UNITED REPUBLIC OF TANZANIA

Ministry of Health

National Training on TB/HIV for Healthcare Workers

Participant Manual for Health Workers

Acknowledgements

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Table of Contents

Abbreviations

ACSM	Advocacy, Communication and Social Mobilisation
AFB	Acid Fast Bacilli
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
CHMT	Council Heath Management Team
CTC	Care and Treatment Clinics
CPT	Cotrimoxazole Preventive Therapy
DCT	Diagnostic Counselling and Testing
DOTS	Direct Observed Treatment Short Course
DTLC	District Tuberculosis and Leprosy Coordinators
EPTB	Extra Pulmonary Tuberculosis
FDC	Fixed Dose Combinations
HAART	Highly Active Antiretroviral Therapy
HBC	Home Based Care
HIV	Human Immunodeficiency Virus
IPC	Infection Prevention Control
IPT	Isoniazid Preventive Treatment
IRIS	Immune Reconstitution Inflammatory Syndrome
MDR TB	Multi-Drug Resistant Tuberculosis
NACP	National AIDS Control Programme
NTLP	National Tuberculosis and Leprosy Programme
OIs	Opportunistic Infections
PEP	Post Exposure Prophylaxis
PITC	Provider-Initiated Counselling and Testing
PLHIV	People Living with HIV and AIDS
PMTCT	Prevention of Mother to Child Transmission
PTB	Pulmonary Tuberculosis
RTLC	Regional Tuberculosis and Leprosy Coordinator
TB	Tuberculosis cases
TLCU	Tuberculosis and Leprosy Central Unit
VCT	Voluntary Counselling and Testing
VMT/ST	Voluntary Muscle Test / Sensitivity Test
WHO	World Health Organisation

UNIT 1: WELCOME AND OVERVIEW OF THE TRAINING PROGRAMME

Goal of This Training

The goal of this training is to build the capacity of primary health care providers to implement collaborative TB/HIV activities.

Objectives of the TB/HIV Course

By the end of this training, you should be able to:

- Describe Tanzania's NTLP, NACP, and identify health care workers' duties and responsibilities
- Identify risk factors for TB transmission, signs and symptoms of TB, and differentiate between TB infection and TB disease
- Explain TB diagnostic approach, treatment regimens and the global and national TB control strategy
- Define HIV, AIDS and identify modes and risk factors for HIV transmission
- Explain methods to prevent HIV transmission
- Describe common opportunistic infections and their management and prevention
- Explain how to manage TB/HIV co-infected patients
- Explain TB/HIV collaborative activities
- Practise HIV counselling skills involved in Provider-Initiated Counselling and Testing (PITC) to TB patients and suspects
- Accurately complete recording and reporting TB/HIV collaborative activities
- Explain the rationale and protocol for infection prevention control (IPC) and post-exposure prophylaxis (PEP)

UNIT 2: INTRODUCTION TO TB, HIV, AND COLLABORATIVE ACTIVITIES

Introduction

The interaction of TB and HIV diseases calls for healthcare workers to be more knowledgeable about the management of patients with TB, HIV, and those co-infected with both diseases. It is very important for them to be familiar with TB, HIV, and the relationship between TB and HIV in order to be able to effectively provide collaborative services. This unit provides an overview on TB, HIV and AIDS, and collaborative TB/HIV activities.

Objectives

By the end of this session, you should be able to:

- Describe the basic facts about HIV and AIDS
- Describe the basic facts about TB
- Explain the relationship between TB and HIV
- Outline collaborative TB/HIV activities
- Explain the roles of NTLP and NACP in relation to collaborative TB/HIV activities

Overview of HIV/AIDS

HIV stands for Human Immunodeficiency Virus. It is a retrovirus which leads to AIDS. It causes immune suppression by infecting and depleting cells of the immune system (CD4). HIV infection means the presence of virus in the human body.

AIDS stands for Acquired Immune Deficiency Syndrome. It occurs when chronic HIV infection progresses to full blown disease as a consequence of immune suppression. Various signs and symptoms lead to progressive immune deterioration.

HIV is transmitted through:

- Unprotected sexual contact with infected partner/s
- Contact with HIV-infected blood/blood products
    - Blood transfusion
    - Injection Drug Use (IDU) through needle-sharing
    - Needle stick accidents
    - Unsterilized needles
- Mother-to-Child transmission
    - In utero, during delivery, through breast feeding

Global HIV Epidemiology

HIV is a problem worldwide. According to UNAIDS, 33.2 million persons are infected globally, 68 percent of whom are in sub-Saharan Africa (22.5 million persons). In 2007 alone, there were 1.7 million new infections 65 percent of which occurred in sub-Saharan Africa.

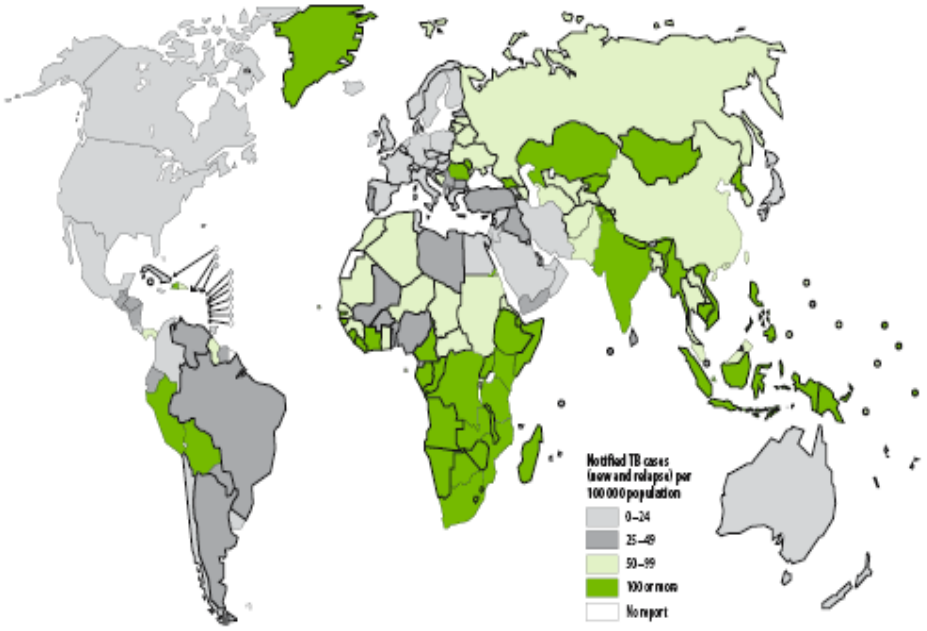
Magnitude and Distribution of HIV/AIDS in Tanzania

The first three cases of AIDS in Tanzania were identified in 1983. There is now a cumulative total of 205,733 reported cases since 1983 in all 21 regions. The national prevalence of HIV/AIDS amongst adults is 7.0%, which is about 2 million people. Some areas of Tanzania have a low prevalence of HIV/AIDS, such as Kigoma with 4.5 percent. Other regions have a high prevalence, such as Mbeya with 15.2 percent, Kagera with 13.6 percent, and Dar and Iringa with 17.4 percent. One million people in Tanzania are in need of clinical care, while 400,000 of them need antiretroviral treatment.

Tuberculosis
Tuberculosis (TB) is a chronic infectious disease caused by M*ycobacterium tuberculosis.* TB transmission occurs mainly through the inhalation of droplets from infected people. The most common form of TB is pulmonary TB, but people can also suffer from extra-pulmonary tuberculosis (EPTB).

Global Tuberculosis Epidemiology
Over 30 percent of the people in the world are infected with TB. The majority of these people (80 percent) are in 22 high burden countries. Tanzania has an incidence of (312/100,000) and of prevalence (459/100,000); it is ranked 14 out of 22 for TB infection amongst the high burden countries. The 22 high burden countries include Afghanistan, Bangladesh, Brazil, Cambodia, China, Democratic Republic of Congo, Ethiopia, India, Indonesia, Kenya, Nigeria, Pakistan, Philippines, Thailand, Uganda, United Republic of Tanzania, Vietnam, Zimbabwe.

Figure 1: Global Incidence of TB in 2005



TB in Tanzania
The number of people with TB is increasing in Tanzania. In 1984, 11,000 people had TB; in 2006, 62,100 new patients tested positive for TB. There are higher rates of TB in Dar es Salaam. The overall increase of TB is mainly due to the HIV epidemic.

Notification rates vary by region. Possible reasons for this include different rates of HIV, rural urban migration, poverty (poor living conditions, malnutrition), health seeking behavior, and access to health care (physical or economical).

Figure 2: TB Rates in Regions of Tanzania (Per 100,000 People)

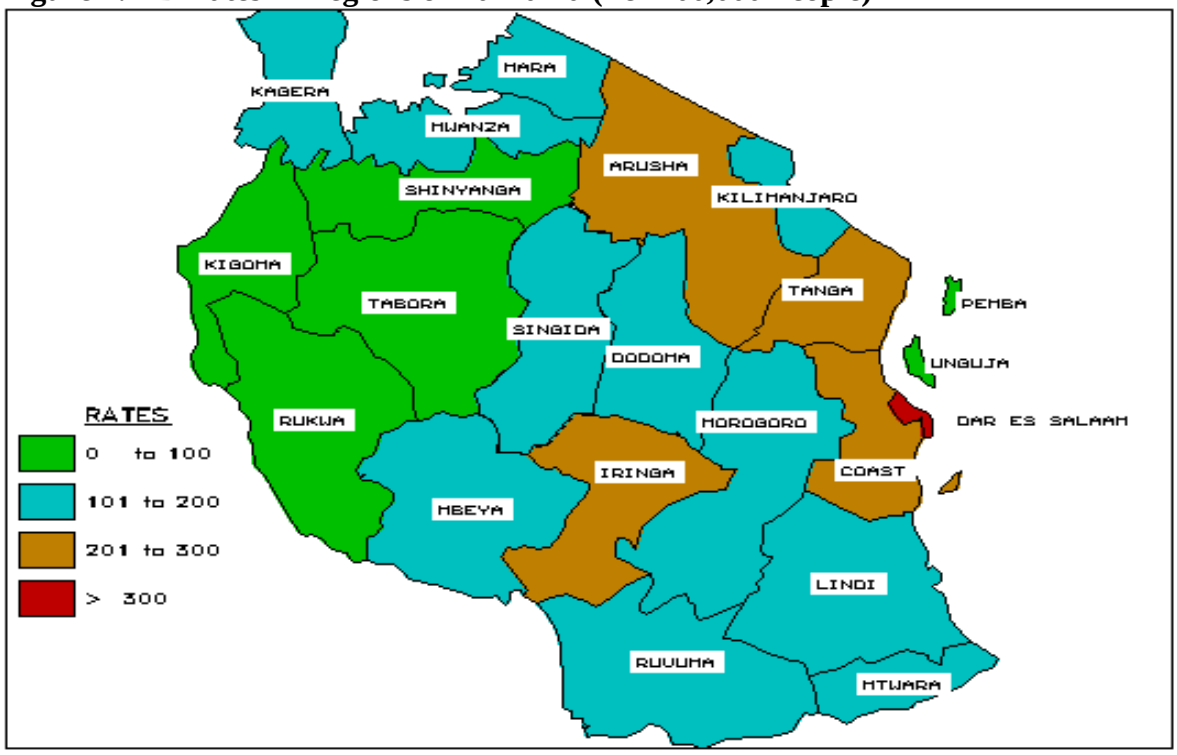
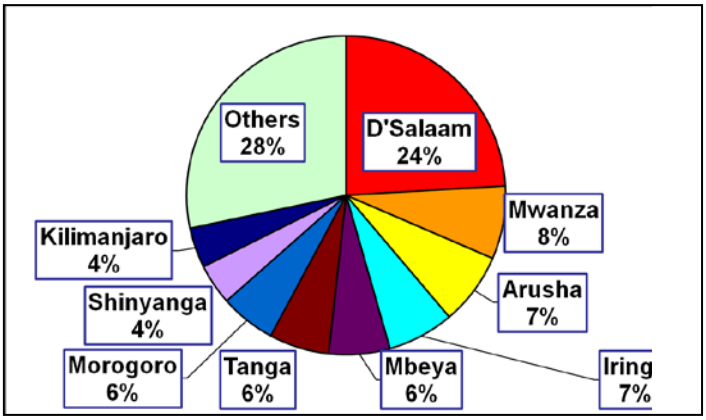


Figure 3: TB Rates in Provinces of Tanzania (Percentages)



TB/HIV Interaction

HIV/AIDS is fuelling the TB epidemic in many parts of the world, including Tanzania. There is a high prevalence of HIV infection in persons with TB. The National Tuberculosis and Leprosy Program (NTLP) estimates 50 percent of TB patients to be co-infected with HIV. There is a high prevalence of TB in persons that are HIV infected; it is estimated that five to ten percent of HIV patients are co-infected with TB.

HIV/AIDS is the leading infectious cause of death in the world, but many people with HIV and AIDS become ill with TB and die with TB. In many countries, the TB and HIV pandemics are fuelling each other. As a result, the global community has adopted the "Two Diseases, One Person" motto for addressing care. Increased TB cases in HIV-infected people pose increased risk of TB transmission to the general community. Due to interaction between these two diseases, it is important that health care providers work together to treat patients effectively.

HIV is the highest known risk factor for developing TB. It promotes progression to active TB in people with both recently acquired and latent *M. tuberculosis*, as well as increasing the risk of recurrent TB. An increase in TB among HIV-infected persons increases the risk of TB transmission in the general population. Impact of TB on HIV is evident: TB is the most common OIs in HIV infected people, increases the risk of progression from HIV to AIDS, and is the leading cause of death among PLHIV. HIV increases risk of recurrent TB through relapse (because of persistence of *M. Tuberculosis*) and re-infection (due to new infection with *M. Tuberculosis*).

Rationale for TB/HIV Collaboration

In order to control the dual infection of TB/HIV, the government of Tanzania has adopted a unified approach: "one person, two diseases", which is a holistic approach to care of TB and HIV patients that is when managing a TB patient should also screen and manage HIV infection and vice verse. Controlling TB and HIV should be the priority of health workers at all levels, thus the need for collaboration between the two (TB and HIV and AIDS) programmes and at the health facility level. For this reason, health workers need to be trained on both diseases at the same time. Because of the relationship between TB and HIV, the scale up of joint TB/HIV interventions is essential. All patients with HIV infection should be screened for TB, and all patients with TB infection should be screened for HIV. TB is not just part of the problem, it is also part of the solution!

Goal and Objectives of the National Collaborative TB/HIV Policy

The goal of the National Collaborative TB/HIV Policy is to decrease the burden of TB and HIV in individuals affected by both diseases. Objectives towards this goal include:

- Establish the mechanisms for *collaboration* between TB and HIV/AIDS programmes
- Reduce the burden of *TB* in people living with HIV/AIDS
- Reduce the burden of *HIV* in TB-infected patients

Roles in Relation to Collaborative TB/HIV Activities

The roles of the NTLP and NACP regarding collaborative TB/HIV activities include:

- Joint planning
- Capacity building
- Supportive supervision
- Resource mobilization
- Advocacy, communication and social mobilisation
- Monitoring and evaluation
- Logistics and supply

The roles of health workers in relation to TB/HIV activities include:

- Screening all TB patients for HIV, and all PLHIV for TB
- Providing care, treatment and support services to TB/HIV co-infected patients
- Referring and linking TB/HIV patients to access services they require
- Recording and reporting TB, HIV and TB/HIV information

Key Points

- Tanzania has a relatively high prevalence of both TB and HIV
- When TB and HIV interact, they intensify and worsen each other
- Collaborative TB/HIV activities should be implemented at all levels in order to mitigate the impact of TB and HIV in people who are dually infected

UNIT 3: UNDERSTANDING TUBERCULOSIS

Introduction

It is estimated that about 30 percent of people in the world are infected with TB. The majority of these are in 22 high TB burden countries, including Tanzania. After HIV/AIDS and malaria, TB is the third highest cause of morbidity and mortality in Tanzania. Immune compromised people are very prone to develop TB, including PLHIV. TB is the leading cause of death for PLHIV and HIV frequently co-exists with TB.

The goal of this unit is to provide participants with knowledge and skills on TB. It will cover the definition of TB as well as TB causes, transmission, and pathogenesis, differences between TB infection and TB disease, and the types, symptoms and signs of TB.

Objectives

By the end of this session, you should be able to:

- Describe what tuberculosis (TB) is and its causes
- Describe ways in which TB is transmitted
- Explain risk factors for TB transmission
- Describe pathogenesis of TB disease
- Differentiate between TB infection and TB disease
- List the different types of TB
- Explain TB signs and symptoms

What is Tuberculosis?

Tuberculosis (TB) is a chronic infectious disease caused by *Mycobacterium tuberculosis.* It is also called Acid Fast Bacilli (AFB) as it resists decolourisation with acid or alcohol, which helps to differentiate it from other bacteria in sputum. *Mycobacterium tuberculosis* are slightly curved, rod shaped bacilli 0.2 - 0.5 microns in diameter and 2 - 4 microns in length.

How is TB Transmitted?

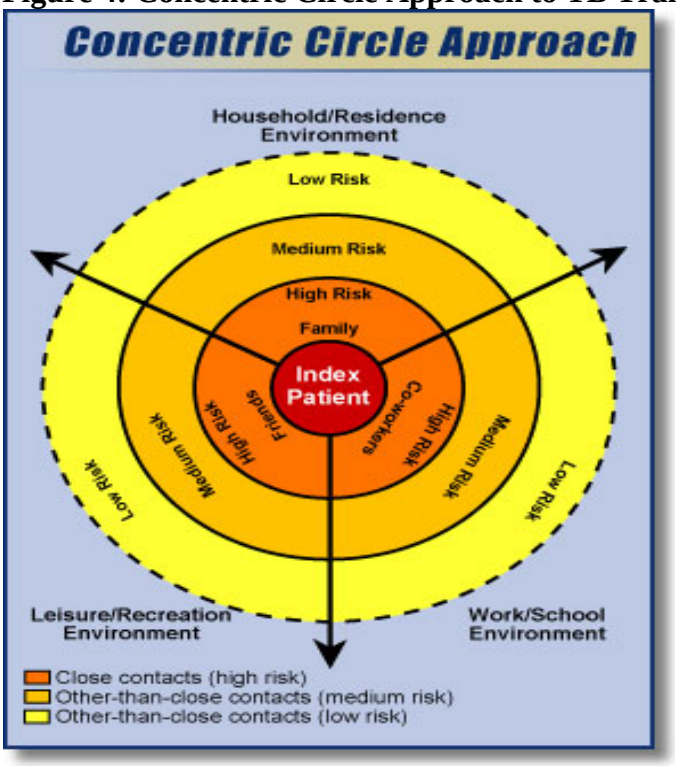
TB transmission occurs from persons with active pulmonary TB. When persons with active pulmonary TB cough, speak or sneeze, TB can be transmitted to others through the inhalation of those droplets. TB droplets remain suspended in the air for hours, making TB more infectious than many other respiratory pathogens. A person must inhale the air containing the droplet nuclei in order for transmission to occur. Each patient with pulmonary TB disease infects on average 20 other people. Although the bacteria can survive in the air for many hours, the bacteria can be killed by direct sunlight or cleared out of a room by opening the windows to let fresh air in.

Less frequently, TB is transmitted by ingestion of *Mycobacterium bovis*, which is found in unpasteurised milk products.

The closer a person is to someone who is infected with TB, the greater the chance that person has of becoming infected. TB transmission is dependent upon a variety of factors including:

- Proximity to the TB suspect
- Actions taken by the suspect (e.g. coughing)
- The type of TB the suspect has such as open pulmonary TB

Figure 4: Concentric Circle Approach to TB Transmission



Risk Factors for Transmission

1) Duration of infectiousness – the longer a person has the disease, the more likely he/she is to infect others. This means that the longer TB goes untreated, the more people will become infected. Untreated pulmonary TB patients can infect many people with whom they come into contact.
2) Bacteriologic status of source – the infectiousness of a person's TB is, whether he/she has TB infection or TB disease, and how much bacterial load he/she has will affect how easily TB can be transmitted. Smear positive cases are the most infectious.
3) Immune system compromise – HIV works to weaken a person's immune system and therefore his/her ability to fight illness. Therefore, if a person is HIV positive and as a result does not have a fully functioning immune system, he or she is more vulnerable to acquiring TB if exposed to someone with TB who is coughing. Other conditions such as malnutrition and alcoholism also predispose a person to getting TB. However, TB can also infect people without any medical condition!

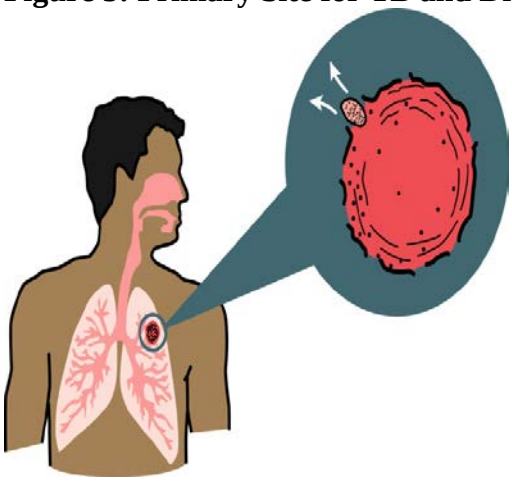
The chance of infection increases when the concentration of TB bacteria circulating in the air increases, more time is spent with the infectious person, and when the exposure occurs in an area where the bacteria can easily survive (e.g. poor ventilation in closed spaces, absence of UV light).

TB Pathogenesis

- Infection: mainly aerosol, but rare cases of ingestion (*M. bovis*).
- Primary site of infection: alveolar macrophages (lung)
- Stages of infection: 3-8 weeks—entry, multiplication, lymphatic spread (Primary complex)

The graphic below (Figure 5) represents the primary site for TB and dissemination of the TB that will eventually be coughed out, potentially infecting other people. HIV positive persons are more susceptible to TB infection.

Figure 5: Primary Site for TB and Dissemination



Ten percent of infected persons with normal immune systems develop TB at some point in their lives. HIV is the strongest risk factor for development of TB if a person is infected. The risk of developing TB disease is five to ten percent each year. Certain medical conditions (diabetes, malnutrition, ageing, silicosis etc.) increase risk that TB infection will progress to TB disease. Other factors that increase risk the of infection include substance abuse, chest radiograph findings suggestive of previous TB, diabetes mellitus, prolonged corticosteroid therapy, and other immunosuppressive therapy.

TB Infection vs. TB Disease

Infection means that the bacteria are living inside a person, but that person does not have any symptoms because his/her immune system is able to control the infection. Not all infected people with TB infection develop TB disease.

Disease occurs when the immune system cannot control the infection and the bacteria multiply to cause disease. TB disease can develop soon after infection, many years after infection, or it may never develop.

TB infection, or TB in a latent stage, involves no active multiplication nor any signs or symptoms. In this stage, TB is not infectious. TB disease, or active TB, is infectious and in this stage the bacilli *actively* multiply. A person with active TB has both the signs and symptoms of TB and the disease involves the lungs, lymph nodes, glands and other sites.

Pulmonary Tuberculosis (PTB)

Pulmonary tuberculosis (PTB) is the most frequent type, accounting for about 80 percent of TB cases. PTB is infectious. Symptoms include cough for two or more weeks and sputum production. Patients may have cavities that are rich in bacilli.

Extra-Pulmonary Tuberculosis

Extra-pulmonary tuberculosis (EPTB) occurs when the bacteria spread outside of the lung and cause disease. With the exception of laryngeal TB, EPTB is not usually infectious. Patients with EPTB disease often also have TB disease in the lungs. EPTB usually occurs in

people with weak immune systems such as those who are HIV-positive or infants. Extra-pulmonary TB is important because it is more likely to occur in persons living with HIV. If someone presents with extra-pulmonary TB and their HIV status is unknown, they should be considered HIV positive and tested promptly.

PLHIV have a higher risk of disseminated TB and extra-pulmonary disease than do those without HIV. As the TB bacteria are inside the macrophage, they can travel through the lymphatic system to regional lymph nodes and through the bloodstream to more distant tissues and organs, including areas in which TB disease is most likely to develop: the apices of the lungs, the kidneys, the brain, and bone.

TB can manifest itself in the following extra-pulmonary ways:

1. Primary
2. Pulmonary
3. Cervical lymph nodes
4. Pleural Effusion
5. Miliary
6. Kidney
7. Spine
8. Meningitis

Sites of EPTB include:

- Lymph nodes
- Disseminated or miliary
- Pleura
- Pericardium
- Abdominal (peritoneal)
- Meninges
- Spine
- Other bones
- Kidney
- Adrenal glands
- Genital –urinary tract
- Upper airway (larynx)

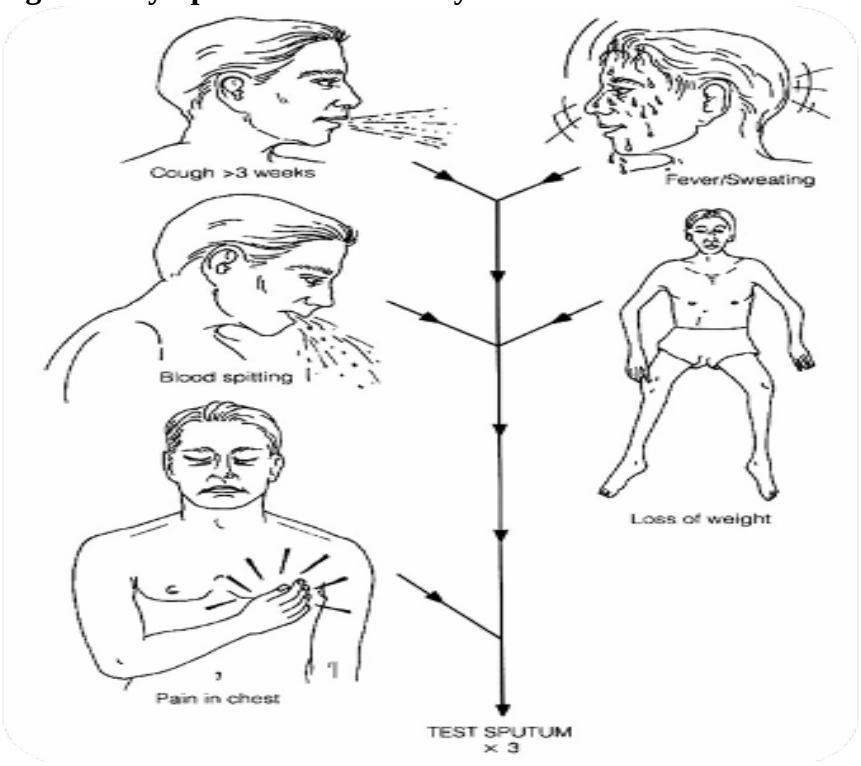
Figure 6: Pulmonary and Extra-Pulmonary TB: A Comparison

Pulmonary	**Extra-Pulmonary**
In the lungs	Other parts of the body
Infectious	Non-infectious
Occurs in both HIV positive and HIV negative persons	More common in HIV-positive persons

Signs and Symptoms of Pulmonary Tuberculosis

Most patients with smear-positive pulmonary TB have a cough lasting two weeks or more. Other symptoms include fever, sputum production sometimes with blood (haemoptysis), excessive night sweats, weight loss, chest pain, and breathlessness. Some of the symptoms experienced may be those of HIV. Breathlessness may indicate co-existent pneumocystis pneumonia.

Figure 7: Symptoms of Pulmonary Tuberculosis



The sputum smear is used to test a suspect for TB. Much like a blood draw and rapid test are used to test for HIV, the sputum smear is collected and then sent to a lab for analysis in order to detect TB.

Signs and Symptoms of Extra-Pulmonary Tuberculosis
The general signs and symptoms of patients with EPTB are fever, excessive night sweats, loss of appetite, and weight loss. Other signs and symptoms depend on the site of the disease.

TB of the spine (also known as Pott's disease or tuberculosis spondylitis) is the most common site of TB-related bone infection. The areas of the spine that are most often affected are the lower thoracic and upper lumbar vertebrae. With advanced disease, collapse of vertebral bodies result in kyphosis (gibbus).

Typical characteristics of sub-acute or chronic meningitis, of which TB is an important cause, include heachache, fever, meningismus, decreasing mental status, and negative blood cultures. A reagin antibody is usually formed against an allergen that has a special affinity for cell membranes and remains fixed on various tissue IgE.

Key Points
- TB is caused by bacteria, most commonly *Mycobacterium tuberculosis*
- TB is transmitted through the air, when a person with TB coughs, speaks, laughs, etc
- Risk factors for TB transmission include duration of infectiousness, exposure, number of TB bacilli, and immune system functioning of recipient
- TB symptoms include cough, sputum production, breathlessness, loss of appetite weight, fever, night sweats
- All persons suspected of TB should get tested for HIV

UNIT 4: TUBERCULOSIS DIAGNOSIS

Introduction

The highest priority in TB control is identification and cure of all infectious TB cases. Therefore, priority is given to the detection of bacilli in sputum samples of all suspected TB cases. This unit covers information about TB diagnosis in adults and children.

Objectives

By the end of this session, you should be able to:

- Describe TB diagnostic approaches
- Explain different methods of TB diagnosis
- Interpret TB investigation results
- Demonstrate the use of NTLP TB diagnostic flow chart

TB Diagnostic Approach

The health worker needs to perform a history and examination of the patient. Laboratory examinations include an AFB microscopy for sputum and aspirates, a culture for sputum and aspirates for EPTB, and a histological examination using biopsy tissue. A chest x-ray (CXR) alone is NOT reliable as there is no x-ray appearance typical for pulmonary tuberculosis (PTB). For all patients with suspected EPTB, specimens should be sent for microscopy, if available culture & histology (ISTC).

Medical History

Taking a good medical history is the first step in diagnosing TB. The health worker should to ask the patient to describe:

- When symptoms first started
- Sputum colour and quantity, if coughing
- History of TB disease/treatment in the past? When/where?
- Any other medical conditions treated for in the past or present?
- History of TB contact

TB Physical Examination

In examining a TB suspect, the health worker should look for the following:

- Appearance: Wasting
- Temperature : Normal or elevated
- Lymph nodes: Enlarged, maybe matted
- Chest:
    - Sounds may be normal, but listen for crackles (rales) and wheezing
    - Respiratory rate may be normal or high, if very high may indicate PCP
    - Dullness on percussion (in case of pleural effusions)
    - Distant heart sounds in pericardial effusion
- Trachea may be displaced in severe disease

Amphoric breathing has a metallic, resonant quality with both inspiratory and expiratory phases that are relatively equal in duration and loudness. Amphoric breath sounds indicate an air-containing space in the lung that communicates with the bronchial tree. Findings indicate the pathologic changes in the lungs rather than the aetiology of lung diseases. For example, the amphoric breathing indicates a large cavity with bronchial connection, dullness on percussion indicates either fluid or consolidation, tracheal displacement indicates fibrosis or collapse of lung or pleural effusion, etc.

Differential Diagnosis for TB Suspects
There are other classic lung disorders that may produce chronic cough in immunologically normal persons. These include:

- Bacterial pneumonia or opportunistic pneumonia
- Pneumocystic jirovecii pneumonia
- Lung abscess or bronchiectasis
- Asthma or chronic obstructive airway disease
- Occupational lung disease
- Lung cancer
- Congestive cardiac failure
- Kaposi sarcoma of the lung

Diagnosis of Pulmonary TB (PTB) with AFB Smear
Suspect PTB in any person with an otherwise unexplained productive cough lasting two weeks or more. Other symptoms include fever, night sweats, loss of appetite, weight loss, and productive sputum that is sometimes blood stained (haemoptysis).

TB diagnosis is determined mainly through the identification of tubercle bacilli by sputum smear microscopy. As the most convenient and reliable method for the diagnosis of TB, AFB microscopy is the cornerstone for the diagnosis of PTB and of the DOTS strategy. It is also used for treatment monitoring and documenting treatment outcomes. Advantages of this method are that it is simple, less expensive, more reliable, and easy to perform. AFB is inexpensive and widely available throughout Tanzania, and it identifies the persons who are most infectious and so most important to treat from a public health perspective. If pulmonary TB (PTB) is suspected, three sputum specimens must be collected for examination within 24 hours: spot-morning-spot. The timing should be spot at the first visit to the clinic, the first morning sputum, and spot at the second visit to the clinic.

Two or more positive sputum smears provide the most reliable diagnosis of pulmonary TB disease. He or she is infectious and needs treatment. Sputum positive means that bacteria can be seen in the sample (AFB seen), whereas sputum negative means that no bacteria can be seen in the sample (no AFB seen). Interpretation of AFB smear results is as follows:

- No AFB, No AFB found in 100 fields
- 1 - 9 AFB, Exact number of AFB found in 100 fields
- 1+ AFB, 1-10 AFB per 10 fields
- 2+ AFB, 1-10 AFB per field
- 3+ AFB >10 AFB per field

Chest X-Ray
A chest x-ray can be used for diagnosis of TB; however, it is not specific. An abnormal x-ray is suggestive of TB. Patients who should have a CXR include those who have had three negative sputum smears but are not improving on broad spectrum antibiotics, those who are severely breathless (dyspnoeic), and those with severe haemoptysis.

Abnormalities of the lungs may be due to granulomas or destruction of the lungs. On a chest x-ray, healthy lungs are black while unhealthy lungs appear white or grayish. Air in the lung appears black and solid abnormalities including fluid may appear white. Other reasons why the lung field may be black include the probability of pneumothorax if the lung field is very black or else chronic obstructive lung disease the lung field is also black because of

emphysema and the patient presents with chronic cough. It is important to note that a chest x-ray cannot tell the doctor for sure if a person has TB disease. For example, a person who is HIV positive and has TB disease can still have a normal x-ray.

Other Diagnostic Methods

Other diagnostic methods include the Tuberculin skin test and Erythrocyte Sedimentation (ESR). The Tuberculin skin test indicates mycobacterium infection, NOT the presence of tuberculosis disease. It is used with children. Erythrocyte sedimentation (ESR) is non-specific and should not be used as a routine diagnostic tool for TB.

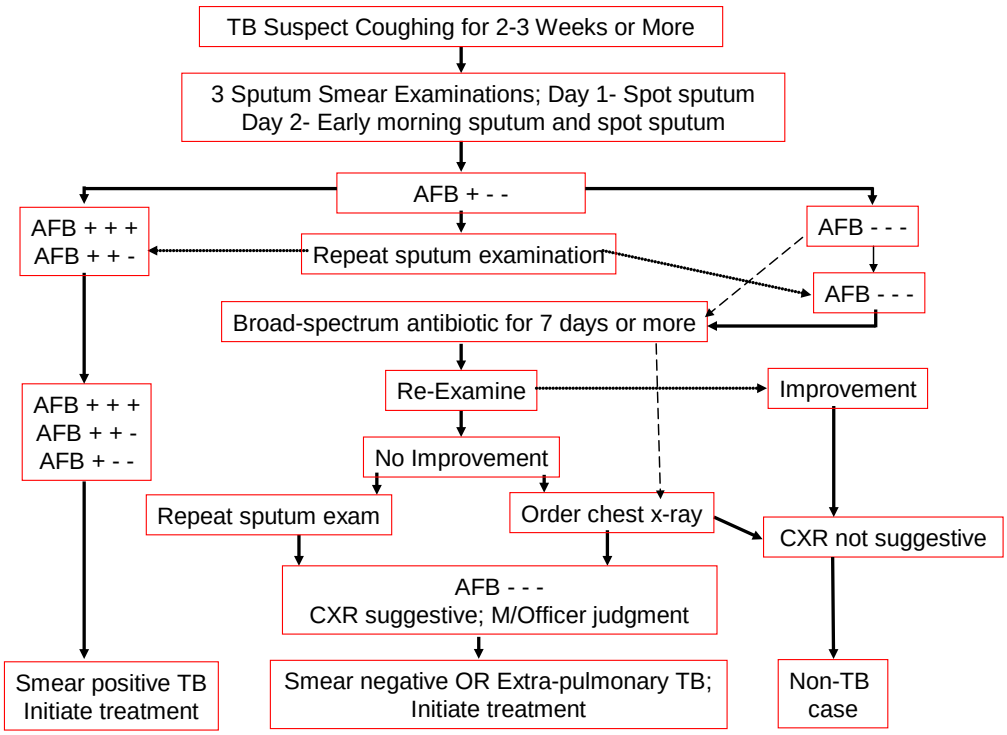
Diagnosis of Sputum Smear Negative TB

Criteria for the diagnosis of sputum smear negative TB are:

- At least 2 or 3 negative sputum smears (incl. one early morning one)
- Chest findings consistent with TB
- Lack of response to broad spectrum antimicrobial agents (Avoid fluoroquinolones!)

Note that this is a presumptive diagnosis.

Figure 8: TB Diagnostic Algorithm



TB Meningitis

Cerebrospinal Fluid (CSF) is used to diagnose TB meningitis. Results for a TB meningitis test include:

- Polys predominate early
- Lymphs predominate later on
- Low glucose, high protein
- Negative gram stain and bacterial culture
- Negative India ink and fungal culture
- Negative CSF VDRL
- AFB stain very low yield; culture low also

There are no typical CSF findings in TB meningitis. Only the AFB stain would be definitive, but it is very rarely positive even when TB meningitis is confirmed by other means. Protein is typically >1g; with severe immunosuppression, up to 40% can have a normal CSF protein. Remember to send serum glucose at the same time as sending CSF glucose. CSF glucose should be less than 2/3 of serum level to be considered low.

