MINISTRY OF HEALTH

NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM

INTEGRATED CURRICULUM PARTICIPANTS MANUAL

September 2017 Edition

MINISTRY OF HEALTH

Integrated Curriculum Participants Manual

National Tuberculosis, Leprosy and Lung Disease Program (NTLD-Program)

This curriculum was developed and published in the Kenyan context and is rolled out through the Ministry of Health.

Foreword

Tuberculosis remains a major cause of morbidity and mortality in Kenya. It affects all age groups, but has its greatest toll in the most productive age group of 15 to 44 years. The major factor responsible for the TB disease burden in Kenya is the concurrent HIV epidemic. To address challenges posed by the tuberculosis epidemic in the era of HIV, the Ministry of Health through The National Tuberculosis, Leprosy and Lung Disease Program (NTLD-Program) has identified areas for increased support which include sustained public health education campaigns to promote early care seeking and adherence to treatment at community level, and health care worker training and support for better TB case management.

This guideline is a revision of the earlier version produced in 2013 and has integrated all the different thematic areas in an easy to read version. The immediate short-term goal is to increase the detection of TB cases and sustain the successful treatment of those diagnosed. All these efforts are designed in a bid to achieve the end TB strategy goal of ending the global tuberculosis epidemic.

This guideline highlights key elements of lung disease to aid in its basic diagnosis and management. The incidence of respiratory diseases has continued to rise due to a rapid increase in a number of risk factors such as tobacco smoking habits in developing countries. Kenya in an effort to improve the health of its population is strengthening the management of lung diseases through a number of approaches, key among them the Practical Approach to Lung Health (PAL) which entails use of standardized regimens, equipping and stocking facilities with necessary medicines and strengthening of community structures.

This guideline should therefore be used as the technical reference material by all health care workers involved in TB, Leprosy and Lung Disease care and can also be used for training of health care workers in conjunction with other training materials.

It is my sincere hope that all healthcare workers will find the integrated manual useful for successful implementation of tuberculosis, Leprosy and lung disease control activities.

Acknowledgements

The Ministry of Health and the National Tuberculosis, Leprosy and Lung Disease Program (NTLD-Program) are indebted to many individuals and organizations whose support and collaboration have made possible the updating of this edition of the national guidelines for the treatment and prevention of Tuberculosis for health workers.

We are grateful to the Global Fund and USAID through TB ARC for providing financial and technical support to enable development of the guidelines. Other partners that collaborated include CDC, KAPTLD, NASCOP, AMPATH, University of Nairobi, Counties, WHO, CHS, MSF, HSO, Stop TB Partnership, PATH, MSH, KNH organizations whose staff put in much effort to ensure the success of this process. Special thanks goes to the NTLD-P staff who worked tirelessly in coordination and development of this guideline.

It is our sincere hope that the guidelines will be useful in improving awareness about TB control in Kenya in an effort to find missing cases.

Acronyms

A&C	Advocacy and Communication
AM	Amikacin
ARI	Acute Respiratory Infections
CHC	Community Health Committee
CHV	Community Health Volunteers
CM	Capreomycin
COPD	Obstructive Pulmonary Disease
CPT	Cotrimoxazole Preventive Therapy
Cs	Cycloserine
CXT	Cotrimoxazole
DM	Diabetes Mellitus
DOT	Directly Observed Therapy
DR-TB	Drug Resistant TB
DST	Drug Susceptibility Testing
E	Ethambutol
EPTB	Extra Pulmonary TB
Eto	Ethionamide
F	Female
FBF	Fortified Blended Flours
FDC	Fixed Dose Combinations
FFT	After failure of First Line Treatment
FRT	After failure of Retreatment
GERD	Gastroesophangeal Reflux
Gfx	Gatifloxacin
H	Isoniazid
HCWs	Health Care Workers
HIV	Human Immunodeficiency Virus
IDF	International Diabetes Federation
IGRA	Interferon Gamma Release Assay
ILDS	Interstitial Lung diseases
IPC	Infection Prevention and Control
IPT	Isoniazid Preventive Therapy
IYCN	Infant and Young Child Nutrition
Km	Kanamycin
LFX	Levofloxacin
LTBI	Latent TB Infection
M	Male
MAC	M. avium Complex
MDR TB	Multidrug Resistance
Mfx	Moxifloxacin
MTB	Mycobacterium tuberculosis
N	New
NACS	Nutrition Assessment Counselling and Support
NSA	Non State Actors
NSP	National Strategic Plan
NTLD-P	National Tuberculosis, Leprosy and Lung Disease Program
NTM	Non-tuberculous Mycobacteria
Ofx	Ofloxacin
PACS	Primary Care Asthma Control Screening Tool
PAL	Practical Approach to Lung Health
PAS	P-aminosalicylic acid
PCR	Polymerase Chain Reaction
PDR TB	Polydrug Resistance
PET	Positron Emission Tomography
PLHIV	People Living With HIV
PTB	Pulmonary TB
Pto	Prothionamide
R	Relapse
R	Rifampicin
RDU	Definition of Rational Drug Use
RR TB	Rifampicin Resistance
RUSF	Ready to Use Supplementary Foods
RUTF	Ready to Use Therapeutic Food
S	Streptomycin
SCHMT	sub-County Health Management Team
SHS	Second Hand Smoke
SLE	Systemic Lupus Erythematosis
TB	Tuberculosis
TI	Transfer in
Trd	Terizidone
TSR	Treatment Success Rate
TST	Tuberculin Skin Test
TWG	Technical Working Group
WHO	World Health Organization
XDR TB	Extensive Drug Resistance
Z	Pyrazinamide

Contents

Five Day Integrated Lung Health Training Schedule

Day 1		
Time	**Topic**	**Facilitator**
8.00 – 9.00 am	Introduction/Norms	Coordinator
	Opening remarks	County Director-Health
	Pre-test	Coordinator
	Objectives of the training	MO/CO/Nurse
9.00 - 9.30 am	Pneumonia	MO/CO/Nurse
9:30 - 10.15 am	Asthma	MO/CO/Nurse
10.15 – 11.00 am	COPD	MO/CO/Nurse
11.00- 11.20 am	TEA BREAK	
11.20 - 11.50 am	Other Respiratory diseases	MO/CO/Nurse
11.50 am - 1.00 pm	Practices	MO/CO/Nurse
1.00 - 2.00pm		
2.00 - 2.30 pm	Introduction and Epidemiology of TB	MO/CO/Nurse
2.20 - 2.50 pm	Active Case finding	MO/CO/Nurse
3.00 - 5.00 pm	Lab Diagnosis of TB	Lab Technologist
5.00 – 5.20 pm	Tea Break	

Day 2		
Time	**Topic**	**Facilitator**
8.00 - 8.20 Am	Recap	Nutritionist
8.20 - 10.00 Am	Treatment of TB	MO/CO/Nurse
10.00 -10.30 Am	Non-tuberculosis Mycobacterium (NTM)	MO/CO/Nurse
10.30 - 10.50 Am		
10.50 - 1.00 Pm	TB and HIV	MO/CO/Nurse
1.00 – 2.00 Pm	Lunch Break	
2.00 – 3.30 Pm	TB in children	MO/CO/Nurse
3.30 – 4.30 Pm	TB in special populations	MO/CO/Nurse
4.30 - 5.00 Pm	Pharmacovigilance	Pharmacist
5.00Pm - 5.20Pm		Lab Technologist
5.20- 6.00 Pm	Plenary	Lab Technologist

Day 3		
Time	**Topic**	**Facilitator**
8.00 - 8.20 AM	Recap	Pharmacist
8.20 - 10.30 AM	Drug Resistant (DR-TB)	MO/CO/Nurse
10.30- 10.50 AM	Tea break	
10.50 - 1.00 PM	Leprosy	MO/CO/Nurse MO/CO/Nurse
1.00 - 2.00PM		
2.00 – 4.00 PM	Nutrition	Nutritionist
4.00 - 5.00 PM	Nutrition Exercises	Nutritionist
5.00- 5.20 pm	Tea Break	Pharmacist
5.20- 6.00 PM	Plenary	Coordinator

