mg once daily
> 9 months to one week after all exposure to breast milk has stopped	40 mg once daily

*Infant ARV prophylaxis regimen is the same, regardless of duration of maternal ARV prophylaxis. This is also the same regimen for infants of mothers living with HIV who had no ARVs during pregnancy.

- a. Based on the dosing required to sustain exposure in the infant of >100 ng/mL with the fewest dose changes.
- b. Low birth weight infants should receive mg/kg dosing, suggested starting dose is two mg/kg once daily.

Source: World Health Organisation: *ARV drugs for treating pregnant women and preventing HIV in infants*, 2010.

11.8.2 ARV Therapy During Pregnancy

Women who are diagnosed with HIV during pregnancy and are eligible for ARV treatment should start treatment as soon as possible. A women's eligibility for ARV treatment can be determined by clinical staging or CD4 levels. If a woman is on ARV treatment during her pregnancy, the regular dosing schedule should continue throughout labour and delivery, as well as the postpartum period. Maternal ART should be coupled with the daily administration of NVP to infants from birth or as soon as possible thereafter until four to six weeks of age, regardless of infant feeding choice

Eligibility Criteria for ART

HIV infected pregnant women in need of ART for their own health should start ART as soon as feasible regardless of gestation age and continue throughout pregnancy, childbirth, breastfeeding (if applicable), and thereafter.

ART for maternal health is indicated in all pregnant women with confirmed HIV infection with CD4 cell count of less than or equal to 350 cells/mm³, irrespective of the WHO clinical staging, and for all women in WHO clinical stage 3 or 4, irrespective of the CD4 cell count.

ARV Prophylaxis for Infants of HIV Infected Women Receiving ART

All infants (regardless of whether breastfeeding or receiving only replacement feeding) born to HIV infected woman receiving ART for their own health should be given daily NVP from birth or as soon as feasible thereafter until four to six weeks of age.

- Women who become pregnant while receiving ARV therapy should continue treatment but may need to change the medications in the ARV regimen to avoid potential birth defects. For example, efavirenz (EFV) can cause birth defects and therefore it should not be used for pregnant women during the first trimester.
- Women who are diagnosed with HIV during pregnancy and who are eligible for ARV therapy should start ARV therapy as soon as possible according to the guidelines. The recommended first-line regimen for HIV-infected pregnant women is zidovudine (AZT) + lamivudine (3TC) + nevirapine (NVP). Women on ARV treatment should not receive a single-dose of NVP during labour.
- Pregnant women receiving ART therapy should receive ongoing care and treatment services. When co-infected with TB, additional drug therapy and clinical management are required to minimise side effects that may occur with co-administration of HIV and TB therapy.

Chapter 12.
Counselling Related to
HIV Testing and Treatment
Adherence



CHAPTER 12: COUNSELLING RELATED TO HIV TESTING AND TREATMENT ADHERENCE

12.1 Introduction

This chapter addresses the primary approaches for providing HIV Testing and Counselling: Provider Initiated Testing and Counselling (PITC), Client initiated Voluntary Counselling and Testing (VCT) and Home Based HIV Testing and Counselling (HBT C). It also provides guidance on ART adherence counselling.

12.2 Counselling for HIV Testing

12.2.1 Provider Initiated Testing and Counselling (PITC)

PITC is a situation where a health care provider recommends and offers an HIV test to a person attending clinical services. Currently this approach is being used to reinforce expansion of access to HIV testing and increase the number of person accessing and utilizing HIV and AIDS related interventions, including PMTCT. Health care providers should recommend HIV testing as a standard of care to all patients in a health facility regardless of whether they have signs or symptoms of HIV infection. This allows health care providers to make specific medical decisions that would not be possible without knowledge of the patient's HIV status. In settings where HIV testing is conducted and results are shared between a client and a service provider, the provision of HIV information will normally precede blood testing as the core of HIV testing and counselling services. Under this approach, clients shall be tested for HIV by offering an informed verbal consent. In case of minors or comatose clients, informed consent should be obtained from a guardian or close relative. In the case of a mature minor, they shall consent on their own.

- In PITC the main aim is to maximize the health and well being of individuals through timely detection of HIV, prevention of HIV transmission and subsequent access to appropriate HIV prevention, treatment, care and support services. Nevertheless, provider initiated HIV testing and counselling must respect human rights and good clinical practices which include (i) the need for a client's consent to undergo testing, (ii) confidentiality of both the process and the test results, (iii) provision of pre-test information, offering correct test results, post test counselling , and support to HIV positive clients to help them cope with their status, and (iv) offering testing only if medical services and a link to clinical HIV care are available.

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

- Should be provided by healthcare providers trained to provide PITC services and not necessarily trained as counsellors.
- The first user of the test results is the health care provider who uses the HIV tests to make diagnosis and provide appropriate treatment and/or referral.
- HIV testing and counselling is conducted in a health care setting 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 counselling (VCT), so the counsellor will be more focused in her/his approach.
- The PITC provider focuses on coping with the HIV positive test result and Positive Health Dignity and Prevention, with little time spent on those who are HIV negative.
- Care of HIV positive clients is provided within CTC, TB, STI, and RCH/PMTCT including referrals to other support services.
- Services provided are confidential and documented in medical records to ensure continuity of care.

- The pre-test information session is conducted to an individual or as a group mainly in high volume settings (high client load).
- Clients retain the right to decline the HIV test without being denied any services to which they are entitled to at the health facility.
- Services provided include basic HIV prevention, treatment, care and support within the facility or in the vicinity of the facility.

12.2.2 Client Initiated Voluntary Counselling and Testing (VCT)

Client initiated VCT, on the other hand, uses the client centred approach to HIV counselling that places less emphasis on education, persuasion and test results and more on personalised risk assessment. The approach encourages the development of a personalised risk reduction plan for an individual, couple or family, which takes into account (i) the client's emotional reactions, (ii) their own situation, (iii) their social/cultural context, (iv) the targeted risk behaviour, and (v) the client's readiness to change the targeted behaviour. In the case of couples and families, it will not include individualised risk assessment. Rather, counsellors discuss the couple's HIV risk concerns, and focus the conversation on the present situation and plans for future.

In this approach, the client voluntarily makes a decision to learn her/his HIV status and seeks counselling and testing services out of her/his 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 counsellor for VCT.
- The counselling gives focus predominantly to addressing risk behaviour 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.

12.3 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 and seek treatment, and follow instructions regarding food and other medications, as well as avoid risk behaviours 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, 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.

12.3.1 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.

Counselling for Treatment Adherence

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

1. 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, counsellors, 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 also 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 criterion 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 to either help clients to overcome the barriers, or to advocate for changes that will remove external barriers that are not under the client's control.
- Adherence monitoring systems at the 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.

2. 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 counselling and testing services, PMTCT services, mental health services, as well as psychosocial support services. These may be in the form of post test clubs, adherence support groups, legal aid, nutrition counselling and income generating support.

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

Specific guidance is listed below for adherence counsellors organized to address issues, which should be done at each of the visits prior to the initiation of ARV drugs and at each subsequent follow up visit.

During the first visit the counsellor should:

- Review client's basic knowledge on HIV infection and development of AIDS and correct misconceptions.
- Review client's understanding of how HIV is transmitted and how ARV drugs affect HIV transmission risk, and provide 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 counselling 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 encourage the client to attend her/his next clinic session with the identified treatment assistant.
- Explore with client the advantages and disadvantages of sharing their test results; address barriers to disclosure and develop with the client a disclosure plan that should be documented for supportive follow up visits.
- Discuss HIV transmission risks, help 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 they might influence current and continued lifelong use of ARV drugs.
- Provide brief counselling interventions for clients that use

alcohol.