Diagnosing TB Lymphadenitis

TB is the most common cause of adenopathy among HIV-infected patients in sub-Saharan Africa. TB lymphadenitis is diagnosed by performing needle aspiration for AFB microscopy and cytological examination (which has a low yield of AFB microscopy). Fine-needle aspiration is an excellent test for TB adenitis in HIV-infected persons – the test can be done the same day in the health facility, has a low rate of adverse effects, and has a high yield for diagnosing TB. Aspiration can be performed in many more health facilities than biopsies, so it makes the diagnosis easier to confirm. If the aspirate is non-diagnostic or negative, then the patient can be referred for a formal biopsy.

Diagnosing Pleural TB

About 95 percent of all pleural effusions occurring in high HIV prevalence areas are caused by TB. The health worker should always perform a diagnostic pleural aspiration if a patient has a pleural effusion. Aspiration of pleural fluid may be enough to give a presumptive diagnosis other than TB. Examination of AFB yields smear positive results in less than ten percent of persons tested. Exudates accumulate in the pleural cavity. TB pleural fluid will be an exudate and high in protein. The gram stain will be negative.

TB Diagnosis in Children

TB risk is increased when there is an active case of TB in same house, or when child is malnourished, HIV-infected or has had measles in the past few months. Consider TB in any child with:

- History of unexplained weight loss or failure to grow normally
- Unexpected fever, especially lasting longer than 2 weeks
- Chronic cough
- Exposure to adult with infectious TB (especially in the same household)

Upon exam, children with TB will present with:

- Fluid on one side of chest
- Enlarged non-tender lymph nodes or lymph node abscess, especially on neck
- Signs of meningitis, especially when developed over several days and spinal fluid contains mostly lymphocytes and elevated protein
- Abdominal swelling
- Progressive swelling or deformity in bones or joints

A score of 9 or higher on the diagnosis chart for children (see Figure 9, below) indicates a high likelihood of TB.

Figure 9: Chart for the Diagnosis of TB in Children

SCORE IF SIGN OR SYMPTOM IS PRESENT						
	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	Reported not proven		Proven smear-/EP	Proven Smear+	
Tuberculin test				Positive		
Malnutrition				Not improved after 4 weeks		
Chronic infant disease		Recurrent		No response to antibiotics		
LOCAL FEATURES						
Chest x-ray				TB suggestive features like infiltration, cavity or hilar lymphnodes		
Lymphnodes				Cervical, submandibular		
Swelling of bone or joint				Suggestive feature on X-ray		
Ascitis			Without abdominal mass	With abdominal mass		
Meningitis				Chronic C.N.S. signs		
Angle deformity of the spine					X-ray feature	
TOTAL SCORE						

If score is ≥ 9 points, TB is highly likely.

Key Points

- Suspect TB in anyone who has an otherwise unexplained productive cough lasting 2 weeks or more
- AFB microscopy is the most convenient and reliable method for diagnosis of TB disease
- For all patients with suspected EPTB, specimens should be sent for AFB microscopy (and if available, culture and histology)
- All sputum smear negative suspect should be sent for x-ray examination; healthcare workers should follow TB diagnostic flow chart
- People with x-ray findings suggestive of TB should have sputum submitted for AFB microscopy

UNIT 5: SPUTUM COLLECTION

Introduction
The aim of this unit is to explain the importance of sputum collection, how to instruct patients to produce a good quality sputum sample, and safety precautions in sputum collection.

Objectives
By the end of this session, you should be able to:
- Describe how to instruct a patient to give a good quality sample
- Describe the safety measures when collecting sputum specimens
- List features of a good sputum specimen
- Practise how to collect sputum sample safely

Infection Control when Collecting Sputum Smears
Instruct patients to cover their mouths when coughing and ensure the availability of posters in the waiting room instructing patients to cover mouth when coughing or sneezing.

When collecting a sputum smear, use appropriate containers with a wide mouth. Label a clean sputum container (on the side and on the lid/cover) before obtaining the specimen. Collect specimens in well-ventilated areas, preferably outdoors and in the sunlight. Ensure that no one stands in front of the patient while he/she is producing the sputum. Ensure that the container is labelled and closed firmly with lid and wash your hands with soap and water after collecting specimen.

Obtaining Sputum Smears
Three sputum smears are recommended for diagnosis of a new case. On day one, the patient is entered into the cough register, a spot specimen is obtained, and the patient is given a container to collect a specimen at home first thing the next morning.

To obtain a spot sputum (immediate specimen):
- Patient rinses mouth
- Cough performed outdoors preferably
- Coach the patient from behind:
    - Inhale deeply 2-3 times, breathe out hard each time
    - Cough deeply from the chest
    - Place the open container close to the mouth to collect the specimen
- Verify that sample contains sputum and not saliva

The patient is then given a container to collect a specimen at home first thing the next morning, which he/she will bring to the clinic. This specimen usually has the highest yield. For the morning collection, the patient should be instructed to:
- Drink plenty of fluid the night before collection if possible.
- Sit upright to collect sputum of the first cough in the morning.
- Rinse mouth with water (if possible), but do not brush teeth before collecting sputum
- Unscrew the lid and hold the container very close to mouth
- Take a few deep breaths and on the third breath cough, deeply from within the chest. Do not contaminate the rim of the container with sputum.
- Do NOT expectorate any saliva or postnasal discharge
- Close lid tightly and return sample to the clinic.

After collecting the morning specimen at home, the patient brings the specimen to the clinic where a third spot specimen is collected in the same manner as on day one. All three samples are sent for AFB smear microscopy within 24 hours, if possible. If the patient does not return on day two, the single specimen from day one should still be sent.

Transport of Sputum Samples

If the health facility is not diagnostic, sputum samples should be transported to the nearest diagnostic center within 72 hours. Transportation of sputum samples should be an immediate process. Samples should be well packed and protected from direct light, and containers should be marked with infectious hazard marks. Samples should be accompanied by a well filled out laboratory record.

Specimen Collection Safety

It is important to remember that the patient who is coughing is a greater danger to staff than the specimen. Instruct patients to cover their mouths when coughing. Never collect sputum in the laboratory and do not stand near patient during specimen collection.

Key Points

- To diagnose TB, the health worker needs to collect three sputum specimens: spot collection #1, early morning sputum collection the next day, and spot collection #2.
- Health workers must follow safe sputum collection steps in order to prevent further infection.
- Wash your hands with soap and water after handling a sample.
- Send specimens immediately to the lab.
- Each specimen should be accompanied by a well filled out laboratory request form.
- If the sample cannot be examined on the same day, the specimen should be stored in a cool dark place or refrigerator if available within three days.

UNIT 6: TUBERCULOSIS TREATMENT

Introduction

The main interventions to prevent the spread of TB in the community include the early detection of patients with infectious TB and providing patients with effective treatment to ensure a rapid and lasting cure. TB treatment is both a matter of individual health and public health and adherence to treatment is essential.

All providers, public and private, treating patients with TB must have the knowledge to prescribe a standard treatment regimen and the means to ensure adherence to the regimen until treatment is completed. TB treatment is essential for TB control. The aim of this unit is to equip participants with knowledge and skills regarding effective TB treatment and the public health importance of TB control.

Objectives

By the end of this unit, you should be able to:

- Describe principles of TB treatment
- Describe the DOTS Strategy and DOT
- Explain TB case definitions
- Describe TB treatment categories
- Discuss treatment regimens
- Explain side effects of anti-TB drugs and how to manage them
- Describe drug resistant TB (MDR/XDR TB)

Principles of TB Treatment

The two cornerstones of TB control are early case finding and adequate treatment. The aim of anti-TB treatment is to cure TB patients, prevent death, avoid relapse, prevent drug-resistant organisms, and prevent transmission of TB to the community. In order to achieve effective treatment, adequate chemotherapy should be prescribed in appropriate combination and with drugs that are taken regularly and for a sufficient period of time.

In order to make TB treatment effective and successful, the directly observed therapy support (DOTS) strategy is essential. DOTS means that an observer watches the patient swallowing his/her tablets everyday for the full duration of treatment. This ensures that a patient takes the right drugs, in the right doses, at the right intervals. Patients must take the full treatment to be cured and to prevent the development of drug resistance.

If patients do not take the drugs as directed or stop before completing the full treatment, they will not get cured and may even die of TB and the disease will be prolonged and more difficult to treat in the future. Patients may miss doses when they start to feel better or discontinue treatment if the drugs lead to side effects. With DOT, patients are watched taking their medicine so there are no missed doses or drug interruptions. The practitioner must be able to diagnose TB, prescribe an appropriate regimen, assess the patient's ability to adhere to the regimen, address poor adherence when it occurs, and ensure adherence to the regimen until treatment is completed.

DOTS strategy is the gold standard of TB control. It has five components:

1. Government political commitment
2. System of case detection based on AFB smear microscopy

3. Standardised treatment regimen using short course chemotherapy with direct observation
4. Assurance of a regular drug supply
5. A strong surveillance and monitoring system – recording and reporting

TB Case Definitions

There are various categories of treatment under which patients may fall. The chart below shows these various categories, and the following definitions serve to further explain these treatment categories:

- New case: a patient who has never had treatment for TB before or has been on treatment for not more than 4 weeks
- Relapse: a patient declared cured or treatment completed who reports back to the health services and found to be AFB positive
- Failure: a patient who, while on treatment, is AFB positive at 5-months or later during the course of treatment
- Return after default: a patient who returns to treatment bacteriologically positive, after having interrupted treatment for 2 months or more and who had been on RX for more than 4 weeks
- Transfer-in: a registered TB patient on RX received from another region
- Other: any TB patient who does not fit in one of the above definitions

Figure 10: TB Treatment Categories

Category	Patients
I	New sputum smear PTB (positive pulmonary TB) and new patients with severe forms of EPTB (Extra pulmonary TB)
II	Relapse Treatment failure and Sputum smear positive return after default
III	New sputum smear negative and EPTB (less severe forms)
IV	Chronic Cases

TB Treatment Regimens

TB regimens are divided into an initial phase (intensive) and a continuation phase. During the initial phase, there is rapid killing of the TB bacilli and patients mostly become non-infectious after about two weeks. Not all patients become non-infectious after two weeks; this depends on their sputum smears. During the continuation phase, drugs kill the persisters and prevent relapse after the completion of treatment.

TB Drugs

First-line therapy includes two treatment regimens: category I for new patients, and category II for re-treatment patients who may have TB resistant to one medication. Essential first line drugs include Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), Streptomycin (S), and Ethambutol (E). Second-line therapy is treatment for patients with TB resistant to more than one drug.

The Action of Anti-Tuberculosis Drugs

The table below (Figure 11) shows the relative ability of the first-line drugs (and thiacetazone, which is no longer used) to: prevent resistance (INH and rifampicin are the best), rapidly reduce the numbers of living mycobacteria in sputum through early bactericidal

activity (INH is the best), and prevent relapse through sterilizing activity (RIF and PZA are the best).

Figure 11: The Action of Anti-Tuberculosis Drugs

Extent of activity	Prevention of resistance	Early bactericidal activity	Sterilising activity
High	Isoniazid	Isoniazid	Rifampicin
	Rifampicin		Pyrazinamide
		Ethambutol	
	Ethambutol	Rifampicin	Isoniazid
	Streptomycin		
		Streptomycin	Streptomycin
	Pyrazinamide	Pyrazinamide	Thioacetazone
Low	Thioacetazone	Thioacetazone	Ethambutol

Reprinted from Tubercle, V66, Mitchinson DA, The action of antituberculosis drugs in short-course chemotherapy, 219-25, © 1985 with permission from Elsevier

Mode of Action of Anti-TB Drugs

The various drugs used for TB treatment include (see also Figure 12, below):

- H: kills rapidly growing organisms and dormant organisms
- Z: kills TB bacilli inside the macrophage and cavities
- R and Z: kill slowly growing organisms (sterilising activity)
- H, R, and E: protect each other from development of resistance

Anti-TB drugs have a synergistic effect on each other: their combined actions produce a greater effect than the sum of the individual components. It is important to use multi-drug therapy because the TB bacilli are in various different states within the body of someone with TB disease. Some TB bacilli will be actively multiplying, some will be dormant, some will be inside macrophages and cavities and some will be in-between growing and dormant (persisters). These three drugs (H, R, Z) are combined to provide modern short course chemotherapy of TB. E is added in case there may be pre-existing resistance to one of these drugs.

Figure 12: Mode of Action, Potency and Recommended Dose of TB Drugs

Essential Anti-TB drugs	Mode of action, most important target	Potency	Recommended dose in mg/kg	
			Daily	3/weekly
Isoniazid (H)	Bactericidal, kills metabolic active bacilli	++++	5 (4-6)	10 (8-12)
Rifampicin (R)	Bactericidal, kills semi-dormant bacilli	++++	10 (8-12)	10 (8-12)
Pyrazinamide (Z)	Bactericidal, kills intra-cellular bacilli	+++	25 (20-30)	35 (30-40)
Streptomycin (S)	Bactericidal, kills metabolic active bacilli	+++	15 (12-18)	15 (12-18)
Ethambutol (E)	Bacteriostatic	++	15 (12-18)	30 (25-35)
Thiacetazone (T)	Bacteriostatic	++	3	NA

Fixed Dose Combination (FDC)

The MOHSW introduced FDC and rifampicin-based regimens during the continuation phase in February 2006. This has reduced TB treatment duration from eight to six months. There are two categories of FDC:

- 4-drug FDC (RHZE) contains:
  - 150mg Rifampicin, 75 mg Isoniazid
  - 400 mg Pyrazinamide, 275 mg ethambutol
- 3-drug FDC (RHE) contains:
  - 150mg Rifampicin
  - 75mg Isoniazid
  - 275mg Ethambutol
- 2-drug FDC (RH) contains:
  - 150 mg Rifampicin
  - 75 mg Isoniazid
  - 2-drug FDC is used during continuation phase

FDCs have been used in the NTLP as 2-drug combinations (Rifampicin-Isoniazid and Ethambutol-Isoniazid) for many years. There is no new drug which is introduced in the current treatment regimen. Change brings a new challenge as DOT will be needed throughout the treatment and not just during the two-month intensive phase.

Treating TB: FDCs

There are various potential advantages of using FDCs to treat TB. These include:

- Increased patient acceptance and compliance with fewer pills
- Short duration of treatment because of RH in the continuation phase
- Improved drug management, ordering, procurement, distribution and dispensing/handling at different levels of the NTLP
- Lowered risk of misuse of single drugs and of emergence of drug-resistant TB due to reduced use of mono-therapy

There are several advantages of FDCs, including increased patient acceptance and compliance with fewer pills, short duration of treatment because of RH in the continuation phase, improved drug management, ordering, procurement, distribution and dispensing/handling at different levels of the NTLP, and a decreased risk of misuse of single drugs and of emergence of drug-resistant TB due to reduced use of mono-therapy.

Blister Colours and Colour Codes

The fixed dose combinations (FDC) are colour-coded. Each box of blister pack has 4-drug FDCs (RHZE), and each blister pack contains 28 tablets. Blister packs are packed into boxes and therefore each box of FDCs or Ethambutol plain contains 24 blisters with 672 tablets. Each box of blister pack with 4-drug FDCs (RHZE) has enough drug for 4 patients during intensive phase and 2 patients for 2-drug FDCs (RH) during continuation phase for patients between 31kg and 50kg in category I and III. Therefore to treat 4 patients during intensive phase and continuation, one box of 4-drug FDCs (RHZE) and 2 boxes of 2-drug FDCs (RH) are needed. A blister pack with 4-drug FDCs (RHZE) has enough drug for 4 patients during the intensive phase.

Currently Used Drugs According to Categories

These are the drugs which should be used, based by category:

- Category I = 2RHZE/4RH
- Category II =2SRHZE/1RHZE/5(RH)3E3
- Category III= 2RHZE/4RH
- Category IV = No agreed regimen

All patients (including those with HIV infection) who have not been treated previously should receive an internationally accepted first-line treatment regimen using drugs of known bioavailability. The initial phase should consist of two months of isoniazid, rifampicin, pyrazinamide, and ethambutol, which is the first-line regimen.

Figure 13: TB Category I & III Treatment Regimen Dose-Body Weight Relation

Duration of treatment	Drugs	CHILD Pre-treatment weight			ADULT Pre-treatment weight	
		5-10kg	11-20kg	21-30kg	31-50kg	>50kg
2 months intensive phase, daily observed	**{RHZE} 150/75/400/275**	**½ tablet**	**1**	**2**	**3**	**4**
4 months continuation phase, daily observed	**{RH} 150/75**	**½ tablet**	**1**	**2**	**3**	**4**

Figure 14: Category II Treatment Regimen Dose-Body Weight Relation

Duration of treatment	Drugs	CHILD Pre-treatment weight			ADULT Pre-treatment weight	
		5-10 kg	11-20 kg	21-30 kg	31-50 kg	>50 kg
2 months intensive phase, daily observed	S i.m	15 mg/kg	15 mg/kg	500 mg	750 mg	1 g*
	{RHZE} 150/75/400/ 275	½ tablet	1	2	3	4
1 month intensive phase, daily observed	{RHZE} 150/75/400/ 275	½ tablet	1	2	3	4
5 months continuation phase, 3 weekly observation	{RHE} 150/75/275	½ tablet	1	2	3	4
	{RH} 150/150**	½ tablet	1	2	3	4
	E 400	¼ tablet	½	1 ½**	3**	4**

***Patients older than 50 years of age should not exceed a dosage of 750 mg Streptomycin.**
Streptomycin should not be given to pregnant women.
****Notice the higher dose-formulation of RH and increase of dosage of ethambutol in the three weekly regimen!**

Monitoring Treatment Progress by Follow-up Sputum Examination

Follow-up sputum examinations are vital to determining a patient's progress, making decisions about care, and establishing a treatment outcome. Follow up is only needed in sputum smear positive cases. For smear negative and EPTB cases, clinical monitoring of the treatment response is sufficient (e.g. no fever, improved appetite, weight gain). Routine monitoring of the treatment response by chest x-ray is usually unnecessary.

Figure 15: Follow-up Sputum Examinations for Smear Positive PTB

	Category I patients	Category II patients
At the end of ...	2nd month 5th month	3rd month 5th month 7th month

For sputum smear positive cases, the continuation phase of treatment should begin at the end of the second or third month if the follow-up sputum is negative. For all other patients (sputum smear negative and extra pulmonary TB), the continuation phase should begin after the patient has taken all the required 56 doses of the initial phase of treatment.

Figure 16: Follow-up Action Based on Smear Results for Sputum Smear Positive Cases

Smear results	Action
Negative at end of initial phase: 2nd month (Cat. I) / 3rd month (Cat II)	Start continuation phase RH (Cat. I) / RHE (Cat. II).
Positive at end of initial phase: 2nd month (Cat. I) / 3rd month (Cat. II)	Extend initial phase RHZE by 1 month. Check early morning sputum at end of 3rd month (Cat. I) / 4th month (Cat. II).
If still positive at end of 3rd month (Cat. I) / 4th month (Cat. II)	Start continuation phase RH (Cat. I) / RHE (Cat. II). Send sputum sample to the TB reference laboratory for culture / susceptibility testing. Change treatment if necessary (refer NTLP manual)

What Happens After Six Months of Treatment?

Category I smear positive patients with negative sputum smear results at five months are bacteriologically cured. The patient should complete the full course of treatment (total of 168 doses and six months treatment).

Category I smear positive patients with positive sputum smear results at five months are experiencing treatment failure. Request a sputum for culture and sensitivity tests, close treatment card (outcome = failure), and open a new treatment card (type of patient = treatment after failure).

Other Category I and Category III patients have completed treatment after taking 168 doses (56 doses in initial phase and 112 doses in continuation phase). If patient has missed some doses, extend duration of treatment until all 168 doses are taken, which may be some days or weeks longer.

What Happens After Eight Months of Treatment?

Category II patients with negative sputum smear results at seven months are cured after taking 144 doses (eight months of treatment). Category II patients with positive sputum smear results at 5 months are experiencing treatment failure. Request sputum for culture and sensitivity tests, close the treatment card (outcome = failure), and open a new treatment card (Type of patient = Chronic excretors).

Figure 17: Follow-up Action Based on Smear Results at End of 5th Month

Smear results	Action
Negative at end of 5th (Cat. I) and 7th month (cat. II)	Patient cured bacteriologically. Continue treatment till all doses taken.
Positive at end of 5th (Cat. I and II)	Treatment failure. Close the TB Treatment card (outcome = treatment failure). For Cat. I open a new treatment card and retreat. For Cat. II refer NTLP manual.

Figure 18: Recording Treatment Outcomes

Outcome	Definition
Cured	Sputum smear positive who is smear negative at end of treatment and at least one previous occasion
Treatment completed	A patient who has completed treatment but for whom smear results are not available at the end of treatment
Failure	A patient who remains or becomes smear positive at 5 months or later
Died	A patient who dies for any reason during TB treatment
Defaulter	A patient who interrupts treatment for two consecutive months or more
Transferred out	A patient who has been transferred to another region and whose treatment result is not known.

Drug Resistant TB

Drug resistant TB is defined as TB for which anti-TB drugs have little or no effect against the TB-causing agent. It is divided into the following categories:

- Mono-resistant: Resistance to a single drug
- Poly-resistant: Resistance to more than one drug, but not the combination of isoniazid and rifampicin
- Multidrug-resistant (MDR): Resistance to at least isoniazid and rifampicin
- Extensively drug-resistant (XDR): MDR plus resistance to fluoroquinolones and at least one of the three injectable drugs (amikacin, kanamycin, capreomycin)

Mono-resistant is the most common single drug-resistance pattern is mono-resistance to isoniazid. In general, this pattern of resistance is not usually associated with a worse outcome and does not require modification of the treatment regimen (as long as there are 4 drugs in the initial phase and rifampicin is included throughout the full duration of treatment). Rifampicin mono-resistance occurs, but is uncommon and is seen mainly in patients with HIV infection. The reasons for this association are not known.

Poly-resistant is a general term used when the organism is resistant to more than one drug, but not the combination of isoniazid and rifampicin.

MDR-TB, resistance to at least isoniazid and rifampicin (the two most effective anti-tuberculosis drugs), has a major adverse effect on the outcome of treatment. Patients with TB caused by MDR organisms generally require treatment with second line drug regimens.

XDR-TB is MDR-TB plus resistance to the 2 most important classes of 2nd-line agents used in MDR-TB treatment: the fluoroquinolones and at least 1 of 3 injectable agents (amikacin, kanamycin, capreomycin). In addition to meeting the defining criteria, XDR-TB cases are often resistant to all four 1st-line agents. Consequently, patients with XDR-TB are significantly more difficult to treat and require specialized care.

Primary drug-resistance occurs in “New Cases”. It is drug resistance in a patient who has never been treated for tuberculosis or received less than one month of therapy. Secondary

(acquired) drug-resistance occurs in “Previously Treated Cases”. It is drug resistance in a patient who has received at least one month of anti-TB therapy.

Risk Factors for Drug Resistance

There are various risk factors for drug resistance which include:

- Drug dose too low
- Inadequate combination of drugs
- Duration too short
- Mono-therapy
- Patient does not take all TB drugs as prescribed
- Irregular and selective intake of drugs
- Use of sub-standard anti-TB drugs
- Adding a single drug to treatment regimen when patient is failing treatment

Diagnosis of Drug Resistant TB

Drug resistance should be suspected when treatment is unsuccessful (relapse, treatment failure, return after default, recurrent TB). It can be proven through culture and drug sensitivity testing (C/DST). However, the C/DST result takes at least 6 weeks and is expensive; it is therefore not a routine test and is performed on indication only.

Prevention of Drug Resistance

The prevention of drug resistance has two steps:

1. Provide high enough concentrations of drugs to kill susceptible organisms
2. Use drug combinations that are able to kill the small numbers of organisms resistant to one or another of the drugs

Drug resistance prevention also involves the use of a potent regimen (bactericidal, R and H) and multi-drug therapy for drugs to protect each other from acquiring resistance. Four drugs should be used in the initial phase in patients with high load of TB bacilli and two drugs should be used in continuation phase.

Drug resistance can also be avoided by using the correct prescription and standardised regimens. Ensure adherence with directly observed therapy (DOT), making sure that all daily doses taken as prescribed for the required duration.

These steps summaries the DOT strategy for preventing drug resistance by providing a potent regimen of adequate doses of an adequate number of drugs in combinations proven to be curative, and ensuring excellent adherence for the entire duration of treatment.

Key Points

- The two cornerstones of TB control are early case finding and adequate treatment
- The aim of TB treatment is to cure patients, and to prevent: relapse, death, drug resistant organisms, and further transmission
- TB treatment needs to be tailored based on the category of TB disease
- TB treatment must be monitored in order to assess adherence, identify side effects, and prevent drug resistance

UNIT 7: UNDERSTANDING HIV

Introduction

HIV is a pandemic affecting all nations but mainly those in sub-Saharan Africa. This unit will provide an overview of the basics about HIV. This will improve knowledge and attitudes and identify strategies to help reduce the impact of HIV in our workplaces and communities.

Objectives

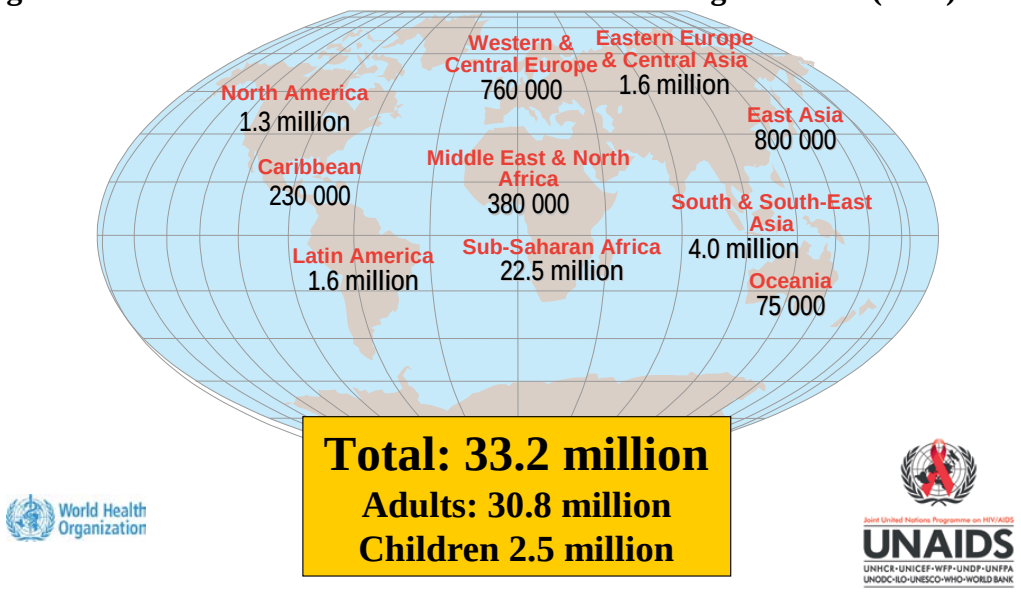
By the end of this unit, you should be able to:

- Explain the epidemiology of HIV and AIDS
- Describe HIV
- Discuss modes of HIV transmission
- Describe how the HIV virus interacts with the human immune system
- Explain progression of HIV infection

Adults and Children Living with HIV

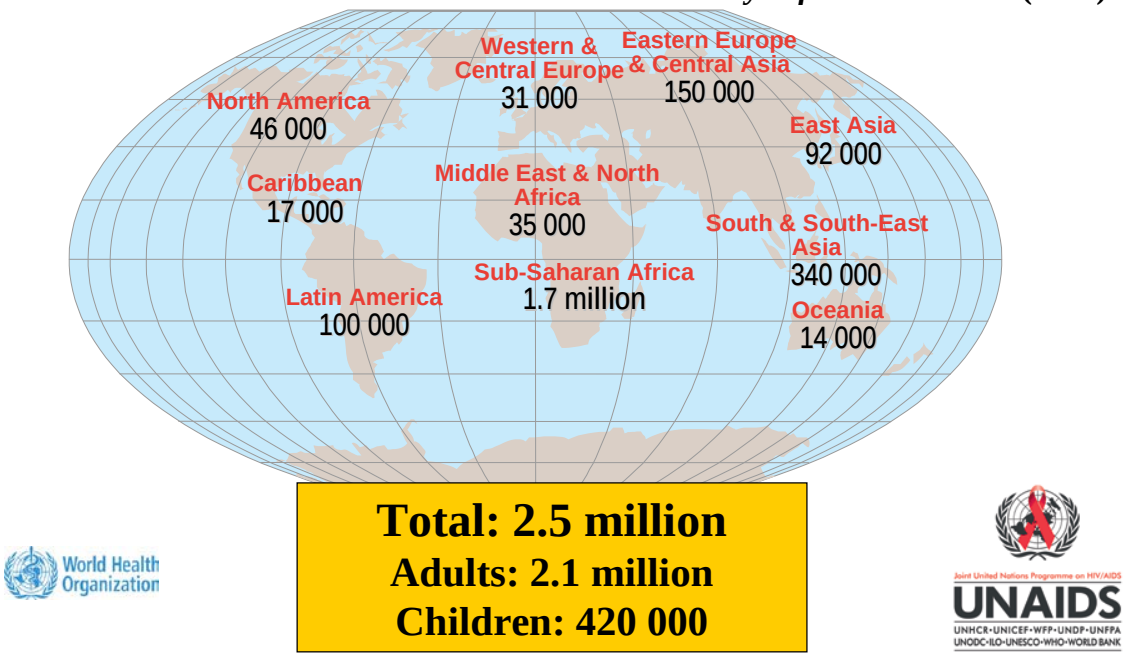
In 2007, there were over 6800 new HIV infections each day. More than 96 percent of new infections are in low and middle income countries. About 1200 new infections are in children under 15 years of age. About 5800 new infections are in adults aged 15 years and older of which almost 50 percent are women and about 40 percent are young people (age 15-24). HIV/AIDS is the fourth biggest killer in the world and most people are unaware they are infected. Young women are the most vulnerable.

Figure 19: Adults and Children Estimated to be Living with HIV (2007)



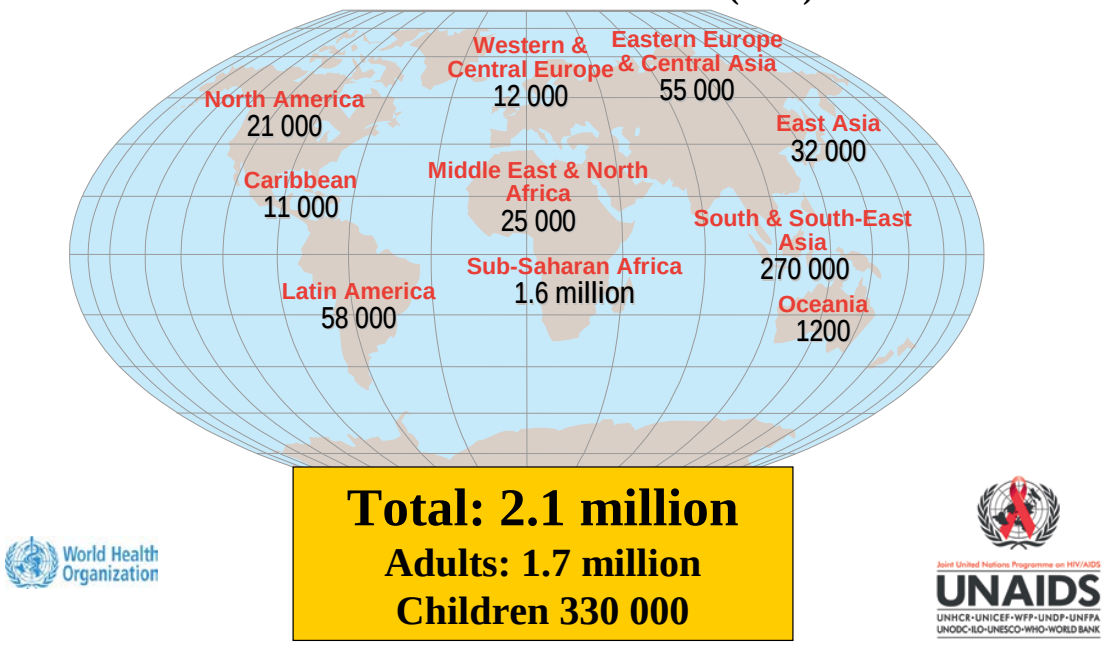
As is evident from the graphic below (Figure 20) sub-Saharan Africa is where most of the new HIV infections occur for adults and children.

Figure 20: Estimated Number of Adults and Children *Newly Infected* with HIV (2007)



By 2010, an estimated 106 million children under age 15 are projected to lose one or both parents, with 25 million of this group orphaned due to HIV/AIDS. The estimated number of orphans in Tanzania is 1,200,000 by year 2003. For example, 21 percent of families in Bukoba district were fostering an orphan.

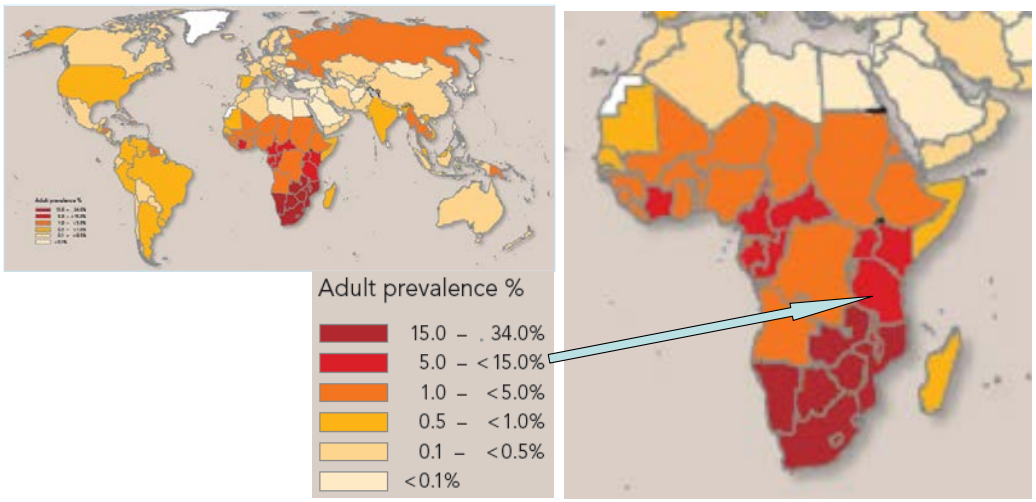
Figure 21: Estimated Adult and Child Deaths from AIDS (2007)



Prevalence of HIV and AIDS

Prevalence is the number of people that have a given disease at a certain point in time. Figure 22 (below) presents the percentage of people living with HIV/AIDS at the end of 2005. Note that Sub-Saharan Africa has the highest rates in the world and HIV is now the leading cause of death in the region. There were an estimated 2.8 million new HIV infections there in 2006.