Day 4		
Time	**Topic**	**Facilitator**
8.00 - 8.20 AM	Recap	Coordinator
8.20 - 10.00 AM	TB Infection Prevention and Control	MO/CO/Nurse
10.00 -11.00 AM	Commodity management	Pharmacist
11.00 -11.20 AM	Tea break	
11.20- 12.20	Commodity management	Pharmacist
12.20 -1.00 PM	Commodity management practical	Pharmacist
1.00 -2.00 PM	Lunch break	Nutritionist
2.00 – 3.00 PM	Community Engagement in TB Activities (ENGAGE TB)	MO/CO/Nurse
3.00 - 4.00 PM	Advocacy and Communication	MO/CO/Nurse
4.00- 5.00 PM	M&E and Data management	MO/CO/Nurse
5.00- 5.20 PM	Tea Break	
5.20 -6.00 PM	Plenary	Pharmacist

Day 5		
Time	**Topic**	**Facilitator**
8.00 - 8.20AM	Recap	Coordinator
8.20 - 10.30 AM	M&E	MO/CO/Nurse
10.30 AM – 10.50 AM	Tea Break	
11.20 AM - 1.00 AM	M&E Exercises	MO/CO/Nurse
1.00 -2.00 PM	Lunch Break	
2.00PM - 3.00 PM	Social Protection / Other determinants of TB	MO/CO/Nurse
3.00- 4.00 PM	Post-test and Training evaluation	Coordinator
4.00 - 4.30 PM	Closing ceremony	CDH

MODULE 1 - INTRODUCTION

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INTEGRATED TB, LEPROSY AND LUNG DISEASE CURRICULUM

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Role of the National Tuberculosis, Leprosy and Lung Disease (NTLD)-Program

- The vision of the NTLD-Program is to reduce the burden of lung disease making Kenya free of TB and Leprosy
- The mandate of the NTLD-Program is to:
  - develop policies, build capacity and provide technical assistance to the county system
  - implement its activities within the framework of the National Strategic Plan for Tuberculosis, 2015-2018, and in line with the End TB strategy

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Purpose of the Integrated Guidelines

- To provide:
  - a public health approach to the management of TB, Leprosy and Lung disease
  - guidance to health care workers (HCWs) on the diagnosis, treatment, prevention and rehabilitation of patients with tuberculosis and leprosy

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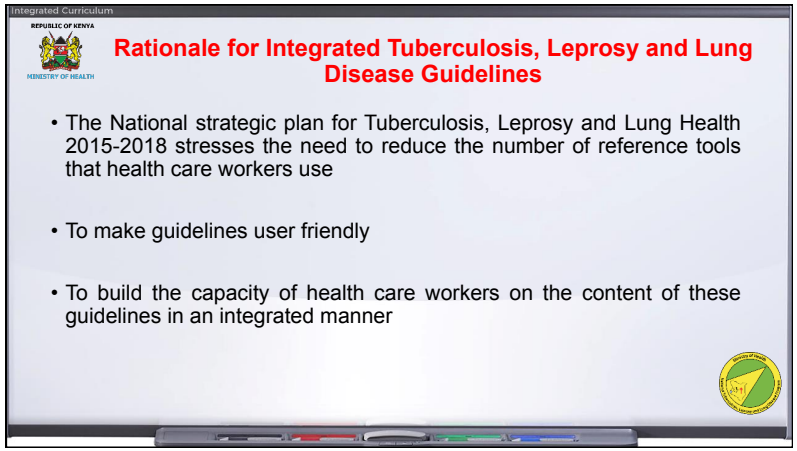
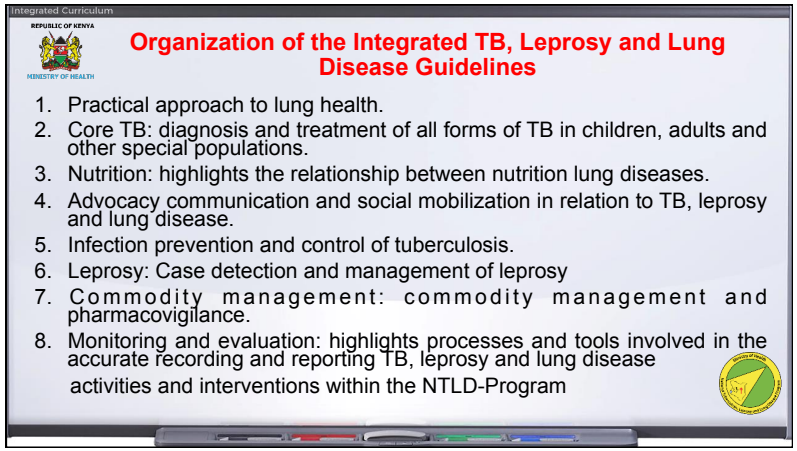
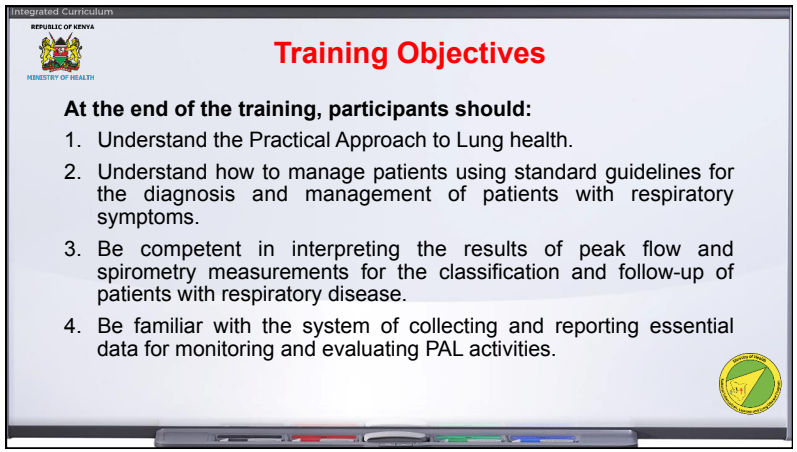
Target Audience for the Integrated Guidelines

- Health care workers who manage TB, Leprosy and Lung disease
- Pre-service clinical training
- Counties tasked with planning and resource allocation
- Policy makers and other line ministries in health, social services, prison services and immigration
- Development partners and organizations involved in funding TB, leprosy and lung disease





MODULE 2 - LUNG DISEASES



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Introduction

- PAL is the strategy adopted for appropriate and systematic diagnosis and management of lung diseases
- Lung health is divided broadly into acute and chronic lung diseases:
- Acute lung diseases
  - Pneumonia
- Chronic lung diseases
  - Asthma
  - Chronic Obstructive Pulmonary Disease(COPD)
  - Tuberculosis
  - Lung cancer
- There is a rise in the incidences of these lung conditions attributed to: tobacco smoking, HIV, urbanization, industrialization, atmospheric pollution, and deterioration of socioeconomic conditions
- Respiratory symptoms are most frequent complaints of those seeking outpatient services

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Practical Approach to Lung Health (PAL) Definition

PAL:

- is the strategy adopted for appropriate and systematic diagnosis and management of these diseases
- is a syndromic approach to the management of patients who attend Primary Health Care (PHC) services for respiratory symptoms
- aims to improve the quality management of respiratory patients aiding early diagnosis of tuberculosis
- targets health care workers in PHC settings

Objectives are to improve the:

- quality of respiratory case management for the individual patient
- efficiency and cost-effectiveness of respiratory care within health systems

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PAL Strategy and Impact

PAL strategy focuses on:

- Acute respiratory infections (ARI), with a focus on pneumonia, Asthma, COPD and TB

The impact of PAL is:

- Provision of essential respiratory care delivery package
- Reduces unnecessary prescription of antibiotics
- Increase facility attendance by respiratory patients
- Strengthens the competence of PHC workers
- Strengthens the confidence of the population in PHC services
- Improves the health management information system
- Improves planning and health resource management
- Improves the referral system

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MODULE 1

Acute Respiratory Illnesses (ARI)

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Objectives

By the end of this module, participants will be able to:

1. Recognize and diagnose ARIs.
2. Standardize management of ARIs.

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Brainstorming

- What are the common ARIs ?
- How do ARIs present?
- How are ARIs diagnosed?
- How are ARIs managed?