- Encourage clients to consider the viability of abstinence from alcohol and other substances of abuse.
- Provide time for questions from the client and responding accordingly.

12.3.2 Second Visit

This adherence counselling 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 counsellor should:

- Review risk reduction and lifestyle change plans and their implementation. Address barriers to implementation and help the client revise their plan if necessary, and document the process.
- Assess the mood of the client, document it and alert a physician if depression or anxiety disorder is suspected. Document and provide supportive counselling.
- Review the client's implementation of disclosure plans and plans for identification of a treatment assistant. If a client has not yet disclosed her/his HIV serostatus or identified a treatment assistant, review the plans and address barriers accordingly.
- Review client's understanding on how ARV drugs work to prevent HIV transmission and correct misconceptions.
- Provide information on first line ARV drugs and potential positive effects and side effects and criteria used to initiate clients on ARVs; discuss ARV drugs as a lifelong treatment and not a cure for AIDS; provide education on reasons for the need to take every dose as prescribed; using pamphlets where available to illustrate the

relationship between missing doses and the development of ARV drug resistance.

- Develop with the client a treatment adherence plan that explores potential barriers and facilitators of adherence to ART including potential solutions to identified barriers. For details see the NACP Adherence Toolkit, section 2.1.
- Provide time for questions from the client and respond accordingly.

12.3.3 Third Visit

The third CTC visit confirms readiness to start ARV drugs and initiates the client on ARV drugs. In adults, when baseline CD4 counts are ≤ 350 copies/ μ l 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 ($\leq 25\%$); During the third visit, the counsellor should:

- Review the implementation of risk reduction and lifestyle change plans with the client, and document successes, barriers and revisions in plans where they 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 counselling if adjustment disorder is identified.
- Review the client's understanding of ART and ARV first line drugs including that of the first line ART regimen, potential positive effects and side effects, and 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 documenting successes, barriers and revisions to plans.
- Review the outcome of implementing solutions previously agreed upon (to be done only for regular start up clients); review with the client their treatment

adherence plan and explore potential solutions for accessing ARV drugs when unexpected travel occurs; and document any changes in adherence plans in the counselling 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 counsellor will:

- Review and document the client's understanding of the ARV drugs prescribed and the dosing. Some tips to assess adherence from self report include:
 - o 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 used each time and timing of use, rather than referring to the last prescription.
 - o Checking prescribed medication to see if it matches the client's reported drug use.
 - o 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.
 - o Explore the number of missed doses of each drug in the past week and the past month. Establish % of total drugs prescribed taken in the past month and document if level of adherence is at >95% or not.
 - o Review the client's understanding of ART as a lifelong treatment, and ARV drugs as treatment and not a cure for AIDS.
 - o Review knowledge of reasons for the need to take every dose as prescribed, using pamphlets where available to

illustrate the relationship between missing doses and the development of ARV drug resistance.

- Explore and document side effects from ARVs and other drugs.
 - o Review information on first line ART regimen and explore experiences with positive effects and side effects.
 - o Discuss with the care provider or adolescent client strategies to minimise drug side effects.
- Explore factors that may prevent or facilitate correct use of drugs in the care provider or adolescent client's environment and discuss with the care provider or adolescent client possible solutions to barriers s/he identifies.
 - o Discuss drug storage in the home.
 - o Review with the care provider or adolescent client their plan to take their ARV drugs as prescribed. Document if any changes occur to previously agreed-upon plan.
 - o Discuss what the care provider or adolescent client will do to ensure they have sufficient drugs in the event of unexpected travel before their next clinic visit.
- Review disclosure and treatment assistants and document the items that follow.
 - o The outcome of the disclosure plan while encouraging or formulating a new plan if disclosure has not occurred.
 - o The presence of a treatment assistant. Encourage the care provider or adolescent client to identify a treatment assistant if none have been identified.
- Preventive counselling including risk reduction and lifestyle change counselling.
 - o Review implementation of risk reduction strategies and encourage change or help care provider or client to plan new strategies.
 - o Review implementation of agreed lifestyle changes and encourage change or help care provider or adolescent

- client to plan new strategies for change.
- o Assess the mood state of the care provider or adolescent client.
- Provide time for questions from care provider or adolescent client and respond accordingly.

Checklists can and should be used in the CTCs to structure adherence counselling sessions and for documentation of counselling sessions. Using checklists and documenting counselling sessions helps to improve the quality of counselling delivered, as it informs on areas that need to be strengthened through supportive supervision and continued in service training. Counselling checklists for children with their care providers and for adolescents' counselling visits can be found in the NACP Adherence Toolkit, section 1.2.

12.4 Adherence Monitoring and Evaluation

12.4.1 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 and loss to follow up of 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 should show commitment in dealing with their clients during clinic visits, and provide ongoing adherence monitoring and timely response to adverse events or interim illnesses.
- Adherence support must be intensified when negative changes are noted. This can be realized by investigating

new barriers, scheduling more frequent visits, involving home care programmes, enlisting the support of family/friends, reviewing teaching, or increasing the frequency of home visits.

- Health care providers should work in a multidisciplinary 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 should be reminded to come with their drug stocks at every visit.
- Pharmacy staff should monitor adherence using self reporting.
- Specific training regarding ART and adherence should be offered and updated periodically for all health care team members.
- All health care team members should have in place systems for adequate documentation of indicators for levels of ARV drug adherence for individual clients, as well as structures for using collected information to assess performance at the site level and for site-based supportive supervision, refresher training, and centralized quarterly reporting to district and regional levels as required.

A 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 six 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 beforehand 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 organisations to support adherence.
- Encourage participation in peer adherence support groups.

Chapter 13.

Management of Mental Health Problems in HIV and AIDS

CHAPTER 13: MANAGEMENT OF MENTAL HEALTH PROBLEMS IN HIV AND AIDS

13.1 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, mental problems are a direct or indirect consequence of the disease itself.

Some of the mental health symptoms of AIDS are:

- Depression, anxiety and abuse of alcohol and other substances
- Delirium, dementia and psychosis associated with viral and opportunistic infections of the brain
- Psychiatric side effects of ARVs
- Social difficulties faced as a result of stigma and discrimination
- Exacerbation of pre-existing mental disorders. Depression, 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. Pre-existing mental disorders are associated with increased risk of acquiring HIV. This group of patients often comes to ART services with special management needs.

13.2 Primary Neurological Complications that have Secondary Mental Health Manifestations

13.2.1 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 judgement, and there may be perceptual disturbances 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. 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 paediatric 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 nighttime 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 to 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 psychiatric management of delirium is the identification and correction of the aetiologic 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.

13.2.2 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 behavioural 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, whose 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 behavioural 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 also shows a highly variable clinical course and a spectrum of signs and symptoms, ranging from subtle cognitive, affective behavioural 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 visuospatial memory (misplacing things), poor visuo-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 in distinguishing 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 subcortical 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, and 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 doses and increased slowly while carefully monitoring side effects and treatment response. Giving haloperidol 1-2mg per day, with a 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 ritonavir, use with caution as increased or decreased levels of psychotropics may occur. Avoid benzodiazepines, which tend to increase confusion and decrease concentration.