Figure 22: Prevalence of HIV/AIDS at the End of 2005



38.6 million people [33.4-46.0 million] living with HIV, 2005

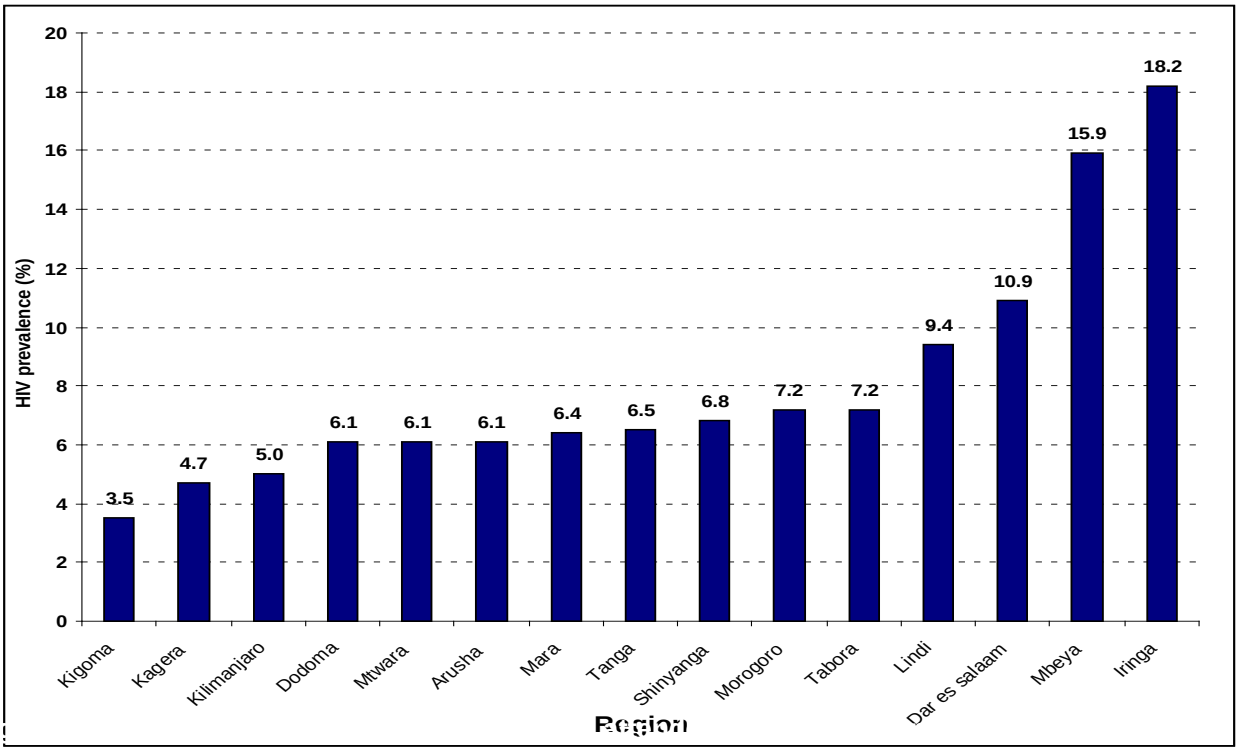
Prevalence of HIV and AIDS in Tanzania

The overall prevalence of HIV and AIDS in Tanzania is seven percent. Distribution by region is as follows:

- Dar es salaam -17.4%
- Iringa -17.4%
- Mbeya -15.2%
- Arusha -11.7%
- Ruvuma - 10.0%
- Rukwa - 7.3%
- Mwanza - 7.2%
- Tabora - 7.2%
- Tanga - 7.2%
- Coast - 6.8%
- Shinyanga - 6.3%
- Mara - 6.2%
- Manyara - 5.9%
- Singida - 5.4%
- Morogoro - 5.4%
- Kilimanjaro - 5.1%
- Kigoma - 4.5%
- Mtwara - 3.6%
- Lindi - 3.2%

The highest prevalence, or number of HIV infections, among antenatal care (ANC) attendees was in Iringa (18.2%), Mbeya (16.9%) and Dar es Salaam (10.9%). Those areas also have the highest prevalence in the country for HIV (Mbeya 14%, Iringa 13%, Dar es Salaam 11%). Note that HIV prevalence is declining in some areas such as Kagera.

Figure 23: Prevalence of HIV Infection Among Antenatal Clinic Attendees by Region, (2005-2006)



Human Immunodeficiency Virus

HIV stands for "Human Immunodeficiency Virus." It is a retrovirus that causes AIDS. A person is said to be HIV infected when antibodies of the virus are detected in the blood. Because HIV is a virus, it needs to enter other cells in order to multiply. It is not possible to tell if someone has HIV/AIDS just by looking at them; history taking, clinical examination and testing are necessary to diagnose someone with HIV/AIDS.

HIV consists of a cylindrical center surrounded by a sphere-shaped lipid envelope. The center consists of two single strands of Ribonucleic Acid (RNA). HIV uses an enzyme reverse transcriptase to make DNA (from RNA) which gets incorporated into the host cell (as provirus). HIV is a retrovirus that uses its RNA and the host's DNA to make pro-viral DNA.

Figure 24: HIV Structure

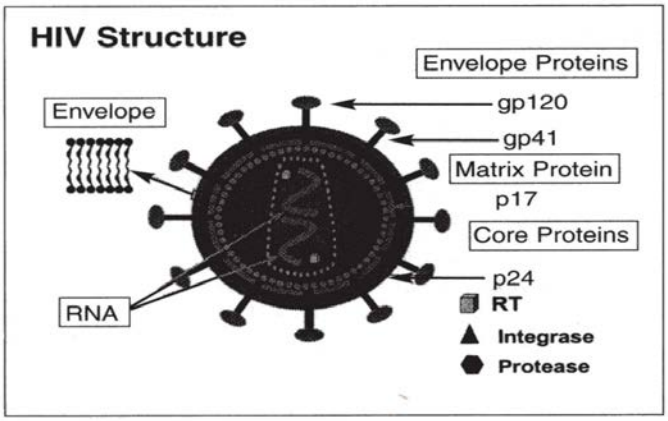


Figure 3. The Human Immunodeficiency Virus

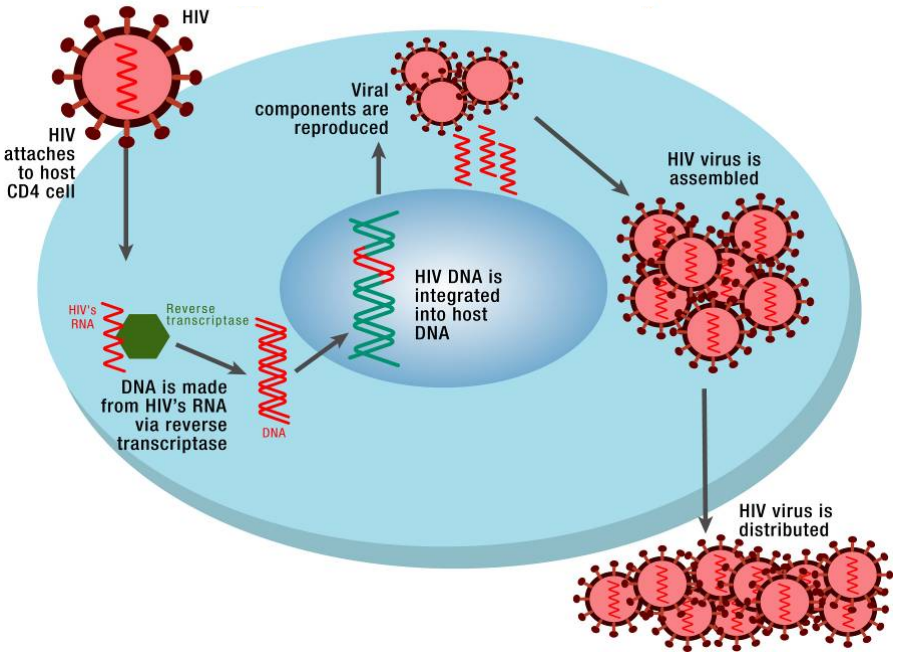
HIV Lifecycle

The major steps in the lifecycle of HIV are as follows:

- **Attachment** though the interaction between viral glycoprotein and the CD4 receptor and co-receptors
- **Fusion and release** of RNA into the cytoplasm of the cell
- **Reverse transcription** to produce proviral DNA (RT)
- **Integration** of proviral DNA to host DNA (intergrase)
- **Synthesis** of viral proteins (protease)
- **Assembly** and release of a complete virion

When HIV binds to the CD4 cell, it turns that cell into an HIV "factory," creating billions of the HIV viruses until the CD4 is eventually destroyed. The new HIV viruses then infect other CD4 cells, repeating the cycle again and again, producing more HIV viruses.

Figure 25: HIV Lifecycle

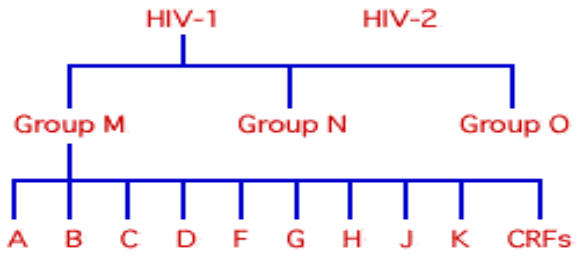


HIV-1 Subtypes

There are 2 types of HIV: HIV-1, of which there are many subtypes, and HIV-2. Both HIV-1 and HIV-2 are transmitted in the same ways, but HIV-2 is less easily transmitted and almost exclusively found in West Africa. Globally, HIV-1 is much more common. There are 9 genetically distinct subtypes of HIV-1. Of these, Group M is the most common of the three groups of HIV-1, with more than 90% of HIV-1 infections. Group O appears to be restricted to West-Central Africa only and Group N is extremely rare and has only been found in Cameroon. Sub-types C and A are the most common in Tanzania, but D is also present.

A person can be co-infected with more than one different sub-type. Occasionally, two viruses of different sub-groups can meet in a cell of an infected person, mix together, and their genetic materials create a new hybrid virus. These hybrid viruses are called "Circulating Recombinant Forms" or CRFs and generally do not survive for long.

Figure 26: HIV-1 Subtypes



Modes of HIV Transmission
HIV can be transmitted through:

- Unprotected sexual contact with an infected partner/s
  - Male-to-female, female-to-male, and male-to-male
- Contact with HIV-infected blood/blood products
  - Blood transfusion, IDU through needle-sharing, needle stick accidents, unsterilised needles
- Mother-to-Child transmission
  - In utero, during delivery, through breast feeding

Worldwide, unprotected sexual transmission is the most predominant mode of HIV transmission. According to the Care and Treatment Guidelines 2008, in Tanzania, 90% of HIV infections are sexually transmitted, 5-10% are transmitted during pregnancy, 10-20% in labour and delivery, and 5-20% are transmitted through breastfeeding .
HIV cannot be transmitted by casual contact, surface contact, or insect bites.

Some biological factors that increase risk of transmission include infectiousness of the host (amount of the HIV virus in blood), susceptibility of the recipient (presence of a sexually transmitted infection, health of recipient), and viral properties.

Factors that decrease the risk of transmission include: abstinence or reduction in number of sexual partners, correct and consistent use of condoms, and antiretroviral therapy (ART). Antiretroviral therapy may decrease, but not eliminate, the risk of HIV transmission and has been shown to decrease mother-to-child transmission. Male circumcision also reduces the risk of acquisition of HIV for the circumcised person.

Risk Factors for HIV Acquisition
Biological (including STDs), social, economic, and behavioural risk factors may increase HIV transmission rates. Social factors facilitating HIV transmission include:

- Social Mobility
  - Mobility depending on socio-economic factors
  - HIV/AIDS follows routes of commerce
  - Sex work
- Socio-economic factors
  - Poverty
  - Children leave home to work at earlier age
  - Loss of community cohesion
- Stigma and Denial
  - Denial and silence is still the norm
  - Stigma prevents acceptance of the problem and early care-seeking

- Cultural Factors
  - Traditions, beliefs and practices (such as polygamy, wife inheritance, female circumcision)
  - Culture can create barriers that prevent people, and especially women, from taking precautions
- Gender inequalities
  - In some cultures men are expected to have many sexual relationships
  - Women suffer gender inequalities, often economic in nature
- Awareness
  - Lack of information necessary to understand and prevent HIV
  - False beliefs about effects of ART
- Conflict and social unrest
  - Civil unrest, especially armed conflict and displacement of people
  - High-risk behaviour of military personnel
- Behavioural Factors
  - Sex practises (unprotected sexual behaviour, particularly among mobile populations with multiple partners)
- Alcohol consumption and drug use
  - Impaired judgment, casual sexual contacts
  - Sharing of needles and equipment

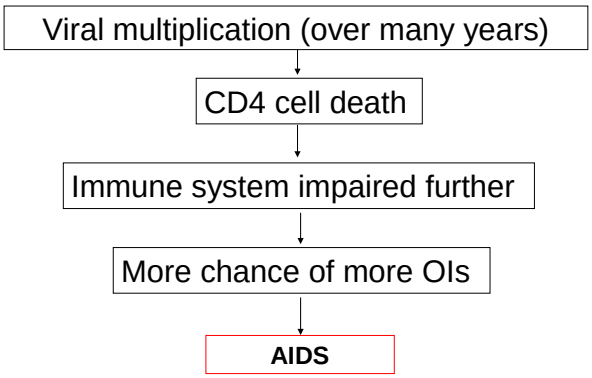
How Does HIV Make You sick?

1. Immune suppression:
   - HIV attacks the white blood cells which protect us from illness
   - Over time, the body's ability to fight common infections is lost and opportunistic infections occur
2. Direct infection of major organ systems:
   - HIV directly affects the brain, gut, lungs, kidneys and heart

HIV uses CD4 cells for reproduction. CD4 cells are cells that carry CD4 receptors on their surface. These are protein molecules and are found on the surface of a variety of cells of the immune system, but mainly on T4-lymphocytes (T-helper cells). T4-lymphocytes are a type of white blood cell that activate the immune system to fight disease. Once infected T-cells are destroyed, the immune system deteriorates and becomes vulnerable to infections.

Many people find it helpful to think of CD4 cells as "soldiers" in the body. Usually any infection entering the body is fought off by the soldiers (CD4 cells). Strong soldiers make a strong immune response and the infection is fought off. However, HIV damages these soldiers, finally killing them. The soldiers are either too weak or too few in number to fight off infection. The immune system is progressively weakened.

Figure 27: How HIV Causes AIDS



Consequences of HIV Infection

With HIV, many CD4 cells die (normal range of 600-1500 cells/mm3), and although the body produces new CD4 cells, the HIV virus uses the CD4 cells to make more viruses. Slowly, over time, CD4 cells are depleted. With loss of CD4 cells, the immune system weakens and many opportunistic infections, some cancers, and other conditions such as skin diseases may occur.

HIV Progression

HIV progresses through three main stages: acute infection (early immune depletion), clinical latency (intermediate immune depletion), and AIDS (severe immune depletion).

Acute infection is characterized by:

- Skin rash, sore throat, muscle aches, confusion, etc.
- Generalized lymph glands
- High viral load at the beginning
- CD4 is normal >500/mm3
- HIV tests usually negative

Illness is followed by full recovery and later patient becomes antibody positive. This stage may not be remembered by patient and is often misdiagnosed as typhoid, mental illness, allergies, etc.

During clinical latency stage, the HIV-infected person may appear to be healthy for many years and then minor symptoms and signs of HIV infection begin to appear. At CD4 cell counts over 500 cells/ml, many complications overlap with conditions found in the general population (malaria, bacterial pneumonia, tuberculosis, minor skin conditions), although they may be more frequent. At CD4 counts between 200 and 500 cells/ml, other conditions, or opportunistic infections, begin to appear (Kaposi sarcoma, oral or vaginal candidiasis, herpes zoster, etc).

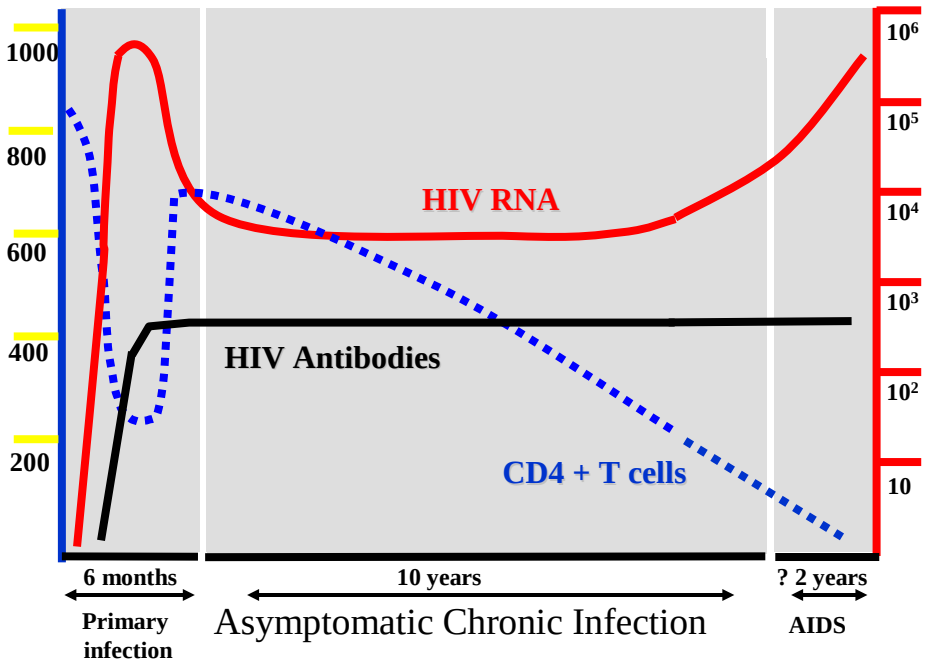
During AIDS (severe immune depletion), the HIV-infected person develops life threatening infections and malignancies such as wasting syndrome, PCP, atypical extrapulmonary TB, oesophageal candidiasis, recurrent invasive herpes simplex, Kaposi sarcoma, and cryptosporidiasis. The viral load increases and the CD4 cells count falls to less than 200 cells/mm.

The graph in Figure 28 (below) represents the typical course of HIV infection, untreated. Throughout the course of HIV infection, the virus replicates and immunodeficiency

progresses steadily, despite the absence of observed disease during the so-called clinical latency period.

The viral load is very high within the first month of infection. This is called the window period, when the infection has just occurred until the time when antibodies are first detected in the serum. The patient is very infectious during this stage, though person will test negative for HIV at this point. Typically the patient will have flu-like symptoms including fever, fatigue, pharyngitis, lymphadenopathy and/or a rash. This high level of virus means the CD4 count drops steeply as it is being attacked by HIV. Then, over the next few months, the immune system makes an attempt to fight the virus. Viral load drops steeply and CD4 count is able to rise slightly. The viral load is very high within the first month of infection. After this initial stage, the HIV disease may then remain latent in the body during which a patient has no symptoms. This asymptomatic phase varies but may last up to 15 years in some patients. Eventually however, the viral load starts increasing as replication continues. The CD4 cells are progressively overwhelmed and the patient becomes symptomatic. This process involves active viral replication during which the viral load gets extremely high and the CD4 cell gets extremely low, dropping to very low levels (sometimes less than 50).

Figure 28: Natural Course of HIV Infection



Key Points

- Tanzania has a high prevalence (7.0%) of HIV
- HIV is transmitted through unprotected sexual contact with an infected partner/s, contact with HIV-infected blood/blood products or other body fluids, and mother-to-child transmission
- HIV causes immune suppression and consequent occurrence of opportunistic infections and the direct infection of major organs

UNIT 8: CLINICAL MANIFESTATION OF HIV AND AIDS AND MANAGEMENT OF OPPORTUNISTIC INFECTIONS

Introduction

Clinical staging is the process of classifying HIV infected and AIDS patients depending upon the degree of severity of infection and which opportunistic infections they have. It is a useful tool for assessing eligibility of TB, HIV and AIDS patients on ART. This unit aims to equip participants with knowledge on WHO clinical staging, common opportunistic infections (OIs) in PLHIV, and management of OIs.

Objectives

By the end of this unit, you should be able to:

- Explain the importance of WHO clinical staging
- Explain the WHO staging for persons with HIV and AIDS (PLHIV)
- Describe common opportunistic infections (OIs) and their management

The Importance of Clinical Staging

The clinical staging of HIV is important in assessing disease severity and determining prognosis, monitoring disease progression, as a criterion for ARV therapy, and in deciding to switch or stop therapy particularly in situations where CD4 is not available. Note that clinical staging should be used where HIV infection has been confirmed.

WHO Staging and Disease Correlation

The following tables (Figures 29-30) depicts how the CD4 count and viral load are connected, and how as one goes up (viral load), the other will decrease (CD4). When CD4 counts begin to decrease, HIV disease progresses. Different HIV-related diseases (opportunistic infections) are related to declines in immune function. This is one way to assess (without the use of CD4 counts) the severity of immune suppression.

Figure 29: WHO Staging and Disease Correlation (Stages 1 and 2)

WHO Stage	Some Typical Diseases (Staging of diseases is approximate and not the same for all individuals)	CD4 Count	Viral Load
I Asymptomatic Persistent Generalized Lymphadenopathy	No symptoms or signs of any illness Patients have enlarged lymphnodes	>500	1000 to 1000000
II Minor Symptoms	Herpes zoster, Recurrent respiratory tract infections, moderate weight loss, angular cheilitis, oral ulcerations, papular pruritic eruptions, seborrhoeic dermatitis, fungal nail infections of fingers	350-500	1000 to 10000

Figure 30: WHO Staging and Disease Correlation (Stages 3 and 4)

WHO Stage	Some Typical Diseases (Staging of diseases is approximate and not the same for all individuals)	CD4 Count	Viral Load
III Moderate Symptoms	Unexplained weight loss, chronic diarrhoea, persistent fever, Oral Candidiasis, Oral Hairy Leukoplakia, Pulmonary Tuberculosis, severe presumed bacterial infections, acute necrotising ulcerative stomatitis, gingivitis, or periodontitis	350 to 200	10000 to 100000
IV AIDS-defining Illness	HIV wasting, Pneumocystis pneumonia, recurrent severe bacterial pneumonia, oesophageal candidiasis, extrapulmonary TB, Kaposi's Sarcoma (KS), MAC, Severe Chronic Herpes Ulcers, Toxoplasmosis	<200	10000 to 1,000,000

Note that while this chart shows what CD4 usually corresponds with a particular clinical stage, we do not use the CD4 count to determine the clinical stage. The staging system was developed to be used in the absence of laboratory findings such as CD4 and viral load. So we use clinical signs and symptoms to determine the clinical stage.

Common Opportunistic Infections and Their Management

Opportunistic infections (OIs) are caused by organisms that would not cause disease in a person with a normal immune system. PLHIV are susceptible to OIs because their immune systems have been suppressed and are not able to fight even common infections. OIs can be fungal, parasitic, viral, or bacterial. Other conditions not directly caused by infections also occur such as cancers and skin conditions. Monitoring CD4+ white blood cells can help health care providers know which OIs to watch for and what treatment options to consider. Examples of common OIs include:

- Pneumocystis jirovecii pneumonia
- Recurrent severe bacterial pneumonia
- Oesophageal candidiasis
- Tuberculosis (pulmonary or extrapulmonary)
- Kaposi's Sarcoma (KS)
- MAC, Severe Chronic Herpes Ulcers
- Toxoplasmosis
- Unexplained weight loss
- Chronic diarrhoea
- Persistent fever
- Oral Candidiasis
- Oral Hairy Leukoplakia

Oral Thrush and Other Oro-Oesophageal Diseases

Treatment for oral thrush should include advice on soft foods, Nystatin oral suspension, Clotrimazole, Ketoconazole, and Fluconazole if oesophageal disease. Note that Ketoconazole can cause certain drug interactions that need to be monitored.

Management of herpes simplex virus infection:

- Acyclovir: 200-400 mg 5 times/d for 10 d

Most of the time aphthous ulcers do not need to be treated unless they are severe and persistent: Topical solutions are preferred initially. The mainstay of treatment for aphthous ulcers would be to consider initiating antiretroviral medication. CMV can also cause ulcers (in addition to HSV). Aphthous ulcers occur less frequently when patients start ART and their immune systems improve. For severe and persistent aphthous ulcers that are difficult to manage, the following can give some relief:

- topical solutions (preferred)
- Prednisolone: 10-20 mgs
- Oral solution of chlorpheniramine
- Viscous lidocaine, and antacid solution *(Magic mouthwash)*

Diarrhoeal Illness

For diarrhoeal illness, empirical treatment is cotrimoxazole and metronidazole, which are effective for Isosporiasis, Giardiasis, and bacterial infections. The symptomatic treatment is anti-diarrhoeal drugs. The health worker should also perform a volume status assessment (often need IV fluids). ART is the best treatment for persistent /resistant diarrhoea (particularly cryptosporidiosis). Note that diarrhoea is very common. If possible, do a stool microscopy and start empiric treatment which can be changed based on the stool results. Primary treatment of diarrhea is with fluid hydration (either orally or IV if severely dehydrated) with appropriate electrolytes. If bloody diarrhea, consider treating for bacterial infection (ie. Shigella or salmonella).

Pneumocystis Jirovecii Pneumonia

Pneumocystis Jirovecii Pneumonia has been reclassified and is no longer referred to as protozoan, but rather fungal. It is also now referred to as Pneumocystis jiroveci, although the term PCP is still used. A person with PCP or Pneumocystis jiroveci presents with cough, shortness of breath/dyspnea, and fever. Patients with suspected PCP should be started on a high dose cotrimoxazole 20/100 mg/kg in 4 doses. If the patient is hypoxic and very sick, the patient should be admitted to the hospital and given IV fluids (such as NS, DNS). After that, the patient should be given Prednisolone 40mg bid on days 1-5, 40mg od on days 6-10 then taper off dose gradually. Oxygen should be given to those in respiratory distress (either cyanosis or oxygen saturation <80%). Recall that SS means single strength whereas DS means double strength.

Figure 31: Adult PCP Management:
Dose of Cotrimoxazole

Patient weight kg	**Dose in mg**	**Dose in tabs 80/400 SS**
30-45	960mg x 4/day	2SS (1DS) x 4/day
45-60	1920mg x 3/day	4SS (2DS) x 3/day
>60	1920 x 4/day	4SS (2DS) x 4/day

Paediatric PCP is managed by administering a high dose cotrimoxazole IV, 20mg/kg TMP/day given every 6 hours for 21 days or oral cotrimoxazole at the same dose if an IV is not available. The patient should also be given Prednisone at 2mg/kg/day for 7-14 days (taper if more than 7 days). Secondary prophylaxis using cotrimoxazole is recommended after an acute episode of PCP.

Cryptococcal Meningitis

A patient with Cryptocccal Meningitis presents with a severe headache developing gradually and worsening over several weeks. This illness is associated with neck stiffness. A lumbar puncture both helps in diagnosis and relieves the severe headache. If the cryptocccal meningitis is acute, the health worker should treat with Fluconazole 400mg OD intravenous or Ampho 0.7 mg/kg/day IV x 14 days. For maintenance, give indefinite treatment with oral Fluconazole (200mg OD) until the patient has a sustained CD4 increase greater than 200 for six months.

Pruritic Papular Eruptions (PPE)

PPE is caused by Eosinophilic folliculitis in which itchiness causes scratching, which leads to lesions. The condition is worse in a person with a low CD4 count, especially below 200. Antihistamines may relieve the itching. Note that it is important to distinguish PPE from other skin conditions such as syphilis, eczema, Kaposi Sarcoma, or other skin infections.

Kaposi Sarcoma

Kaposi Sarcoma is a common cancer in PLHIV and can occur at any level of CD4. The less extensive disease responds to ART, but patients with more severe Kaposi Sarcoma should be referred.

Herpes Zoster (Shingles)

This illness can occur at any CD4 level, but is more frequent at lower CD4 counts (CD4 < 350). It responds to acyclovir (800 mg x5/day for up to 10 days) if begun within 72 hours of onset of symptoms. Post-herpetic neuralgia is a serious complication. Use amitryptyline for burning pain, Carbamazepine for stabbing pain, and be sure to note that the Opthalmic zoster requires urgent ophthalmic evaluation to prevent blindness. It is also important to be careful using carbamazepine (it has liver toxicity and needs to be monitored for side effects (literature does not show great success of pain control with this medication). Start with low dose amitryptiline (not high dose). Slowly titrate up (in clinical practice if there is no improvement in pain at doses 50 mg or less, most likely higher doses will not help much).

Molluscum Contagiosum and Other Dermatologic Conditions

This condition is very uncomfortable but not invasive, and it responds to ARVs. Patients may feel stigmatized by this condition. Seborrheic dermatitis and psoriasis are other skin conditions which may affect PLHIV. Note that syphilis can mimic all of these skin conditions.

HIV Manifestations in Children

Children get many of the same illnesses as seen in adults. Certain illnesses, however, occur primarily in children. These include lymphoid interstitial pneumonitis (LIP), malnutrition and failure to thrive, and parotid enlargement.

Common Paediatric OIs include:

- Bacterial Pneumonia
- Wasting Syndrome/Failure to thrive
- Candida oropharyngitis/oesophagitis
- PCP
- Lymphoid Interstitial Pneumonitis (LIP)
- HIV Encephalopathy/Progressive multifocal leukoencephalopathy (PML)
- Anaemia
- Pulmonary/Extrapulmonary TB
- Dermatitis

Opportunistic Infection Prophylaxis

Opportunistic infection prophylaxis is preventive treatment to help patients avoid disease. It is very useful among HIV-infected persons. In Tanzania, cotrimoxazole is used for the prevention of pneumocystis pneumonia and other infections and Isoniazid Preventive Therapy (IPT) is used as well to prevent TB.

Cotrimoxazole Prophylaxis

Cotrimoxazole prophylaxis greatly reduces the risk of Pneumocystis jirovecii (jiroveci) pneumonia. It also reduces the risk of bacterial pneumonia, toxoplasmosis, malaria, isospora, and salmonella bacteremia.

CTX Prophylaxis in Adults

CTX prophylaxis should be prescribed to adults who are:

- Asymptomatic HIV-infected individuals with CD4 count < 200 cells/cu mm
- Clinical Stage III or IV
  - All adults with symptomatic HIV disease
  - Pregnant women from second trimester and before 37 weeks (give with folate/vitamin)

Dose: 160/800 mg daily

- 2 single strength tablets (80/400 mg tablets) daily

CTX Prophylaxis in Children

- All children born to HIV positive women should start at 6 weeks of age until proven HIV negative or CTX intolerant
- All children <1 yr of age documented to be HIV positive regardless of symptoms or CD4 %
- After 1 yr of age, recommended for symptomatic children (WHO clinical stages 2,3 and 4) or children with CD4 <25%
- All children who begin CTX prophylaxis should continue until the age of 5 when they can be reassessed

Note that for children, the dose is based on weight and will need to be adjusted (frequently) as the child grows. Additionally, adult clinical staging and CD4 count thresholds for CTX initiation or discontinuation apply to children older than 5 years of age. It may be questionable to start CTX earlier 6 weeks old.

Key Points

- WHO clinical staging and case definition of HIV help health workers manage the illness
- Opportunistic infections occur in persons with HIV disease because their immune systems are suppressed
- CPT is very useful and prevents several OIs
- IPT can be used in some situations
- Treating OIs is very important for persons living with HIV

UNIT 9: MANAGEMENT OF HIV INFECTION AND AIDS

Introduction

The main goal of antiretroviral therapy (ART) is to prevent morbidity and mortality in people with HIV and AIDS by suppressing viremia and thereby restoring immune capacity. In so doing, ART both prolongs and improves quality of life. This units aims to equip health workers with knowledge and skills on how to manage patients with HIV infection and AIDS using ARVs.

Objectives

By the end of this unit, you should be able to:

- Describe goals and benefits of ARV therapy
- Explain how ARVs work
- Discuss ART eligibility
- Outline first and second line ARV drug regimens used in Tanzania for adults and children

Goals and benefits of ARV Therapy

The goals of ARV therapy include:

- Maximal & durable suppression of viral load to undetectable levels, thus:
  - Halting disease progression
  - Preventing/delaying resistance
  - Significantly interrupting viral replication
- Restoration/preservation of immune function
- Improve quality of life
- Reduce HIV morbidity/mortality (prolong survival)

ARV therapy benefits both adults and children and changes HIV from a terminal (fatal) disease to a "chronic disease." It prevents opportunistic infections, alters or reverses the course of existing opportunistic infections, decreases hospitalizations, increases survival, improves quality of life, restores hope, and reduces HIV transmission. In addition, ARV therapy improves the immune system and so prophylaxis can be stopped as the CD4 increases.

ARV Drugs

There are five classes of ARV drugs. They are:

1. Nucleoside Reverse Transcriptase Inhibitors (NRTI)
   - Stavudine, Lamivudine, Zidovudine, Abacavir and Didanosine
2. Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)
   - Nevirapine and Efavirenz
3. Protease Inhibitors (PI)
   - Saquinavir, Kaletra (Ritonavir and Lopinavir)
4. Fusion inihibitors- not available (e.g T20)
5. Integrase inhibitors – not currently available

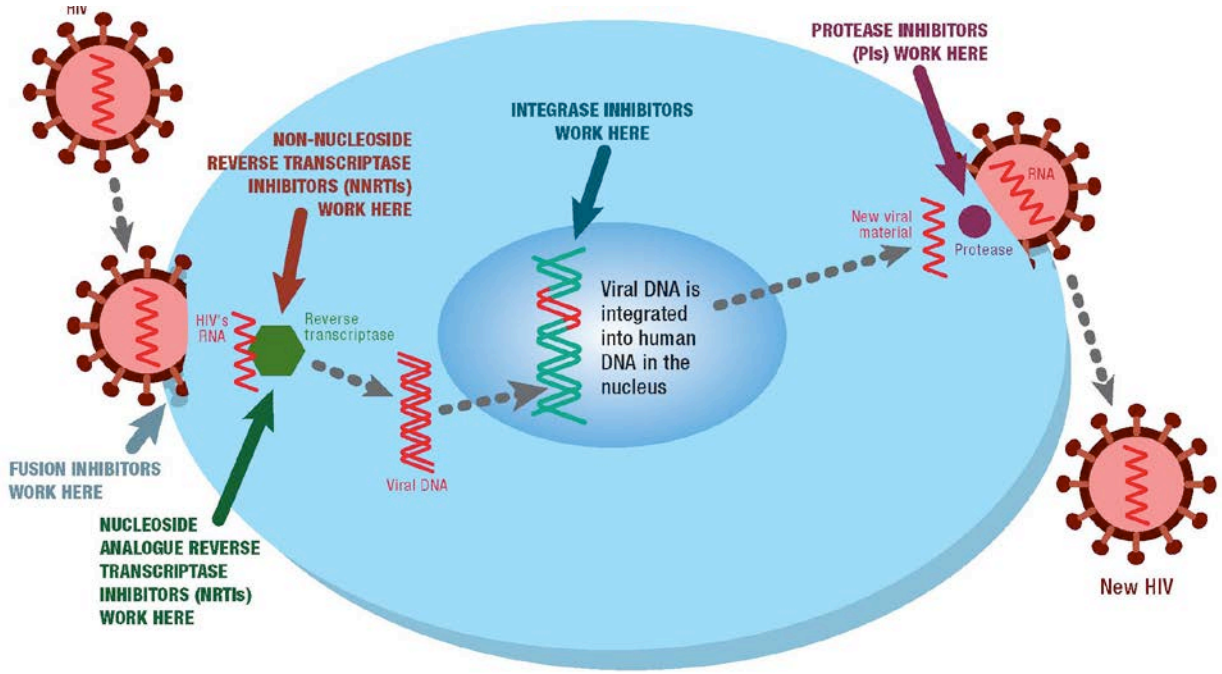
ARVs: Mode of Action

ARVs fight HIV by interfering with its reproductive cycle. The main ways in which these drugs work are by:

- Inhibiting reverse transcriptase enzyme to interrupt the production of proviral DNA
- Preventing formation of proviral DNA

- Inhibiting maturation of virus by interrupting the protein processing and virus assembly

Figure 32: How ARVs Work



Assessing ART Eligibility

Assessing ART eligibility requires:

- Laboratory confirmed HIV infection
- Clinical assessment of HIV infection and HIV Disease (WHO staging system)
- Assessment of CD4 cell count

Preparing the Patient for ART

Preparing a patient for ART involves conducting a baseline clinical assessment, preparing the patient for lifelong treatment, and taking a baseline in depth medical history. This medical history should include information such as:

- Current symptoms
- Previous/current ART use
- Use of traditional remedies
- Opportunistic infections (OIs), e.g. TB
- Other major illnesses
- Length of time since diagnosis of HIV infection

Perform a thorough physical exam, paying close attention to the patient's weight, skin, mouth, and eyes. The potential toxicities of ART could affect major illnesses and other non-HIV related illnesses. Such illnesses include liver disease (HBV, HCV), cardiac disease, diabetes, and dsylipidemia. Baseline laboratory investigation (CBC, LFT, CD4) should also be conducted. The health worker will also want to exclude TB disease by using the TB screening tool; if the patient has any of the following symptoms consider them a "TB suspect" and investigate:

- Cough≥ 2 wks?
- haemoptysis?

- Fever≥ 2 wks?
- Weight loss ≥ 3kg?
- Night sweats

When to Consider ART

The patient must express preparedness and be ready to start and commit to therapy for life. The decision to begin treatment should be individualised based on:

- The degree of HIV-related disease
- The degree of HIV-related immunosuppression
- A solid adherence plan and a working relationship with the health care system

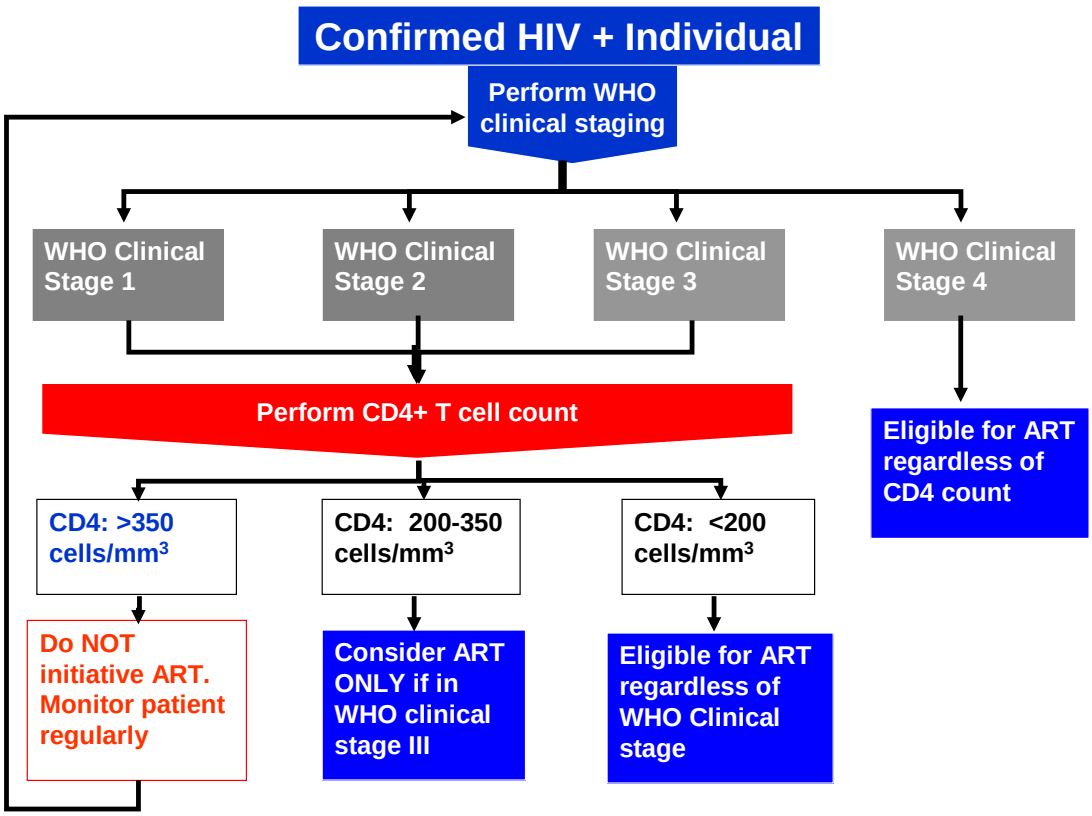
When to Start ART in Adults

ART should be initiated for:

- All patients who are in WHO stage IV, regardless of CD4+ cell count
- All patients who have a CD4+ count ≤ 200 cells/mm3 regardless of stage of illness
- ART should be considered those who are in WHO Stage III clinical criteria and have CD4 cell counts ≤ 350/mm3

Remember that CD4 cells are a type of T-cell (other types of T-cells include CD8, CD3, etc). CD4 cells are the specific type of T-cells that HIV targets.