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Acute Respiratory Illnesses (ARI)

Common ARIs include:

- Common cold: acute rhinitis, coryza
- Pharyngitis and tonsillitis: cute inflammation of the pharynx and tonsils
- Deep neck infection: cellulitis or abscesses in the potential spaces around the neck
- Diseases of the adenoids
- Sinusitis
- Acute epiglottitis
- Pneumonia in children above five (5) years

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Management of ARIs

- Analgesics and plenty of fluids.
- Manage specific conditions according to the national IMCI guidelines.
- Early diagnosis and proper treatment of pneumonia in children is essential to reduce mortality.
- This is because severe forms of ARI are responsible for high mortality in children under five (5) years of age.

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MODULE 2

Pneumonia

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Objectives

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

1. Define pneumonia
2. Classify pneumonia
3. Diagnose and manage pneumonia in:
   - Children above five (5) years
   - Adults

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Pneumonia

Definition: infection of the lung parenchyma

Pneumonia can be classified as:

1. Community Acquired (CAP)
2. Hospital Acquired (HAP)
3. Ventilator Associated (VAP)
4. Primary: occurring in a previously healthy person living in the community. It is usually lobar due to Pneumococcal and presents with a very short history
5. Secondary: develops in association with prior diseases/conditions
   - Immune compromised patients
   - Debilitated patients
   - Alcoholics
   - Post-operative patients

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Etiology and Diagnosis

- Typical pathogens
  - Streptococcus pneumonia
  - Staph Aureus
  - Klebsiela pneumonia
  - Haemophylus influenza
- Atypical pathogens
  - Mycoplasma pneumonia
  - Legionella pneumonia
- Respiratory viruses
  - Influenza
  - Adeno
  - RSV

- Diagnosis of pneumonia involves
  - Good history taking
  - Physical examination
  - Clinical presentation
  - Investigations

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Clinical Presentation

Symptoms

- Breathlessness
- Cough with or without sputum (which may be rust colored)
- Fever
- Pleuritic chest pain

Signs

- Bronchial breathing
- Reduced chest movement
- Reduced breath sounds
- Tachypnoea
- Crackles
- Percussion dullness

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Investigations

1. Total Blood Count Hemogram - HB, WBC
2. Sputum microscopy: gram and ZN staining
3. Chest x-ray
4. Blood slide for malaria parasites
5. Targeting etiology
   - Culture of sputum including TB culture
   - Blood cultures
   - Antigen tests
   - PCR
   - Serology

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Treatment of Community Acquired Pneumonia

Outpatient Treatment

- IM Benzyle Penicillin stat then Amoxicillin for 7 days
- If Penicillin allergy is present, Erythromycin for 7 days
- Alternative antibiotics include Cotrimoxazole
- Analgesics: Paracetamols or Salicylic acid (aspirin)

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Treatment of Community Acquired Pneumonia

Who To Admit

- Admit patients with the following:
  - Cyanosis
  - Respiratory distress (RR>25per minute)
  - Heart failure or pleural effusion
  - More than one lobe is involved
  - Poor response as outpatient
  - Dehydration
  - Secondary pneumonia is suspected

In-Patient Treatment

- IV/IM Crystalline Penicillin till response then discharge on Amoxicillin
- If allergic, give Erythromycin or Cotrimoxazole
- If no response, consider investigation for TB

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Management of Secondary Pneumonia

- Admit patient.
- Treat with Benzyl Penicillin 2 Mega Units six (6) hourly with Gentamycin 240mgs IM/IV once a day for five (5) days OR IV Cetrtiaxone 2 Mega Units for 24 hours OR Erythromycin 500mgs six (6) hourly for five (5) days.
- In case of aspiration, add Metronidazole 500mgs IV eight (8) hourly or use amoxiclav 1.2gms eight (8) hourly in place of Benzyl Penicillin.
- If streptococcus is suspected, add Flucloxacillin 500mgs IV six (6) hourly.
- If no improvement, consider pseudomonas and streptococcus.
- For children, calculate dosages according to weight.

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Prevention

- Cough hygiene.
- Hand washing with soap.
- Reducing household air pollution.
- HIV prevention and Cotrimoxazole prophylaxis for HIV-infected and exposed children.
- Vaccinations –pneumococcal vaccines, H.Influenza.

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MODULE 3

Chronic Lung Diseases

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Chronic Lung Disease

- Chronic lung diseases include:
  - Asthma
  - COPD
  - Lung Cancer
  - Interstitial Lung Disease
- Presents with chronic cough - cough lasting 14 days or more
- May be associated with fever, poor weight gain in children or weight loss

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Conditions Associated with Chronic Cough

- Tuberculosis.
- Asthma.
- Foreign body aspiration, usually children under five years
- HIV infection - chronic chest signs with clubbing of fingers and toes but no cyanosis
- Bronchiectasis - Purulent sputum, bad breath, finger clubbing
- Lung Abscess - Reduced breath sounds over affected part
- Heart disease - Either due to congestive cardiac failure

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MODULE 4

Asthma

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Objectives

At the end of the module, participants will be able to:

1. Define Asthma
2. Describe how Asthma presents
3. Discuss the risk factors for Asthma
4. Discuss the diagnosis of Asthma
5. Manage and control Asthma
6. Have the knowledge to prevent an Asthma attack

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The Asthma Burden

- Asthma is characterized by:
  - chronic airway inflammation
  - A wheeze, chest tightness, shortness of breath and cough that may vary over time and intensity, together with variable air flow limitation
- Asthma is the most common chronic disease in the world with about 300 million people currently affected
- The rate of asthma increases with urbanization
- Number of disability-adjusted life year (DALYs) lost due to asthma is about 15 million per year

Accounts for about 1 of all DALYs lost reflecting its high prevalence

Risk Factors

Non Modifiable Factors

- Gender: Early Male>Female and Later Female>Male
- Atopy
- Airway hyper responsiveness

Modifiable Factors

- Allergen Exposure
- Infections and infestations
- Breastfeeding
- Air pollution
- HIV infection
- Occupational exposures
- Tobacco smoking including environmental tobacco smoke (passive smoking)

Risk Factors (cont.)

Modifiable Factors - Environmental

- Indoor allergens
  - House dust mite (*Dermatophagoides* Spp)
  - Animal allergens (cat, dog, rodents)
  - Cockroach
  - Fungi – molds especially A*lternaria*
- Outdoor allergens
  - Pollens from trees, grasses and weeds- Seasonal asthma
  - Fungi – *Alternaria* and *Cladosporium*
- Occupational sensitizers: e.g. isocyanates in spray painters

Diagnosis

Typical Patterns

- Wheezing, cough and breathlessness
- Symptoms mainly at night and early morning hours
- Disappear spontaneously or after bronchodilator use

Atypical Patterns

- Mainly in children
- Do not respond to symptomatic treatment
- Chest tightness with wheezing that occurs only after exercise

Classification of Severity

CLASSIFY SEVERITY
Clinical Features Before Treatment

	Symptoms	Nocturnal Symptoms	FEV_1 or PEF
STEP 4 Severe Persistent	Continuous Limited physical activity	Frequent	≤ 60% predicted Variability > 30%
STEP 3 Moderate Persistent	Daily Attacks affect activity	> 1 time week	60 - 80% predicted Variability > 30%
STEP 2 Mild Persistent	> 1 time a week but < 1 time a day	> 2 times a month	≥ 80% predicted Variability 20 - 30%
STEP 1 Intermittent	< 1 time a week Asymptomatic and normal PEF between attacks	≤ 2 times a month	≥ 80% predicted Variability < 20%

The presence of one feature of severity is sufficient to place patient in that category

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Evaluation of Asthma

Clinical

- Frequency and severity of the clinical symptoms at initial and follow-up visits:
- wheeze attacks
- breathlessness or chest tightness
- cough

Lung Function Tests

- *Measurement of Peak Expiratory Flow (PEF) using* Peak flow meter (PFM)
- PEF is correlated with the one second Forced Expiratory Volume (FEV1)
- Spirometry

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Management of Asthma

Aims of Treatment

- Prevent complications of Asthma
- Maximize quality of life/ health status of patients by:
  - Clearing symptoms.
  - Enabling normal. activity/sports.
  - Avoid serious drug SE.