Long-term Treatment

Involve family members/treatment assistants in both medication management and clinic attendance, 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.

13.2.3 AIDS-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. Behavioural changes include 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 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 to two weeks of treatment, as carbamazepine induces liver enzymes and increases its own metabolism as well as that of other drugs metabolised 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 the 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 her/his sero-status to others. HIV-related self stigmatization has been noted to be a major barrier to sharing test results, 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 her/his care

Management

Supportive medical/clinical counselling is the mainstay of more positive adaptive responses to HIVD diagnosis. Issues to consider during counselling following loss and crisis are noted below.

13.3 Addressing Loss and Crisis Among 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 hope 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 break-up of an intimate relationship, the aftermath of an earthquake, or rape or other forms of assault. A crisis situation is a critical situation in which a person is unable to use her/his 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 counselling. This is a form of supportive counselling with the objective of identifying loss events and responses to these events with the patient, as well as aiding the processes of acceptance and constructive adaptation.

A crisis situation may manifest itself in the form of a blow, withdrawal and finally acceptance; and as with loss events, is best managed through counselling. Note: Health care workers are encouraged to refer to a manual on HIV and AIDS counselling for issues related to different aspects of counselling.

13.4 Anxiety Disorders

The initial fear accompanying an HIV diagnosis tends to subside and then persist at a lower level. When anxiety symptoms are severe or persistent, patients may have any of the following anxiety disorders: panic disorder, generalized anxiety disorder, obsessive compulsive disorder, or post traumatic stress disorder. 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. 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 counselling 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. Amitriptyline 25 mg daily may alleviate the symptoms.

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.

13.5 Major Depressive Disorder

Definition

Depression is a common mood disorder characterised 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. Behavioural 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, should be addressed accordingly.

Epidemiology

About 20% of PLHIVs accessing medical services suffer from depression. 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 the dosage for a 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 minimise risk of serious side effects. Tricyclic antidepressants can be used, but selective

serotonin reuptake inhibitors such as fluoxetine that have fewer side effects are recommended. It is important to ensure adequate doses for adequate duration (maintenance drug treatment provided at therapeutic dose for six months after resolution of symptoms), combined with supportive counselling.

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.

Table 13.1 Antidepressant Dosage and Possible ART Interactions.

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

13.6 Alcohol and Substance Use Disorders

Definition

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.

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.

Alcohol Use and HIV

Drug abusers have special clinical needs that require mental health skills and sensitivity, in terms of assessing patients’ risk behaviours and preparedness of HIV counselling and testing.

People who misuse alcohol are more likely to engage in HIV transmission 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. 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. Bars and drinking parties serve as convenient social settings for meeting potential sexual partners. Alcohol misuse also occurs 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.

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? Is there evidence of tolerance (reports of needing to use larger amounts to become intoxicated) to alcohol and/or avoidance of withdrawal symptoms by drinking in the morning? If the answer is yes to any two 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.

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, 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).

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.

Social Complications

These include marital problems, domestic violence, child abuse or neglect, missed work, various forms of irresponsibility.

Differential Diagnosis

Symptoms of anxiety or depression may occur with heavy alcohol use. Reassess 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).

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 risks 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.

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 120mg, day 210 mg, day 35 mg) in case of severe withdrawal symptoms.

Other Drugs

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). Even though this fact is less well appreciated, drug using behaviours 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. The high degree of association between injection and non-injection drug use underscores the importance of primary care providers' being able to diagnose drug using behaviours.

Diagnosing drug dependence or addiction is not an easy task. 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.

Management

Assessment and support should be similar to what you do with alcohol dependent persons. It is best to involve a mental health expert in the management of the patient.

13.7 Primary Psychosis

Psychosis can be a manifestation of delirium, affective disorders, or schizophrenia, but it can also 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; 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 various antipsychotic medications to control the delusions, hallucinations, and overall level of disorganisation. 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. Counselling for HIV testing should be avoided when persons with mental illness are acutely ill and too disorganised 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 counselling and strategies should be addressed at each counselling session. Monitoring drug treatments for schizophrenia and bipolar disorder should prevent or decrease relapse of episodes. When episodes do occur, they should be treated (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 14.

Community and Home Based Care for People Living with HIV and AIDS

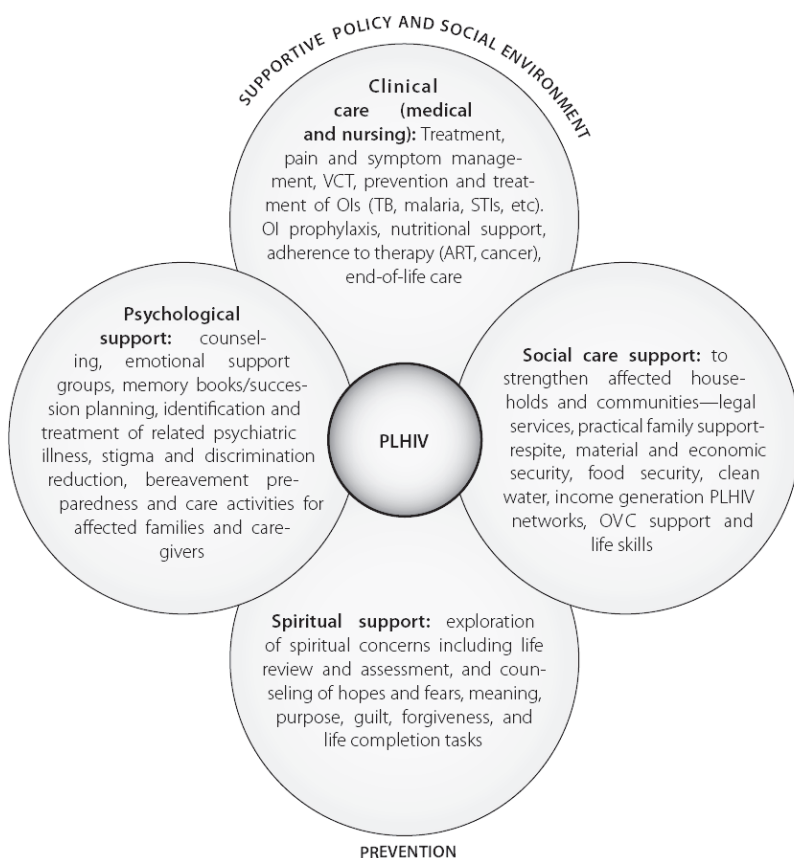
CHAPTER 14. COMMUNITY AND HOME BASED CARE FOR PEOPLE LIVING WITH HIV AND AIDS

14.1 Introduction

The Health Sector HIV and AIDS Strategic Plan II (HSHSP) 2008-2012 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 comprehensive care across a continuum**. The importance of compliance with treatment regimes and adherence to treatment has resulted in new roles for Community Home Based Care programmes (CHBC). CHBC has a key role in treatment advocacy, information and literacy; as well as monitoring and support to PLHIV efforts towards universal access to HIV prevention, care, treatment and support. CHBC services also enhance HIV and AIDS awareness, reduce stigma, and mobilize communities to use HIV testing and counselling services.

PLHAs 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. This is illustrated in Figure 14.1.

Fig 14.1 Comprehensive HIV and AIDS Care Support.



The care provided to PLHIV in their homes and communities must therefore address the needs of not only the patients but their caregivers and household and community members. In order to effectively ensure networking and link patients across a continuum of care services, an inventory or directory of services providing organisations in the local community or district needs to be available at all clinics and programmes. In addition, regular coordination is needed between the

CHBC programmes, community and district health authorities and CTC staff.