Figure 33: Criteria for ART Initiation in Adults and Adolescents



When to Start ART in Children

When initiating ART in children, consult with experienced HIV physician. In general, the following children should begin ART:

- Any child WHO Stage 4
- Infants younger than 18 months with CD4% under 20%
- Infants older than 18 months with CD4% under 15%
- Children older than 6 years with CD4 <200 cells/ml (as in adults)

Note that some CD4 machines in regions and districts may not be able to provide percentages, so they will need to be calculated them from the complete blood count (CBC).

Figure 34: Criteria for ART Initiation in HIV-Exposed Children UNDER 18 Months

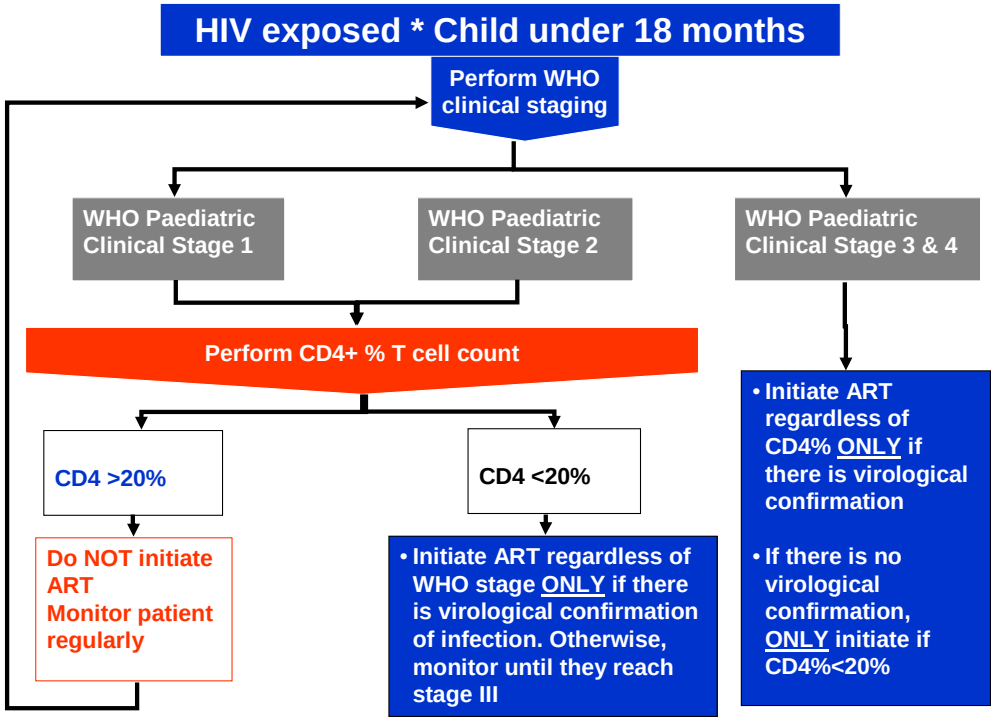
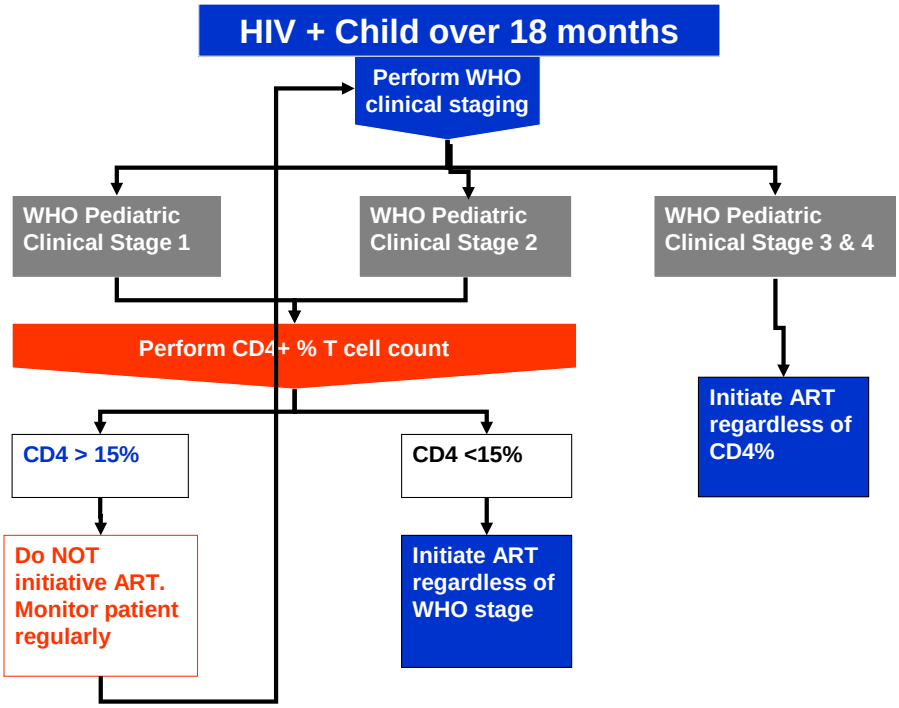


Figure 35: Criteria for ART Initiation in HIV-Positive Children OVER 18 Months



Virological confirmation (DNA-PCR) is only done in 2 centres in Tanzania: Muhimbili and Bugando.

Figure 36: Special Considerations of ART in TB and HIV Co-infected Patients

CD4 > 350	Treat TB, reassess for ART after completion of TB treatment
CD4 200-350	Treat TB first for 2 months before starting ART
CD4 < 200 or CD4 < 15% or WHO HIV stage 4	Begin ART as early as 2 weeks after initiation of TB treatment

Tanzania Recommended First-Line Regimens for Adults/Adolescents

The recommended first-line regimens for adults and adolescents in Tanzania are:

- AZT + 3TC + NVP (female of childbearing age) or EFV (male)
    - If anaemic (Hg < 7.5 gm/dl) or if AZT is contraindicated:
        - Replace AZT with Stavudine (d4T) 30mg regardless of body weight =
        - d4T + 3TC + NVP (female) or EFV (male)
    - If affordable and available:
        - TDF + FTC + EFV (male) or NVP (female)

Nevirapine should be taken at a half dose for the first two weeks to avoid toxicities. If the patient is anaemic, d4T replaces AZT. d4t may cause peripheral neuropathy. There is a risk of lipodystrophy with the use of d4T-40; prescribe d4T-30 instead. Efavirenz is recommended in patients on Rifampicin, NOT Nevirapine. 3TC is the safest ARV drug out there, and does not cause anaemia or very many other side effects.

Recommended Second-Line Regimens for Adults and Adolescents in Tanzania

- 2 *new* NRTIs + (boosted) PI:
  - ABC (Abacavir) + DDI (Didanosine) PLUS:
    - **Either** LPV/r-Lopinavir/ritonavir (Kaletra or Aluvia)
    - **OR** SQV/RTV (Saquinavir/ritonavir)
  - Alternative Second-Line Regimens
    - TDF instead of ABC or DDI
    - Can use Atazanavir instead of Kaletra

The second-line contains new NRTIs not previously used in the first-line regimen. Boosting, which means the additional use of a smaller dose of ritonavir, has positive effects with less severe side effects. Two protease inhibitors, when used in conjunction, can enhance the effectiveness of the other. This is referred to as PI Boosting. For example, low dose Ritonavir, when used in conjunction with another PI, can enhance the effectiveness of that PI. Among PIs, RTV is most potent inhibitor of P450 enzyme system. Low dose RTV will slow metabolism of LPV and other PIs. RTV is used to increase the level of LPV or SQV when given concurrently, reducing dose and dosage frequency. The combination LPV/RTV or SQV/RTV has multiple benefits:

- Reducing pill burden
- Improving medication adherence
- Reducing risk of toxicity
- Reducing cost

These combinations are now used in a number of settings as recommended first or second line treatments

First-line drugs can be used as alternative second line drugs if there are no other options and they have not been used already, resistance has not been demonstrated, or if one of the new drugs enhances the action of the first line drug.

Tanzania Recommended Regimens for Children

The recommended drug regimens for children are:

- First line regimen (Under age 3 years):
  - AZT (zidovudine) and 3TC (lamivudine) and NVP (nevirapine)
- First line regimen (Over age 3 years):
  - Can use EFV or NVP
- Second line regimen
  - ddI (didanosine) and ABC (abacavir) and LPV/RTV (kaletra) or alternate PI: NFV (nelfinavir)
  - If under 6 months old (body weight less than 10 kg), replace LPV/RTV with NFV

The national guidelines recommend using d4T/3TC and NVP as the first line regimen. This can be used for all ages. D4T/3TC and EFV is not recommended below 3 years. As with pregnant women, EFV has not been proven safe in children under age 3 years. highly variable drug exposure remains a significant problem in the use of VIRACEPT in pediatric patients because of increased clearance compared to adults and difficulties with compliance and variable food intake with dosing.

Reasons for Changing or Stopping ARVs

Reasons for changing within the first line regimen:

- Drug specific side effect (such as anaemia, systemic allergic reactions, liver toxicity, neuropathy)
- TB disease requiring treatment during ART
- Pregnancy during EFV-based regimen

Reasons for stopping or changing the entire first line regimen:

- Treatment failure (non-responsiveness to 1st line usually after 3 months)
- Multiple first-line drug side effects, in which case patient should be referred to a specialist at a referral hospital

You may stop just one drug in a regimen if there is a drug-specific side effect or a condition that contraindicates one of the drugs only.

Treatment failure may manifest as:

- Occurrence of new opportunistic infections and other HIV-related illnesses or malignancies at least three months after ART initiation
- Recurrence of weight loss
- Recurrence of failure to thrive (children)
- Immunological treatment failure (significant decline of CD4 counts—at least 30%)
- Virological treatment failure (significant rise of viral load—more than 1000copies/ml)

IRIS, which will explained in much more detail in the session on side effects and IRIS, usually occurs within the first 3 months of ART initiation, while treatment failure usually occurs between 3 and 6 months after initiation of ART. IRIS is usually characterized by a lower viral load and a high (or healthy) CD4 count, whereas treatment failure is characterized by high viral load with lower CD4 count.

Monitoring Treatment

Clinical signs of improvement include weight gain, patient subjectively feels better, and illnesses occurring less frequently or not at all. Laboratory findings that indicate improvement include sustained CD4 count increase and viral load decrease. (Viral load is the amount of virus in a person's blood. CD4 rises while VL decline. Viral load testing is done at referral hospitals.) Note that during the first few weeks of therapy, the patient should also be monitored for IRIS.

Key Points

- For a patient to start ARV therapy, the health worker needs to:
  - Assess eligibility, including the patient's understanding, WHO staging criteria, and interpreting CD4 counts
  - Prepare the patient for lifelong adherence
  - Know the various medication/ regimens
  - Know reasons for stopping or changing ARV therapy
  - Monitor treatment

UNIT 10: PATIENT MONITORING SYSTEMS: HIV AND ART

Introduction
Patient monitoring is key to the provision of good quality care. It is one of the ways to measure programme success. The purpose of this unit is to enhance health care workers' knowledge about recording and reporting for TB/HIV co-infected patients.

Objectives
By the end of this unit, you should be able to:
- Describe the patient monitoring systems in the care & treatment of TB/HIV co-infected patients
- Identify important tools for patient information
- Describe the line of HIV data flow from health facilities to NACP headquarters
- Identify TB/HIV indicators for patient monitoring

Definition of Monitoring
Monitoring is a process whereby an individual or organisation routinely gathers information on aspects of a project or programme. For patients, this involves routinely collecting information about patients at the clinic, hospital, region, and national level.

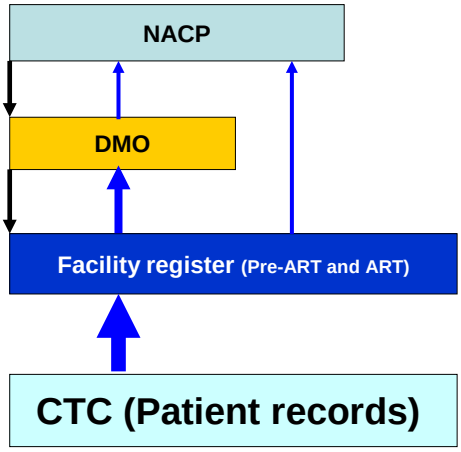
Importance of Patient Monitoring
Patient monitoring enables effective clinical management of patients. It also helps to address extremely long follow-ups, multiple consultations and hospitalisations per patient, associated opportunistic pathologies, complex therapy, and adherence issues. Patient monitoring data are used for program monitoring and management.

Program Monitoring
Program monitoring involves routine tracking of priority information about a program and its intended outcomes. Aggregate data from different programs and health facilities at district and provincial level are needed to evaluate different outcomes and impact at the national and regional levels.

Who Uses the Information?
The information gathered through patient and program monitoring is used at various levels. The clinical team uses the information for individual patient follow-up, and to assess progress. Hospitals or program directors use the information to evaluate programs, outcomes of clinical care and quality of clinical care. They also synthesize the data to report to the NACP and the NTLP. Funding recipients and policymakers use the data to report to donors such as PEPFAR and the Global Fund.

Data Flow
There are two parallel data flow levels: CTC to DMO to NACP *and* CTC to NACP.Data volume decreases at the higher levels. CTC data is both for patient and program management. Information also flows from the NACP to the DMO and to the Facility registers.

Figure 37: Data Flow



Pre-ART Register

The pre-ART register lists all patients receiving HIV care in a facility. This includes patients transferred in without a record and patients transferred in with records who had previously received care. The pre-ART register monitors patients in care and tracks their progress as they become eligible for ART. When patients start ART they are transferred to the ART register and are no longer tracked in the pre-ART register. Each row of the pre-ART register is one patient, and information is collected on a group of patients. It lists all patients who enroll in HIV care.

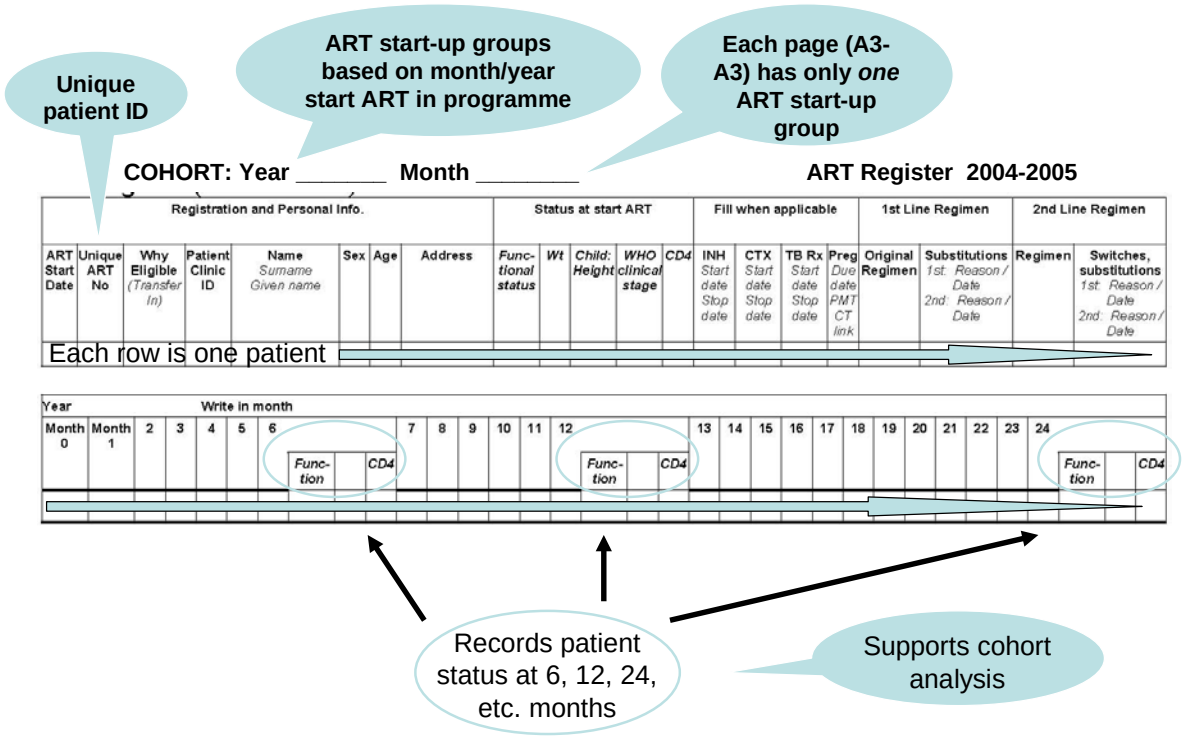
Figure 38: Pre-ART Register

Registration								Fill when applicapable							WHO Clinical Stage – insert date				ART						
Date enrolled in chronic HIV care	Patient clinic ID No.	NAME IN FULL Upper Space: surname Lower Space: given name	Age	Sex	*Address*	*Entry point*	Confirmed HIV+ date	*INH Start Date Stop Date*	*CTX Start Date Stop Date*	*Fluconazole Start Date Stop Date*	*TB Rx Start Date Stop Date*	*Preg Due Date, PMTCT link*	If pt is DEAD before start ART, write DEAD and Date	LOST or Transfer Out (TO) before starting ART and Date	1	2	3	4	Date medically eligible for ART	Clinical stage at start of ART	Why medically eligible	Date eligible & ready for ART	Date eligible, ready & selected by committee for ART	Date ART started transfer to ART register	Unique ART number

ART Register

The ART register is for patients who are on ART. Each patient is recorded in a row as (s)he becomes eligible for ART. Patients are grouped in cohorts as of when they started taking ARVs by month and year. Transfer patients with records who are already on ARVs are recorded in this register, and they are included in the cohort for when they started taking ARVs. The register allows us to track important variables at six months, 12 months, and then yearly. The ART register tracks patient progress for the rest of their lives.

Figure 39: ART Register



Reports

Reports include cross-sectional reports (monthly and quarterly) and the cohort analysis report form. Reports are filled in using information from the registers (Pre-ART and ART).

The cross-sectional (monthly and quarterly) reporting form is designed as a summary of patients newly enrolled in the current reporting period, the cumulative total at the end of the current reporting period, and the total of those currently enrolled at the end of the previous reporting period.

Figure 40: Monthly Report Form

1. HIV care (non-ART and ART) - new and cumulative number of persons enrolled			
	Cumulative number of persons ever enrolled in HIV care at this facility from the quarter which ended 3 months ago	New persons enrolled in HIV care at this facility during the previous quarter	Cumulative number of persons ever enrolled in HIV care at this facility at end of the previous quarter
1. Males (>14 years)	a.	h.	o.
2. Non-pregnant females (>14 years)	b.	i.	p.
3. Pregnant females (>14 years)	c.	j.	q.
4. Males (0-14 years)	d.	k.	s.
5. Non-pregnant females (0-14 years)	e.	l.	t.
6. Pregnant females (0-14 years)	f.	m.	u.
Total	g.	n.	v.
	Total number of persons who are enrolled and eligible for ART but have not been started on ART		w.
	Number of persons already enrolled for HIV care who transferred in from another facility during the previous quarter		x.

Figure 41: ART Forms, Reports, and Registers

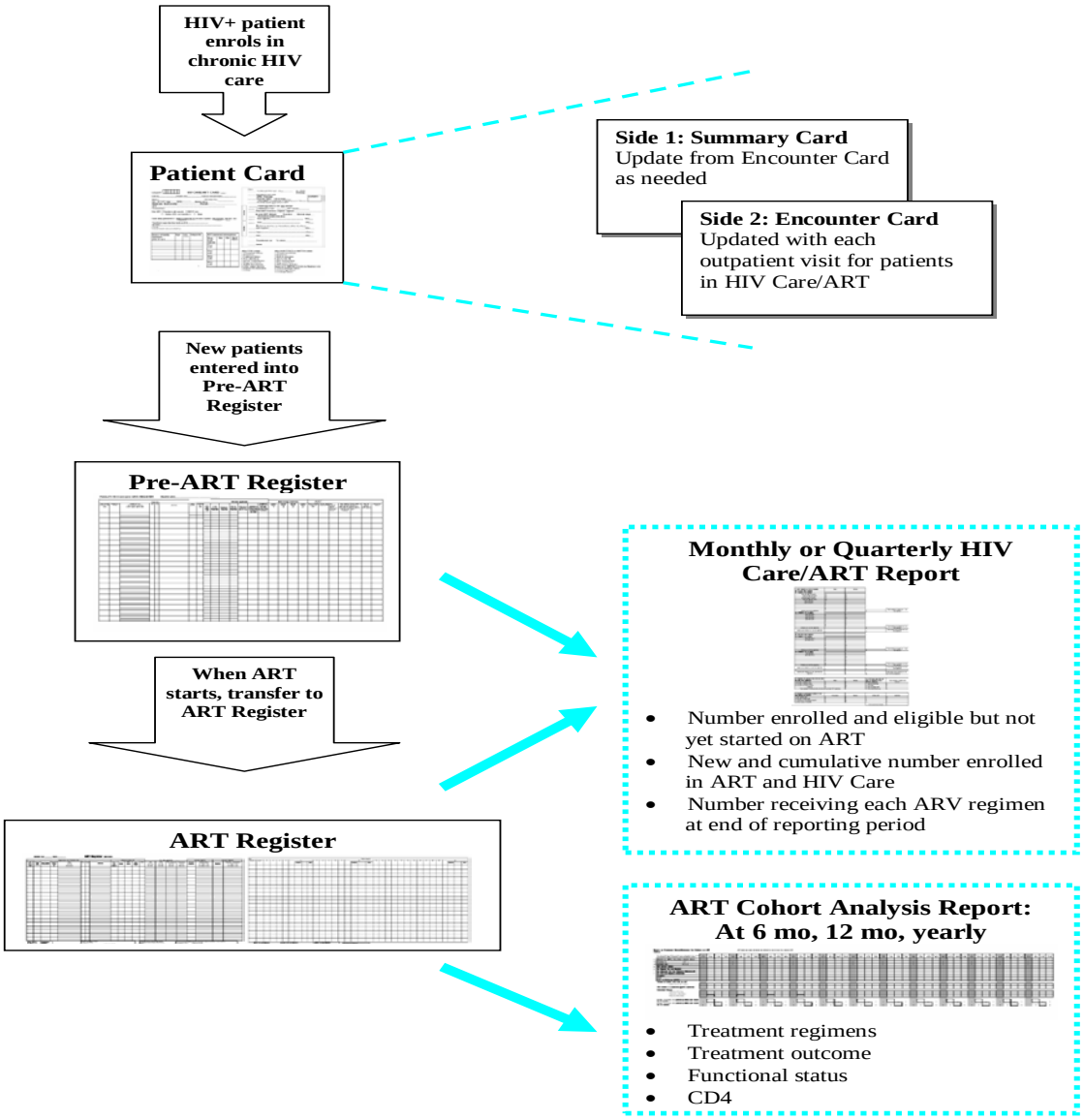
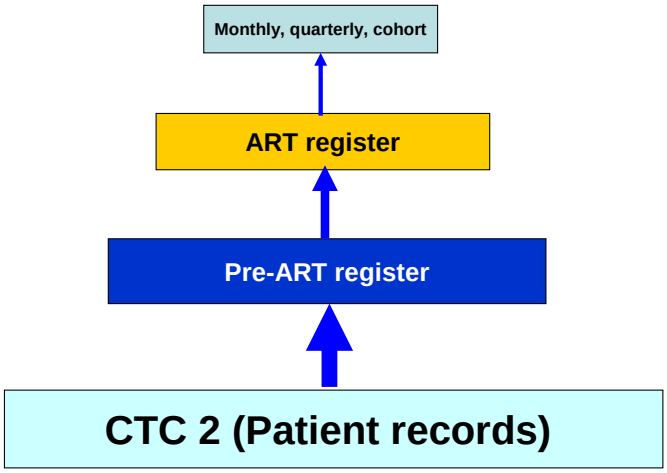
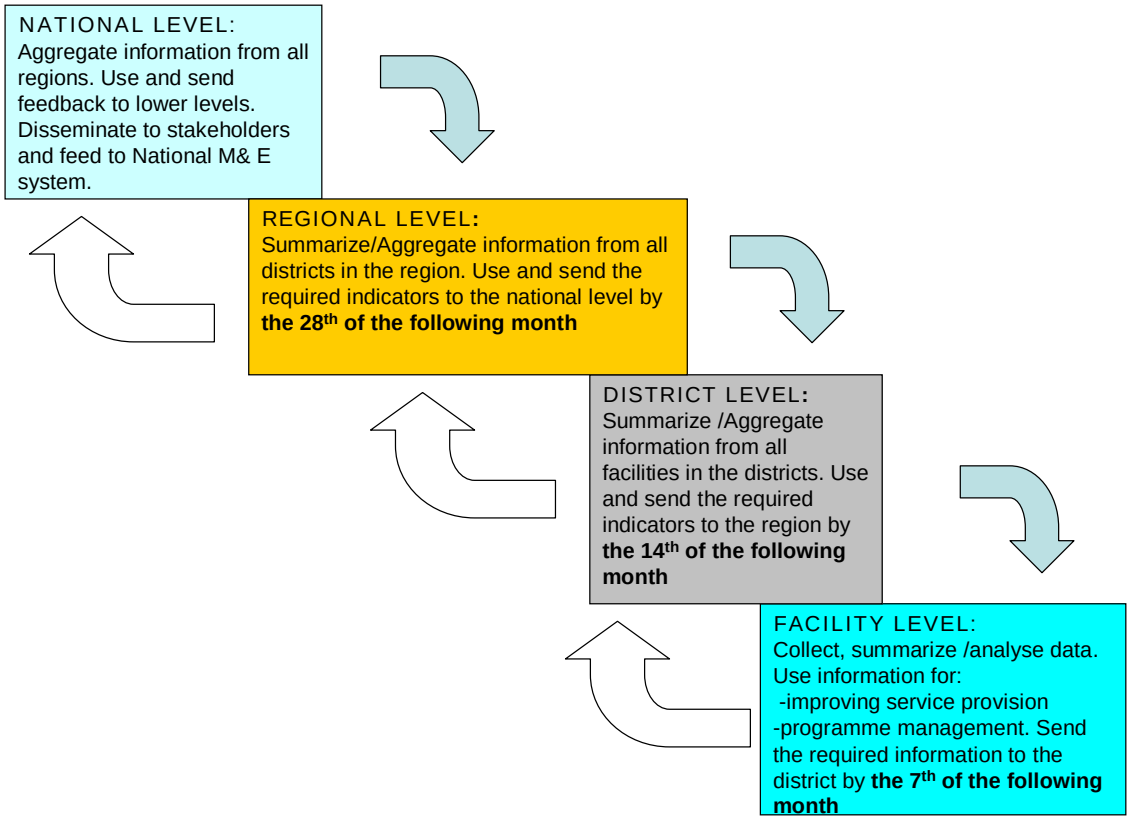


Figure 42: Data for HIV Clinics



Note that there are fewer data elements at higher levels.

Figure 43: Information Flow and Timeline



TB/HIV Indicators

The proportion of PLHIV screened for TB can be obtained from ART or pre-ART registers. Chart reviews as part of continuous quality improvement. The proportion of PLHIV receiving Isoniazid Preventive Therapy (IPT) and the proportion of PLHIV on TB treatment can be obtained for register.

Key Points

- Patient monitoring is important because it enables effective clinical management of patients and patient monitoring data are used for program monitoring and management
- Forms include the Pre-ART register, ART register, cross-sectional reports, and cohort analysis report form.

UNIT 11: RECORDING AND REPORTING TOOLS

Introduction
Proper and reliable recording and reporting systems are essential for monitoring programme performance. This unit aims to enable participants to understand the different types of data collection tools and to appreciate the importance of proper record keeping regarding TB and TB/HIV.

Objectives
By the end of this unit, you should be able to:
- Explain the importance of recording and reporting information on TB and TB/HIV
- Describe how to use different forms and registers used in TB clinics and HIV clinics
- Explain the data flow from health facility through district, region to the national level
- Identify key indicators used for reporting TB and TB/HIV activities

Definitions: Recording and Reporting
Recording is capturing data on patient management over time and across clinical sites. Information is written directly on paper forms or entered into a computer. Reporting is routine tracking (monitoring) of priority programme management information of summary patient outcome data (evaluation) at facility, district, regional, and national levels over time.

Importance of Recording and Reporting
Recording and reporting are essential for good programme management and patient care and involve accurately recording all individual patients started on treatment, using information at the facility, updating registers, and sending reports to district, regional and national levels for decision making. All providers must report both new and re-treatment tuberculosis cases and their treatment outcomes to local public health authorities, in conformance with applicable legal requirements and policies (ISTC #17).

Recording and reporting are used to assist in case holding and patient monitoring (e.g. attendance and treatment outcomes), establishment of baseline information, planning, establishment of trend, notification, and treatment outcomes, decision-making on treatment, and improving services.

Benefits of Keeping Good Records
For patients, benefits of good record keeping include being able to assess patient progress, provide adequate services, and ensure patient quality of care, continuum of care, sharing of information with patients, and transfer of information between health facilities. For the programme, benefits of good record keeping include monitoring and evaluation by programme managers at different levels, assessing programme performance, programme planning and budgeting, and accountability and decision-making.

Recording
Health care workers should make sure that cards and registers are up-to-date, complete, accurate, and reliable. Data collected at any level should be used locally for planning, monitoring purposes, and making evidence-based decisions.

Types of TB Data Collection Tools

The different types of TB forms and registers include the following TB forms and cards, registers, TB/HIV forms, and CTC Forms. Specific TB forms and cards for patient management include:

- TB 01 – Tuberculosis treatment card
- TB 02 – TB Identity card (Kadi ya mgonjwa)
- PCT 1 – Treatment supporter card
- TB/LEP 01TB – Laboratory request form for AFB microscopy
- TB 06 – Culture and sensitivity request form
- TB07 – TB quarterly notification form
- TB08 – TB drugs and supplies form
- TB09 – TB treatment outcome form
- TB 11 – Treatment outcome of transferred in TB patients
- TB/HIV 01 – TB/HIV notification form
- TB/HIV 02 – TB/HIV treatment outcome form
- TB/HIV 03 – TB/HIV referral/transfer form

There are two types of TB registers: paper, which are filled out at facility or district, and electronic (ETR, Net), which are filled out at the district level. TB 03 is the Tuberculosis Unit Register. It records important information on every patient taking TB drugs in the clinic. Data from this register provide the foundation for the District TB Register as information forms the basis for major decisions. It is filled out by health workers in TB clinics who provide drugs, treatment, and counselling to patients. Other TB registers include:

- TB 04 – TB district register
- TB 05 – Tuberculosis laboratory register
- TB 10 – TB culture and DST register

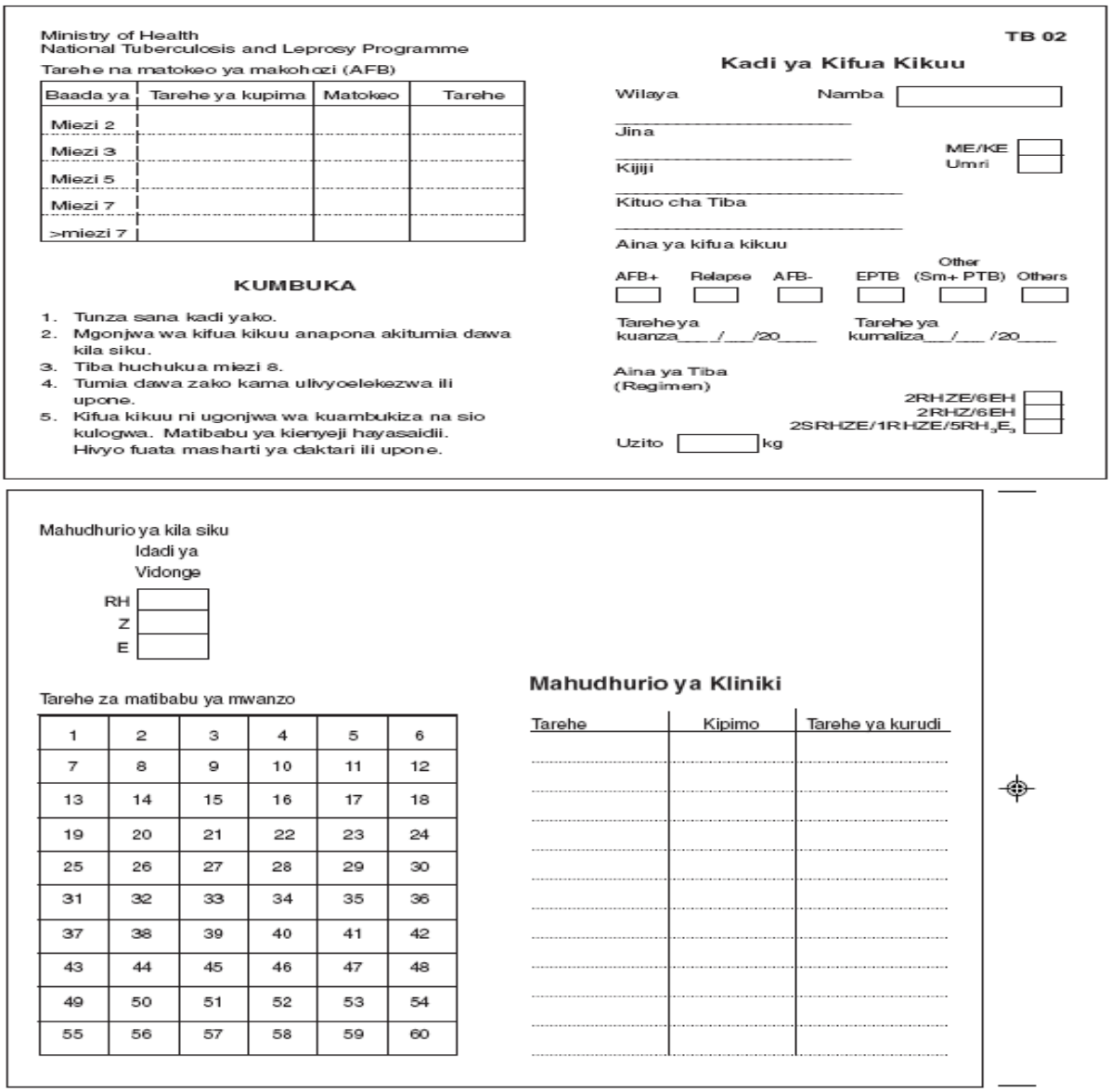
TB 01 – Tuberculosis Treatment Card

TB 01 is focused more on the clinical aspects of patient care and is filled out at every patient visit by the health worker who manages the patient's treatment. TB 01 keeps an individual record of diagnosis, treatment, and follow-up of each TB patient for proper case management at the clinic.

TB 02 – Kadi ya kifua Kikuu/TB Identity Card

TB 02 is filled out by the health worker when TB treatment is started and then kept by the patient. This card provides evidence of previous treatment history and enables the patient to collect drugs.