Goals of Treatment

- Achieve and maintain control of symptoms
- Prevent asthma exacerbations
- Maintain lung function as close to normal as possible
- Maintain normal level of activity including exercise
- Avoid adverse effects of asthma meds
- Prevent development of irreversible airflow limitation
- Maintain normal growth velocity in children
- Prevent asthma mortality

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Managing Asthma

- **Five Components**
  - Develop patient/health provider partnership
    - Patient education
  - Identify and reduce exposure to risk factors
  - Assess, treat and monitor asthma
    - Long term indication plan
  - Manage asthma exacerbations
  - Special considerations

- **Asthma Drugs**
- 2 types of drugs:
  1. Anti-inflammatory: taken daily on a long term basis, these can control the disease
  2. Bronchodilator: their principal role is to relieve the patient's symptoms

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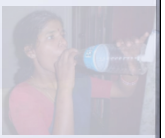
Anti-inflammatory medicines

- Corticosteroids
  - The most effective drugs with anti-inflammatory actions
- Systemic and oral corticosteroids
  - Short term safe; Long term major side effects
- Inhaled corticosteroids
  - Minor local side effects (dysphonia, oral candidiasis)
  - Rare systemic effects prevented by use of a spacer and rinsing the mouth after inhaling
- The commonest include:
  - Beclomethasone dipropionate
  - Budesonide
  - Fluticasone



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Bronchodilators

- Short-acting inhaled beta2 agonists bronchodilators act quickly:
  - Examples - Salbutamol, fenoterol, terbutalin have similar effectiveness.
- Rare side effects.

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Patient follow up

- Measure PEF before and after inhaled salbutamol compared with initial best PEF.
- Find out:
  - How many times per day the patient needed inhaled salbutamol over the last 2 weeks.
  - If patient has visited emergency room or how many times has been hospitalized since the last planned visit.
  - If asthma symptoms have limited activities.
  - Drugs taken each day (If different from prescription, ask patient why).

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Patient follow-up visits

- Planned Follow up (appointment) visits:
  - weekly visit until asthma is well controlled by the initial treatment for at least 2 months. Maintain this treatment for at least 3 months.
  - Then, quarterly visits to adapt the treatment, usually step down.
- Unplanned follow up (appointment) visits:
  - exacerbation or insufficient control of asthma.
  - other reason: side effects, non-availability of drug, social problems etc.

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Before discharge

- Identify and avoid the cause of the attack.
- Verify that inhalation technique is correct.
- Provide a prescription that includes inhaled beta2-agonists and a short course of oral corticosteroids to prevent relapse.
- Arrange follow-up at the health centre where the patient is registered.

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Module 5

Chronic Obstructive Pulmonary Disease (COPD)

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Objectives

By the end of this module, participants will be able to.

1. Differentiate between asthma and COPD.
2. Manage patients with COPD.
3. Carry out lung function assessments.

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COPD : Definition

- Chronic Obstructive Airway Disease is a term used to describe progressive lung disease that makes it hard to breathe.
- It includes chronic bronchitis and Emphysema.
- It is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases.

Global strategy for the diagnosis, management, and prevention of Chronic Obstructive Pulmonary Disease updated 2015

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Risk factors and symptoms for COPD

- Risk factors for COPD
  - Active Tobacco smoking.
  - Secondary tobacco smoking.
  - Indoor air pollution due to the use of bio fuels and coal for cooking.
  - Occupational dusts and chemicals.
  - Frequent lower respiratory tract infections .
  - Post Tuberculosis- lung damage.
  - Age of 40 years and above.
  - Family history of COPD.
- Symptoms
  - Dyspnea that is progressive, persistent and worsens with exercise
  - Chronic cough which maybe intermittent and productive or not productive
  - Chronic sputum production
  - Wheezing

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Distinguishing asthma and COPD

- **Asthma Likely**
  - Onset before 20 years of age.
  - Associated hay fever, eczema, allergies.
  - Intermittent symptoms, with normal breathing in between.
  - Symptoms worse at night, early morning, with cold or stress.
  - Personal or family history of asthma.
    - **Asthma likely.**
  - Confirm diagnosis - Give routine asthma care.
- **COPD likely**
  - Onset after 40 years of age.
  - Symptoms are persistent and worsen slowly over time.
  - Cough with sputum starts. long before difficult breathing.
  - Client is or was a heavy. smoker and had TB.
  - Previous diagnosis of COPD.
    - **COPD likely.**
  - Confirm diagnosis - Give routine COPD care.

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Clinical features and diagnosis of COPD

- **Clinical features**
  - Onset after age of 40.
  - Symptoms are persistent and worsen over time.
  - Cough progresses to difficulty in breathing.
  - Sputum production.
  - Previous diagnosis of COPD.
- **Diagnosis of COPD**
  - **Spirometry** is the Gold standard for clinical diagnosis and monitoring COPD.
  - Post bronchodilator FEV_1/FVC less than 70% confirms the presence of persistent airflow limitation.
  - To diagnosis, manage and follow up COPD patients one should have access to Spirometry facilities.
  - Others
    - Chest X- ray

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Management of COPD

Goals of COPD management.

- To relieve symptoms
- Prevent disease progression
- Prevent and treat complications and exacerbations
- Reduce risk of dying

Treatment of COPD

- Smoking cessation- highest impact in reducing disease progression
- Prevention of occupational exposure
- Reduction of exposure to indoor pollutants e.g. bio fuels in poorly ventilated houses
- Physical exercise
- Pharmacotherapy

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Pharmacotherapy

COPD severity classification	Mild COPD	Moderate COPD	Severe COPD
Signs and symptoms	Breathlessness with strenuous activity e.g. climbing stairs	Breathless at normal pace e.g. walking	Breathless with activity of daily living e.g. dressing
Inhaled beta agonist	2puffs when needed (up to 4 times a day)	2 puffs when needed (up to 4 times a day)	2 puffs when needed (up to 4 times a day)
Inhaled Ipratropium bromide (Hospital level)		2 puffs when needed (up to 4 times a day)	2 puffs when needed (up to 4 times a day)
Slow release theophylline (Hospital level)			200-300mgtwice day taken long term.