14.1.1 Definitions

The **continuum of care** is a set of comprehensive and linked care, treatment, and support services provided at all levels, from health facility, community to home. Services are provided by the government, NGOs, community-based organisations (CBOs), faith-based organisations (FBOs), community members and by PLHIV and their family members.

Home-based care (HBC) is defined as any form of care given to chronically ill people in their homes. It includes activities that provide physical, psychological, social, and spiritual support (WHO/GPA, 1993). Families are the central focus and form the basis of community HBC.

Home based care services involve 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. Palliative care is usually provided by the patient's family, friends, volunteers and members of the community who are trained and supported by skilled health care workers. The care given may include physical, psychosocial, spiritual and material support, and should adapt to the patient's needs.

Palliative care contains a set of supportive interventions that improve the quality of life of patients and their families who face problems associated with a chronic disease or life threatening illness. This can be done through the prevention and relief of the broad spectrum of suffering which could be physical, psychological or spiritual.

14.1.2 Coordination at the CTC

The main role of the HBC coordinator at the CTC of the facility is to link patients attending the CTC to HBC services within their community. The HBC coordinator maintains and updates the HBC directory of services and keeps record of referrals.

The HBC coordinator liaises with community home based care (CHBC) programmes and performs supervisory and monitoring duties. S/he forms the secretariat of the district based community home based team (CHBT) or continuum of care committee, which should keep the council health management team (CHMT) informed of its activities on a regular basis.

14.1.3 Functions of CHBC or Contrinuum of Care Committee

- To facilitate training of home-and community-based care providers or volunteers and support them through regular supportive supervision to ensure provision of quality palliative care within homes.
- To mobilize resources (human and material through partner organisations and individuals) and coordinate them towards providing care for PLHAs and their families.
- To ensure that local community organisations and families are involved before the patient is discharged in order to link them with care in the community/home and to encourage referral back to health institutions where indicated.
- To ensure networking of local stake holders in order to provide coordinated palliative care services.
- To promote treatment linked activities within HBC services such as adherence and referrals.

14.1.4 Benefits of home-based Care

Home based care has the following important benefits to PLHIVs, their families and the community.

Benefit for PLHIV:

- Helps them to stay healthier life
- Permits them to receive care and treatment in a familiar and supportive environment
- Enhances adherence to popylaxis (MTCT) and ART
- Allows them to continue participating in family life matters
- Maintains a sense of belonging in social groups
- Maximizes their emotional health and thus keeps a positive attitude
- Makes it easier for them to accept their condition
- Is cost saving
- Reduces stigma and discrimination
- Enables them to prevent new HIV infections

Benefits the family:

- Strengthens family ties/attachment
- Helps the family to accept the patient's condition
- Provides opportunity to learn about HIV and AIDS
- Can reduce medical and other care-related costs
- Makes it easier for family members who provide care to PLHAs to attend to other responsibilities
- Makes it easier for the family to support the patient in taking life long ART treatment as well as other medications
- Involvement of the family in care enables the grieving process to be easier
- Enables promotion of hygiene and infection control (i.e TB)

Benefits the community:

- Promotes awareness about prevention of infection, care, treatment and support of HIV and AIDS, and thus helps to reduce stigma
- Helps the community to understand the disease and to correct myths and misconceptions about HIV and AIDS prevention and treatment

- Promotes ART preparedness and support
- Encourages sustainability of care services
- Makes it easier for the community to provide support by tapping all possible resources in the community
- Helps to set up long-term care and other services in the community

14.2 Components of Home-Based Care

Home based care is a mechanism of palliative care provision that includes various components as elaborated below.

Physical Care

For this kind of care, providers should always

- Assess and screen for TB: chronic cough, weight loss and night sweats (annex 9).
- Refer if needed
- Ensure that the patient gets treated for opportunistic infections and appropriate nursing care at all times
- Maintain preventive therapies such as CPT and IPT
- Provide ART monitoring for early side effects and continuous adherence
- Administer pain relief with appropriate medication (such as use of NSAID's, codeine and other opioids such as liquid morphine)
- Support the prevention of malaria through use of insecticide treated bednets (ITN)
- Offer reproductive health care such as family planning advice, and referral and care for pregnant mothers (MTCT interventions including during delivery at home)

Nutritional Care and Support

Patients should be educated on appropriate nutrition using locally available foods, and guided on feeding patterns and preparation of foods to suit the condition of the patient (for details see Chapter 15, Nutrition, and Appendix 7, The Role and Sources of Selected Micronutrients).

Hygiene

Practical ways of encouraging hygiene, particularly personal hygiene (e.g. mouth, skin and hair care) and environmental care within the household and outside including garbage disposal should be promoted. Patients should be encouraged as much as possible to do their own hygiene care as far as possible so as to maintain their self respect and hope. Nursing care should be reserved for only what is necessary for the patient in order to maintain the dignity and comfort of the patient.

Exercises

Patients need to exercise regularly, and if they are too weak the HBC providers or family members should assist them in doing passive exercises for body movement and blood circulation, thus reducing the risks of complications such as bed sores and pulmonary problems.

Caring for chronically ill persons and PLHAs must always consider prevention of spread of infection to protect the patients and those around them. Hand washing, care of the nails, keeping the body, clothing and bed linen clean, care of sores and broken skin, proper storage of food and observing cleanliness in handling food are some of the ways in which infection can be prevented. Gloves should be worn when the caregiver is handling any type of body fluids or waste, or when the patient or caregiver has an open wound that will come in contact with the other person.

Emotional Support

Persons suffering from any chronic or terminal illness usually have many fears and worries. Caregivers should therefore help them to talk about their condition and concerns. Emotional support helps to reduce stress and anxiety and promotes positive living including adherence to treatment.

Social Support

Patients may suffer from loneliness and neglect aggravated by stigma and even discrimination within the household or community.

Care givers should interact with patients and household members to promote their involvement in social interactive and recreational activities. Patients should be encouraged to form and or join PLHA groups for social support.

Spiritual Support

Addressing spiritual needs is an important aspect in any type of palliative care. Chronically ill patients often lose hope and reason to continue living, which is often relieved through reassurance and spiritual care. Faith based organisations and religious leaders in the community should be involved in HBC programmes.

Legal Support

Patients should be informed about how and where to get legal aid that they may need especially for matters concerning inheritance, writing of wills and human rights related issues.

Economic Support

When a person is diagnosed with HIV or has AIDS, the financial burden to the family increases, given the resulting additional transport and medical expenses. If the affected party is the main bread earner, this further constrains the limited family resources available. It is therefore necessary for home based caregivers to be aware of economic support networks and income generating projects and link PLHIV to them.

14.3 Palliative Care

Palliative care aims at:

- Providing comfort and enhancing quality of life
- Providing relief from pain and other distressing symptoms
- Integrating psychological and spiritual aspects of patient care
- Enhancing the quality of life, and may also positively

- influence the course of illness
- Offering a support system to help patients live as actively as possible
- Offering a support system to help the family cope during the patient's illness
- Using a team approach to address needs of patients and their families, including bereavement counselling, if indicated
- Affirming life as it regards dying as a normal process
- Neither hastening nor postponing death

Palliative care can be provided to in-patients in a hospital, at clinics or health centres, or within a home care program.