Figure 44: TB 02—Kadi ya kifua Kikuu/TB Identity Card



Ministry of Health
National Tuberculosis and Leprosy Programme

TB 02

Kadi ya Kifua Kikuu

Tarehe na matokeo ya makohozi (AFB)

Baada ya	Tarehe ya kupima	Matokeo	Tarehe
Miezi 2			
Miezi 3			
Miezi 5			
Miezi 7			
>miezi 7			

Wilaya _____ Namba _____

Jina _____

Kijiji _____ ME/KE ☐ Umri ☐

Kituo cha Tiba _____

Aina ya kifua kikuu

AFB+ ☐ Relapse ☐ AFB- ☐ EPTB ☐ Other (Sm+ PTB) ☐ Others ☐

Tarehe ya kuanza___/___/20___ Tarehe ya kumaliza___/___/20___

Aina ya Tiba (Regimen)

2RHZE/6EH ☐
2RHZ/6EH ☐
2SRHZE/1RHZE/5RH$_3$E$_3$ ☐

Uzito ☐ kg

KUMBUKA

1. Tunza sana kadi yako.
2. Mgonjwa wa kifua kikuu anapona akitumia dawa kila siku.
3. Tiba huchukua miezi 8.
4. Tumia dawa zako kama ulivyoelekezwa ili upone.
5. Kifua kikuu ni ugonjwa wa kuambukiza na sio kulogwa. Matibabu ya kienyeji hayasaidii. Hivyo fuata masharti ya daktari ili upone.

Mahudhurio ya kila siku

Idadi ya Vidonge

RH ☐
Z ☐
E ☐

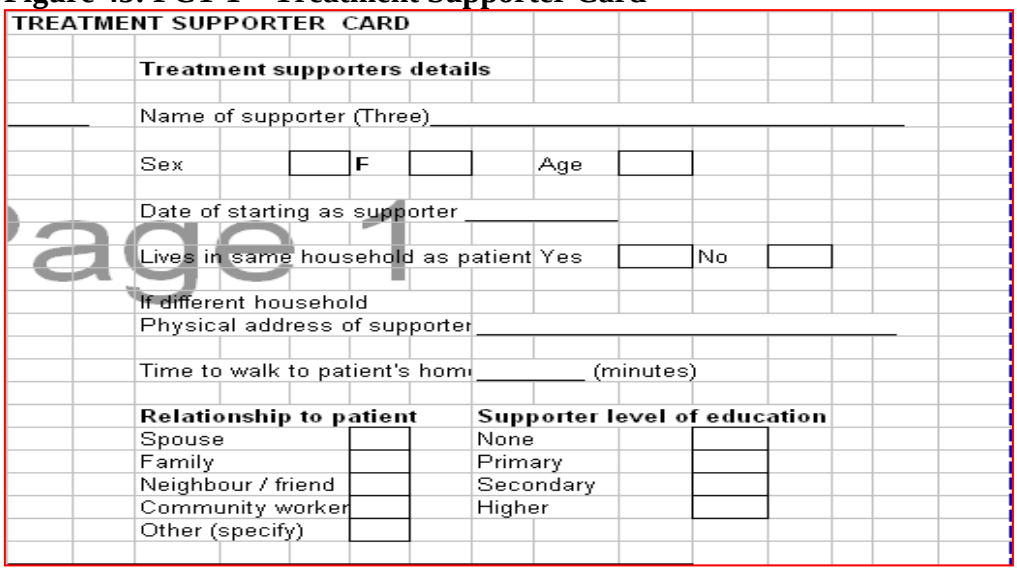
Tarehe za matibabu ya mwanzo

1	2	3	4	5	6
7	8	9	10	11	12
13	14	15	16	17	18
19	20	21	22	23	24
25	26	27	28	29	30
31	32	33	34	35	36
37	38	39	40	41	42
43	44	45	46	47	48
49	50	51	52	53	54
55	56	57	58	59	60

Mahudhurio ya Kliniki

Tarehe	Kipimo	Tarehe ya kurudi

Figure 45: PCT 1 – Treatment Supporter Card



TREATMENT SUPPORTER CARD

Treatment supporters details

Name of supporter (Three)_____

Sex ☐ F ☐ Age ☐

Date of starting as supporter _____

Lives in same household as patient Yes ☐ No ☐

If different household

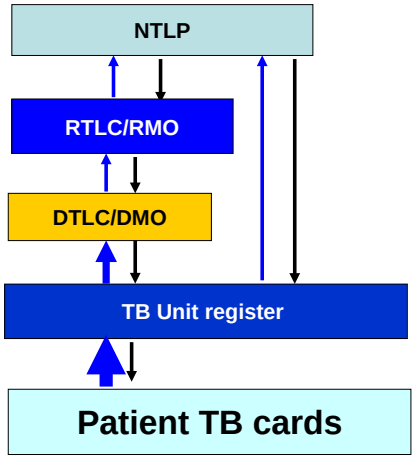
Physical address of supporter _____

Time to walk to patient's hom_____ (minutes)

Relationship to patient		**Supporter level of education**	
Spouse	☐	None	☐
Family	☐	Primary	☐
Neighbour / friend	☐	Secondary	☐
Community worker	☐	Higher	☐
Other (specify)	☐		

Data Flow for TB
Data flows from peripheral to central areas and data volume decreases at the higher levels. Data are also useful at the clinic level for planning.

Figure 46: TB Data Flow



TB/HIV Indicators
An indicator is a variable used to measure progress towards the stated goal, objectives and targets of the programme. TB/HIV indicators are used to measure progress towards the goal, objectives, and targets for implementation of TB/HIV activities.

WHO Recommended Indicators
WHO recommended indicators for TB/HIV collaborative activities fall under the following objectives:

1. Establish mechanisms for TB/HIV collaboration
2. Decrease the burden of TB in people living with HIV and AIDS
3. Decrease the burden of HIV in TB patients

1) Establish Mechanisms for TB/HIV Collaboration
Indicators:

- Existence of coordinating body for TB/HIV activities effective at all levels
- HIV sero-prevalence among all TB patients
- Existence of joint planning for collaborative TB/HIV activities
- Presence of National M & E system for collaborative TB/HIV activities

2) Decrease the Burden of HIV in TB Patients
Indicators:

- Number of PLHIV screened for TB
- Number of health facilities and/or congregate settings with a written infection control policy

3) Decrease the Burden of TB in People Living with HIV/AIDS
Indicators:

- Number of registered TB patients who counselled and tested for HIV
- Number of TB patients who received their HIV test results
- Number of TB patients who tested HIV positive

- Availability of free condom at TB services
- Number of HIV positive TB patients referred to HIV care and support services
- Number of HIV positive TB patients who received CPT
- Number of HIV positive TB patients who started on ART

Key Points

- Recording and reporting are essential to a facility's success, as they help health workers to assess patient progress, ensure quality of care, sharing of information between patient and health workers, conduct monitoring and evaluation activities, assess program performance, plan programs, and demonstrate accountability
  - Learning how to use all of the different forms is key to successful reporting
  - The more successful reporting is, the more likely health workers will meet collaborative TB/HIV objectives

UNIT 12: ADHERENCE COUNSELLING FOR ART AND TB TREATMENT

Introduction

The purpose of this unit is to equip heath workers with knowledge about treatment adherence to anti-TB and ARV drugs. Adherence to treatment is important to manage HIV and cure TB, improve the health of patients, and prevent the development of resistance.

Objectives

By the end of this unit, you should be able to:

- Describe adherence in TB and HIV treatment
- Identify factors affecting a person's adherence to treatment
- Describe strategies to enhance adherence
- Describe the roles of provider, supporter and patients in adherence to treatment
- Assess adherence

Adherence vs. Compliance

Adherence is a shared decision making process between the patient and the healthcare provider that requires commitment and knowledge on the part of PLHIV. The patient understands and agrees to make necessary adjustments to improve health. Motivation and dedication are an important part of this process. Compliance is simply following instructions and doing as you are told.

Why is Adherence to Anti-TB and ART Important?

It is important to address adherence to both TB and HIV treatment in order to improve the overall health of patients. Adherence to TB treatment throughout the six to eight month therapy is important in order to cure TB and to prevent further transmission of TB and resistant (MDR) TB. Lifelong adherence to HIV treatment is important to manage HIV and prevent transmission to others. Adherence to both treatments is essential to preventing resistance to the drugs. In order to achieve these goals, patients need to be set up for adherence success.

Adherence Dimensions

Adherence dimensions include the following:

- The right drugs
  - Rifampicin/NVP
  - PIs/Rifampicin
- All the time
  - >95% adherence
- At the right time
  - Every 8 hours
  - 3 times a day
  - Sufficient period of time (6 months for TB, lifelong for ART)
- The right way
  - With food
  - Without food
  - Alcohol
  - Avoiding traditional herbs
  - Right number of pills

Patients need to make sure to take medications exactly as they have been told, being sure to be as close to 100 percent adherent as possible. Patients will need very clear instructions on which pills to take at what times, whether with food or not with food. They will need to be told if there are any drug interactions possible, or if alcohol will affect whether the drugs work. Some drugs should not be used together. For example:

- Rifampicin decreases the effectiveness of Nevirapine by inducing the liver's enzyme systems and vice versa.
- Similarly, Rifampicin and Protease inhibitors should not be given together for the same reason.

In order for ART and anti-TB treatments to work, providers must make sure that patients are completely clear about the right way to take them.

Factors Affecting Adherence to ART/TB Treatment

Patient factors that affect adherence include:

- Readiness to begin ART
- Person's knowledge of his/her disease (TB/HIV) and treatment
- Confidence about whether treatment will work
- Lifestyle of PLHIV (e.g. poverty)
- Access to nutritious food and meeting living conditions

Lifestyle issues include drug or alcohol abuse, work schedule, personal hardships, frequent travel and some cultural beliefs. All of these factors have an influence on how stable one's life is and whether one is able to stick to a routine such as a treatment regimen.

Some medications need to be taken with food, and if a person does not have access to food, he or she may not be able to take the medications. Also, if a person has poor nutrition, this may affect how well the drugs are absorbed, make side effects feel worse for the patient, and make the drugs less effective because the patient is weaker at baseline due to poor nutritional intake.

Regimen factors that affect adherence include:

- Number of pills (FDCs are better than single pills)
- Number of times taken
- Other instructions (very complicated instructions are difficult to follow and may confuse the patients)
- Other drugs taken (such as cotrimoxazole or vitamins)
- Side effects

Side effects such as diarrhoea, vomiting, and nausea may make a person want to stop therapy because the medications are making them feel worse than they were before they started taking them. It is important to tell patients that usually these side effects will subside after about a month, but that they should not stop taking their medications due to moderate side effects. If side effects are severe, they should speak with their doctor.

Patient-provider relationship issues that affect adherence include:

- '*Superiority*' attitude of doctors and nurses
- Contradicting information from doctor, nurse, pharmacist
- Lack of trust and confidence of PLHIV in their care providers
- Poor support by care providers

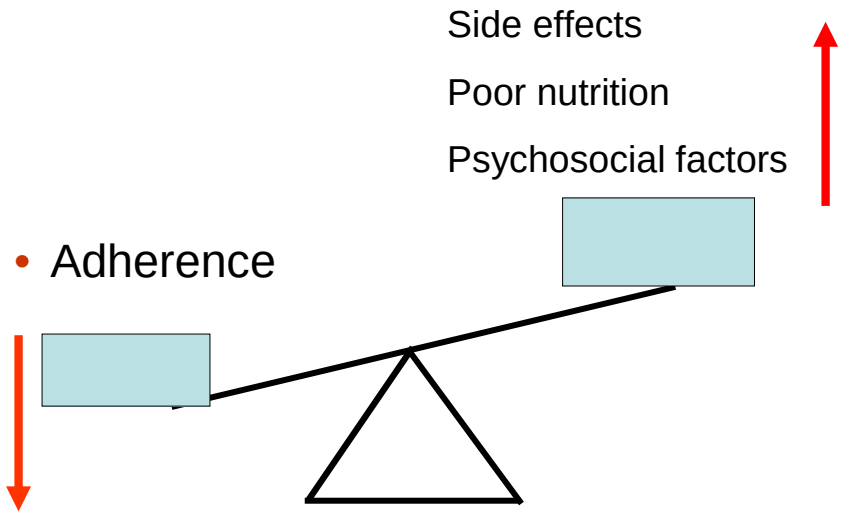
Psychosocial issues that affect adherence include:

- Depression
- Stigma
- Lack of family support
- Disclosure issues
- Religious/cultural beliefs

Health services factors that affect adherence include:

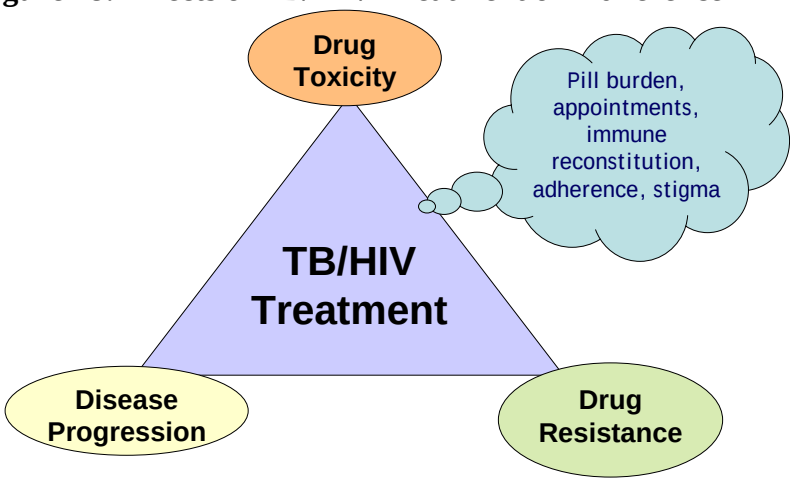
- Accessible clinic; pharmacy
- Experienced and well-trained staff
- Good patient follow-up

Figure 47: Factors Affecting Adherence



During treatment, toxicity to the drugs may develop, which may make the patient feel physically poor and lead him/her to stop taking the medications. If a patient has to take many tablets, he or she may have difficulty keeping track of all of the pills, may make mistakes in terms of which pills to take at which time, or may just get tired of taking so many pills and stop. All of these factors affect adherence. If a patient has difficulty getting to appointments at the TB or CTC clinic, this can affect adherence. Reasons may include scheduling conflicts, lack of transportation, lack of childcare, dislike of health care provider, etc. IRIS may affect adherence by making the patient feel worse as IRIS related symptoms develop. This may make the patient want to stop taking his/her medications. Disease progression – Patients always expect to get better when taking medications but if they do not get better immediately, patients may be discouraged from continuing to take medicine. Drug resistance may prevent a patient from getting healthier, and this, in turn, may discourage the patient from taking medication.

Figure 48: Effects of TB/HIV Treatment on Adherence



Strategies to Ensure Adherence

In order to ensure adherence amongst patients, it is important that providers build a trusting relationship with patients, involve patients in the decision making process about adherence, and demonstrate supportive and non-judgmental attitudes and behaviours. This will encourage patients to be honest about adherence and about problems they have with adherence. Providers should also monitor and encourage adherence at every clinical encounter as motivation fluctuates over time, prepare patients on adherence for several sessions before starting ART, and communicate effectively between the clinical team and home-based care providers.

Effective Communication in Adherence

When communicating with patients it is important that providers identify patient needs, invest time and energy to ensure adherence, establish a trusting relationship with patients and their families, and individualise care.

Adherence to TB treatment

In order to achieve effective treatment, adequate chemotherapy should be prescribed in an appropriate combination and taken regularly for a sufficient period of time. Direct observation of medication ingestion (DOTS) strategy is the gold standard and is important in the prevention of MDR TB and ensures rapid sputum conversion of infectious patients. It is important to let the patient identify appropriate ways to remember to take ART. Some examples include watches, the sun, radio and news, and alarms.

Improving Adherence with FDCs for TB/HIV

Fixed dose combinations (FDCs) help patients to achieve better adherence with fewer pills. They allow for a short duration of treatment because of RH in the continuation phase. In addition FDCs promote improved drug management, ordering, procurement, distribution and dispensing/handling at different levels of the NTLP. There is a lowered risk of misuse of single drugs and of emergence of drug-resistant TB due to reduced use of mono-therapy. The only problem is if one drug must be started or stopped at different times (such as NVP).

Roles of Staff and Patients

To support adherence, the practitioner must be able to:

- Prescribe an appropriate regimen
- Assess the adherence of the patient to the regimen

- Address poor adherence when it occurs
- Ensure adherence to the regimen until treatment is completed

To support adherence, the patient must be able to do the following:
- Report side effects
- Discuss treatment with HCW
- Provide honest feed back of treatment
- Share concerns with family

Treatment Supporters
Examples of treatment supporters include:
- Family members
- Friends
- Other PLHIV
- Cured TB patients
- Staff members who are PLHIV
- Others

Starting ART Among TB Patients
When starting a TB patient on ART it is important to assess and prepare carefully. The priority is to treat the TB and not rush into ART. In this process, it is also worth exploring whether DOT can work with ART.

How to Assess Adherence
When assessing adherence it is important to be non-judgmental, encourage patients to report, and assess adherence at every visit. Develop measures that are appropriate to your settings and ask patients if they have had difficulty with their pills and how many pills they have missed in the last 3, 7 or 30 days.

The following methods can be used to assess adherence:
- Pharmacy patient refill patterns
- Self report
- Pill counts (at clinic visits or announced home visits)
- Others (used for research purposes)
    - MEMS (Microchip Electronic monitoring
    - Drug levels

Adherence Support
Any practitioner treating a patient for tuberculosis is assuming an important public health responsibility. To fulfill this responsibility the practitioner must not only prescribe an appropriate regimen but, also, be capable of assessing the adherence of the patient to the regimen and addressing poor adherence when it occurs. By so doing, the provider will be able to ensure adherence to the regimen until treatment is completed. (ISTC #7)

To foster and assess adherence, a patient-centered approach to administration of drug treatment, based on the patient's needs and mutual respect between the patient and the provider, should be developed for all patients. Supervision and support should be gender-sensitive and age-specific and should draw on the full range of recommended interventions and available support services, including patient counselling and education. A central element of the patient-centered strategy is the use of measures to assess and promote adherence to the

treatment regimen and to address poor adherence when it occurs. These measures should be tailored to the individual patient's circumstances and be mutually acceptable to the patient and the provider. Such measures may include direct observation of medication ingestion (directly observed therapy—DOT) by a treatment supporter who is acceptable and accountable to the patient and to the health system.

Adherence should be tailored to individual patient's circumstances. It should be mutually acceptable to the patient and provider and can include a DOT-supporter who is acceptable to patient and accountable to health system. Adherence support should involve:

- Recognising and understanding difficulties faced by patients
- Supporting patients using appropriate interventions to promote adherence
- Patient-centered approach to drug treatment
- Supervision and support should be gender-sensitive and age-specific
- Use of measures to assess and promote adherence
- Patient counselling and education

Summary

In adherence, it is important to take time to understand lifestyle of patient, develop strong provider-patient relationship, educate the patient on all aspects of TB and HIV therapy, work as a team (clinician, nurse, counsellor, dispensing pharmacist and home care provider), involve a treatment supporter, monitor pill use, and develop a site-specific approach.

Key Points

- It is important to address adherence to both TB and HIV treatment in order to cure TB and manage HIV, prevent the development of resistance, and to prevent further transmission of HIV, TB, and MDR TB.
- Successful adherence depends on: patient, regimen, patient-provider relationship, psychosocial, health services-related factors
- Good communication, assessment, support and rapport are all essential to adherence success!

UNIT 13: SIDE EFFECTS OF ANTI-TB AND ARV DRUGS, DRUG INTERACTIONS, AND IRIS

Introduction

Just as with other drugs, anti-TB and ARV drugs have side effects. Understanding drug side effects is essential to proper patient management. The purpose of this unit is to equip health workers with knowledge on common anti-TB and ARV drug side effects, drug interactions, Immune Reconstitution Inflammatory Syndrome (IRIS), and how to manage all each of these.

Objectives

By the end of this unit, participants should be able to:

- Identify the most common side effects of anti-TB and ARV drugs
- Describe characteristics and consequences of side effects
- Describe the interaction between anti-TB and ARV drugs
- Explain how to manage the side effects of anti-TB and ARV drugs
- Describe IRIS and its management

Overview of Side Effects

Side effects are unwanted effects of drugs which are uncomfortable for the patient. They can be minor or major (potentially dangerous). Minor side effects are mild not life-threatening (such as skin rash, nauseas, dizziness, joint pains); major side effects are severe and life threatening (such as jaundice, Steven Johnson syndrome). Possible consequences of side effects include effects on adherence, increased morbidity, effects on quality of life, and death. When anti-TB and ARV drugs are used together, there is an increased risk of severe side effects. Many drugs may cause the side effects of nausea, vomiting, and abdominal pain.

Figure 49: Side Effects to Anti-TB Drugs

Caused by	Adverse Reaction	Signs and Symptoms
Any drug	Allergy	Skin rash
Ethambutol	Eye damage	Blurred or changed vision Changed color vision
Isoniazid, Pyrazinamide, or Rifampicin	Hepatitis	Abdominal pain Abnormal liver function test results Fatigue Lack of appetite Nausea Vomiting Yellowish skin or eyes Dark red urine
Isoniazid	Peripheral neuropathy Liver problems-Hepatitis Rash, fever, N&V	Tingling sensation in hands and feet Yellow eyes
Pyrazinamide	Gastrointestinal intolerance Arthralgia Arthritis	Upset stomach, vomiting, lack of appetite Joint aches Gout (rare)
Streptomycin	Vestibulo-cochlea (Ear damage) Kidney damage	Balance problems Hearing loss Ringing in the ears Abnormal kidney function test results
Rifampicin	Thrombocytopenia Liver problems – Jaundice Gastrointestinal intolerance	Easy bruising, Slow blood clotting Yellow eyes and skin Upset stomach, nausea and vomiting

Note that many drugs may cause the side effects of nausea, vomiting, and abdominal pain**.** Also, Rifampicin interacts with several drug medications, such as oral contraceptives and ARVs (such as Nevirapine and PIs).

Figure 50: Side Effects of ARVs

Stavudine	**Peripheral neuropathy**	**Tingling sensation in hands and feet**
	Lipodystrophy	**Fat loss or accumulation**
	Lactic acidosis	**Nausea, vomiting, abdominal pain, difficulty in breathing**
Zidovudine	**Gastrointestinal intolerance**	**Upset stomach, vomiting, lack of appetite**
	Anaemia, neutropenia	**Weakness, fatigue, shortness of breath**
	Lipodystrophy	**Fat loss or accumulation**
	Others	**Discolouration of nails, headache, myopathy**
Didanosine	**Peripheral neuropathy**	**Tingling sensation in hands and feet**
	Lipodystrophy	**Fat loss or accumulation**
	Pancreatitis	**Abdominal pain**
Abacavir	**Hypersensitivity reaction**	**Fever, Skin rash (often mild, in 70% of cases)** **GI complaints: nausea, vomiting, diarrhoea, abdominal pain** **Respiratory Symptoms: cough, dyspnoea** **Other: arthralgia, myalgia, headache, oedema, paraesthesia**
Nevirapine	**Hepatotoxicity esp in women with CD4>250 and men with CD4>400** **Rash**	**Upset stomach, vomiting, lack of appetite** **Yellow eyes**
Efavirenz	**Neuropsychiatric manifestations** **Liver problems** **Skin rashes**	**Dizzyness, drowsiness, confusion** **Nightmares, Vivid dreams** **Yellow eyes**

Note that lipodystrophy can present as wasting of the face, arms and legs (lipoatrophy) or fat accumulation in the breasts or abdomen. The life threatening side effects are lactic acidosis and pancreatitis. Anaemia and neutropenia can be serious and may necessitate a change of drugs. The side effects which are harmful, and can be chronic but not life threatening are lipodystrophy and peripheral neuropathy. The milder side effects include gastro-intestinal effects.

How to Assess Side Effects

To help assess side effects, create opportunities for reporting by asking, looking, or using a checklist. If side effects are minor, then they will stop on their own in a few days. If the side effects are major (such as severe hepatotoxicity [jaundice] or Stevens Johnson syndrome), advise patients to stop taking the drug seek medical attention immediately. Any side effect should immediately be reported to TFDA using Adverse Drug Reaction (ADR) form.

Monitoring Side Effects

Monitor side effects every one to two weeks initially and then monthly. During these sessions, assess adherence and identify any side effects. If the patient is symptomatic, then order renal function test, liver function test (AST, ALT, bilirubin, and platelet count if

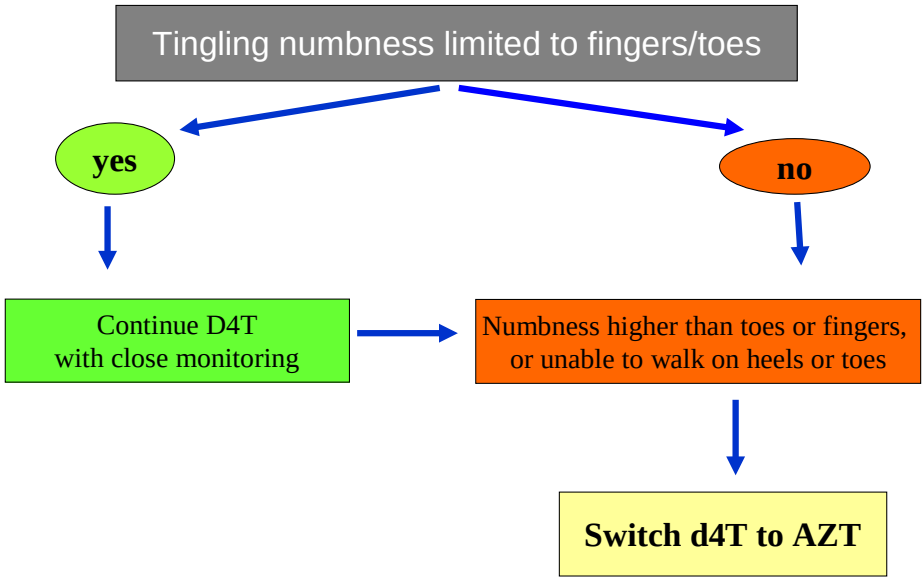
abnormalities at baseline), and visual and colour vision monthly 1-2 weekly initially then monthly if EMB used > 2 months or doses > 15-20 mg/kg. A written record of all medications given, bacteriologic response, and adverse reactions should be maintained for all patients (ISTC Standard 11).

Management of Side Effects
A common side effect that patients may suffer from is peripheral neuropathy. Peripheral neuropathy is usually due to Isoniazid and may be made worse by other drugs such as ARVS (DDI, D4T), alcoholism, or metabolic disease (diabetes). It is rarely severe enough to require drug withdrawal.

Management of Peripheral Neuropathy
Peripheral neuropathy is usually due to Isoniazid, d4T and sometimes DDI. It may be made worse by other drugs, alcoholism, and metabolic disease (diabetes). Peripheral neuropathy is rarely severe enough to require drug withdrawal.

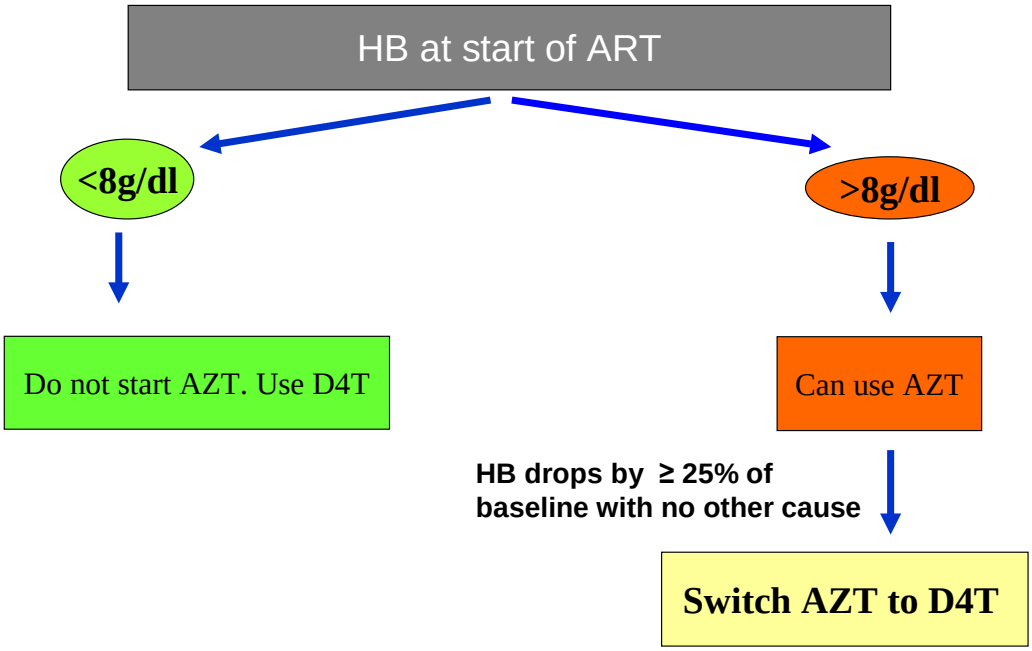
Peripheral neuropathy is preventable with pyridoxine, 25-50 mg daily. Once it manifests, it can be treated with high dose pyridoxine (100-150mg daily). To relieve symptoms, use analgesics, tricyclic antidepressants (amitriptylline) for burning sensation, and anticonvulsants (carbamazepine) for stabbing pain.

Figure 51: How to Manage d4T or DDI-induced Peripheral Neuropathy



Management of AZT-Associated Anaemia
To manage AZT-associated anaemia, follow the algorithm in Figure 52 (below).

Figure 52: Management of AZT-Associated Anaemia



See the revised National Guidelines, which recommend the use of Tenofovir if AZT is contraindicated (due to anaemia) and d4t is contraindicated (due to peripheral neuropathy). Tenofovir is not yet available in Tanzania, but the National Guidelines recommends Tenofovir once it becomes available (if D4T and AZT are contraindicated).

Management of Drug-Induced Hepatitis
To manage drug-induced hepatitis, first exclude other causes of hepatitis such as hepatitis viruses A, B, or C and hepatotoxicity from other drugs. Drugs should be temporarily withdrawn if the patient is severely jaundiced, has raised LFTs, or is very sick. Once the overt disease clears and LFTS return to normal values, the drugs can be reintroduced sequentially.

Severe Skin Reaction: Stevens Johnson Syndrome
Stevens Johnson syndrome is caused by several drugs, including Cotrimoxazole and ARVs (Nevirapine). It usually occurs within about two to three weeks after initiating therapy and is more common in HIV-infected patients. To manage, discontinue the offending drug and begin high dose Prednisone. Prescribe anti-histamines and analgesics as needed; although there no evidence of their effectiveness, they may offer symptomatic relief. Do not re-start the offending drug and admit the patient to hospital.

Re-Introduction of Anti-TB Drugs Following a Drug Reaction
Following an adverse reaction to anti-TB drugs, it is good to restart therapy with Isoniazid because it is the least likely cause of drug reaction. Start with a challenge dose (incase of INH 50 mg in adults) and if there is no reaction increase the dose to the normal dose on day four. After that, add Rifampicin and then the other drugs. If the patient experiences a reaction when a drug is added, that is the causative drug and it should be stopped.

Figure 53: Re-Introduction of TB Drugs Following a Drug Reaction

Anti-TB Drug	Day 1 (challenge dose)	Day 2	Day 3	Day 4
Isoniazid	50 mg	100 mg	200 mg	300 mg
Rifampicin (RH)	75 mg	150 mg	300 mg	Full dose
Pyrazinamide	250 mg	500 mg	1 g	Full dose
Ethambutol	100 mg	200 mg	400 mg	Full dose
Streptomycin	125 mg	250 mg	500 mg	Full dose

Overlapping Side Effects of Anti-TB and ARV Drugs

When starting many drugs at the same time, it is difficult to know which drug is causing a side effect, should one occur. This is particularly a problem in the treatment of HIV-related TB because both diseases have to be treated with multi-drug therapy and the drugs used to treat these two diseases can have the same side effects. An additional factor is that many patients also need to receive other drugs, most often cotrimoxazole for PCP prophylaxis, and this can cause a rash and hepatitis.

Figure 54: Overlapping Side Effects of Anti-TB and ARV Drugs

Side Effect	Possible Causes	
	Anti-tuberculosis Drugs	Antiretroviral drugs
Skin rash	SM, PZA, RIF, INH	NVP, EFV, ABC
Nausea, vomiting	PZA, RIF, INH	ZDV, RIT, AMP, PIs
Hepatitis	PZA, RIF, INH	NVP, PIs, immune reconstitution
Leukopenia, anemia	RIF	ZDV

SM (streptomycin), NVP (nevirapine), EFV (efavirenz), ABC (abacavir), ZDV (zidovudine), RIT (ritonavir), AMP (amprenavir), IND (indinavir), PI (protease inhibitors)

Overlapping side effects include hepatotoxicity, peripheral neuropathy, and hypersensitivity reactions (rash, itching).

Drug Interactions
The following drugs should not be used together because of interactions:

- Rifampicin and Nevirapine
  - Rifampicin decreases the effectiveness of Neverapine and vice versa
  - When rifampicin is used, Efavirenz should be used instead of NVP
- Rifampicin and protease inhibitors
- Isoniazid, didanosine and stavudine
  - They all cause peripheral neuropathy
  - Used together they may lead to added potential toxicity
  - Give high dose of pyridoxine (100-150mg daily) and assess whether neuropathy is due to isoniazid or ARV medication
    - If cause is ARVs and the side effect is intolerable substitute stavudine with zidovudine

What is IRIS?
IRIS stands for Immune Reconstitution Inflammatory Syndrome. It is also known as Immune Reconstitution Syndrome, immune restoration syndrome or disease, or paradoxical reactions. IRIS typically occurs when the immune system (CD4 cell count) has improved (both in quantitative and qualitative terms) with the initiation of ART therapy, but then responds to a previously acquired opportunistic infection with an overwhelming inflammatory response that paradoxically makes the symptoms of the infection worse. It usually occurs in the first weeks of therapy; however it can be seen after several months as well.

IRIS occurs in PLHIV who start ART at a low CD4 (<100) count and is characterized by:

- Clinical symptoms consistent with an inflammatory process
- Decrease in HIV-1 RNA (viral load) level from baseline
- Increase in CD4 cell count from baseline (may lag behind viral load reduction)

These symptoms may be confused with side effects, relapse of a condition or resistance to treatment. The clinical course is NOT consistent with the expected course of a previously or newly diagnosed OI, nor with drug toxicity.

Risk Factors for IRIS
The frequency of IRIS ranges from 10-50 percentof people depending on the setting and type of infection.

Risk factors for IRIS include persons who:

- Initiated ART within close proximity of diagnosis of their opportunistic infection
- Had a decrease in plasma HIV RNA (viral load) levels
- Had low baseline CD4 counts
- Had a robust virologic and immunologic response to ART
- Are ART naïve at time of diagnosis of their opportunistic infection

Some patients with IRIS lack any of these risk factors. *Mycobacterium Tuberculosis* IRIS, for example, often develops in patients whose CD4 counts prior to ART are greater than 50 cells/mm^3.

Clinical Presentations of IRIS
IRIS typically presents with fever, sweating, lymphadenopathy, fatigue, or other features characteristic of the underlying infection or condition. Signs and symptoms typically develop

within the first several weeks after ART initiation and can be severe enough to cause considerable morbidity and mortality.

Infections and Conditions Implicated in IRIS
A wide variety of conditions have been described in association with IRIS. The most common IRIS reactions involve mycobacterial disease (especially TB), cryptococcal disease or viral diseases from the herpes virus family. The possible presentation of IRIS is very broad and includes both infectious and non-infectious etiologies. Case fatalities have been seen with previously undiagnosed hepatitis with IRIS flare leading to liver failure, IRIS with KS can cause severe complications if present in the lungs or GI tract. CMV can lead to serious retintis/uveitis, iritis and blindness.

Infectious presentations of IRIS include TB (most common), MAC, PCP, Cryptococcus, CMV, HSV or VZV, Hepatitis B/C, PML, and toxoplasmosis.

Non-infectious presentations of IRIS include lymphoma, Kaposi sarcoma, Graves disease, rheumatoid arthritis, Guillain-Barre, sarcoid, and skin conditions.

Figure 55: Summary Timeframe for IRIS

Immune Recovery Disease	Clinical Presentation	Onset After ART	Outcome
MAC	Lymphadenitis, abscess, fever, lung infiltrates	1-12 weeks	Resolves with ART/MAC Rx, steroids
CMV	Retinitis, vitritis, uveitis	1-2 months	Resolves with ART/CMV Rx
H. Zoster	Typical attack	1-4 months	Resolves with Acyclovir
TB	Fever, lymph nodes, lung infiltrates	1-6 weeks	Resolves with ART/TB Rx, Steroids
Cryptomenigitis	Typical Symptoms	1 week-8 months	Resolves with ART and antifungal Rx

Diagnosis of IRIS
There are no widely accepted case definitions that exist, though diagnostic criteria have been proposed. Key elements favouring diagnosis of IRIS include:

- Low pre-treatment CD4 count
- Robust virologic and immunologic response to ART
- Temporal association between initiation of ART and onset of illness
- Presence of clinical signs & symptoms of inflammation
- Absence of evidence for other causes

Differential Diagnosis of IRIS
Some medication toxicities (for example drug induced hepatitis, allergic/hypersensitivity reactions) can present with signs and symptoms suggestive of IRIS, and the timing of typical IRIS reactions overlap with ARV-associated toxicities in the patient who has recently initiated ART. Failure of therapy of a pre-existing OI should also be considered in the patient with suspected IRIS.