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Routine care for COPD patients

- Aim of care is to stop further deterioration of lung function and to recognize and treat acute exacerbations early.
- At each visit provide the following care:
  - Smoking cessation: This is the mainstay of care
  - Assess severity of COPD and treat according to severity
  - Ensure optimal delivery of drugs by educating patients on correct use of inhalers
- Treat infective exacerbations. LRTIs occur commonly in COPD patients
- In patients previously treated for TB, repeat TB tests only if other TB symptoms develop

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Lung function testing Spirometry

- **Spirometry**
  - Is used for the diagnosis and assessment of COPD
  - It is the gold standard test for diagnosing COPD
  - It is reproducible, standardized and objective way of measuring airflow limitation
- **Spirometry: Parameters**
  - FEV1 –forced expiratory volume in one second
  - FVC –forced vital capacity
  - FEV1/FVC -The percentage of FVC expired in one second
- **Diagnosis of COPD**
  - FEV1/FVC <70%
  - FEV1<80% predicted (after bronchodilator) confirms the presence of airflow limitation that is not fully reversible

MODULE 3: TUBERCULOSIS

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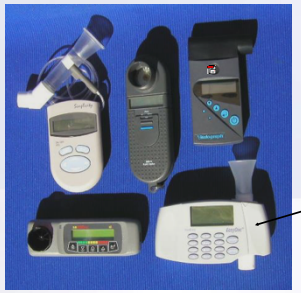
Many models of portable spirometers



- ndd EasyOne

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TUBERCULOSIS

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Background

- It has been two decades since WHO established a global TB monitoring system; since that time, 20 annual rounds of data collection have been completed in the annual WHO Global TB report.
- This report consists of data from 205 countries and territories, which account for more than 99% of the world's population.
- The year (2015) is a year of transitions:
  - from the MDGs to a new era of Sustainable Development Goals (SDGs), and
  - from the Stop TB Strategy to the End TB Strategy

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2015 Global TB statistics

- 10.4 million estimated TB cases (11% HIV positive)
  - 5.9 million men and
  - 3.5 million women
  - 1.0 million children.
- Only 6.1 million new TB cases notified
- 1.4 million TB deaths (0.4 million HIV-positive)
  - 860 000 men,
  - 350 000 women and
  - 170 000 children.
  - 1.1 million HIV deaths, 35% (0.4 million) due to TB

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2015 Global TB statistics

- 480 000 estimated cases of multidrug-resistant TB (MDR-TB)
- 100,000 Rifampicin resistant (RR)
- Out of the 580, 000 estimated cases, only 125 000 (20%) were enrolled on treatment

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African TB statistics, 2015

- The African Region had 26% of the world's cases in 2015, (275/100 000) people, almost double the global average of 142/100,000.
- 84% of TB deaths were in the African region

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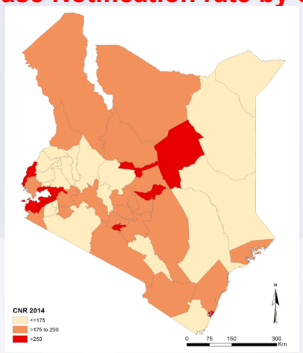
Kenya Case Notification rate by county



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Kenya Epidemiology 2015

- Total TB cases were 81,518
  - 50890 (61%) were males
  - Children comprised of 8.5% (6,968)
  - 25,030 (31%) were HIV+
- 433 DRTB Cases,
  - 368 (RR)
  - 1 XDR

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Module 2

Introduction to TB

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Introduction

- Tuberculosis is caused by a bacteria called ***Mycobacterium tuberculosis (M. tuberculosis)***
- M. tuberculosis is transmitted through the air
- ***M. tuberculosis*** is from the family of bacteria called ***Mycobacteriaceae***
- Humans are the only known reservoir of ***M. tuberculosis***

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Etiology

- *Other Mycobacteria that may cause* disease in humans include:
  - *Mycobacterium Avium Complex (M. Avium and M. intracellulare)*
  - *M. bovis*
  - *M. africanum*
  - *M. microti*
  - *M. caprae*
  - *M. pinnipedii*
  - *M. canetti*
  - *M. mungi*
- The majority of TB cases are caused by ***M. tuberculosis***

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Risk factors for TB infection and disease in children

- TB infection
  - **Contact with source case**
    - –Closeness of contact
    - –Duration of contact
  - **Source case**
    - –Smear positivity
    - –Cavities on CXR
  - **Increased exposure**
    - –Living in high TB endemic communities
    - –Children of families living with HIV
- TB disease
  - **Young age**
    - –Especially 0-2 years
  - **HIV infection**
    - –Risk of infection and disease
  - **Other immunosuppression**
    - –Malnutrition
    - –Post-measles
  - **Not BCG vaccinated**
    - –Risk of disseminated disease

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TB Infection in children

- Exposure to the *Mycobaterium tuberculosis* leads to the development of a primary lesion in the lung with spread to the regional lymph nodes (Ghon focus).
  - **This is called latent TB infection**
- The immune response develops about 4–6 weeks after the primary infection and this immune response stops the multiplication of *M. tuberculosis* bacilli at this stage

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Risk factors for TB Transmission

- **Susceptibility of the contact**
- **Infectiousness of the index case**
  - Presence of cough
  - Presence of pulmonary or laryngeal disease
  - Poor cough etiquette
  - Cavitatory disease
  - Positive smear or culture
- **Exposure to the infectious case**
  - Duration of exposure
  - Frequency of exposure
  - Physical proximity
- **Environmental factors**
  - Concentration of bacilli in the environment of the child
  - Small enclosed spaces
  - Poor ventilation
  - Poor air circulation
  - Poor specimen handling
  - Positive air pressure into room

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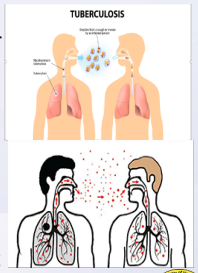
Transmission

- ***M. tuberculosis*** is carried in airborne particles, called droplet nuclei, of 1– 5 microns in diameter
- Infectious droplet nuclei are generated when persons who have pulmonary or laryngeal TB disease cough, sneeze, sing, talk or laugh
- These tiny particles can remain suspended in the air for several hours
- Transmission occurs when a person inhales droplet nuclei containing ***M. tuberculosis***
- TB is not transmitted by shaking hands, sharing food, toothbrushes or touching bed linen or toilet seats used by infected persons



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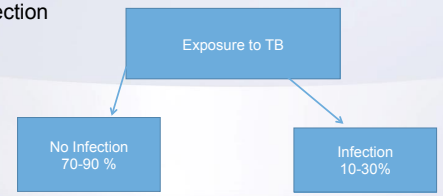
Natural history

- Upon exposure to infected droplets from the environment, one may inhale air that contains droplets with ***M. tuberculosis*** bacilli
  - These travel through the respiratory tract to reach the small air sacs of the lung (the alveoli), where infection may begin
- 10-30% of persons exposed to TB bacilli will develop infection



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Natural history…cont'd

- Once infected, the bacilli pass through the respiratory tract
  - In the alveoli, some of the bacilli are killed, a few multiply in the alveoli while others may enter the bloodstream and spread throughout the body
- The immune cells in the alveoli may form an immune capsule that keeps the bacilli contained
  - This is the **Ghon focus**
- If the Ghon focus also involves infection of adjacent lymphatics and hilar lymph nodes, it is known as the **Ghon's complex or primary complex**
- 90% of persons who are exposed and infected with TB bacilli do not develop signs and symptoms of TB disease and are referred to as having **Latent TB infection**

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Natural history…cont'd

- In some people, the bacilli overcome the defenses of the immune system and begin to multiply
  - This results in the development of signs and symptoms and this is known as **Active TB disease**
- 5% develop TB disease within 2 years of infection
  - This is known as **primary TB disease,** and usually occurs in young children or in severe immune-suppression
- 5% develop TB disease later on in life when their immune system becomes weak
  - This is known as **secondary TB disease**
    - Secondary TB disease can be as a result of reactivation of LTBI or re-infection

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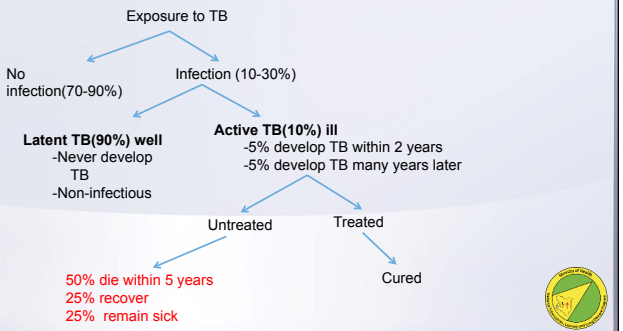
Summary of the natural history of TB infection



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Risk Factors for Tb infection and disease