Many aspects of palliative care, such as pain management, symptom control and psychological support are applicable early in the course of the illness and therefore the palliative care needs of persons with AIDS vary from person to person and from illness to illness. When patients choose to be cared for at home, caregivers can be trained to effectively provide the prescribed palliative medications and other physical and psychological support.

Symptom Management

Pain

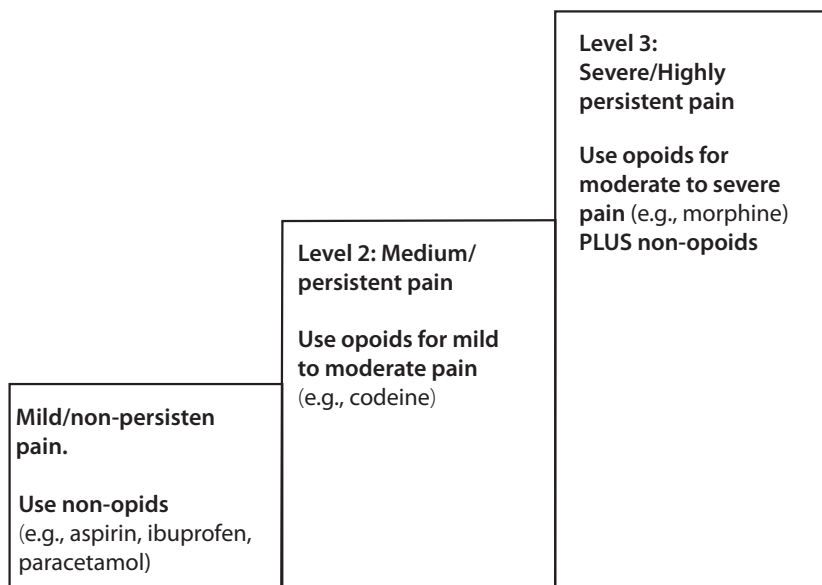
Determine the site of the pain and grade the severity of the pain. Pain control in adults should be achieved as follows:

Initially use non opioids such as aspirin 600 mg every four hours, increasing to 1,000 mg every six hours, or paracetamol 500 mg every four to six hours, or ibuprofen 400 mg every six hours.

The next level of treatment for pain control is with a mild opioid such as codeine given in a dose of 30mg every four hours. If this still does not control pain, then a strong opioid such as oral morphine may be used initially in a dose of 5mg every four hours. This dose should be increased to levels that control pain.

Chronic pain should be treated on a regular basis. It is advisable to start with mild analgesia and progress in a step wise fashion to more potent analgesics and opioids if necessary. The pain control “ladder” is shown in Figure 14.2.

Figure 14.2 Achieving Pain Control in Persons with Chronic Pain.



Medication options: Move up the ladder* as pain persists or progresses

*Size of bar indicates pain level and/or its persistence

Breathlessness

Persons with HIV and AIDS often develop severe breathlessness that can be terminal. This may be the result of a severe non-responding lung infection or cancer such as Kaposi’s sarcoma or lymphoma affecting the lungs and pleura. In such patients, alleviate dyspnoea by propping up the patient and then refer to a nearby health facility for further management.

Vomiting

Vomiting may lead to poor fluid intake and dehydration, which it may be necessary to correct. Patients should be encouraged to take small amounts of fluids frequently. Vomiting may be relieved by administering promethazine 25 mg PO TID or metoclopramide 10mg PO TID.

Oral Care

Good oral care should always be practiced. This includes regular teeth brushing with a soft toothbrush and gargling with mouth wash solutions or weak salt solutions after food. Oral care helps for persons with mouth sores. If the sores are painful the patient will not be able to eat or swallow and should be given soft foods and liquid diets. If a specific cause for the ulcers is found, it should be treated as described.

Itching

To relieve itching, bath oils or other emollients such as emulsifying ointment may be used. If a rash is present, then antifungal creams will help if the rash is due to a fungal infection or topical steroids to relieve inflamed areas of the skin if a bacterial or viral infection is not present. Orally administered antihistamines, such as chlorpheniramine (piriton) 2 mg PO given at night may reduce the pruritus and allow a relatively more comfortable sleep.

Comfort

Prevent the development of bedsores by changing the position of the patient every four hours and arrange for the patient to lie on an extra soft material. Avoid pressure on any one part of the body for prolonged periods of time. Protect areas that have become inflamed because of pressure by avoiding any pressure at all on the area and by applying soothing lotions. Change soiled bed sheets immediately. Massage pressure points such as the heels, elbows, ankles, back and hips frequently. Cover all open sores with a gauze bandage after applying an antiseptic cream.

Terminal Care

The main aim of terminal care providers should be to improve the

quality of life by removing or alleviating unpleasant symptoms and helping to prevent the patient from suffering, fear or loneliness. Quality care must be provided wherever the patient is, be it at home or in the hospital. Nowadays, because of the home based care approach for HIV and AIDS, many patients are dying at home. As part of the continuum of care, health care providers are expected to extend their services by training and supporting family members to ensure that terminally ill patients at home are well cared for.

All persons with terminal illnesses need end of life care. Towards the end of their life it is essential that patients and their families have access to social, emotional and spiritual support. Palliative care in terminal illness allows the patient to die with dignity and relieve her/him of distressing symptoms. Palliation also offers support to help the patient live as actively as possible until death and enables the family to cope with their loved one's illness and with their own bereavement. The care provider needs to listen with empathy and should encourage communication within the family. Issues such as family and child support, schooling and welfare should be discussed. The patient should be constantly told that they are loved and will be missed by family members. Spiritual support and discussion with a religious leader may help to relieve feelings of guilt. The care provider should be available and should visit regularly, and bereavement counselling be made available to family members including children.

Care of the Deceased

Care after death is part and parcel of comprehensive HIV and AIDS care. Standard precautions stipulate that all people, no matter what they have died from, should be treated in the same manner. These precautions should be applied also to people who have died of AIDS. People preparing the bodies should be instructed to put on gloves and follow the hand washing procedure. Bleach powder should be used if the body is oozing fluids; the bleach will immediately kill the virus. However, it is not necessary to cover the body with plastic. Disposal and care of linen, instruments, and other materials should follow the same procedure of disinfection, sterilization and disposal as discussed in Chapter 4.

Chapter 15.

Nutrition in HIV and AIDS

Chapter 15.

CHAPTER 15: NUTRITION IN HIV AND AIDS

15.1 Introduction

Malnutrition and HIV are related, and aggravate each other in a vicious cycle. HIV infection can lead to under nutrition and malnutrition affects HIV transmission and disease progression.

HIV and AIDS impair the body immune system of infected persons increasing vulnerability to infections. Infections lead to increased loss of nutrients which, if replenished, may lead to malnutrition. Malnutrition, on the other hand, leads to immune impairment which in turn speeds up the progression of HIV and AIDS. When a malnourished person acquires HIV, the progression to AIDS is fast 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 process of HIV progression 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 secretion of nutrients. The indirect effects are those that lead to household food insecurity.

Malnutrition in HIV-infected person manifests itself as weight loss, muscles wasting, reduced immune system functions, mineral and vitamin deficiencies and increased susceptibility to infection.