Management Principles of IRIS
The following management principles for IRIS are from the draft of the WHO IMAI 2nd Level Clinical Manual, 2007.

1. Consider other possible aetiologies

2. Continue ART if possible
3. Attempt to diagnose the infection or condition responsible for IRIS
    - Aspirate and culture any easily accessible abscesses or lymphadenopathy
    - Obtain bacterial, mycobacterial and (if available) fungal cultures
4. Initiate disease-specific therapy (such as TB treatment), if not already in place
    - Development of IRIS does not require re-initiation of antimicrobial therapy or change in maintenance therapy, for the responsible infection if the patient is already on appropriate therapy
    - Initiation of empiric therapy is reasonable for highly suspected conditions when the diagnosis is not immediately apparent
5. Provide anti-inflammatory therapy
    - NSAIDS for mild-moderate cases
    - Corticosteroids from moderate-sever cases
6. Consider interruption of ART for patients with life-threatening IRIS or who do not clinically stabilise with other measures

Prevention of IRIS
The best approach is to screen and manage all opportunistic infections before the initiation of ART and complete screening x-rays to exclude asymptomatic tuberculosis. Additionally, it is important that providers ensure a timely initiation of ART which can be achieved through routine HIV testing and starting persons on ART before they are severely immune-suppressed. The timely initiation of ART means initiating ART according to National Guidelines for the Clinical Management of HIV and AIDS (CD4 cell count $\leq$ 200cells/mm3).

TB IRIS
TB IRIS is very common in endemic regions and usually presents within the first two months of ART (typically within three weeks). Presentation is usually extra-pulmonary or disseminated and is accompanied by severe fever and pneumonia. It can present as intracranial TB (tuberculoma or TB meningitis), effusions, enlarged liver and spleen, ascites, and lymph node involvement.

TB IRIS typically occurs when the patient is unknown to have TB at the start of ART (pulmonary TB) or the patient is on TB treatment before or at the start of ART and experiences a worsening of the lesions.

TB IRIS should be suspected with a worsening x-ray or worsening symptoms. It is important to differentiate IRIS from a new infection or drug toxicity. The AFB smear and culture may be negative, but the disease can be severe (and require hospitalisation due to danger of respiratory failure). If severe, ART can be stopped until patient is able to tolerate ART or inflammatory reaction has subsided.

Management of IRIS
TB IRIS can be serious. No consensus on treatment exists. ART should be continued if tolerated, but if severe, the patient needs to be hospitalised for fear of respiratory failure and ART discontinued until the patient is able to tolerate ART or the inflammatory reaction has subsided. TB medications should be started or continued and treatment may need to be expanded.

Use steroids when a severe inflammatory response is present and life-threatening (especially in case of severe dyspnoea, TB meningitis or chronic abscesses). Higher doses are typically

used initially (such as 60 mg oral prednisone or equivalent IV if needed.) For less severe presentation, NSAIDS may be an option.

Key Points

- All anti-TB and ARV drugs have side effects and some may have overlapping side effects
- In case of TB/HIV co-infection, priority should be to start with TB treatment
- In case of unexplained symptoms in a person on ARVs, first exclude a side effect of the treatment and then look for opportunistic infections and immune reconstitution
- IRIS is one of the complications of ART
- Diagnosis is challenging because IRIS can be confused with toxicity or treatment failure
- IRIS is not treatment failure but rather a recovery of the immune system and exaggerated presentation of unmasked infection
- Need to continue disease specific treatment (i.e. TB)
- Continue ART if possible and stop if severe toxicity is suspected or confirmed

UNIT 14: NUTRITION IN TB AND HIV

Introduction
Both TB and HIV are chronic infections that adversely affect nutrition. For this reason, good nutrition is as important to TB and HIV care as ART or anti-TB drugs.

Objectives
By the end of this unit you should be able to:
- Explain the relationship between HIV and AIDS, TB and nutrition
- Identify different TB, HIV and AIDS-related complications which can be managed by diet
- Identify ways to manage nutrition complications
- Discuss nutrition interventions for patients on ART and TB treatment

Why is Good Nutrition Important?
Nutrition helps keep cells healthy so that they can fight infections; malnutrition reduces the quality and life expectancy of PLHIV. TB infection adds to the nutritional needs of PLHIV. Malnutrition is poor nourishment of the body often due to not eating healthy foods, improper digestion, poor absorption of nutrients or a combination of these factors. Malnutrition also occurs when a person eats too much of one food and not enough of another. On its own, poor nutrition or malnutrition has a damaging effect on the immune system and the body. In combination with HIV, it leads to HIV related complications, accelerates the progression of HIV to AIDS, and consequently decreases life expectancy.

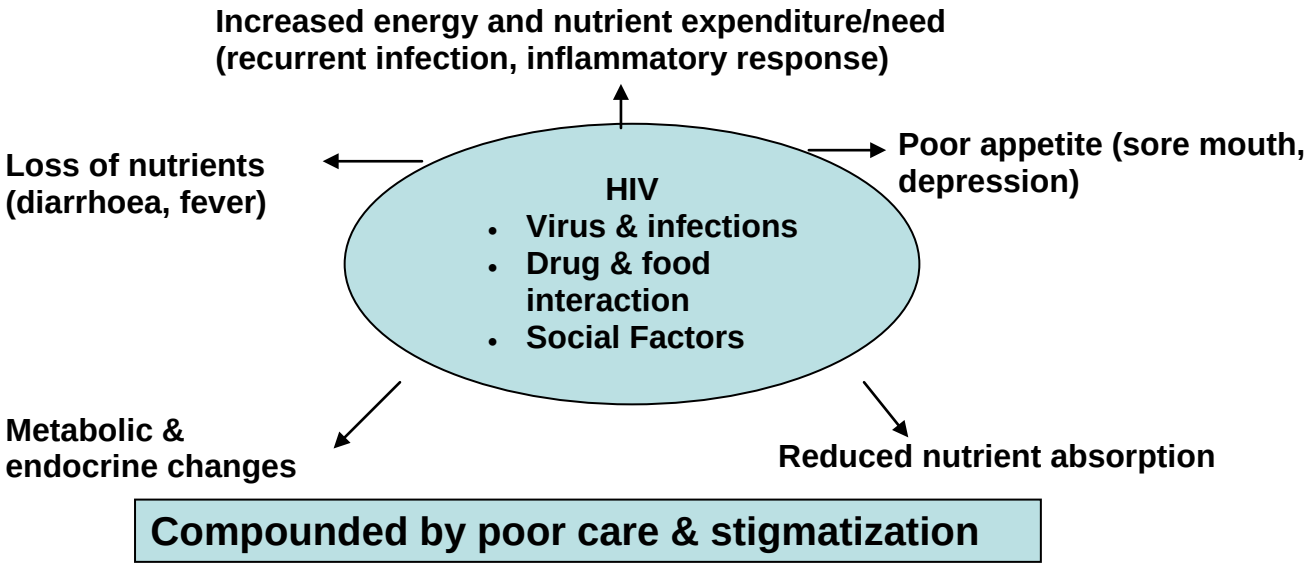
Although HIV cannot be cured by nutrition, optimal food intake can keep the cells strong to fight off HIV-related infections. In a non-HIV infected person, the immune system fights off germs and bacteria, and for viruses it makes antibodies to remember and fight them off in the future. These cells are made up of various nutrients-mainly proteins, fats, vitamins and minerals. So the more of these nutrients we can get from food, the stronger our cells will be to fight off infections. With HIV, however, the immune system is weakened and the body actually needs more nutrients to function normally. But nutrients can still help prevent HIV from multiplying and making the immune system weaker.

HIV/TB Impact on Nutrition
Infections add an extra burden of stress on the body, which increases the body's energy and protein needs from food. There is also a tendency for a sicker individual to eat less, as well as to have less absorption of the foods (s)he eats. This, in turn, leads to an increase in side effects, micronutrient deficiencies, weight loss and progression of HIV.

Early intervention can dramatically improve an individual's chances for survival and improved quality of life. This can involve an early nutrition assessment, education and counselling to prevent malnutrition, and treatment of nutrition-related problems.

TB and HIV are an extra burden on body. They can result in decreased food intake and decreased absorption. Providers can help patients to avoid this by offering early nutritional status assessment, nutrition education and counselling to prevent malnutrition, and early treatment of nutrition-related problems.

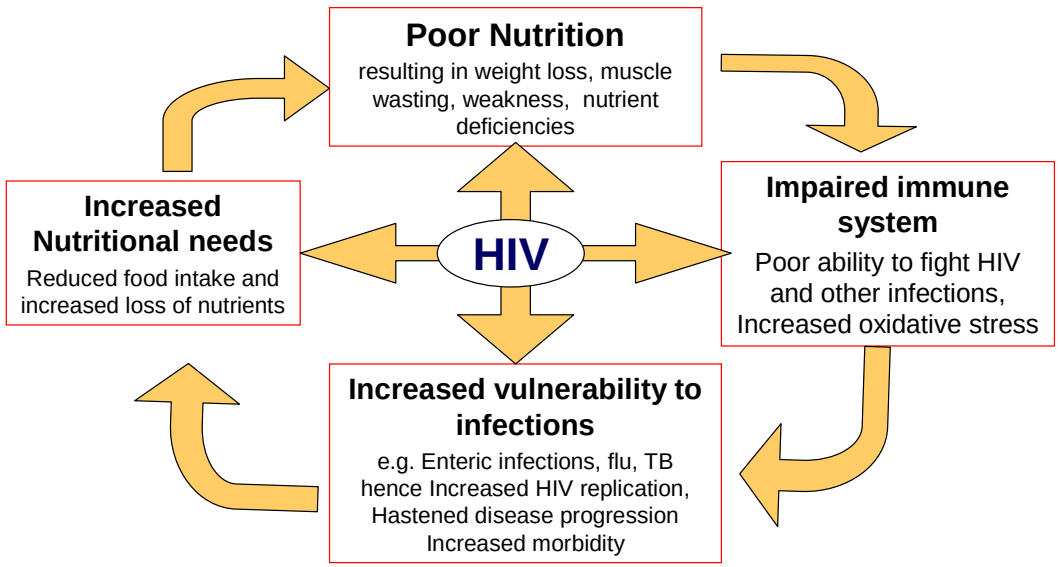
Figure 56: Reasons that PLHIV Experience Malnutrition



Vicious Cycle of Malnutrition and HIV

In the vicious cycle of malnutrition and HIV, poor nutrition leads to an impaired immune system, and in turn an increase in opportunistic infections and progression of HIV, leading to an increase in nutrient needs.

Figure 57: Cycle of Malnutrition and HIV



Nutrition Requirements for HIV

Calories/energy are needed to increase to fight infections and prevent weight loss. The caloric need for PLHIV is ten percent more than for those not infected with HIV. Patients with symptoms (WHO stage ≥2) need 20 to 30 percent more calories.

Protein intake is important for keeping the immune system strong and preventing wasting, but until a person with HIV starts to develop many infections, his/her protein needs are the same as a non-infected person. This means that he/she should have a portion of animal products with each meal or every time he/she eats. During infections, he/she will need to increase the portion of protein.

Because HIV causes the immune system to become weak and allow more infections, a person with HIV will need more energy or calories from food to stay strong. For an HIV-infected person who is in the early stages of HIV, his/her energy needs increase by about 10 percent of normal. So during counselling, we can suggest to a patient to add 1 or 2 teaspoons of extra oil to their meals, or have an extra serving. Energy comes from the staples, animal products and fat food groups, so keep these foods in mind when counselling on increasing energy intake. When an HIV-infected person begins to progress, his/her energy needs will increase even more, especially if he/she has lost weight or is having diarrhoea.

Nutrition & Complications Related to HIV/AIDS

Nutrition complications like having a poor appetite or diarrhoea can reduce the amount of food that one eats, leading to weight loss or micronutrient deficiencies leading to a decline in immune system function and overall health. Other complications include:

- Weight Loss
- Wasting syndrome
- Loss of appetite
- Nausea and/or vomiting
- Fevers
- Diarrhoea or malabsorption
- Sores of the mouth or throat
- Changes in taste
- Metabolic or endocrine changes
- Vitamin & mineral deficiencies

For these complications, some suggestions for management are provided below, but the provider will need to always take a patient's individual situation into consideration so that the provider is not just telling the patient what to do, but is suggesting things the patient can do to improve his/her nutrition and health.

Nutrition Management

Nutrition management refers to the provision of counselling and nutrition advice to assist a person in improving his or her nutrition and overall health status. Food is not a cure for HIV, but can help a person feel better and live longer with HIV. Nutrition counselling and education should be given in an integrated way, with other medical treatments or services such as provision of medications or immunisations.

Phases of Nutrition Care

There are the four phases of nutrition care: nutritional assessment, nutritional diagnosis, nutrition intervention (counselling), and monitoring and evaluation.

Phases 1 and 2: Nutritional Assessment and Diagnosis

The first phase involves gathering information about current nutritional status and adequacy of the diet. This involves measuring weight (including taking the weight history), conducting

a dietary assessment, gathering information about risk factors that may cause nutrition complications, and determining a diagnosis (i.e. underweight).

Weight is a proxy for nutritional status, it helps with early identification of wasting and with monitoring. There are two ways to determine weight status, one of which is BMI (body mass index), the other is weight history. BMI used to assess an individual's weight based on his or her height. It is a quick and easy way to estimate weight status (e.g. underweight, normal weight, overweight). Weight history allows us to assess the individual's weight over time.

To calculate weight history, divide the patient's current body weight by his/her usual body weight. Multiply that by 100 and the answer is the patient's percentage of his/her normal body weight. 85 to 90 percent of normal body weight is a mild depletion, 75 to 84 percent is moderate depletion, and less than 75 percent is severe depletion.

It is important to conduct a dietary assessment to determine the adequacy of the diet. This should include a current dietary intake (quantity, frequency). The patient's typical daily diet or 24 hour recall may be used. It is important to assess the following possibilities:

- Changes in appetite
- Chewing and swallowing problems
- Food intolerance, allergies or restrictions, likes and dislikes
- Nutrition related deficiencies and diseases
- Use of vitamin and mineral supplements
- Substance abuse (alcohol, tobacco)
- Ability to acquire and prepare food
- Use of food programmes

Phases 3 and 4: Nutritional Intervention and Monitoring and Evaluation

For phases 3 and 4, the provider should tailor nutrition counselling to suit the needs of the individual. This includes recording the patient's weight, age, complications, and physiological state. The provider will also want to make sure that the patient is eating a balanced diet from the 6 food groups, based on dietary guidelines.

Five Food Groups

PLHIV patients should be encouraged to use of a variety of foods from the five food groups. The emphasis should be on locally available affordable foods. Foods that come from animal products are high in protein. Foods that come from the staples and fats categories supply energy to the body.

Guidelines for using the 6 food groups in counselling PLHIV:

- Use a good amount of staple foods. They should be the main source of energy
- Use foods from animals as generously as can be tolerated
- Use legumes as often as can be tolerated
- Use fruits and vegetables generously
- Use fats and oils as moderately as can be tolerated
- Use a generous amount of fluids

Food groups are divided as follows:

- Cereals, roots, tubers and cooking bananas
- Pulses, nuts and foods of animal origin
- Fruits

- Vegetables
- Fats and oils

Many PLHIV need high protein and high energy diets. Foods from animals are rich in protein. Fats and sugars are high in energy.

Nutrition Counselling for PLHIV

Nutrition counselling or advice refers to the suggestions provided to a person when discussing food. This does not include telling a person what to eat or how often to eat. However, it does include an assessment of a person's normal eating patterns and food intake, and from there, providing advice on how to improve his/her nutrition status. Providers should encourage patients to:

- Try to eat foods from each of the six food group
- Eat at least 3 times a day to maintain weight and prevent side-effects and nutrient deficiencies
- If 3 large meals are not possible, try smaller meals more frequently
- Discourage excessive use of alcohol
- Exercise
- Handle and prepare food safely

When providing nutrition counselling, remember to emphasize the importance of safe food handling which includes hand washing, safe food storage, using clean utensils, and such.

Weight Loss

Weight loss includes loss of adipose tissue (fat) and lean tissue/BCM (body cell mass). Weight loss follows two patterns:

- Chronic weight loss: slow progressive weight loss. It sets in as the viral load increases
- Acute weight loss: episodic weight loss from secondary infections

For PLHIV, weight loss is extremely dangerous because it leads to loss of immune function, increased risk of infection, and shortened survival. Key interventions to counteract this are preventing weight loss and malnutrition, identifying and treating weight loss early, managing nutrition, and measuring weight and height and determining BMI = weight/height2 (in metres).

Any amount of weight loss is dangerous for a person with HIV because as soon as a person begins to lose weight unintentionally, their immune function decreases, their risk of infection increases, and their chances of survival diminish. This is particularly true for children as well.

The first key intervention related to weight loss is to prevent any loss from the time of diagnosis. This can be done with nutrition promotion and identification of gaps in access to a balance diet. Weight loss can also be managed appropriately with early detection and treatment. Nutrition management of weight loss and other related side effects (diarrhoea, poor appetite, etc) can also help manage weight loss and promote weight gain. Each patient assessment should include measurements of height, weight, and body mass index.

Weight Loss: Nutrition Management

Nutrition management should include increasing energy intake from food, addressing other symptoms, addressing food availability issues, obtaining weight at each visit. Encourage the patient to increase his/her energy intake from food. This would include adding higher calorie foods to staple foods: i.e. groundnuts, oils, butter, eggs, milk/milk products, etc. A patient can also increase energy intake by eating more frequently.

Other symptoms, such as diarrhoea, poor appetite, mouth sores, should be addressed as well. Health workers should also discuss food availability and access issues with patients. Patients who have lost significant amounts of weight should be monitored closely and weighed regularly to track their progress.

Loss of Appetite

When dealing with an illness, people often lose their desire to eat and consequently do not eat very much. This is called anorexia or loss of appetite. This can be serious because it means that the person is probably not getting all the nutrients they need. Loss of appetite can be caused by medications or illness. Management should include frequent small, high energy meals, eat most when feeling hungry, and exercise regularly if physically able.

Poor appetite or loss of appetite can be managed by eating smaller meals more frequently, but high energy meals. Patients should eat the most when they are hungry or have an appetite to make up for times when they do not want to eat. Patients should be encouraged to exercise (e.g. walking, gardening) to help improve the appetite as well.

Sores in the Mouth

Mouth sores can be caused by medications or infections and are fairly common among HIV-infected patients. To manage mouth sores with nutrition, patients can be encouraged to try softer, mashed food or drinks. Because mouth sores can be irritating, acidic foods might worsen the pain. Therefore, these foods should be avoided – foods such as oranges, lemons/lemon juice, and tomatoes. For extra vitamin C from non-acidic foods, suggest that the patient eat more potatoes, which have vitamin C but will not irritate the mouth. Liquids should be taken through a straw to keep the mouth dry, promote healing, and prevent dehydration. The moister the mouth remains, the slower wounds may heal. However, make sure that the patient does not become dehydrated by not drinking enough liquids. Patients should also be encouraged to:

- Eat soft, mashed foods
- Avoid acidic, salty and spicy foods
- Select moist foods, but avoid foods that stick to the mouth
- Drink liquids with straw
- Avoid hot or very cold foods
- Encourage good oral hygiene - rinse mouth with salty water
- Serve highly nutritious food

Nausea and/or Vomiting

Nausea and/or vomiting can lead to poor food intake and weight loss because a person who is nauseated may not want to eat anything. These symptoms are often caused by medications, HIV, and other infections and lead to poor food intake and weight loss.

In order to manage nausea and/or vomiting, patients should eat smaller meals, more frequently through the day. Nausea may be worse when the stomach is empty. They can also try eating dry foods such as biscuits and toast, as these tend to ease the stomach. Patients should avoid lying down after meal. Suggest that after eating a meal, they remain sitting up for at least 30 minutes. Lying down after eating or drinking anything might worsen the nausea. Another way to prevent or lessen nausea and vomiting is to drink liquids between or after meal, rather than during the meal because liquids fill the stomach fast. Patients should avoid spicy, strong smelling and greasy foods as well as very sweet foods. They should also check with the doctor about the timing of medicine and notify their doctor if they are taking TB medications and have new onset nausea or vomiting. If available, tea with ginger can also soothe the stomach.

Changes in Taste

Medications that PLHIV often take, such as ARVs, can cause changes in taste or a metallic taste in the mouth. This can also happen when someone has many mouth sores or mouth infections. In order to manage changes in taste, it is important to first treat any mouth sores if applicable. Management consists of treating the sores, encouraging the maintenance of oral hygiene, and using flavour enhancers such as salt or lemon to stimulate taste buds. Health workers can help patients by providing treatment or ointments, suggesting that patients add herbs or seasonings to foods in order to improve flavour, and encouraging patients to practice good oral hygiene, such as brushing teeth often.

Persistent Diarrhoea

Diarrhoea can be one of the most serious problems for people with HIV. It is caused by malabsorption, HIV, other infections, and/or medications and can lead to weight loss, dehydration, and malnutrition. (Malnutrition is thepoor absorption of nutrients into the body.) Encourage the use of locally available fluids such as coconut water and locally made oral rehydration solution.

Diarrhoea can lead to rapid weight loss, dehydration, and malnutrition. It is caused by malabsorption, HIV, other infections, and/or medications, leading to weight loss, dehydration, and malnutrition.

Diarrhoea can become a serious problem; refer the patient to a doctor, if necessary. When managing diarrhoea, the first priority is to treat dehydration. This can be done by using oral rehydration solution (ORS) or if that is not available, using one of the following homemade solution for rehydration:

- Sugar-salt solution: 8 teaspoons sugar plus ½ teaspoon salt added to 1 litre clean water
- Cereal and salt solution: 2 handfuls of powdered cereal or grain (give an example of a locally available grain) plus ½ teaspoon of salt added to 1 litre clean water.

These solutions should be made correctly and given in small portions throughout the day, especially after each loose stool.

Nutrition management of diarrhoea:

- Treat dehydration (oral rehydration solution, home solution, coconut water)
- Easy-to-digest foods
- Give a lot of fluid, avoid soft drinks, chocolate, tea
- Small meals, frequently
- Avoid fatty foods (with fat malabsorption)

- Avoid high sugar foods
- Give potassium rich foods and starchy meals
- Avoid dairy products (milk)
- Admit patient is severely dehydrated
- Eat warm meals rather than hot or cold foods.

Micronutrient Deficiency

There are several types of micronutrient deficiencies, but the most common among PLHIV are anaemia or iron deficiency and vitamin A deficiencies. Since anaemia can often be a mask for other internal bleeding or infections, a full medical assessment is necessary, including a diet history to see how much iron the patient is getting from food. Vitamin deficiencies tend to increase as the disease progresses, and may even begin in asymptomatic cases including those who are eating well.

Key Points

- Proper nutrition leads to a stronger immune system, slower progression to AIDS and fewer side effects
- Malnutrition and weight loss are serious for people living with HIV and AIDS
- A nutritional assessment should determine the patient's weight and adequacy of their diet
- Nutritional counselling should encourage a diet that includes a balanced diet from all six food groups
- Nutritional interventions can help PLHIV manage nutrition complications and side effects

UNIT 15: COLLABORATIVE TB/HIV ACTIVITIES

Introduction

In order to provide comprehensive care to patients who are dually infected with TB and HIV, health workers need to be familiar with a range of activities intended to reduce the burden of TB and HIV. This unit will cover the main objectives of collaboration as well as the activities to be implemented within the first objective.

Objectives

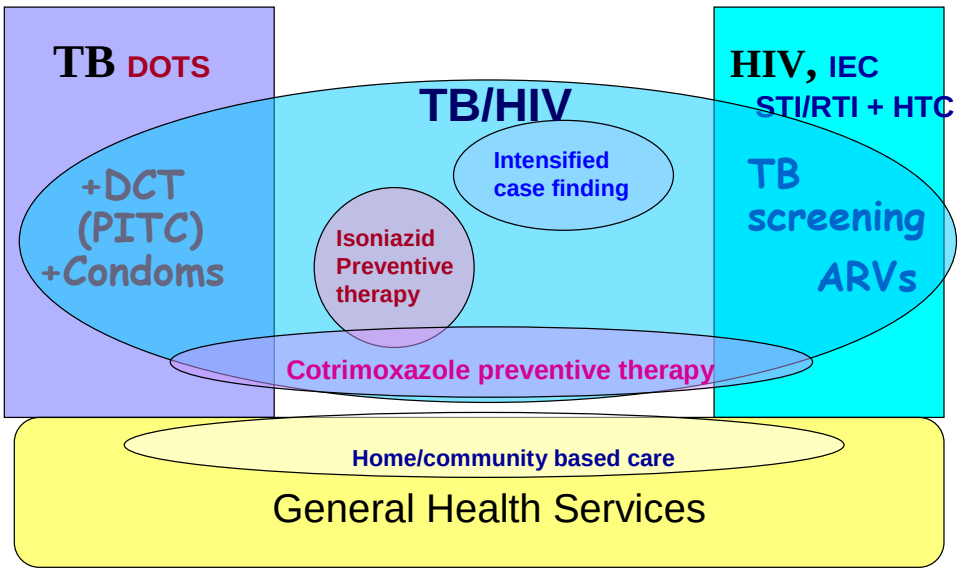
By the end of this unit, you should be able to:

- Describe the goal of collaborative TB/HIV activities
- Identify objectives of collaborative TB/HIV activities based on the TB/HIV national policy
- Describe the recommended activities of collaborative TB/HIV activities within the first objective

Goal of Collaborative TB/HIV Activities

The goal of collaborative TB/HIV activities is to reduce the burden of TB and HIV for individuals affected by both diseases. In the past, patients had to seek care for TB and HIV separately: TB programmes were providing DOTs services and HIV programmes were providing care and treatment services but none of the programmes were managing the patients holistically. The goal of the collaborative TB/HIV activities is to close this gap thus provide comprehensive care to reduce the burden of the two diseases.

Figure 58: Current Status of TB and HIV Activities



Objectives of Collaborative TB/HIV Activities

The objectives of collaborative TB/HIV activities are as follows:

1. Establishment of mechanism for collaboration
2. Decrease the burden of TB in PLHIV
3. Decrease the burden of HIV in tuberculosis patients

Objective 1: Establish Mechanisms for Collaboration

Recommended activities:

- Set up coordinating body for TB/HIV activities that are effective at all levels
- Establish positions of collaborative TB/HIV coordinators and officers at all levels
- Conduct surveillance of HIV prevalence among TB patients
- Joint TB/HIV Planning
- Conduct Monitoring & Evaluation
- Facilitate partnership development and coordination

Setting up coordinating body for TB/HIV activities that are effective at all levels involves coordinating committees at national, regional and district levels. These committees should have between 14 and 18 members and meet quarterly. Members can include CHMTs, representatives from NGOs, FBOs, and private health facilities, and TB/HIV patients. The committee's function is to:

- Translate policies and directives for implementation at the district and community level
- Facilitate the joint planning and integration of TB/HIV activities into CCHP
- Mobilize and allocate adequate human, financial and material resources needed for collaborative TB/HIV activities
- Oversee implementation of joint TB/HIV activities in the district and community level
- Review progress of implementation of TB/HIV activities in the district
- Provide support for regular monitoring and supervision of collaborative TB/HIV activities in the district
- Coordinate and harmonize different TB/HIV implementing partners in the district

Key Points

- The goal of collaborative TB/HIV activities is to reduce the burden of TB and HIV for individuals affected by both diseases
- Objectives of collaborative TB/HIV activities are to establish the mechanisms for collaboration, decrease the burden of TB in PLHIV, and decrease the burden of HIV in TB patients
- Some of the activities included under the first objective include setting up the coordinating body for TB/HIV activities that are effective at all levels, conducting surveillance of HIV prevalence among TB patients, joint TB/HIV planning, conducting monitoring & evaluation, and facilitating partnership development and coordination

UNIT 16: DECREASING THE BURDEN OF TUBERCULOSIS IN PEOPLE LIVING WITH HIV AND AIDS

Introduction
Reducing the impact of TB in PLHIV is important for improving the quality of life of people with HIV and AIDS and improving TB control efforts in order to mitigate the impact of both diseases to the public. The purpose of this unit is to equip health workers with knowledge to implement HIV care and treatment services so they can carry out activities to reduce the burden of TB in PLHIV.

Objectives
By the end of this unit, you should be able to:
- Identify activities aimed at decreasing the burden of TB in PLHIV based on TB/HIV national policy guidelines
- Explain procedures for TB screening among PLHIV
- Describe the protocol for initiating IPT in Tanzania
- Describe TB infection control measures

The Importance of Reducing the Burden of TB amongst PLHIV
PLHIV are more vulnerable to acquiring TB than are those whose immune systems are not compromised. PLHIV with TB have a lower survival rate because their bodies are less able to fight TB. Increased TB cases in HIV-infected people pose increased risk of TB transmission to the general community.

Main Activities to Reduce TB Burden amongst PLHIV
In order to reduce the burden of TB amongst PLHIV, provides should:
- Establish intensified TB case-finding
- Introduce Isoniazid (INH) Preventive Therapy
- Ensure TB infection control in healthcare settings and congregate settings (places where large numbers of people come together)

Establish Intensified TB Case-Finding
Use a standardized TB screening tool with a minimum set of questions based on symptoms and signs. Review patients' TB status at each visit to ensure early diagnosis of TB suspect based on national TB algorithm. Those found with TB should be promptly referred to TB clinic for treatment, while those screened negative for TB should be evaluated for IPT. Ensure functioning referral system between HIV care and treatment clinics and TB diagnostic and treatment centres.

Good TB screening questions include:
- Have you been coughing for two weeks or more?
- Have you lost weight recently?
- Do you have excessive night sweats?
- Do you have a fever?
- Are your lymph nodes enlarged?
- Have you lost your appetite?
- Do you have history of coughing up blood stained sputum?

Figure 59: TB Screening Questionnaire

MINISTRY OF HEALTH AND SOCIAL WELFARE
COLLABORATIVE TB/ HIV ACTIVITIES

TB SCREENING QUESTIONNAIRE FOR HIV/AIDS PATIENTS

Date: _____ Reg. Number: _____
Patient's name: _____
Physical Address: _____
Contact telephone (if available) _____
Area leader/ neighbor: _____
Sex: Male _____ Female: _____ Age _____

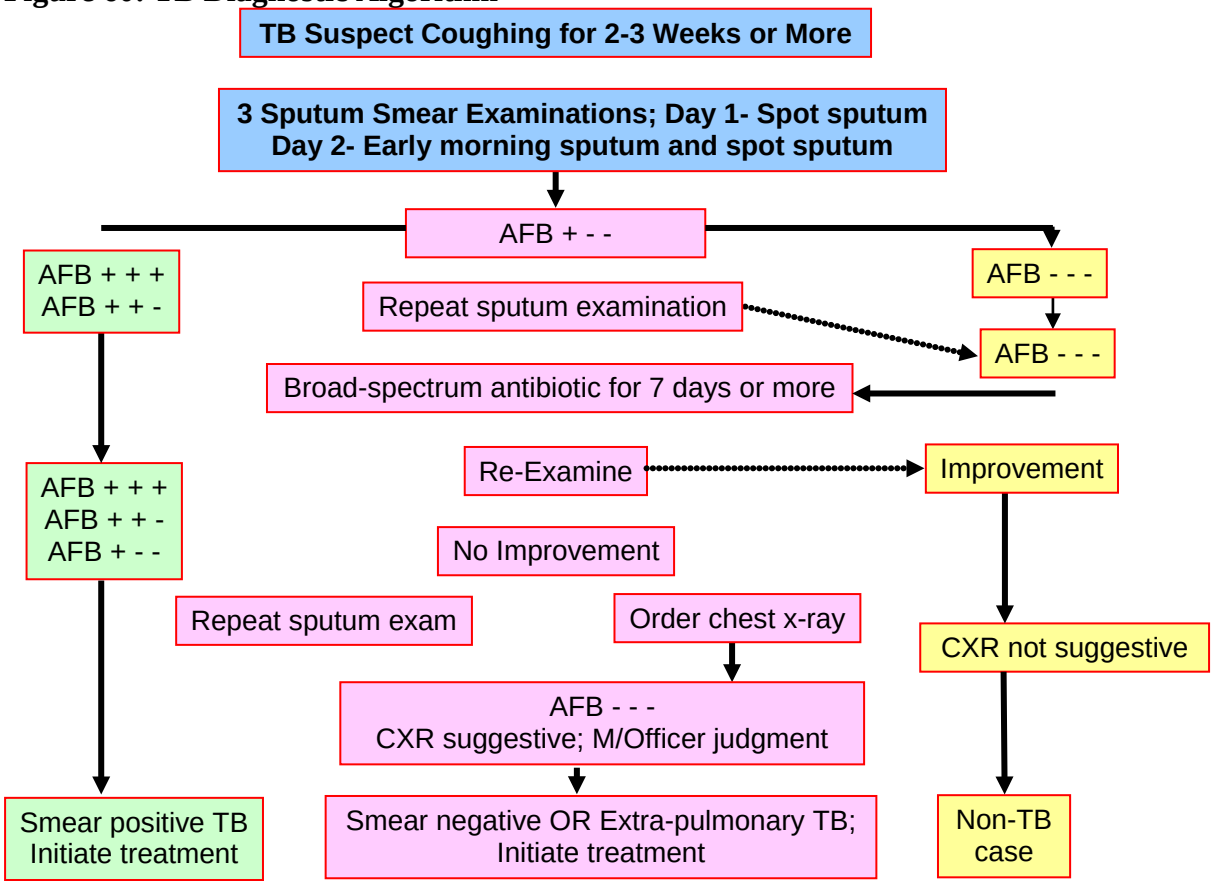
Tick appropriate response

Do you have the following:	Yes	No
1. Cough for two or more weeks?	{ }	{ }
2. Coughing up bloodstained sputum (haemoptysis)?	{ }	{ }
3. Fevers for two or more weeks?	{ }	{ }
4. Noticeable weight loss for new patients or a 3 kgs weight loss in a month (subsequent visit) ?	{ }	{ }
5. Excessive sweating at night for two or more weeks?	{ }	{ }

- If 'YES' to <u>one or more</u> questions:
  Do sputum examination and continue evaluation according to the TB diagnostic flowchart of the National Tuberculosis and Leprosy Program (NTLP)
- If 'No' <u>to all</u> questions: stop TB investigations and repeat screening at the subsequent visit (every month)

Action taken	Date	Result
Sputum smear		
Chest x - ray		
Appointment for next visit		
Refer for clinical assessment		
Started broad spectrum antibiotics		
Started anti – TB treatment		

Figure 60: TB Diagnostic Algorithm



Introduce Isoniazid Preventive Therapy (IPT)

HIV infection is the strongest known risk factor for the progression of latent TB infection to active TB disease. In countries with high TB prevalence, between five and ten percent of HIV-infected adults may develop active TB each year.

TB preventive therapy should be part of package of care for people living with HIV. PLHIV who screen negative for TB should be evaluated for IPT as evidence shows that IPT is effective in HIV-infected people, who have a higher risk of developing TB. IPT should only be used where it is possible to exclude active TB, ensure appropriate monitoring and follow up, and ensure that adherence is possible. Information about TB, including preventive therapy, should be made available to PLHIV.

ISTC, Standard 16 states: all providers of care for patients with tuberculosis should ensure that persons (especially children under 5 years of age and persons with HIV infection) who are in close contact with patients who have infectious tuberculosis are evaluated and managed in line with international recommendations. Children under 5 years of age and persons with HIV infection who have been in contact with an infectious case should be evaluated for both latent infection with M. tuberculosis and for active tuberculosis.

Who Can Get IPT in Tanzania?
In Tanzania, people who are at high risk for TB can get IPT. These populations include:

- HIV exposed and unexposed infants of mothers with TB
- All children younger than five in contact with smear positive TB patient
- Hospitalised and outpatient HIV positive patients
- HIV positive household contacts of TB patients
- HIV positive health workers
- HIV positive prisoners
- Other HIV positive individual in congregate settings

Who is NOT Eligible for IPT in Tanzania?
Patients who are:

- Currently on TB treatment or have a history of completed TB treatment in the last 2 yrs
- TB suspect or with confirmed active TB
- Medically contraindicated to INH
- Abusing alcohol
- Pregnant
- In WHO clinical stage 4
- Non-adherers

Medical contraindications and a history of completed TB treatment can be either documented OR self-reported. Contraindications to INH are allergies to INH/acute liver disease

Refer to the National TB Guidelines for further information on IPT.

Preparation for IPT
In order to prepare a patient for IPT, the patient should be educated on the effects of TB in PLHIV, the importance of preventing TB, and the differences between TB infection and TB disease. The patient should also be informed that he/she has been exposed to TB and will need to start IPT to prevent TB disease. The provider should counsel the patient to take all medications and educate him/her on the effects of non-adherence. The patient should be prescribed Isoniazid (5mg/kg-max 300 mg) daily for 6 months and pyridoxine to prevent peripheral neuropathy, and the patient should be registered in the IPT register and supplied one month treatment.