Risk factors for TB infection (exposure)(LTBI)	Risk factors for active TB disease
High prevalence of TB disease in population	Immunosuppression e.g HIV, diabetes, Malnutrition, alcoholism, smoking, immunosuppressant therapy,silicosis
Smear positivity of cases in population (infectivity of cases)	Recent prior infection
Type of TB disease (e.gcavitary, pulmonary more infectious)	Poorly treated previous TB
Proximity and duration to infectious cases (contact)	Extremes of age
Environmental factors e.g poor ventilation, overcrowding	

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TUBERCULOSIS

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Module 3

Management of *Mycobacterium* tuberculosis

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Diagnosis of Tuberculosis

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Case Definition of TB

1. **Presumptive TB:** Case is one who presents with symptoms or signs suggestive of TB (previously known as a TB suspect)
2. **Case of TB:** A patient who has been diagnosed with TB in the either one of the following
   - **A bacteriologically confirmed TB case**; one from whom a biological specimen is positive by smear microscopy, culture or WRD (WHO-approved Rapid Diagnostics such as Xpert MTB/ RIF)
   - **A clinically diagnosed TB case**; One who does not fulfil the criteria for bacteriological confirmation but has been diagnosed with active TB by a clinician or other medical practitioner who has decided to give the patient a full course of TB treatment

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Case definition of TB…cont'd

This definition includes:

- cases diagnosed on the basis of X-ray abnormalities
- suggestive histology
- extrapulmonary cases without laboratory confirmation

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Case definition of TB…cont'd

- Clinically diagnosed cases subsequently found to be bacteriologically positive (before or after starting treatment) should be reclassified as bacteriologically confirmed
- All such cases should be notified regardless of whether TB treatment was started or not

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Diagnosis of Drug Sensitive TB

- **The diagnosis of TB depends on numerous factors including;**
  1. High index of TB suspicion among community members
  2. High index of suspicion among health care workers
  3. Turnaround time for delivery of laboratory results
  4. Capacity to conduct active tracing and screening of contacts,
  5. Capacity to follow up all patients with positive lab investigations (bacteriologically confirmed) for timely treatment initiation.
  6. Integration of TB services within other areas such as maternal and neonatal child health, nutrition, diabetes and HIV clinics

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Diagnosis of pulmonary TB (PTB)

History

- TB should be suspected in any person presenting with the following;
  - Cough
  - Fevers
  - Night sweats
  - Loss of weight
  - Chest pain
  - Shortness of breath
  - History of contact with an adolescent or adult with proven or suspected TB should be taken for all children suspected to have TB. aaaa

Physical examination

- Physical signs may include:
  - Bronchial breath sounds
  - Tachypnoea
  - Wasting
  - Haemoptysis
  - Anaemia
  - Asymmetrical/persistent wheeze that does not respond to broncho-dilators (airway compression due to enlarged tuberculous hilar lymph nodes)
- In children there may be atypical clinical presentations, such as the following;
  - Acute severe pneumonia
  - Presents with fast breathing and chest in-drawing
  - Occurs especially in infants and HIV-infected children
- Suspect PTB if response to antibiotic therapy is poor
- If HIV infected suspect other HIV-related lung diseases e.g. PCP
- aaaa

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Diagnosis of pulmonary TB (PTB)

- **Investigations**
  - **All attempts must be made to make a bacteriological diagnosis of PTB in both adults and children**
  - **Sputum for AFB or Gene Xpert is therefore mandatory for all presumptive cases of PTB**
- Investigations for the diagnosis of Pulmonary TB should be preceded by proper history taking and a thorough physical exam
- Investigations should be conducted to confirm a diagnosis based on the symptoms a patient presents with

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Test	Target Group	Purpose
1. Gene Xpert	The first line test for all presumptive TB in; •Children, •PLHIV •HCWs •Prisoners, •Smear negative persons •Previously treatment TB	For diagnosis of TB
2. Smear microscopy (FM & light microscopy)	All presumptive Pulmonary TB	Detect TB disease Monitoring smear positive and gene xpert positive TB patients on treatment at months 2, 5 and 6
3.Chest X-ray	All presumptive pulmonary TB	Support TB diagnosis especially where sputum for AFB/gene xpert is negative.
4.Histology	All presumptive EPTB	Tissue diagnosis in suspected EPTB e.g TB adenitis
Other supportive tests		
5. Tuberculin skin test	Children with presumptive TB	As an adjunct test to detect TB exposure in children, whose TB diagnosis is not obvious. Conducted in tertiary institutions
6. ESR	In presumptive TB	Erythrosite Sedimentation Rate (ESR) is usually elevated in active TB. This test is however neither sensitive nor specific enough to be of value in the diagnosis of PTB.

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Sputum smear examination

- TB diagnosis using sputum for ZN and FM microscopy involves collection of 2 sputum samples:
  - A spot and,
  - A morning sample

Sample	When is it collected?	Where is it collected?
Spot-1st sample	On the spot when patient presents to facility	In the health facility
Morning -2nd sample	Patient collects upon waking up the following morning	At home and brings to health facility (Or in hospital if patient is hospitalized)

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Quality sputum specimen collection

Instructions to patient

- The patient should
1. Take a deep breath
2. Cough severally
3. Attempt sputum production. Number 1 to 3 can be repeated several times
4. Spit sputum (and not saliva) into the provided container
5. Close the lid tightly
6. Submit to laboratory as soon as possible

Instructions to health care worker

1.Label the sputum containers on the side (***not on the lid***) prior to sputum collection

2.Fill in the sputum examination forms ensuring that the patient's contacts are included

3.Instruct the patient to collect sputum samples in a well ventilated area preferably outdoors (not in the facility lavatories)

4.Give patients clear instructions on when to return for their results

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In patients who cannot expectorate, sputum may be obtained through:

1. Gastric aspiration; Through insertion of a nasogastric tube (NGT) to aspirate gastric contents
2. Sputum induction done through nebulization with hypertonic saline (greater 0.9%) solution, followed by aspiration through suction.
3. Bronchial wash or broncho-alveolar lavage sample obtained through fiberoptic bronchoscopy

NB. Sputum induction and bronchoscopy may lead to a substantial generation of infectious aerosols, and should only be carried out in clinical environments with appropriate infection prevention measures in place.

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Sputum culture examination

Indications for sputum TB culture and DST include:

1. All previously treated patients including:
   - Relapse
   - Treatment after failure
   - Treatment after loss to follow up
   - Other previously treated patients
2. Patients who remain smear positive at end of month 2 while on first line treatment
3. Patients with treatment failure:
   - Smears still remains positive at month 5 or later during treatment
4. Symptomatic contacts of drug resistant TB cases
5. Health care workers

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Gene Xpert

- This is a molecular test to detect *M. Tuberculosis* & Rifampicin resistance
- It is more sensitive and specific than sputum micsroscopy in detecting TB
- It is the preferred test of choice for TB diagnosis among children, PLHIV, HCWs, prisoners, smear negative persons and previously treated persons
- Test takes 2 hours

GENEXPERT ALGORITHIM

Indications for GeneXpert

1. **TB Diagnosis**
   - HIV positive with TB symptoms
   - Children under 15 years with TB symptoms
   - All smear negative TB cases
2. **MDR TB surveillance**
   - All previously treated patients: a. failures; b. relapses; c. treatment after loss to follow up
   - DR TB contacts
   - Healthcare workers with TB symptoms
   - Patients who develop TB on IPT
   - Refugees with symptoms of TB
   - Smear positive at 2 months
   - Prisoners with TB symptoms

In areas where GeneXpert is available: this should be the first test. Patients diagnosed with GeneXpert should be followed up with microscopy

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Chest X-ray

- The chest x-ray may aid the diagnosis of PTB but it should not be used as the sole means of establishing a TB diagnosis
- Radiographic features suggestive of PTB include:
  - Patchy opacification in the upper zone of lung
  - Cavitations and scarring (fibrosis)
  - Mid-zone shadows and the presence of hilar or mediastinal lymph node enlargement
  - Miliary mottling
  - Pleural and/or pericardial effusion
  - In HIV infected persons the radiological picture is more often atypical with the lower or generalized opacifications