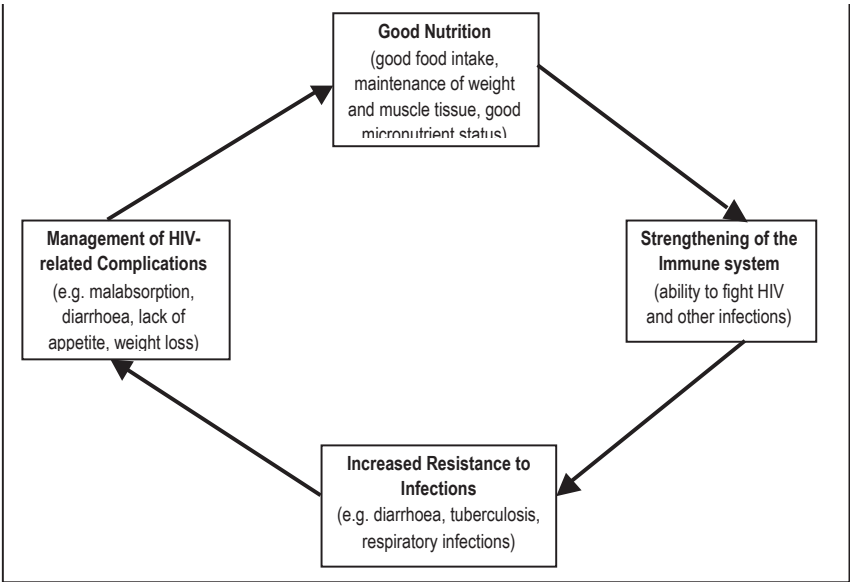
This vicious circle contributes to repeated illnesses, deterioration of health, and eventual death of the infected individual.

Generally, good nutrition increases resistance to infection and disease, providing energy, building up the body and stabilizing the immune system. Timely improvement of nutrition can help strengthen the immune system, prevent weight loss and delay disease progression.

15.2 Relationship Between Good Nutrition and Resistance to Infection

Good nutrition helps persons with HIV and those who are suffering from AIDS to fight infection, strengthen their immune system, and manage HIV-related complications. The specific benefits of good nutrition in developing resistance to infection are illustrated in the figure below.

Figure 15.1: *The Cycle of Good Nutrition and Resistance to Infection in Context of HIV/AIDS.*



Nutritional Considerations at Different Stages of HIV Infection

At different stages of HIV infection, some health problems may be experienced, such as sore mouth and throat and diarrhoea. Infection puts extra demand on the weakened immune system, increasing the body’s requirement for energy, and may cause deficiency of other nutrients. See Table 15.1.

Table 15.1 Nutrition, Care and Support Priorities by Stage.

HIV stage	Features	Nutritional Advice
Early Stage (Stage 1& 2 of WHO clinical staging)	Asymptomatic or mild symptoms: weight loss under 10% of presumed or measurable body weight	Counsel on healthy diet and healthy lifestyle
Middle Stage (Stage 3 of WHO clinical staging)	Weight loss over 10% of presumed or measurable body weight; Opportunistic infections	<ul style="list-style-type: none"> • Counsel to minimise 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)	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

15.3 Nutrient Requirements for People Living with HIV (PLHIV)

Energy requirements

The HIV infected person has additional energy needs because of:

- Energy used for HIV infection and opportunistic infections
- Nutrient malabsorption
- Altered metabolism

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 healthy non—HIV-infected 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 healthy non-HIV-infected 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 healthy non-HIV infected persons of the same age, sex and physical activities level.

Micronutrient requirements

HIV infected individuals are encouraged to achieve this by consuming a variety of foods 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 Appendix 7, The Role and Sources of Selected Micronutrients).

15.4 Healthy Eating for People Living with HIV

People living with HIV should choose and eat 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 undernutrition.

The main food groups are:

- Cereals, roots, tubers and cooking bananas; should include maize, millet, rice, sorghum, cassava, yams, potatoes and bananas.
- Legumes, nuts and foods of animal origin; should 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: should include all types of fruits commercial and indigenous such as mangoes, oranges, guava, tangerines, bananas, baobab fruit (ubuyu), tamarind (ukwajumabungo), 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), and 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. Since 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 a Healthy and Nutritious Lifestyle for PLHIV.

- Eat variety of foods, emphasizing 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)

15.5 Nutritional Issues Associated with ARVs and Other Modern Medicines

People infected with HIV may take various modern medications, including antibiotics to treat opportunistic infections, ARVs to treat HIV/AIDS, anti-malarial, anti-helminthes, and anti-fungal medications

to treat other conditions such as malaria, intestinal parasites, and thrush.

Foods and medications can interact in four major ways to create health and nutritional positive and negative outcomes in PLHIV. These are shown below:

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

Drug-Drug Interactions

Drug interactions need to be managed adequately in order to ensure that the prescribed drug combination improves drug efficacy, decrease side effects, and does not affect the nutritional status.

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, more sour, or too salty, which, in turn, may cause an individual to consume less food. This can be addressed by using flavour

enhancers such as salt, sugar, spices, vinegar, or lemon to stimulate the taste buds, increase taste acuity, and mask any unpleasant flavours. Adding spices like onions to soup will boost flavour and can help to improve intake.

- **Anorexia**

Several medications, such as isoniazid and the ARVs lamivudine and stavudine, may cause anorexia and lead to reduced food intake. The dietary management of anorexia requires eating small and frequent meals and favourite foods. PLHIV who 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.

Note: Some side effects of ARVs are similar to symptoms of opportunistic infections, such as diarrhoea, e.g. Tenofovir, Ritonavir, and 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

Patient who are on multiple medications for conditions such as HIV and TB require many pills on a daily basis, which can make it difficult to maintain food intake. Multiple medications have multiple food-drug interactions and side effects that require setting specific timing and identifying recommended foods. Health workers should counsel on the dietary management.

Table 20, below, lists some of the medications used in Tanzania. The table shows their purpose, potential side effects and nutritional recommendation. (see Annex 8)

Table 15.1 Food Interactions and Side Effects of Isoniazid.

Medication	Dietary interactions and the medication's side effects	Dietary advice
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 favourite foods.
	Diarrhoea	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, and 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; therefore, 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 though 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 counselling plan.

Biochemical Assessment

- Biochemical assessment of nutritional status is done in the laboratory where nutrient deficiencies are detected. Where available, test for blood protein (e.g. Serum albumin), micronutrients (e.g. iron) and lipid (e.g. Cholesterol); these indicators can be used to monitor nutritional status of PLHIV. Haemoglobin level is one of the indicators used to monitor anaemia.

Anthropometry Assessment

- Anthropometry assessment includes recording of age, sex and anthropometric measurements (Mid Upper Arm Circumference, height, weight).
- Patients who have their 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 square of height (m^2). A normal BMI is 18.5 – 24.9 kg/m^2 . ABMI <18.5 denotes underweight; that between 25.0 and 29.9 kg/m^2 is overweight, and >30.0 kg/m^2 is obesity. For patients with BMI <18.5 nutritional education is required and food supplementation recommended, if any.

It should be noted though that even without using BMI, unintended weight loss of between 6-7 kg in one month is not a good sign. Therefore the weight of PLHIV need 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 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 treatment. For prescription criteria, refer to national guidelines for management of acute malnutrition.

Table 15.2: Indicators for Acute Malnutrition.