Can Your Facility Provide IPT?
In order to determine whether a facility can provide IPT, the following questions should be asked:

- Ability to exclude active TB?
- Adequate trained staff?
- Enough quantities of Isoniazid?
- Capacity to follow up patients on IPT and ensure adherence?
- Good recording and reporting

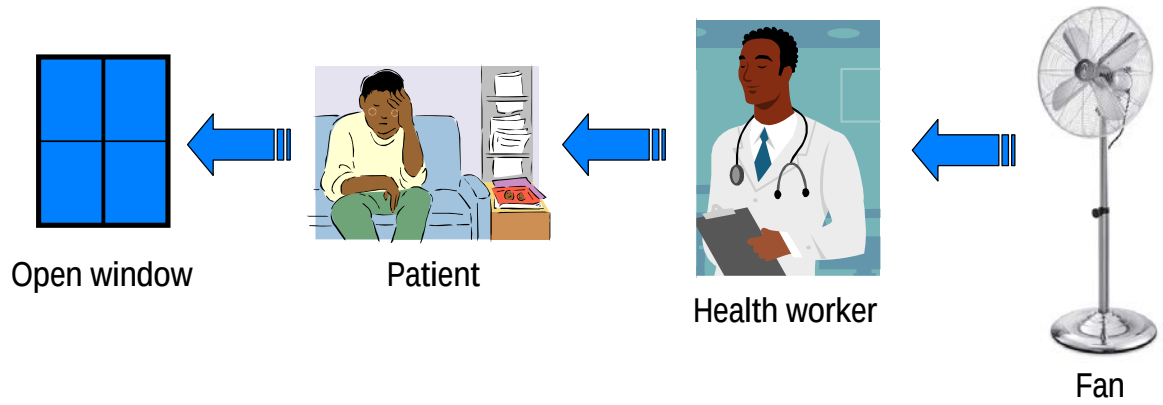
Ensure TB Infection Control in Health Care Settings
Infection control can be divided into two main categories: work practice/administrative control measures and environmental control measures. Workplace practice and administrative control measures include an infection control plan, administrative support for procedures in the plan including quality assurance, training of staff, and education of patients and

increasing community awareness. Environmental control measures include ventilation (natural and mechanical), filtration, and ultraviolet germicidal and irradiation.

Known HIV-positive health workers should not work with sputum smear PTB cases. Minimise contact between HIV-positive patients and patients with active TB. Patients with suspected TB should be examined in a well-ventilated room and avoid hospitalisation of infectious TB patients whose medical condition does not require inpatient care.

Good ventilation is the most essential part of infection control. If possible, positioning a ground fan behind the provider so air blows from the provider to the patient to outside. If no fan is available, be sure to position yourself upwind from TB patient, preferably by an open window or other well ventilated area.

Figure 61: Proper Airflow Direction



Ensure TB Infection Control in Laboratory Settings

In order to ensure TB infection control in laboratory settings, sputum containers should be opened carefully and should not be shaken. In addition, sputum smear preparation should be done carefully in a well-ventilated place. Normal detergents are adequate for cleaning (Lysol or phenol-derived soap mixtures are recommended), and infectious material should be discarded carefully by incineration.

Ensure TB Infection Control in Congregate Settings

Congregate settings include prisons, schools, refugee camps, and army camps. In order to ensure TB infection control in congregate settings, providers should screen new arrivals in uniform (army, police, prisons) for TB. Army camps should undergo regular screening. In prisons, new inmates should be screened and decongested. Those with TB may need to be isolated, and started on DOTs. Both refugee camps and schools should provider education on TB/HIV.

Provide Information About TB and Treatment

Emphasize to patients that TB can be cured. Other information and education about TB should include:

- Explanation of TB
- How TB spreads
- How to prevent TB from spreading
- Who else should be examined or tested for TB

- Necessity of directly observed treatment (DOT)
- Explanation of TB treatment; dose, duration and adherence
- What to expect and what to do next

Key Points

- All PLHIV should be screened for TB
- IPT can be provided to PLHIV after excluding active TB
- Infection control is an important aspect of TB/HIV collaborative activities and should be implemented in all health facilities and congregate settings

UNIT 17: DECREASING THE BURDEN OF HIV IN TUBERCULOSIS PATIENTS

Introduction

HIV and AIDS are fuelling the TB epidemic in many parts of the world, including Tanzania. TB is also the most common opportunistic infection and leading cause of death among people with HIV and AIDS. The purpose of this unit is to equip healthcare workers implementing TB control activities with the knowledge and skills they need to screen TB patients for HIV and provide them with care and treatment.

Objectives

By the end of this unit, you should be able to:

- Identify activities aimed at decreasing the burden of HIV in TB patients
- Explain components of comprehensive care, treatment and support
- Describe methods for the prevention of HIV transmission

Activities to Decrease the Burden of HIV in Tuberculosis Patients

The main activities to decrease the burden of HIV in TB patients include:

- Providing HIV counselling and testing
- Introduction of HIV prevention methods
- Introduction of cotrimoxazole preventive therapy (CPT)
- Ensuring care and support
- Providing ARV therapy

HIV Testing and Counselling

HIV testing and counselling should be offered to all TB patients. TB programmes should mainstream provision of HIV counselling and testing or establish a referral linkage with HIV and AIDS programmes.

HIV Prevention Methods

TB programmes should implement comprehensive HIV prevention strategies or refer patients to an HIV/AIDS programme (ABC: abstinence, be faithful, use condoms). TB patients should be screened for STIs/RTIs using simple questionnaires and pregnant TB patients to be referred to for preventing mother to child transmission (PMTCT).

There are various ways to reduce heterosexual transmission of HIV. These include improved coverage for HIV testing and counselling services, a supportive social environment to change social norms and sustain behavioural change, reduced stigma and discrimination against people with HIV, encouragement of disclosure, and the promotion of male circumcision. Other prevention methods include sexual abstinence or the delayed onset of sex especially for adolescents, faithfulness, safer sex practices, including consistent and correct use of condoms, and better recognition and management of STIs.

Cotrimoxazole Preventive Therapy (CPT)

Cotrimoxazole preventive therapy (CPT) should be provided to TB patients co-infected with HIV. All TB/HIV co-infected patients are eligible for CPT. TB patients should start CPT as soon as they are identified to be infected with HIV, as it prevents many opportunistic infections (OIs), such as *S. pneumonia, S. typhimurium*, parasitic infections (*Toxoplasma gondii, Isospora belli,* malaria), and fungal infections (*Pneumocystis jirovecii*). CPT is

indicated for all TB/HIV patients; however it can be stopped when the patient's immune system has significantly improved.

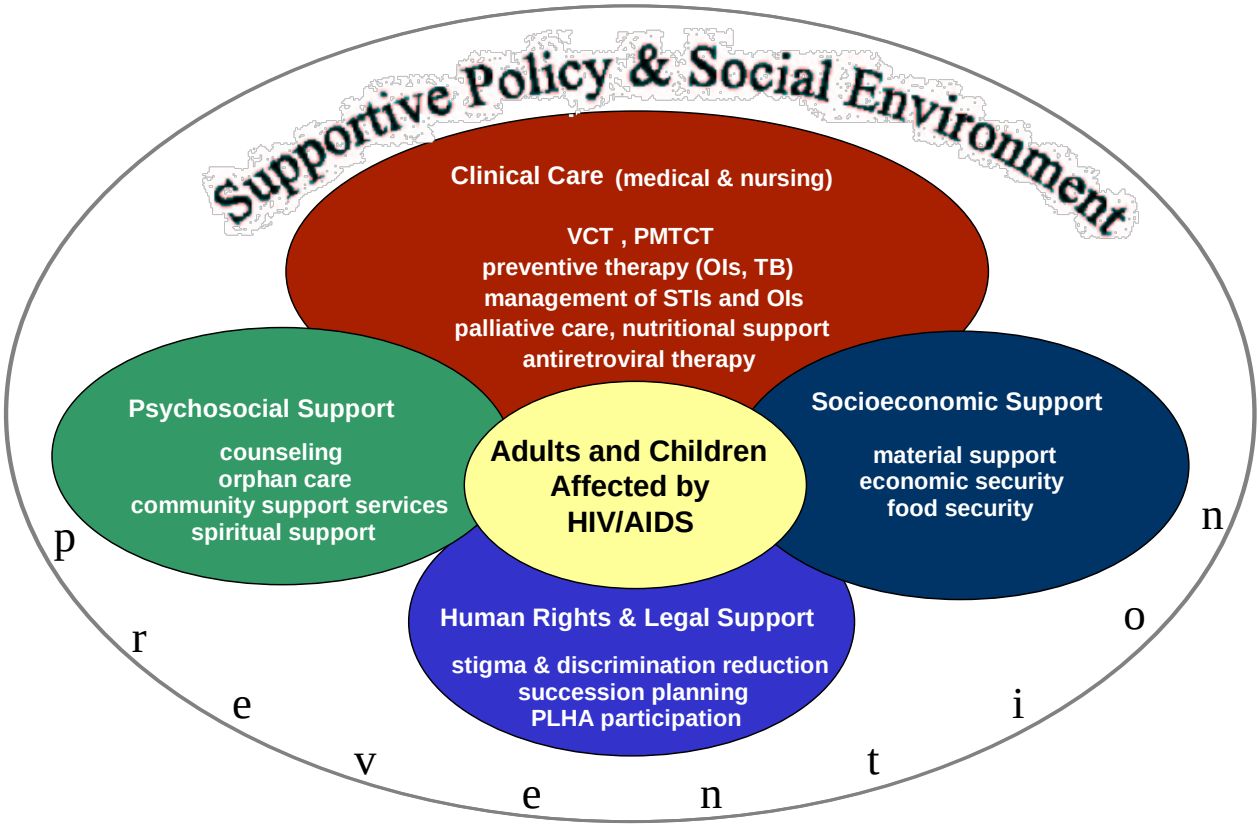
An adult needs one double strength tablet (160/800mg) or two single strength tablets (80/400) once a day. Children who weigh below 10 kg should receive 5mg/kg, children who weigh between 10-15 kg should receive ½ a tablet single strength, and children who weigh more than 15 kg should receive 2 tablets single strength.

CPT prophylaxis is for life for both adults and children who are not on ARVs. For those on ARVs, CPT prophylaxis can be stopped if CD4 is greater than 200. CPT should be stopped if the patient is having severe cutaneous reactions, severe jaundice, severe anaemia, or pancytopenia.

CPT should involve regular follow up every month for the first three months and then every three months if the medication is well tolerated. The provider should monitor side effects and adherence, which includes a skin assessment for skin reactions, measurement of Hb and white blood cell (WBC) every six months.

Ensure Care and Support
TB patients should be provided with HIV and AIDS care and support services. TB programmes should establish a referral linkage with HIV and AIDS programmes for continuum of care and support for PLHIV.

Figure 62: Components of HIV/AIDS Care and Support



ARV Therapy

Based on eligibility criteria, ART should be offered to all TB patients who are HIV-positive. TB and HIV/AIDS programmes should create the mechanism to provide ARV to eligible HIV-positive TB patients. Either of two approaches can be used refer TB patients to CTC for ART or offer ART within the TB clinic.

Key Points

- In order to decrease the burden of HIV in tuberculosis patients, providers should know how to:
  - Provide HIV counselling and testing
  - Introduce HIV prevention methods
  - Introduce cotrimoxazole preventive therapy (CPT)
  - Ensure Care and support
  - Provide ARV therapy

UNIT 18: TB/HIV REFERRALS AND LINKAGES

Introduction
An effective and functioning referral and linkage system assists chronically ill patients in receiving appropriate services of care, treatment and support within their respective communities and homes. TB/HIV patients may receive care in different settings and the coordination of care in different settings promotes continuity of care. Clinicians treating TB/HIV patients are in a key position to refer patients to appropriate services. Timely information on where to seek services and strong referral linkages are of vital importance.

Objectives
By the end of this unit, you should be able to:
- Discuss the importance of referrals and linkages
- Explain the referral flow chart for TB/HIV services
- List the components of comprehensive care, treatment and support
- Outline the steps to facilitating referrals

Reasons for Referral and Linkages
Patients have a variety of needs that cannot be met by a single organization, so referrals and linkages ensure the continuum of care for services not available at the current facility. Meeting the needs of patients requires partnerships and networks of stakeholders, including governmental agencies, community-based organizations (CBOs), faith-based organizations (FBOs) and similar agencies.

What are Linkages?
Linkages are formal networks between organizations or an agency and the community. Linkages facilitate the referral of the patient and his/her family for needed services. Linkages can also facilitate the referral of people living with TB/HIV from the community into services. The goal of linkages is to provide a "seamless" continuum of care delivered efficiently and conveniently as if there were a single entity delivering care.
TB/HIV programmes should have linkages with tertiary referral hospitals, district hospitals, peripheral health facilities, intersectoral linkages within the district (i.e., with education, agriculture, local government, etc.), the communities they serve, and non-governmental and faith based community organizations.

Community Linkages
Linkages to community-based organisations can provide resources to help TB/HIV patients and their families cope with the isolation, social stigma, and emotional pressures that often accompany their diagnoses. Healthcare workers can facilitate connections within the community by networking with supportive community agencies, identifying key partners and formalising methods of contact and communication. Resources can include support groups, social activities, community-based organisations, paid work to help families meet specific needs, and faith-based organisations and churches. Where no such organisations exist, healthcare workers can foster their development through community mobilisation.

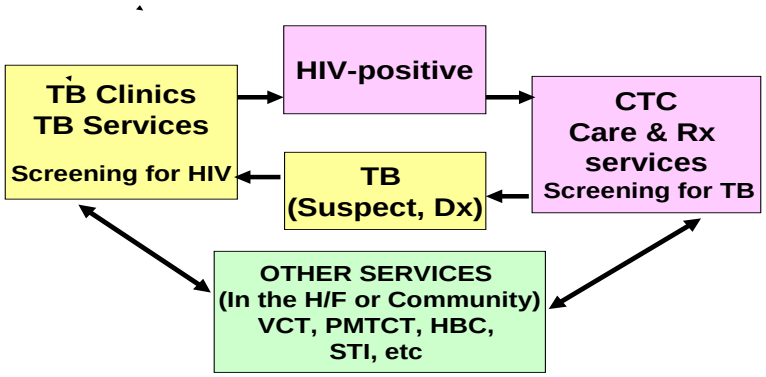
Facilitating Strong Linkages
A number of factors facilitate the building of strong linkages, including informal personal relationships, communication and transport systems. Additionally, the integration of management and support functions such as planning, education and training, supplies and management also enhance the strength of linkages.

Advantages of Strong Linkages
Strong linkages lead to better access to key HIV, TB, family planning, and care and treatment services tailored to the patients' needs. Additionally, strong linkages can result in the promotion of TB/HIV activities and messages among healthcare workers, the reduction of HIV and AIDS-related stigma and discrimination, improved coverage of underserved and marginalized populations, improved quality of care, and enhanced programme effectiveness and efficiency. Linkages not only provide patients with comprehensive care, but also enable the development of a sense of joint purpose and joint achievement. They enable healthcare workers to feel part of the broader strategy to improve the health of the community and, as such, increase staff motivation and satisfaction.

On the other hand, poor linkages can lead to negative consequences such as gaps in services, service duplication and inappropriate division of tasks.

What are Referrals?
Referrals involve guiding patients to obtain services based on their specific needs. The patient can be referred to another service if the patient or family member has unmet needs or by patient or family request. Referrals can also be arranged when there is unavailability or inaccessibility of services at the facility.

Figure 63: Referral Flow Chart for TB/HIV Services



Comprehensive Care, Treatment and Support
Includes:

- Medical and nursing care
- Psychological support
- Socioeconomic support
- Involvement of HIV positive individuals and their families
- Respect for human rights
- Legal support

Referral tools should be used to assist patients in accessing services, including: Unit TB registers, TB/HIV referral forms, and referral directories.

Steps for Making Referrals
First, the need for a referral must be identified and discussed with the patient. It is important to involve the patient in the initiating of a referral in order to create ownership around the referral decision. Next, the patient should be guided through the process, including filing out referral forms and reaching the referred service. The facility directory/inventory should be used and all referrals should be properly documented. Additionally, follow-up with the patient after the referral is a vital step of the referral process in order to determine if the required services were received. If the proper services were not received, find out the reason and assist the patient in overcoming any existing barriers to service.

Monitoring Referrals
Feedback from referrals is important as a quality assurance mechanism so that referring facilities can assess the success and appropriateness of their referrals. Ideally, the organization receiving the referred patient will review the records for patterns indicating that a healthcare worker needs additional technical support or training.

Key Points
- Community linkages expand the services available to TB/HIV patients
- Referral networks are essential to the success of comprehensive care
- The healthcare worker plays a critical role in facilitating referrals and linkages

UNIT 19: INFECTION PREVENTION AND CONTROL AND POST-EXPOSURE PROPHYLAXIS

Introduction
Health workers and their patients are exposed to blood and other body fluids in health facilities. This can increase their vulnerability to infections such as HIV, HBV and HBC. Standard precautions should be observed by all healthcare workers, patients and other caregivers in the health care setting. Health facility managers are responsible for creating a safe and friendly environment for health workers and patients. The purpose of this unit is to equip health workers with knowledge about infection prevention and control and standard precautions so that they can implement them in their work places. This will enable them to prevent further infection among themselves, patients and other caregivers.

Objectives
By the end of this unit, you should be able to:
- Define Infection Prevention and Control (IPC)
- Discuss the importance of IPC
- Describe Standard Precautions
- Explain the process of hand washing
- Describe handling of needles and sharps in health care settings
- Describe Post-Exposure Prophylaxis (PEP)

Infection Prevention and Control
Infection prevention and control (IPC) refers to strategies that aim at achieving safe and effective health care practices at the facilities to protect health workers, patients, community from acquiring nosocomial infections and protection of the environment from pollution.

Why is IPC Important?
Coming in contact with human blood or blood products is potentially hazardous. Safety and infection control involve taking precautions to protect yourself, your colleagues, your patients, and other people who may come in contact with body fluids and contaminated instruments. Infection control is also important in order to protect the integrity of test products and to protect the environment from hazardous material. IPC is essential to help prevent patients from getting nosocomial infections which are difficult and costly to deal with (e.g broad spectrum antibiotics). In addition, health workers are highly exposed to occupational exposures to blood and other body fluids to acquire infections such as HIV, HBV and HBC, so IPC is essential for them. Finally, the community benefits from IPC in that poor health care waste disposal leads to the transmission of diseases to the community (e.g needles and sharps, cans).

Standard Precautions
Standard precautions refers to guidelines that enable health care providers to both use protective barriers when caring for patients regardless of their diagnosis, and also to protect patients from nosocomial infections.

Minimum Standard Precautions
Limited supplies and resources may prevent a public health facility from using all standard precautions all the time. However, health facilities should establish and maintain a basic, practical level of standard precautions that can be used routinely with all patients. These include a source of clean water, routine hand washing before and after any contact with a

patient, and the use of protective barriers such as bandages, masks, and gloves. Health workers will also want to practise the safe handling and disposal of sharps, instruments and equipment, including needles and syringes, and use a "sharps box" at every ward.

When Do You Need to Wash Your Hands?
Handwashing is one of the best ways to prevent infection. Health workers should wash their hands:

- Before and after patient contact
- When preparing food or serving food
- After removing gloves
- When hands are visibly dirty for any reason
- After using the toilet
- Before and after eating
- After contact with blood or body fluids (taking specimens to the lab, but also after sneezing, coughing or blowing one's nose)

Gloves are <u>not</u> a substitute for hand washing and need to be removed between patients.

Hand washing helps to stop the spread of germs amongst patients and also between staff and patients. Washing hands with soap and water eliminates microorganisms from the skin and hands, and as such it is the most important precaution for the prevention of infections; it protects both the patients and the caregivers.

At the minimum, healthcare facilities should provide:

- Soap and soap dishes (with openings to allow water to drain away)
- Running water or a bucket kept full with clean water
- A bucket for collecting rinse water and a ladle for dipping, if running water is not available
- One-use towels (paper towels, or cloth towels that can be used once and laundered; if not available, hands should be air-dried)

Steps in Hand Washing

1. Place soap in palm of one hand
2. Wash the opposite hand and forearm
3. Rub surfaces vigorously for at least 10 seconds; move the soap to the opposite hand and repeat
4. Use clean water to rinse both hands and forearms
5. Dry the hands and forearms with a clean, one-use towel, or let rinsed hands and forearms air dry

If running water is not available, pour clean water from a bucket over the soapy hands and forearms; rinse water should drain into another bucket.

Figure 64: Hand Washing

Barrier Protection
Disposable gloves should be worn to empty bedpans or urinals, clean up spills of blood, vomit, urine, or faecal materials, and while doing any invasive procedure such as drawing blood or starting an IV line. Scrapes, hangnails, and rashes should be covered with band-aids or bandages. Goggles, masks, gowns or aprons should be worn when there is a risk of splashing.

Gloves are not needed for casual contact such as giving a back rub or touching intact skin, nor are they needed for giving oral medications. If possible, disposable gloves should never be reused.

Other barrier protection methods include:

- a mask if you think a procedure may splash your mouth or nose with blood
- a gown or apron if you think fluids could splash or drip onto your clothing
- eye coverings or goggles if you think fluids could spray or splash into your eyes

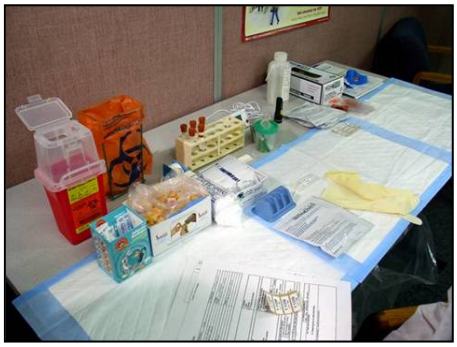
Health workers should do everything possible to avoid being stuck by a used needle. Needle sticks generally occur when the health worker is lacking concentration, inexperienced, has a lack of concern for others, or improperly disposes of sharps.

Principles of Handling and Disposing of Sharps
The sharps user is responsible for the disposal of sharps. Used disposable needles and syringes should be discarded in a puncture-resistant container labelled “sharps box,” not on the floor or in the office waste bin. If puncture-resistant containers are not available, use empty water, oil, or bleach bottles made with plastic or another burnable material. These can be adapted for use as puncture-resistant containers. Sharps containers should be readily available in the workplace and sealed and removed when the box is ¾ full. Then, the waste should be burned in an incinerator or pit for burning.

Figure 65: How to Dispose of Sharp Instruments Safely

Figure 66: Do Not Dispose of Sharp Objects in These Ways

Figure 67: Where Sharps Containers Should be Kept



Disposable needles and syringes should be used only once and needles should not be removed from the syringes. Needles should never be re-capped after use. Do not break, bend, re-sheath/re-cap or reuse lancets, needles or syringes. Do not shake sharps containers to create space. Never place needles or sharps in office waste containers.

Incineration is burning contaminated waste to destroy and kill micro-organisms. Incineration is effective against potential re-use, protects the environment, and must be supervised.

Disinfecting Reusable Equipment and Instruments
Disinfection kills germs and pathogens, keeps work surfaces clean, prevents cross-contamination, and reduces risks of infection. In order to properly disinfect equipment, the health worker should:

- Soak the instruments in 0.5% chlorine for 10 minutes
- Thoroughly wash with clean water while putting on protective barriers
- Let them air dry ready for sterilization or High level disinfection (0.5% chlorine for 20 minutes)

Keep bleach away from work areas when not in use, and do NOT mix bleach with alcohol or other chemicals.

In Case of a Spill or Splash
In case there is a spill or a splash, the health worker should wear clean disposable gloves and immediately and thoroughly wash any skin splashed with blood. For large spills, cover with paper towels and soak with 10% household bleach and allow to stand for at least five minutes. For small spills, wipe with paper towels soaked in 10% bleach. Discard contaminated towels in infectious waste bins. Never leave spills unattended.

Post-Exposure Prophylaxis
Word by word, post-exposure prophylaxis (PEP) means:

- Post = after
- Exposure = someone has been exposed to a disease or infection
- Prophylaxis = there are means by which that person may still be able to prevent disease

Contact with blood and other body fluids is one of the most common sources of infection in health facilities and community. PEP is an intervention taken to prevent infection after exposure to infected source.

PEP: Risk of Transmission
Transmission risk depends on the type of contact. The transmission risk of percutaneous contact depends on the depth of injury and needle type; in general, it is about 0.3% risk per contact, which is higher than the sexual risk. The transmission risk of mucosal contact depends on the estimated volume of exposure; in general, it is about 0.09% risk per contact, which is about equal to the sexual risk. The transmission risk of cutaneous contact is unknown, but probably less than mucosal. It depends on the condition of skin and duration of contact.

Exposure characteristics increasing risk of transmission include a large quantity of blood, injury with a hollow-bore needle, or a source patient with acute or late stage HIV infection. In

cases of large quantities of blood, the device may be visibly contaminated with source point's blood, the procedure-involving needle may have been placed directly into source point's vein or artery, or the injury could be deep.

In Case of an Accident

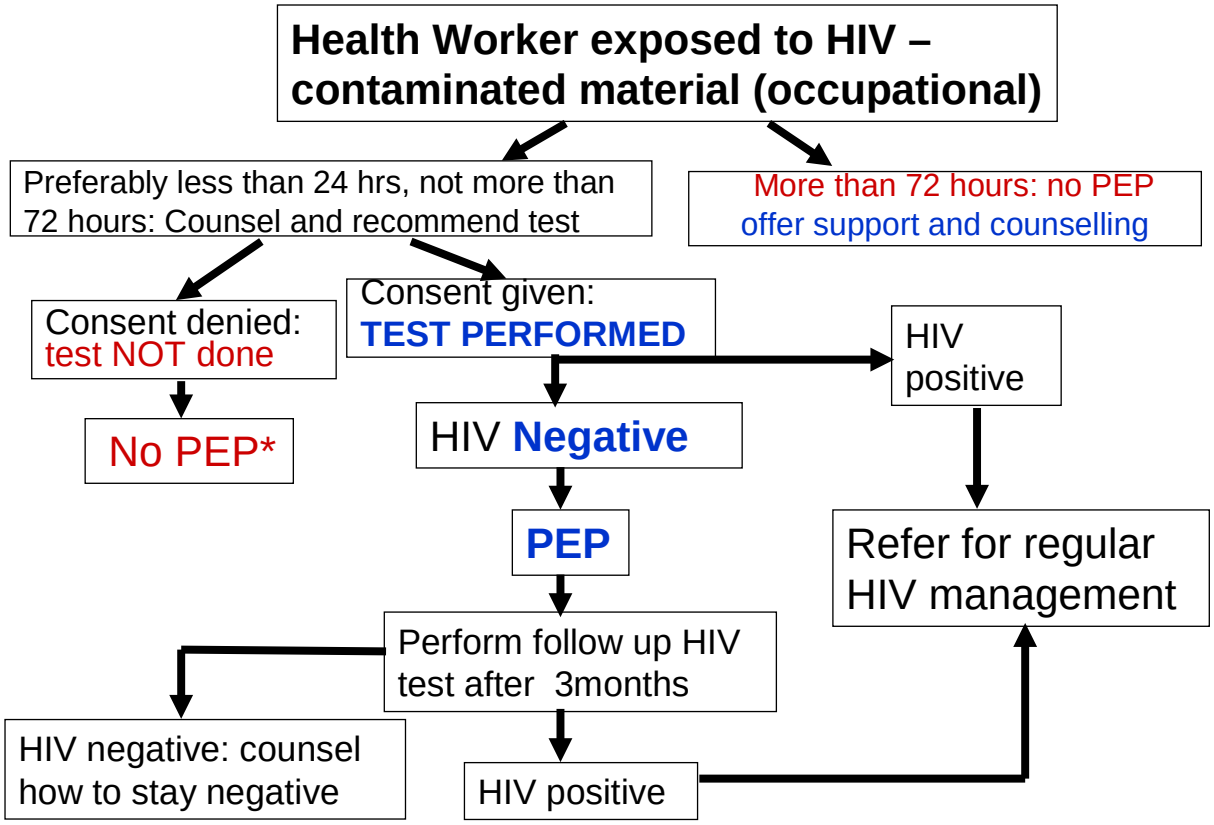
In case of occupational exposure, first check the source patient for HIV and check patient record for Hepatitis B infection. Contact the supervisor, clinician, or nurse on duty immediately and record the accident using the Occurrence Report form.

Management of Occupational Blood Exposure

Post-exposure programmes are key to the timely and effective response to an occupational exposure. They should include standards and protocols for responding to exposures, including provisions for immediate care (wash wounds with soap and running water; flush mucous membranes with water), taking a risk assessment (type of fluid and type of exposure), and evaluating the source. The source person should be counselled and tested for HIV serology, preferably using a rapid test if available. The exposed person should be counselled and tested, and then PEP should be initiated as quickly as possible.

With regard to follow-up, the health worker should determine the HIV exposure and whether the source person has positive HIV serology or acute HIV with positive HIV RNA. Follow-up HIV serology should also be done with the exposed individual at baseline, 6 and 12 weeks, and 6 months. The health worker should then reevaluate and adjust the regimen within 72 hours (depending on the availability of results), if the person is taking PEP. A pregnancy test should be done for all exposed females in reproductive age if their pregnancy status is unknown. Finally, the person on PEP should be monitored for drug toxicity.

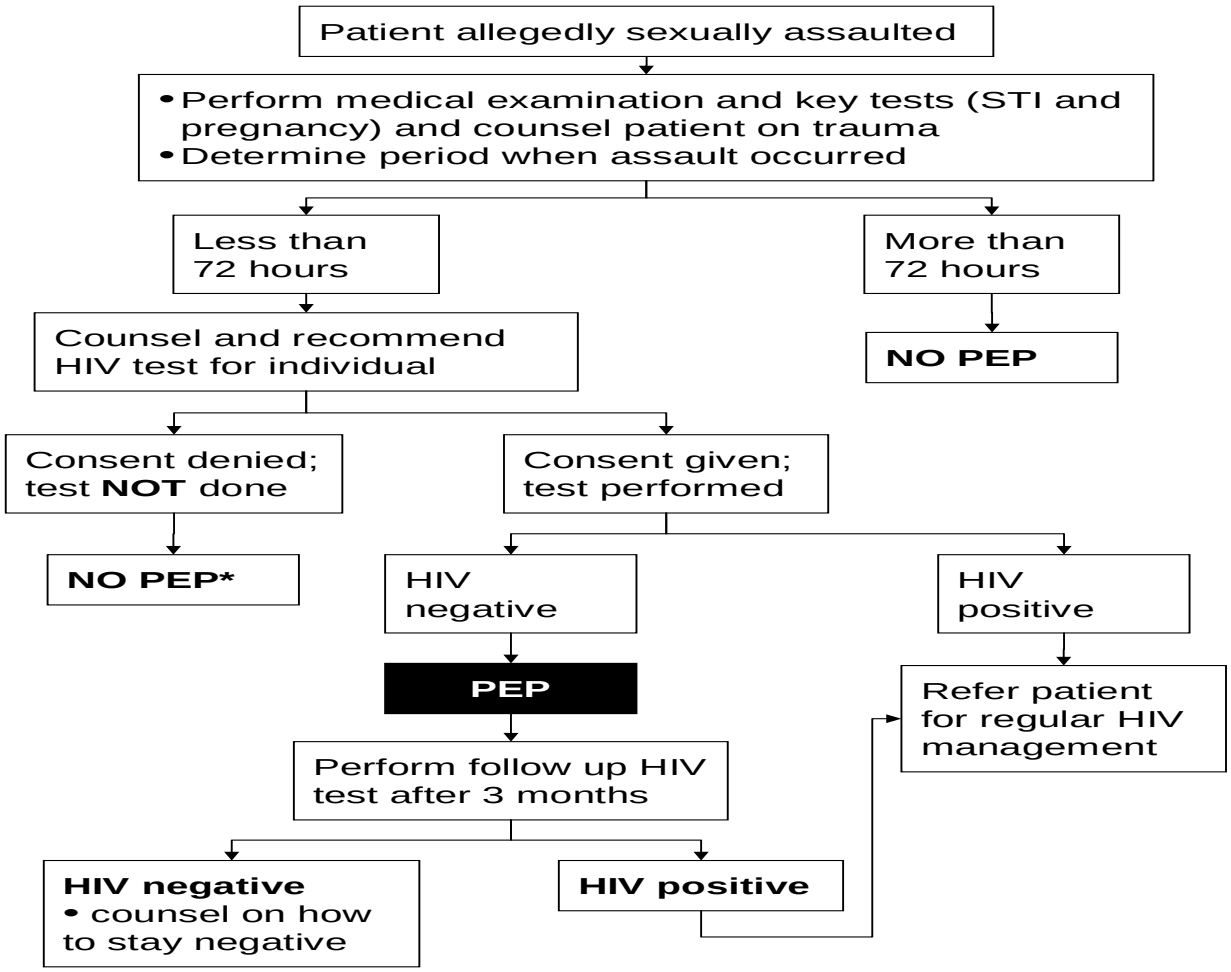
Figure 68: PEP Protocol for Occupational Exposure



Non-Occupational Blood Exposure

An example of non-occupational blood exposure is rape. When deciding whether to offer PEP, consider if any of the following factors were present during the assault: presence of blood, survivor or assailant with a sexually transmitted disease with inflammation (gonorrhoea, Chlamydia, herpes, syphilis, bacterial vaginosis, tichomoniasis, etc), significant trauma to the survivor, ejaculation by assailant, or multiple assailants or multiple penetrations by assailant(s).

Figure 69: PEP Protocol for Non-Occupational Exposure



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

HIV PEP Administration

Administer prophylactic ARV treatment as soon as possible, within 36 hours of exposure (AZT 300mg bd+ 3TC 150 mg bd for 4 weeks). Consider an additional 3rd drug (EFZ) if source individual is symptomatic or large volumes of blood is transferred or, in case of multiple perpetrators, anal penetration or trauma. Prophylaxis should be continued for 4 weeks, if tolerated, and the exposed person should be re-evaluated within 72 hours as additional information about the source is obtained (serologic status, viral load, current treatment, any resistance test results, information about factors that would modify recommendations).

If available, an HIV antibody test should be used to monitor for seroconversion and should be performed at baseline, 6 weeks, 3 month, and 6 months post-exposure. Viral load tests for screening are not recommended in the exposed person unless there is an illness compatible with acute retroviral syndrome. If PEP is given, the exposed person should be monitored for drug toxicity at baseline and at 2 weeks with Full Blood Picture and hepatic function tests. HCWs should be asked to commit to behavioural measures, e.g., sexual abstinence or condom use for several weeks to two months, the greatest risk being during the first 6 to 12 weeks post-exposure.

Females should be advised for family planning. Females with known or possible pregnancy should be treated as anyone else, except for the selection of drugs, when should involve a discussion of benefits and risks between the HCW and her health care provider. Efavirenz is

contraindicated in pregnancy especially in the first trimester. An alternative drug should be discussed with your supervisor in this case [e.g. Kaletra]. EFV and the combination d4T and ddl should be avoided.

Key Points

- Infection prevention and control includes hand washing, incinerating waste, disinfecting work areas, wearing protective barriers when performing procedures, and properly disposing of sharps
- Post-exposure programmes are key to the timely and effective response to an occupational exposure
- In order for PEP to be successful, health workers need to understand PEP protocols and be prepared to respond

UNIT 20: ADVOCACY, COMMUNICATION, AND SOCIAL MOBILISATION

Introduction
Effective implementation of collaborative TB/HIV activities requires the support of stakeholders and the public in general. The aim of this unit is to provide health workers with knowledge about using communication principles to create community awareness, mobilisation, and advocacy.

Objectives
By the end of this unit you should be able to:
- Describe ACSM
- Explain the importance of addressing both TB and HIV
- Identify ways to create awareness about TB/HIV
- Describe the advantages and disadvantages of different communication channels

What is ACSM?
The 3 main components of ACSM are:
1. Advocacy
2. Communication
3. Social mobilisation

Advocacy
Advocacy involves actively engaging and empowering the community in the fight against TB. It uses behaviour change strategies and ensures access to TB treatment for all.

Communication
Communication is the process that people use to exchange information. All communication involves a channel of communication (conversation, television, newspaper, etc.). Communication should be understandable and effective. Communication is frequently a two-way process, involving participation and dialogue.

Social Mobilisation
Social mobilization is the process of bringing together allies to raise awareness of and demand for a particular programme, assist in the delivery of resources and services, and strengthen community participation for sustainability and self-reliance. Social mobilisation is geared towards motivating individuals or groups to take action.