All patients with chest x-ray features suggestive of TB should have sputum specimens submitted for bacteriologic examination

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Differential diagnosis for Pulmonary TB

1. Chronic bronchitis/ COPD
2. Bronchiectasis
3. Lung abscess
4. Lung cancer
5. Heart failure
6. Sarcoidosis
7. Pneumocystis *jirovecii*
8. Atypical pneumonias e.g. (caused by unusual pathogens such as fungi)

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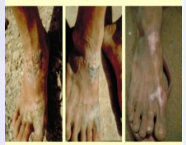
Type of EPTB (3)	Typical Symptoms	Confirmatory tests
TB encephalitis including Tuberculoma	•Headaches •Vomiting •Convulsions •Limb weakness •Cranial nerve palsies	**Brain CT scans** ; useful in demonstrating lesions Often it is difficult to confirm the diagnosis of brain TB and most patients are treated on an empiric basis
TB of the skin Response to chemotherapy of tuberculosis verrucosa cutis  At diagnosis After 15 days After 3 months	***Lupus vulgaris:*** Persistent and progressive form of cutaneous TB It occurs as small sharply defined reddish-brown lesions with a gelatinous consistency (called apple-jelly nodules) Untreated, lesions persist for years, leading to disfigurement ***Scrofuloderma:*** Skin lesions result from direct extension of underlying TB infection of lymph nodes, bone or joints Often associated with TB of the lungs. Firm, painless lesions that eventually ulcerate with a granular base. May heal even without treatment but this takes years and leaves unsightly scars	**Skin biopsy;** The diagnosis is usually made or confirmed by a skin biopsy Typical tubercles are caseating epithelioid granulomas that contain acid-fast bacilli. These are detected by tissue staining, culture and polymerase chain reaction (PCR)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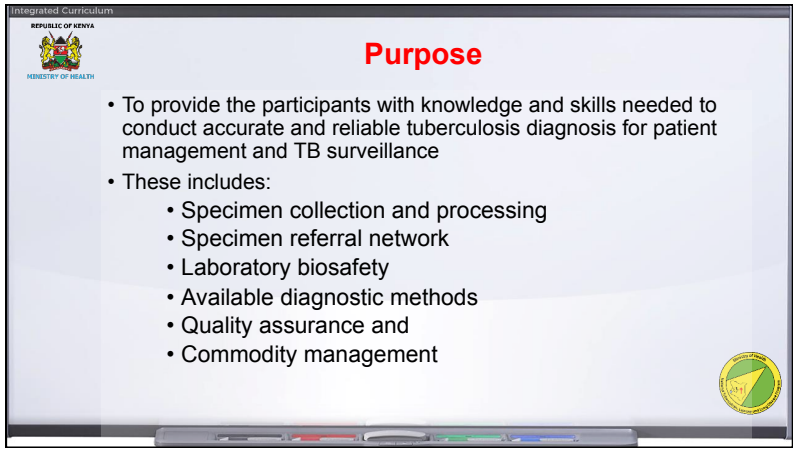
Kenya Lung health Training Course
Laboratory Diagnostic Services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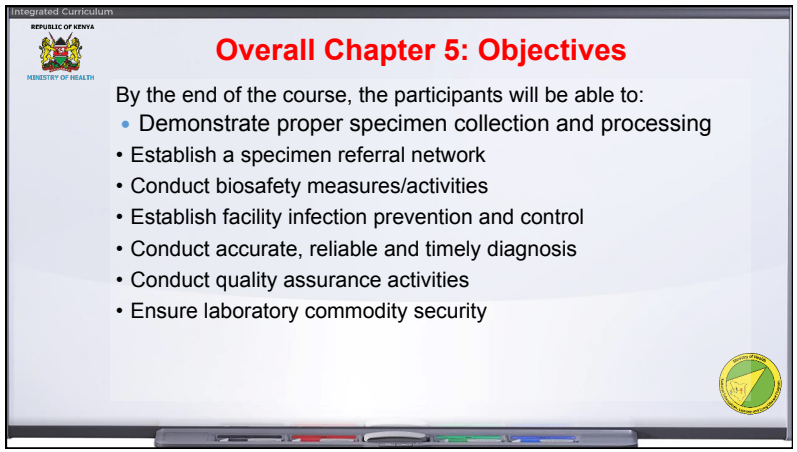
Purpose
• To provide the participants with knowledge and skills needed to conduct accurate and reliable tuberculosis diagnosis for patient management and TB surveillance
• These includes:
• Specimen collection and processing
• Specimen referral network
• Laboratory biosafety
• Available diagnostic methods
• Quality assurance and
• Commodity management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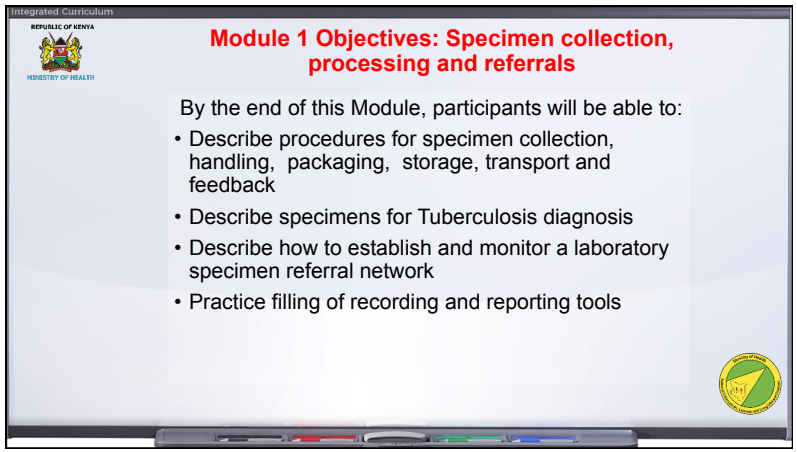
Overall Chapter 5: Objectives
By the end of the course, the participants will be able to:
• Demonstrate proper specimen collection and processing
• Establish a specimen referral network
• Conduct biosafety measures/activities
• Establish facility infection prevention and control
• Conduct accurate, reliable and timely diagnosis
• Conduct quality assurance activities
• Ensure laboratory commodity security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Module 1 Objectives: Specimen collection, processing and referrals
By the end of this Module, participants will be able to:
• Describe procedures for specimen collection, handling, packaging, storage, transport and feedback
• Describe specimens for Tuberculosis diagnosis
• Describe how to establish and monitor a laboratory specimen referral network
• Practice filling of recording and reporting tools

Integrated Curriculum

Collection sputum samples

• Sputum must be collected in the open air or in a well-ventilated room reserved for this purpose, as far away as possible from other people

• Trained health personnel must:

✓Explain to the patient how to cough to bring up sputum from as deep as possible in the lungs

✓Open the sputum container, stand behind the patient and ask him/her to expectorate with his/her mouth close to the sputum container

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Collection of sputum sample

- Close the sputum container securely.
- Wash their hands with soap and water before giving a new container to the patient to be returned to the health facility the next day with a new sputum sample
- Ensure that the patient has understood how to collect a sputum sample the next morning and how to close the container securely
- Check the quality and quantity of sputum collected (2–3ml of sputum containing solid particles)

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Sources of TB samples

Site	Specimen
Lungs	Sputum
Pleura	Pleural Fluid
Central nervous system	CSF
Lymphatic system	Lymph fluid, Biopsy
Genitourinary systems	Urine
Bones and joints	Synovial fluid
Whole body (generalized)	Disseminated (milliary TB)

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At the community level, CHV will be supported by the diagnostic facilities to

✓Understand sample collection SOP
✓Sample packaging procedures
✓Storage and transportation of the samples (sample should be delivered in 24 hours
✓Timelines for the results back to the patient care point

- Samples should be examined at health Centre daily or sent to a testing laboratory
- For storage and transport of the samples, special transport boxes should be used that can each hold 10–20 containers

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Laboratory request tools for AFB Microscopy, GeneXpert and Culture