Age category	Mild	Moderate	Severe
Children 5 - 9 years	MUAC W/H -2 SD to < +1 SD	MUAC 13.5 – 14.4 cm W/H -3 SD to < -2 SD	MUAC < 13.5 cm W/H < -3 SD
Children 10 - 14 years	MUAC W/H -2 SD to < +1 SD	MUAC 16 –18.4 cm W/H -3 SD to < -2 SD	MUAC < 16.0 cm W/H < -3 SD
Adolescents (15 years and above) and adults	MUAC BMI ≥ 17 – 18.4	MUAC 19 cm – 21.9 cm BMI ≥ 16 – 17	BMI < 16.0 MUAC < 19.0 cm

Note: Visual assessment is not recommended as the primary method for screening or nutritional assessment.

Further reading

1. National Guidelines for Management of HIV and AIDS, Second edition (Revised February, 2009)
2. WHO Antiretroviral Therapy for Adults and Adolescents (2010 Revisions)
3. WHO Antiretroviral Therapy for Infants and Children (2010 Revisions)
4. UNAIDS Global AIDS Epidemic Report (2010)
5. Tanzania National PMTCT Guideline (Revised 2011)
6. The national Operational Guide Positive Health, Dignity and Prevention, 2011
7. The revised National Guideline for Home Based Care services (2010)
8. HIV and AIDS Prevention Act 2008 and its regulation
9. National VCT guidelines/PITC Guidelines
10. Health Sector HIV and AIDS strategic Plan 11(2008-2012)
11. The second National Multi-sectoral Strategic Frame work on HIV and AIDS (2008-2012)
12. Training materials for community positive health dignity and prevention
13. Revised National training package for Pediatric HIV and AIDS care and Treatment.
14. National Guideline for Initiating and Managing Community Based Reproductive and Child Health Services
15. A National Guideline for TB/HIV services.
16. National Guideline for Palliative Care

17. National Tuberculosis Treatment Guidelines 2009
18. National Guidelines for Quality Improvement of HIV and AIDS
19. Adherence Counseling Toolkit, (NACP, 2007)
20. National Essential Health Sector HIV and AIDS Intervention Package (MOHSW, 2010)
21. A manual for Comprehensive Supportive Supervision and Mentoring on HIV and AIDS Health Services (MOHSW, 2010)
22. National Medical Male Circumcision Strategy (NACP)
23. National Tuberculosis and Leprosy Report, (NTLP, 2009)

ANNEX 1: WHO CLINICAL STAGING OF HIV DISEASE IN ADULTS AND ADOLESCENTS

CLINICAL STAGE 1

Asymptomatic

Persistent generalized lymphadenopathy

CLINICAL STAGE 2

- 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

- 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 diarrhoe 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 WHO 2007 Case Definitions of HIV for Surveillance and Revised Clinical Staging available on line <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

- 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

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

Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy

Pneumocystis pneumonia

Recurrent severe bacterial infections (such as empyema, 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 or 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

Ref: <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 nail bed) or onycholysis (painless separation of the nail from the nail bed). Proximal white subungual onychomycosis is uncommon without immunodeficiency.	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 pseudomembrane.	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 cythematous 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 cardrum (otitis media), sore throat with productive cough (bronchitis), sore throat, (pharyngitis), and barking croup like cough (Laryngotracheal bronchitis [LTBI]). 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.
Unexplained persistent fever (intermittent or constant, for longer than one month)	Reports of fever or night sweats 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°C with negative blood culture, negative malaria slide and normal or unchanged CXR, and other obvious foci of disease
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

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 M. tuberculosis 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 M. tuberculosis on sputum culture
Severe recurrent presumed bacterial pneumonia	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.	Isolation of bacteria from appropriate clinical specimens (induced sputum, bronchoalveolar lavage [BAL], lung aspirate).
Acute necrotizing ulcerative gingivitis or stomatitis, or acute necrotizing ulcerative periodontitis	Severe pain, ulcerated gingival papillae, swelling of teeth, spontaneous bleeding, bad odour, and rapid loss of bone and/or soft tissue.	Clinical diagnosis
Symptomatic lymphoid interstitial pneumonitis [LIP]	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.

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 (<8g/dl), or neutropenia (<0.5 x 10 ⁹ /L) or chronic thrombocytopenia (<50 X 10 ⁹ /L)	No presumptive diagnosis.	Laboratory testing, not explained by other non-HIV conditions, or not responding to standard therapy with harminics, antimalarials or antelmintics 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 -3 SDs, as defined by WHO IMCI Guidelines.	Confirmed by documented weight loss of > -3 SD +/- oedema

Pneumocystis pneumonia (PCP)	Dry cough progressive difficulty in breathing, cyanosis, tachypnoea and fever; chest indrawing or stridor. (severe or very severe pneumonia as in 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 months 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

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) responds to specific treatment. In young children, suspect particularly if oral candida observed and food refusal occurs and/or difficulties/ crying when feeding.	Confirmed by macroscopic appearance at endoscopy, microscopy of specimen from tissue or macroscopic appearance at bronchoscopy or histology.
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, meanings, confusion, behavioral changes that responds to cryptococcal therapy.	Isolation of Cryptococcus neoformans from extrapulmonary 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
Didanosine (ddI)	>60 kg: 400gm once daily
Buffered tablets or enteric coated (EC) capsules	<60 kg: 250 mg once daily
Lamivudine (3TC)	150 gm twice daily or
Stavudine (d4T) 30 mg twice daily	30 mg twice 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 Two tablets twice daily irrespective of co administration with EFV or NVP (400/100 mg twice daily)</p> <p>Tablets (heat-stable formulation) Lopinavir 200 mg /ritonavir 50 mg</p> <p>Treatment-experienced patients Three tablets twice daily when combined with EFV or NVP (600/150 mg twice daily)</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 6 weeks of age and above										Strength of adult tb (mg)		Number of tablets by weight-band	
		Number of tablets by weight-band morning and evening													
		3-5.9 kg		6-9.9 kg		10-13.9		14-19.9		20-24.9					
		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	1
ABC	60	1	2	1.5	1.5	2	2	2.5	2.5	3	3	300	1	1	1
NVP	50	1	2	1.5	1.5	2	2	2.5	2.5	3	3	200	1	1	1
ddl	25	2 ^a	2 ^a	3	2	3	3	4	3	4	4	25	5	5	5
COMBINATIONS															
AZT/3TC	60/30	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300/150	1	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	1
ABC/AZT/3TC	60/30/30	1	2	1.5	1.5	2	2	2.5	2.5	3	3	300/150/150	1	1	1
ABC/3TC	60/30	1	1	1.5	1.5	2	2	2.5	2.5	3	3	b			
d4T/3TC	6/30	1	2	1.5	1.5	2	2	2.5	2.5	3	3	30/150	1	1	1
d4T/3TC	6/30/50	1	1	1.5	1.5	2	2	2.5	2.5	3	3	30/150/200	1	1	1
LPV/r ^c	100/50	NR	NR	2	1	2	2	2	2	2	2	100/25	3	3	3

a This dose of ddl is only appropriate for children 3 months of age or older and weighing between 5kg and 5.9kg

b See ABC/3TC FDC dosing table.

c Higher doses of LPV/r may be required when co-administered with enzymes-inducing drugs such as NVP,EFV, los-ampernavir (FPV), rilampicin

Simplified table giving ml of liquid formulation and number of tablets or capsules of adult solid formulation formorning and evening dosing

Drug	Strength of paediatric 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		10-13.9kg		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
d4T	1mg/ml 150 mg	6 ml	6 ml	9 ml	9 ml	1(15 mg)	1(15 mg)	1(20 mg)	1(20 mg)	1(20 mg)	1(20 mg)
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
ddl	10 mg/ml; 200 mg	3 ml ^a	3 ml ^a	5 ml	5 ml	6 ml	6 ml	4	3	4	4
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

^a This dose of ddl is only appropriate for children 3 months of age or older and weighing between 5kg and 5.9kg

^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

Simplified table giving number of tablets of child-friendly solid formulations for once-daily dosing

Drug	Strength of tab (mg)	Number of tablets or capsules by weight-band once daily					Strength of tab/cap (mg)	Number of tablets or capsules by weight-band once daily
		3-5.9 kg	6-9.9 kg	10-13.9	14-19.9	20-24.9		
		Once daily	Once daily	Once daily	Once daily	Once daily		25-34.9
								Once daily
SINGLE DRUGS								
EFV ^a	200 mg	NR	NR	1	1.5	1.5	200	2
ddl ^b	125 mg or 200 mg EC	NR	NR	NR	1(200 mg)	2(125 mg)	125 mg EC	2

^a EFV is not recommended for children below 4 years and weighing less than 10 kg.