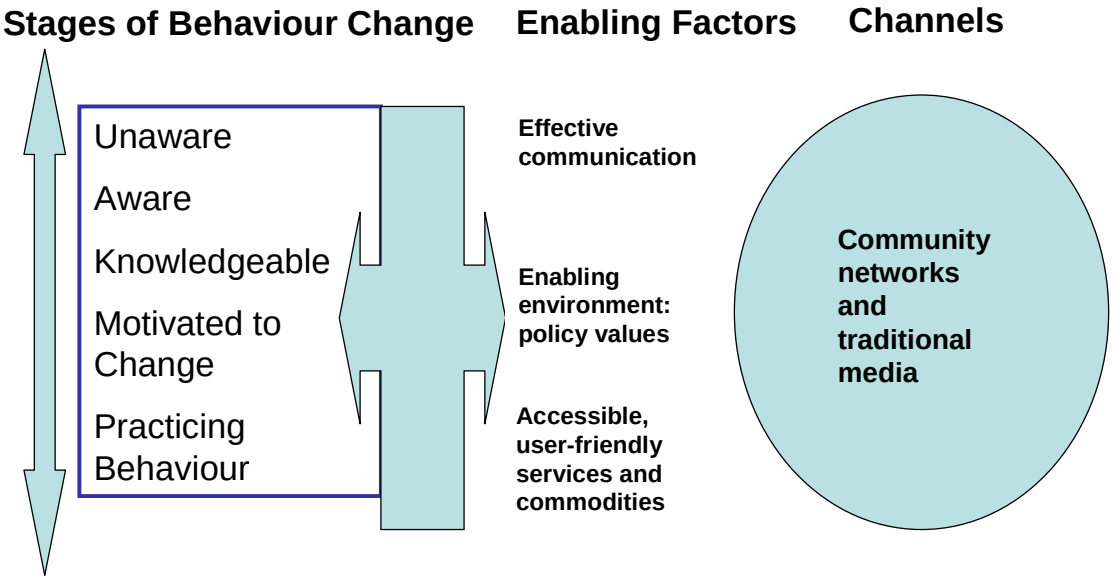
Purposes of ACSM
The purposes of ACSM include communicating health information to individuals and groups, motivating people to learn, influencing policy, and encouraging individuals or groups to take actions to improve their health, which includes modifying attitudes and behaviours and change social conditions. Other purposes include improving case detection and treatment adherence, combating stigma and discrimination, empower people affected by TB, and mobilising political commitment and resources for TB.

What Can ACSM Strategy Achieve?
ACSM strategy serves to improve case detection and treatment adherence, combat stigma and discrimination, empower people affected by TB, and mobilise political commitment and resources for TB.

ACSM Goals and Approach
The goals of ACSM are to motivate people to learn, change attitudes, and encourage individuals or groups to take actions to improve their health by modifying their behaviour and changing social conditions.

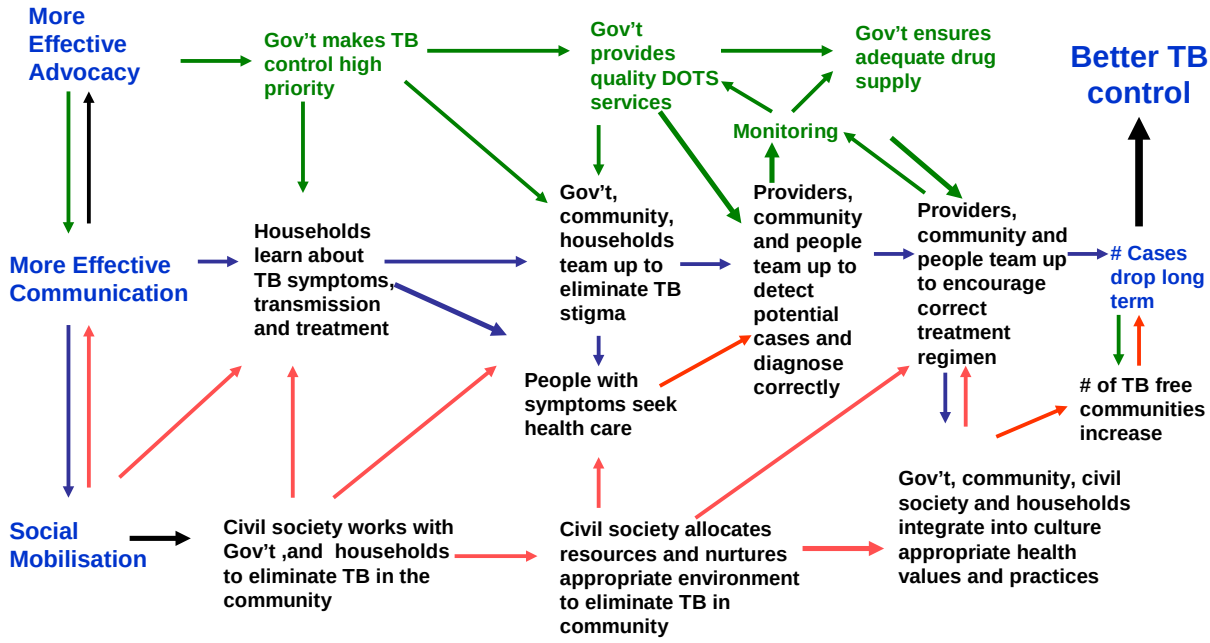
The ACSM approach includes community awareness and information, education and communication (IEC). Community awareness creates a supportive environment, strengthens community participation and involvement, and changes community behaviour. IEC uses educational techniques to communicate important information, uses a wide range of communication media, and promotes behaviour change by providing information to individuals and the community.

Figure 70: Behaviour Change Framework in IEC



Behaviour Change Framework in IEC
Behaviour can change based on factors such as effective communication, an enabling environment, and accessible services. A variety of channels can provide the communication and help create the environment that makes behaviour change possible.

Figure 71: Benefits of ACSM TB Control



Steps in Developing IEC Materials

The steps in developing IEC materials are as follows:

- Plan of action (goals and objectives)
- Needs assessment (think about what attitudes, policies, or behaviours could be changed by the communication of information)
- Development of IEC materials
- Pre-testing and revision
- Dissemination and use of IEC (identify appropriate and effective media for communicating information)
- Periodic monitoring and evaluation (questions to ask include: Is the communication achieving the intended goal? How could it be changed to be more effective?)

Effective IEC Messages

Effective IEC messages should :

- Appeal to the target population
- Are positive, attractive and call for attention
- Avoid themes that can encourage discrimination or stigmatise people
- Use themes that are sensitive to tradition, culture, norms and values
- Meet behaviour change communication (BCC) objectives and stimulate community dialogue and action
- Address social conditions of the target audience

Channels for Creating Awareness

There are a variety of communication tools which can be used in order to create awareness. Each has advantages and disadvantages and may reach different audiences. Effective communicators are acceptable to the community and understandable. Various methods of communication include:

- Traditional media
  - Spoken word (talking, meetings, stories)
  - Performance (local dancing, plays, and shows)
- Print media
  - Posters, leaflets, banners
  - Exhibitions
- Mass media
  - TV, video, film
  - Radio,
  - Newspapers

Traditional Media

Traditional media is typically used to share information and pass it on to younger generations. Communicated through spoken word or performance art, traditional media addresses issues that affect people's daily lives such as marriage, religion, relationships, family life, authority, and conflict. Traditional media builds on the community's resources, and its entertainment value creates a more effective learning atmosphere.

Print Media

Print media includes posters, banners, brochures, slides, bulletins, and exhibitions. It involves materials that can be produced centrally and distributed. Print media addresses the needs and context of the target audience and members of the target audience can help both design and test the materials.

Mass Media Channels

Mass media channels of communication include TV, video, films, and newspapers. These channels are popular, but may be accessible only in urban settings. Radio is the most popular and is widely accessible communication media in rural Tanzania.

Examples of mass media ACSM Activities include interviews, short presentations, announcements, documentaries, and screening videos or films at community gatherings. Short presentations might be like advertisements. They could last a minute or less and are designed to catch the attention of the audience and convey information or encourage them to take an action.

General Advantages of Various Channels

Mass media can reach many people quickly and at the same time, provide a credible source of information, provide reminders to reinforce behaviour change, create awareness and bring new ideas to people's attention, build public opinion, and provide a forum for debate and mobilise people.

Figure 72: Advantages and Disadvantages of Specific Channels

Media/channels	Advantage	Disadvantages
Television	Dynamic; sight, sound, motion; high attention and interest	Expensive; audience mostly urban; less audience selectivity
Radio	Mass use, high coverage, low cost	Short-term exposure; low attention; target audience may have no time to listen
Pamphlets and flyers	Flexible; broad acceptance by government, donor community, and experts	Small, pass-along audience; short life span; distribution problems
Billboards and posters	High repeat exposure, low cost	No audience selectivity; static
Caps and T-shirts	Messages attractively presented, appealing	Short-term exposure; targets only leaders, project staff and a few in target audience; expensive
Traditional	Accepted; no value, norm nor cultural barriers; sources acceptable; message design and presentation stimulating; message with source identity	Not yet given priority
Drama	Dynamic, entertaining; audience participation and dialogue; flexible, mobile	Entertainment value can overshadow messages; requires skilled actors

Key Points

- The 3 main parts of ACSM are advocacy, communication, and social mobilisation
- Goals of ACSM include motivating people to learn, changing attitudes, and encouraging individuals or groups to take actions to improve their health
- ACSM uses information, education, and communication (IEC) strategy to tailor effective messages
- Health workers can create effective, tailored messages, which are targeted to a specific audience and are culturally appropriate through traditional media, print media, and mass media

UNIT 22: PROVIDER INITIATED TESTING AND COUNSELLING

Introduction
Various counselling skills can be used with different people and in different situations. HIV testing and counselling offered by the health care provider is part of clinical management for patients who present with signs and symptoms of HIV related diseases. All TB patients will be offered HIV testing and counselling as part of comprehensive care because of the dual epidemics of HIV and TB diseases.

Objectives
By the end of this unit, participants should be able to:
- Define PITC
- Describe the different approaches of HIV testing and counselling in Tanzania
- Differentiate between VCT and PITC
- Explain the importance of providing HIV testing to TB patients (DCT)
- Identify the basic communication and counselling skills used in PITC
- Demonstrate effective communication skills in PITC

HIV Counselling and Testing Approaches Used in Tanzania
The following are the HIV counselling and testing approaches used in Tanzania:
1. Patient-Initiated HIV counselling and testing = Voluntary Counselling and Testing (VCT)
2. Provider-Initiated HIV testing and Counselling (PITC)
3. Mandatory HIV screening
4. HIV testing for medical research and surveillance

In the case of mandatory screening or in some medical research, individuals may not receive counselling before testing.

HIV testing without counselling/consent will be allowed in certain circumstances such as in unconscious patients, mandatory testing following a court order, and military order for military service. Patients who have been tested without counselling while unconscious should be counselled when they regain consciousness. In medical research, there should be surveillance screening of blood, organ and semen donors. In all these cases those tested will be informed of their test and will have the right to access their results if they wish.

Definitions
Voluntary Testing and Counselling (VCT): HIV testing and counselling which is initiated by the patient seeking to learn his/her HIV status.

Provider-Initiated Testing and Counselling (PITC): HIV testing and counselling initiated and recommended by a health care provider for all persons attending health care facilities with or without HIV symptoms as a standard component of medical care.

VCT is more for the purpose of prevention of HIV infection and life planning and PITC is more for the purpose of HIV diagnosis and clinical care management. One advantage to the increased testing and counselling that PITC affords is that it serves to increase provider knowledge about patient health in order to enable specific decisions to be made, andor

specific medical services to be provided that would not be possible without knowledge of the person's HIV status.

PITC Principles
PITC should follow the 3 "C"s: counselling, confidentiality, and consent. This will be observed with patients retaining the right to refuse HIV testing without compromising their right to access all relevant services in health facilities.

The PITC guidelines recommend:
- Simplified pre-test information
- HIV test recommended for ALL patients
- "Opt-out" approach; patients may decline testing
- Patients will require more discussion on the right to decline, benefits of HIV testing/disclosure, and available social support
- Provide access or referral to HIV prevention, treatment, care and support services

PITC Rationale
Knowing one's status is a crucial aspect of effective care, treatment, and prevention of HIV, yet only a small percentage of people are accessing VCT. Only 15 percent of people infected are aware of their status (THIS, 2004). More than 50 percent of hospital beds occupied in urban settings are occupied because of HIV-related illness and the majority of these patients are discharged without PITC. Some of these patients are offered this service at an advanced stage of the disease. There is a need to scale up HIV testing beyond the VCT approach.

Benefits of PITC
PITC goes beyond VCT; it takes place quickly and in clinical settings by health care providers (HCP). PITC increases access to quality HIV/AIDS care, treatment, support and prevention services through a rapid scale up of HIV testing and counselling services aimed at mitigating the impact of HIV/AIDS. It also allows patients the opportunity to be tested for HIV when accessing TB and other services (such as ANC, STI).

Different Types of PITC
PITC follows the "opt out" approach. At the TB clinic, it is also called Diagnostic Counselling and Testing (DCT)-TB. Home based testing and counselling is door-to-door and uses index case to counsel and test family members. This occurs when a patient has been tested and is on treatment, creating an entry point for other family members to access testing and counselling services in their homes. Door to door is testing and counselling done after community sensitization.

Figure 73: Differences Between VCT and PITC

	VCT	*PITC*
Clients/ Patients:	• **Come for HIV test** • **Expect to get tested for HIV** • **More likely asymptomatic**	• **Come because they are sick** • **Not expecting HIV test** • **Symptomatic**
Initiated By:	**Client**	**Provider**
Providers:	**Trained counsellors, not necessarily a HCP**	**HCP trained to provide counselling**
Results:	**Anonymous**	**Linked**
Aim:	**Preventing HIV transmission through risk assessment, risk reduction plan**	**For appropriate management and referral for HIV care and treatment**
Pre-test Counselling	• **Client centered** • **Long discussion about need for HIV testing** • **Explore whether they wish to be tested for HIV** • **Discuss the results with negatives and positives clients because of the focus on prevention** • **Risk assessment and risk reduction plan**	• **Provider centered** • **Limited discussion about need for HIV testing** • **Provider recommending HIV test to patients** • **Focus on those who test positive with emphasis on their medical care**
Duration	**Long: 1-2hrs**	**Short: 20-30 min**

Importance of HIV Testing in TB Patients

It is important to integrate HIV testing and counselling into TB services because:

- HIV increases the occurrence of recurrent TB, as well as the progression from TB infection to active TB
- Tanzania is facing a generalized HIV/AIDS epidemic
- There are increasingly high rates of HIV among TB patients in Tanzania and many countries
- People often die from both diseases together

PITC in TB clinic aims at identifying TB patients who are HIV positive because 50 percent of patients with TB are also likely to have HIV infection, there is a higher mortality rate among TB patients co-infected with HIV, and health care workers should take care of both diseases at the same time.

Definition of Counselling

Counselling has been defined as a process which gives individuals an opportunity to explore, discover and clarify ways of living more resourcefully, with a greater sense of well-being. Counselling is an interpersonal relationship between healthcare worker and patient(s). Counselling is actually done by all members of the health care team. Healthcare workers give

the patient correct information to make informed decisions; helping the patient help him or herself. Counselling is an ongoing process and occurs in formal and informal ways and may be concerned with addressing and resolving specific problems, making decisions, coping with crises, working through conflict, or improving relationships.

Counselling is a professional activity that enables people to develop greater self awareness, self-growth, and to make positive changes in their lives others. Professional counsellors work within a clearly contracted, principled relationship which is designed to manage a specific problem, situation, or life change and helps patients to develop their capacity to resolve emotional, personal, family, work-related and relationship issues. Professional counselling works at considerable depth, with a focus on change, may be a shorter term or a longer-term treatment option, and is designed to manage a specific problem, situation or life change.

Counselling Procedures in PITC
Counselling in PITC involves providing basic information on TB and HIV to all patients. Healthcare workers should inform them about services available, including TB diagnosis and treatment, HIV testing, and management of HIV. Individual TB patients should also be offered pre-test information (brief counselling).

A Good Counsellor
A good counsellor has good communication skill, is genuine with the patient, shows warmth, exhibits a non-judgmental attitude, shows complete acceptance of the patient, and shows empathic understanding of patient. These are essential qualities of a good counsellor—communication is one of the most important skills to master!

Building Rapport
Non-verbal tools may be used to ensure a patient's level of comfort and interest. In order to build rapport (a positive relationship) with a patient, the health worker should:

- Shake hands
- Introduce himself or herself
- Use the same language of the patient
- Be patient
- Not interrupt
- Make eye contact and nod your head to encourage speaker to keep talking
- Not attend to other patients while busy with another
- Say "yes", "um-hum" or use a non-verbal gesture so they know you are interested

Communication Skills for PITC
Building rapport with patients is an important skill. In order to enhance communication with patients, the health worker should try to:

- Make the patient feel valued by building good rapport with patients
- Be a good communicator
  - Verbal (paraphrase, summarize, actively listen)
  - Non-verbal (nod, smile, lean forward, make eye contact)
- Respond appropriately to patient questions

Counselling Skills
Encourage the patient to tell his/her story and listen for factual information and emotional information. This involves understanding a patient's mood, feelings, and underlying messages that are conveyed through verbal and non-verbal cues.

It is important to maintain eye contact, show signs of encouragement, acknowledge the patient's feeling, and present messages that are brief and clear. The health worker should also ask relevant, open-ended question one at a time while showing signs of encouragement, acknowledging the patient's feelings, and presenting messages that are brief and clear.

Pre-test Information (Group)
Group counselling is a good way to provide patient education, especially in preparation for a patient to see his or her provider. Group counselling topics may include:

- TB basics
  - What is TB
- HIV/AIDS basics:
  - What is HIV/AIDS, causes, and modes of transmission
  - Difference between HIV infection and AIDS
  - ARV and other services available (available and free)
  - Prevention and risk reduction
- TB/HIV basics:
  - Relationship TB/HIV
  - Need for HIV testing
  - Benefits of HIV testing

Pre-Test Information (Individual)
Before giving the patient information, it is very important to find out how much information the patient already has about HIV (from the group session) and remind the patient if necessary what was discussed in the group session. When working with an individual, introduce the topic of HIV again and inform the patient of the need to test for HIV. Reassure him or her about the 3 Cs (confidentiality, counselling, and consent) and address different scenarios accordingly (if the patient refuses or accepts).

Testing Process
If the patient accepts the test, the healthcare worker should inform him/her that HIV test requires taking a sample of blood from finger or arm, performing a rapid test, and interpreting the results. During post-test counselling the patient is given his/her results.

When patients refuse to be tested, it is important to know the reasons why the patient has refused. Guiding questions that can be used to find out this information include:

1. Could you tell me why decided not to have an HIV test today?
2. How can I help you to get ready to take an HIV test?

Acknowledge and discuss the patient's reasons for not getting an HIV test.

Individual Pre-Test Counselling
The provider's job is to strongly encourage HIV testing, but that patients still have the right to refuse testing, if they feel it is not in their best interest. The HIV test will be done unless the patient objects. The provider should make sure to answer any questions or concerns that the patient may have. Pre-test counselling is often called the initial provider encounter in PITC. This involves:

- Step 1: Establish rapport
  - Discuss the basics of TB,HIV, and TB/HIV
- Step 2: Provide information
  - Introduce the topic of HIV

    - Inform patient of need to test for HIV
    - Rationale for testing for HIV
    - Benefits of HIV testing
- Step 3: Obtain consent
- Step 4: Draw blood and test

After the patient's HIV test, the health worker will provide post-test counselling

- Step: 5 Provide results
    - For Negative HIV test results: provide information on results and prevention and emphasize the importance of repeating the HIV test three months after negative results
    - For Positive HIV test results: provide information on results and on prevention and discuss coping, care, treatment and support
- Step: 6 Closure
    - Acknowledge the patient for coming in to the clinic, encourage him/her to come back, and strongly suggest continuing with anti-TB treatment.

Post-Test Counselling: Negative

Post-test counselling could take between 10 and 20 minutes. The provider's job is to be supportive to patient and provide referrals for care and treatment services. The provider should also make sure to answer any questions or concerns that the patient may have. It involves an explanation of the test result, including information about the window period for the appearance of HIV-antibodies and a recommendation to re-test in case of a recent exposure, basic advice on methods to prevent HIV transmission, and the provision of male and female condoms and guidance on their use. The health care provider and the tested person shall jointly assess whether the person needs referral to more extensive post-test counselling session or additional prevention support.

Steps in post-test counselling for HIV-negative patients:

- STEP 1: Inform patient of result
- STEP 2: Discuss window period; encourage patient to go to VCT for further prevention counselling and possible re-test
- STEP 3: Brief prevention messages, condoms
- STEP 4: Advise patient to encourage sexual partner(s) to be tested in case of HIV infection
- STEP 5: Provide patient with information about community VCT sites, prevention/counselling support

Test Counselling: Positive

Explain the result to the patient simply and clearly and give the patient time to consider it. Ensure that the patient understands the result and describe follow-up services that are available in the health facility and in the community, with special attention to the available treatment, PMTCT, and care and support services. Provide information on how to prevent transmission of HIV, including provision of male and female condoms and guidance on their use, and information on other relevant preventive health measures such as good nutrition, use of co-trimoxazole and, in malarious areas, insecticide-treated bed nets. Discuss possible disclosure of the result and when and how this may happen and to whom. Allow the patient to ask questions and help the patient to cope with emotions arising from the test result. Discuss any immediate concerns and assist the patient to determine who in her/his social network may be available and acceptable to offer immediate support. Encourage and offering referral for

testing and counselling of partners and children. Assess the risk of violence or suicide and discuss possible steps to ensure the physical safety of patients, particularly women who are diagnosed HIV-positive. Arrange for follow-up visits or referrals for treatment, care, counselling, support and other services as appropriate (e.g. tuberculosis screening and treatment, prophylaxis for opportunistic infections, STI treatment, family planning, antenatal care).

Steps in post-test counselling for HIV-positive patients:

- STEP 1: Inform patient of positive result
- STEP 2: Support patient in adjusting
- STEP 3: Inform patient of need for HIV care and treatment
- STEP 4: Provide HIV prevention information
- STEP 5: Advise patient to get encourage partner to get tested; partner may be negative
- STEP 6: Refer patient to appropriate HIV prevention, care and treatment services (CTC, clinic, VCT) in community

Recording Test Results

It is very important to record HIV test results in all the appropriate documents, and to maintain patient confidentiality. Record HIV test results on an HIV test result slip. After the patient visit, HIV test results should be recorded in all records (HIV test results register and TB treatment cards). Protect sensitive information and patient confidentiality. Records should be kept in a safe place.

Key Points

- VCT and PITC are examples of different models used for HIV Testing and Counselling
- PITC is provider-initiated and aims to link PLHIV with appropriate care, treatment and support services
- All TB patients will be offered HIV testing and counselling as part of comprehensive patient care, because of the dual epidemics of HIV and TB
- Information giving is essential to ensure acceptance of HIV testing
- Effective communication skills (verbal and non-verbal) are essential components for counselling patients and maintain client-oriented health care settings and good working relationships between providers
- Important steps in pre and post-test counselling include:
    - Step 1: Establish rapport
    - Step 2: Provide information
    - Step 3: Obtain consent
    - Step 4: Draw blood and test
    - Step 5: Provide HIV test results
    - Step 6: Closure

UNIT 23: HIV TESTING

Introduction
This unit will cover information about HIV rapid tests. Rapid tests are qualitative assays used to detect HIV antibodies. Most detect HIV-1 and HIV-2. They provide same-day results and do not require additional equipment.

Objectives
By the end of this unit, you should be able to:
- List the supplies and materials used in HIV testing
- Explain how to perform rapid HIV tests using national algorithm
- Interpret individual test results accurately
- Record HIV test results in the register accurately
- Define Quality Control (QC)
- Explain the benefits of QC in rapid testing
- Explain how to differentiate between internal and external controls
- Discuss common problems associated with invalid test results
- Describe how to prevent and detect errors before and after testing

Supplies & Materials
The following supplies and materials are needed to perform an HIV rapid test. These may be obtained locally, through central stores, or externally.
- Gloves
- Aprons or laboratory coats
- Timer, clock, or wrist watch with minute hand
- Transfer pipettes, pipette tips
- HIV rapid testing kits
- Alcohol swabs
- Cotton gauze/wool
- Sterile lancets and syringes
- Vacutainer tubes
- Safety box/sharps bin or disinfectant jar for lancets
- Marker pen for marking or labelling
- Paper towels (for bench coating, cleaning, and hand washing)
- Soap for hand washing
- Leak-proof bag for containing or moving labeled biohazard waste for incineration
- Disinfectant e.g. Jik, Clorox
- Band-Aids or plasters

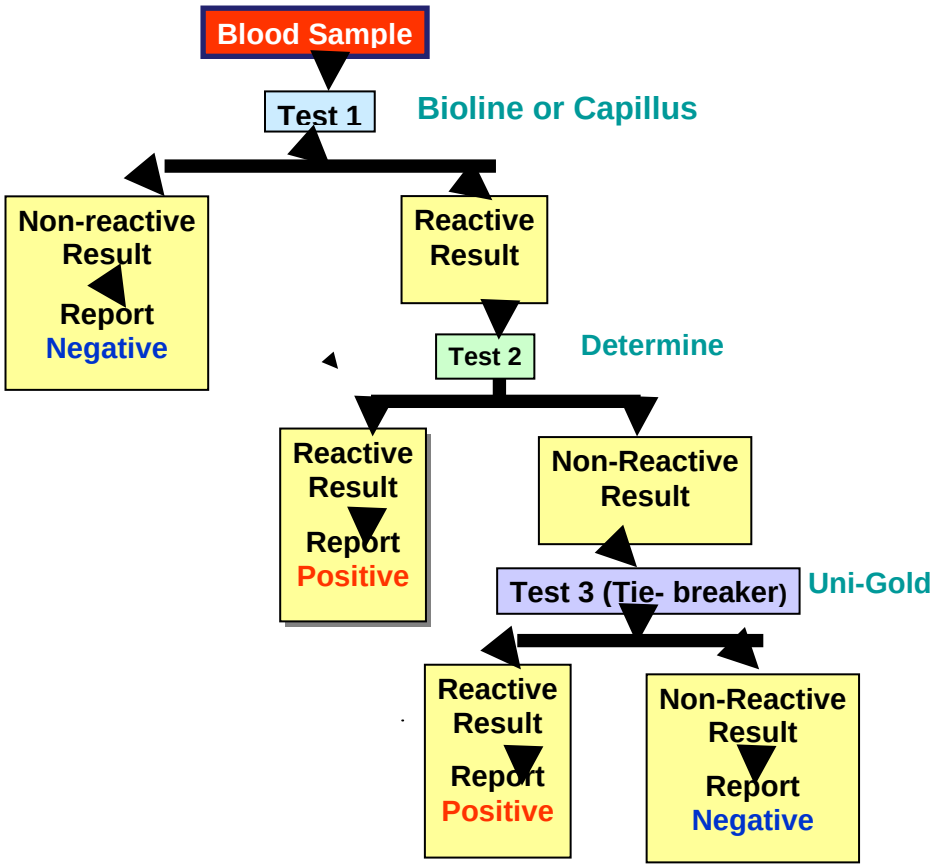
Also, do not forget to have the following on hand:
- Known positive and negative controls
- Register or book for recording results
- Spray bottle for making bleach solution
- Standard Operating Procedures
- Room thermometers

Examine Test Kits
There are different components found in each of the rapid test kits so it is important to examine the different components found in each of the rapid test kits such as:
- Desiccant packet:

- This is not used when performing the test.
- It only serves to keep the packet contents dry before use.
- It should be discarded when the test kit packet is opened.

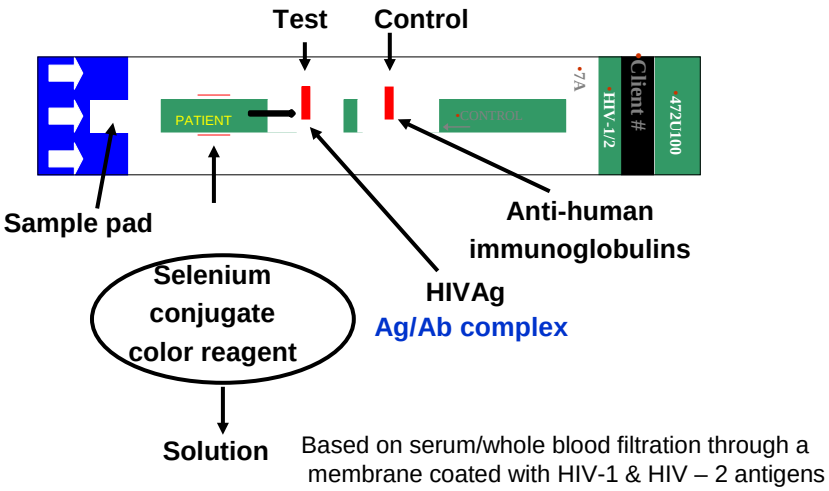
- Buffer solution
  - Required by some kits

Figure 74: National (Serial) Testing Algorithm



HIV rapid tests are performed on a testing step. They are based on serum/whole blood filtration through a membrane coated with HIV-1 and HIV-2 antigens.

Figure 75: Example of HIV Rapid Test Testing Strip



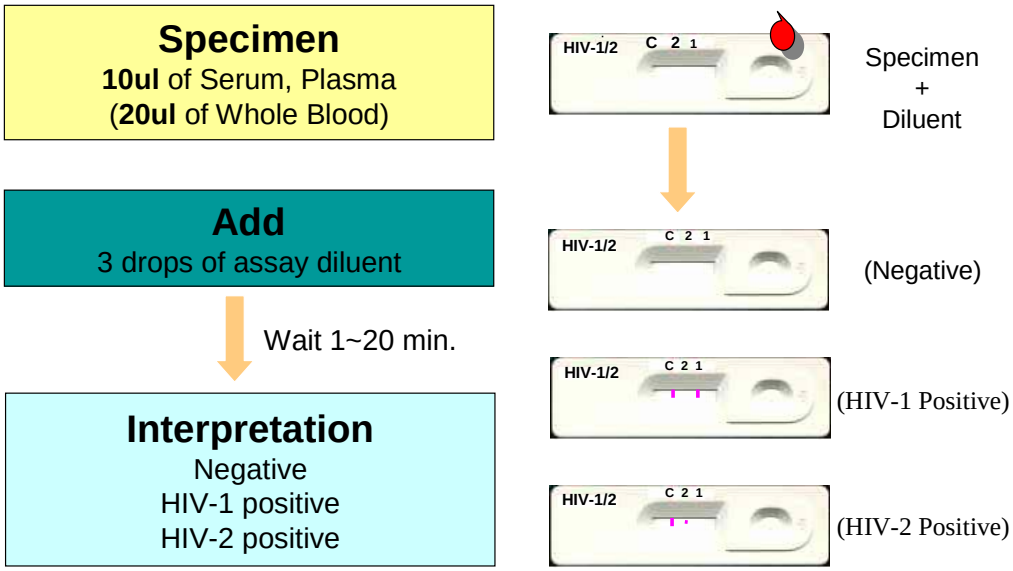
Safety Precautions
Overall, it is important to observe safety precautions as recommended by the Ministry of Health and Social Welfare. Remember to:

- Use gloves when performing finger-pricks
- Do not smoke or drink when handling specimens (risky)
- Do not pipette by mouth
- Take precautions to prevent injuries caused by sharp instruments

Finger Prick – Finger Preparation
1. Position hand palm-side up. Choose whichever finger is least calloused.
2. Apply intermittent pressure to the finger to help the blood to flow.
3. Clean the fingertip with alcohol. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry.
4. Hold the finger and firmly place a new sterile lancet off-center on the fingertip.
5. Firmly press the lancet to puncture the fingertip
6. Wipe away the first drop of blood with a sterile gauze pad or cotton ball
7. Collect the specimen. Blood may flow best if the finger is held lower than the elbow
8. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops

Bioline HIV ½
The SD BIOLINE HIV-1/2 3.0 Test tests for the detection of human antibodies to the HIV virus and is specific to HIV-1 and HIV-2. Serum, plasma, or whole blood can be used.

Figure 76: Bioline Test Procedures



Determine
1. Collect test items and other necessary lab supplies
2. Use 1 strip per test and be sure to preserve the lot number on the remaining packet of strips
3. Label the test strip with patient identification number
4. Pull off the protective foil cover

5. Collect 50 µl of specimen using a precision pipette or 1 drop using a plastic transfer pipette
6. Apply the specimen to the absorbent pad on the strip
7. For whole blood only, add 1 drop of chase buffer to the specimen pad
8. Wait 15 minutes (no longer than 60 minutes) before reading the results
9. Read and record the results and other pertinent info on the worksheet.

Uni-Gold

1. Collect test items and other necessary lab supplies
2. Remove device from package and label device with patient identification number
3. Collect specimen using the disposable pipette
4. Add 2 drops (approx. 60µl) of specimen to the sample port in the device
5. Add 2 drops (approx. 60µl) of the appropriate wash reagent to sample port
6. Wait for 10 minutes (no longer than 20 min.) before reading the results
7. Read and record the results and other pertinent info on the worksheet

Capillus

1. Collect test items and other necessary lab supplies
2. Label the device with patient identification number
3. Place slide on the black interpretation card. Ensure that slide is right side up.
4. Gently mix the latex reagent well ensuring that it is homogenous
5. Use the dropper to draw the latex reagent up to the calibration mark. Avoid drawing up air bubbles.
6. Dispense the reagent into the mixing well, away from the capillary channel. Do not allow the dropper to touch the slide.
7. Collect 10 µl of specimen using a new disposable pipette tip with the pre-calibrated pipette.
8. Hold the pipette directly over the well and dispense the specimen directly into the latex solution
9. Mix the specimen and latex by gently pumping the mixture in and out of the tip 3 times. Stir in a circular motion at least 5 times.
10. Initiate the capillary flow by moving the mixture to the opening of the channel using the pipette.
11. Allow the latex mixture to flow through the entire channel and into the viewing window (about 3-7 min.) before reading the results.
12. Read and record the results and other pertinent info on the worksheet.

Quality Assurance in HIV Testing

Quality assurance entails doing the right thing the first time and always thereafter. This means there is no need for re-doing a procedure or inflicting harm to patients and providers. This ensures cost saving, safety, effectiveness, and efficiency. These are essential elements of a laboratory quality system.

Quality Control in HIV Testing

Quality control (QC) is the measures taken to monitor the quality of the test itself. QC for HIV rapid testing includes testing of samples with known results to verify if the procedure is working properly and interpreting the presence or absence of control bands/lines within the device itself. If an error occurs, do not release or report results until you have corrected the error.

A quality system has several benefits. It allows for the monitoring all parts of the testing system, detection and reduction of errors, improvement of consistency between testing sites, and it helps to contain costs.

Quality is the foundation of everything we do. It considers all components within a system together, rather than individually. More specifically, it sets the standard for level of quality, meets customer expectations, provides means to prevent, detect and correct problems, becomes the core of a monitoring, evaluation and improvement system, and reduces costs.

Figure 77: The Lab Quality System

Laboratory management and programme staff establish and oversee quality assurance procedures. Test site personnel implement the quality assurance procedures.

Figure 78: Different Between Quality Assurance and Quality Control

	Quality Assurance	Quality Control
Definition	Activities to ensure process are adequate for a system to achieve its objectives	Activities to evaluate a product or work result
Examples	• Establish standard procedures for sample collection • Define criteria for acceptable samples	• Analyze known QC sample to determine if a test is valid • Decide if a sample is acceptable for testing

Common Problems Associated with Invalid Test Results

- Individual responsibilities unclear
- No written procedures
- Written procedures not followed
- Training is not done or not completed
- Checks not done for transcription errors
- Test kits not stored properly
- QC, EQA not performed
- Equipment not properly maintained

Pre-Testing Errors

Pre-testing errors may occur when specimens are mislabeled or unlabeled, the wrong specimen or specimen container is used, or the specimen stored inappropriately before testing. Other sources of pre-testing error happen if the specimen is transported inappropriately, or if test kits are stored inappropriately.

To prevent and detect errors before testing:

- Check storage and room temperature
- Collect appropriate specimen
- Use appropriate Specimen Container
- Select an appropriate testing workspace
- Check inventory and expiration dates
- Review testing procedures
- Record pertinent information, and label test device

Testing Errors

Various errors can also occur during the testing process. These include:

- Country algorithm not followed
- Incorrect timing of test
- Results reported when control results out of range
- Improper measurement of specimen or reagents
- Reagents stored inappropriately or used after expiration date
- Dilution and pipetting errors
- Incorrect reagents used

In order to prevent and detect errors during testing, the health worker should perform and review Quality Control (QC), follow safety precautions, conduct the test according to written procedures (Follow SOP), and correctly interpret test results.

Post-Testing Errors

After the patient has been tested, other errors may involve transcription error in reporting, the report may be illegible, the report may be sent to the wrong location, or else the information system may not be properly maintained.

In order to prevent and detect errors after testing, the health worker should re-check the patient/patient identifier, write legibly, clean up and dispose of all waste accordingly, and package EQA specimens for re-testing, if needed.

Key Points

- Effective HIV testing requires specific materials, supplies, and preparation
- There are various types of HIV tests: Bioline, Determine, Capillus, and Uni-Gold
- Health workers should feel comfortable performing each of these tests and reading the various results
- Quality at a testing site is essential to all aspects of patient health, including prevention, care and treatment
- A quality system monitors all parts of the testing system, detects and reduces errors, improves consistency between testing sites, and helps contain costs
- A quality system involves coordination and excellence in:
    - Organization, personnel, and equipment
    - Purchasing and inventory
    - Process control
    - Documents and records, information management
    - Occurrence management
    - Assessment, process improvement, and customer service
    - Facilities and safety
- Errors can occur at any point throughout the testing process, therefore diligence is essential to error prevention and detection