^b ddl EC is not recommended for children weighing less than 10 kg; this dose is recommended only for those 10 kg and above.

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) | NVP/D4T/3TC (50 mg/6mg/30mg) |
D4T/3TC (6mg/30mg) | NVP/D4T/3TC (100 mg/12mg/60mg) | D4T/3TC (12mg/60mg)

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	1A.M	1.5A.M	2A.M	2.5 A.M	3 A.M	4 A.M or 1 tab OD of 200/300/150mg (Adult formulation)
NVP/AZT/3TC(50/60/30mg) Tablet						
AZT/3TC(60/30mg) Tablet	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	1 BD	1.5 BD	2 BD	2.5 BD	3 BD	4 BD or 1 tab BD of 200/300/150mg (Adult formulation)
NVP/AZT/3TC(50/60/30mg) Tablet						
INDUCTION DOSE	1A.M	1.5A.M	2A.M	2.5 A.M	3 A.M	4 A.M or 1 tab OD of 200/300/150mg (Adult formulation)
NVP/D4T/3TC(50/6/30mg) Tablet						
D4T/3TC(6/30mg) Tablet	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 orrmulation)
MAINTANANCE DOSE	1 BD	1.5 BD	2 BD	2.5 BD	3 BD	4 BD or 1 tab BD of 200/30/150mg (Adult formulation)
NVP/D4T/3TC (50/6/30mg) Tablet						

<u>INDUCTION DOSE</u> NVP/D4T/3TC(100/12/60mg) Tablet	0.5 A.M	1 A.M	1 A.M	1.5 A.M	1.5 A.M	2 A.M or 1 tab OD of 200/30/150mg (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)
<u>MAINTANANCE DOSE</u> NVP/D4T/3TC (100/12/60mg) Tablet	0.5 BD	1 A.M 0.5 P.M	1 BD	1.5 A.M 1 P.M	1.5 BD	2 BD or 1 tab BD of 200/30/150mg (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
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, shellfish 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/everages/Herbs to Avoid	Potential Side Effects
Sulfonamides: Sulfamethoxazole, Cotrimoxazole	Antibioticfor treating pneumonia and toxoplasmosis	Take with food		Nausea, vomiting, abdominal Pain
Rifampin	Treatment ofTB	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, 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
Stavudine (d4T) NNRTI	Antiretroviral	Can be taken without regard to food	Limit alcohol	Nausea, vomiting, diarrhoea, 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
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
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 9. TB SCREENING TOOLS FOR HIV/AIDS PATIENTS

MINISTRY OF HEALTH AND SOCIAL WELFARE
COLLABORATIVE TB/ HIV ACTIVITIES



TB SCREENING QUESTIONNAIRE FOR CHILDREN
ABOVE AGE 6 YEARS AND ADULT HIV/AIDS PATIENTS

Patient’s name:

CTC Reg. Number:

Date of birth: .../.../... Sex: ☐ Male ☐ Female

Physical Address:

Area leader/ neighbor:

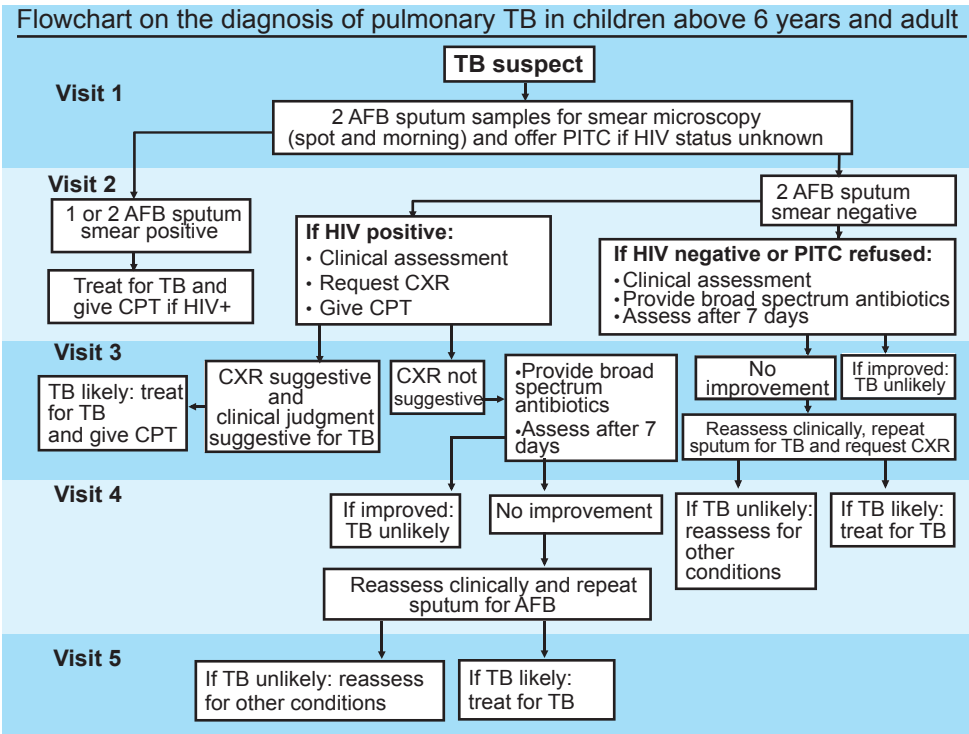
Contact telephone (if available).....

Date																		
Tick appropriate response	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N
Cough for ≥ 2 weeks?																		
sputum (haemoptysis Coughing up bloodstained)?																		
Fevers for ≥ 2 weeks?																		
Noticeable weight loss for new patients or a 3 kgs weight loss in a month (subsequent visit)?																		
Excessive sweating at night for ≥ 2 weeks?																		

If ‘YES’ to one or more questions enter the code “TB Susp” in the TB status column of the CTC2 form and complete the respective column in the table below:

Date			
Do sputum smear for AFB and enter results (pos / neg)			
If sputum negative, do chest X-ray and enter result (suggestive or not suggestive)			
Outcome of assessment (TB or No TB)			

If ‘No’ to all questions: Do not initiate TB investigations and repeat screening at the subsequent visit. Enter the code “NO” in the TB status column of the CTC2 form



Chat for the Diagnosis of TB in Children						
	0	1	2	3	4	Score
General Features						
Duration of illness	Less than 2 weeks	2-4 weeks		More than 4 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 4 weeks		
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 like infiltration, cavity or hilar lymph nodes		
Lymph nodes				Cervical, sub-mandibular		
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						