- Samples request forms for AFB, Genexpert and Culture
- TB AFB/GeneXpert laboratory registers
- Sample tracking logs

Note: Laboratory request form should be fully filled

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The following rules must be followed in sample packaging and transportation

✓Each sputum container must be clearly identified by a label with the patient's family name, first name and register number **on the side of the** container

✓The transport box with the sputum containers should be kept as cool as possible. If the samples are to be cultured they should be refrigerated at +4°C. (if not refrigerated, the sample should reach culture lab within 48 hours)

✓A list of the patients' names and information should be sent with the transport box

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How to establish a specimen referral network

- Identify specimen referral coordination and logistics lead at each level
  - Facility, Sub-County, County and Culture laboratories
- Mapping of all TB treatment and diagnostic facilities
- Line listing of TB treatment facilities nearest to diagnostic sites (network)
- Identification of a dedicated specimen transport system (Motorbike, bicycle, vehicles, hand delivery, courier e.t.c.)
- Identification of results feedback

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How to establish a specimen referral network

- Ensure proper use of specimen recording and tracking tools
- Training of HCWs at facilities on specimen flow and results feedback
- Training of specimen transporting personnel on tracking, safety and timeliness requirements
- Sensitizing HMTs on specimen referral budgetary allocation needs
- Train specimen referral coordinators on monitoring and evaluation, targeting key performance indicators
- Routinely track and address needs for continuous improvement

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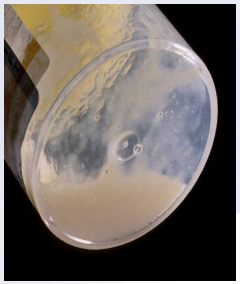
Acceptable Specimen quality



Purulent

Mucoid

(Images courtesy of A. Van Deun)

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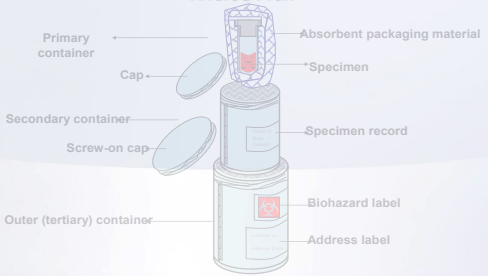
Sample packaging

Packing & shipping infectious material



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Specimen referral networks

Where to send specimens for testing:

- Within the Gene Xpert machine facility
- To the nearest Gene Xpert machine facility either within or outside your County

How to send specimens for testing:

- Ensure specimens are properly and safely packaged
- Use available facility transport(GOK, partner)
- Facilities are encouraged to integrate Xpert specimen referral with existing CD4, viral load, EID networks

How will results be returned?

- Electronic through emails
- Hard copy using existing transport mechanisms(partner, GOK)

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Why take a skin smear for leprosy diagnosis?

- To confirm a diagnosis of skin smear-positive multibacillary leprosy in a suspect
- To help diagnose multibacillary relapse in a patient who has previously been treated
- To help with the classification of new patients

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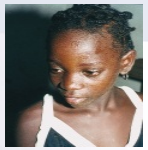
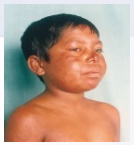
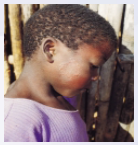
Sites for skin snip

You should take a smear from two sites only:

1. One ear lobe.
2. One lesion. Select the most active-looking lesion, but not
   - ✓on the face. 'Active' means raised and reddish in colour
   - ✓Take the smear in the most active area of the lesion
   - ✓(usually the edge)

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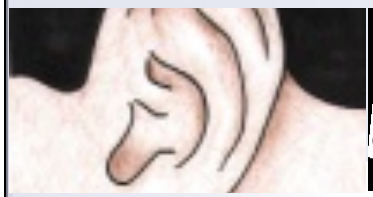
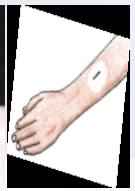
Sites for skin snip and procedure

- Procedure
  - ✓Taking a skin smear is an invasive procedure. Wash your hands, wear gloves, and use
  - ✓sterilised equipment and a new blade for each patient. Do not take skin smears unnecessarily

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Role play

- Filling of laboratory request forms
- Sputum collection procedures

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Module 2: Laboratory biosafety

Objectives

At the end of this module the participants should be able to understand:

1. The transmission of TB bacilli
2. Risk assessment and precaution levels
3. Safety practices in the TB microscopy laboratory and the Xpert MTB/RIF laboratory
4. Safe disposal of infectious waste

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Importance of safety in the laboratory

- Following laboratory biosafety procedures prevents laboratory staff from becoming infected with TB and prevents microorganisms from being released into the environment
  - ✓Specialized equipment may aid good laboratory practice but does NOT replace it
  - ✓Always wear gloves and laboratory coats when handling samples from patients

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Transmission of TB bacilli in the laboratory

- The main risks in a TB laboratory are related to the aerosols generated during the procedures that could be inhaled by laboratory workers
- The risk of aerosolization is associated with the:
  - ✓Type of procedure
  - ✓Frequency of testing, and the laboratory's workload
  - ✓Consistency of the material and its predisposition to aerosolize (for example, viscous liquids versus dry solids)
  - ✓Bacillary load of the materials

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New approaches to biosafety are based on risk assessments

- WHO has adopted an approach that assesses the risks associated with different technical procedures performed in different types of TB laboratories.
  - ✓Risk-group classifications and containment levels (BSLs) are no longer used.
  - ✓WHO's biosafety manual for TB laboratories describes the MINIMUM requirements for facilities, and the practices that can be adopted following a risk assessment

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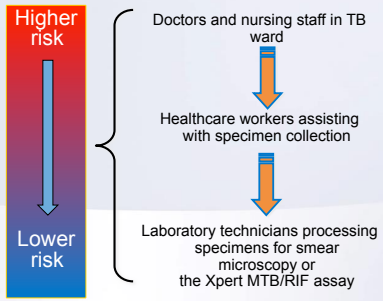
What is a risk assessment?

- A risk assessment is simply a careful examination of what in your work could cause harm to people.
- A risk assessment must consider:
  - ✓The bacterial load of materials, and the viability of TB bacilli
  - ✓The route of transmission of TB
  - ✓Whether the materials handled and the manipulations required for each procedure are likely to generate infectious aerosols
  - ✓The number of manoeuvres in each technique that may generate aerosols
  - ✓The workload of the laboratory and of individual staff members
  - ✓The location of the laboratory
  - ✓The epidemiology of the disease and the patient population
  - ✓The level of experience and competence of lab staff
  - ✓The health of lab staff (especially HIV-positive staff)

What are the steps in conducting a risk assessment?

- Identify potential hazards.
- Decide who might be harmed and how.
- Evaluate the risks and decide on precautions:
  - Determine the suitability of the physical space
  - Evaluate the staff's proficiency in following safe practices
  - Evaluate the integrity of safety equipment
- Record your findings and implement any necessary changes.
- Review your assessment and update it when necessary.
- A risk-assessment tool is available at http://www.gliquality.org/

Relative risks from exposure to infectious Tuberculosis



Risk precaution level: Low risk

Risk level of TB laboratory	Laboratory activities	Assessment of risk
Low risk	Preparing specimens for smear microscopy or Xpert MTB/RIF testing	Procedures have a low risk of generating infectious aerosols from specimens; the concentration of infectious particles is low

Risk precaution level: Moderate risk

Risk level of TB laboratory	Laboratory activities	Assessment of risk
Moderate risk	Processing and concentrating specimens for Xpert MTB/RIF testing or inoculation onto primary culture media; splitting specimens; direct DST (for example, LPA on processed sputum)	Procedures have a moderate risk of generating infectious aerosols; the concentration of infectious particles is low to moderate

Risk precaution level: High risk

Risk level of TB laboratory	Laboratory activities	Assessment of risk
High risk (TB-containment laboratory)	Culture manipulation for identification; DST or LPA on cultured isolates	Procedures have a high risk of generating infectious aerosols; the concentration of infectious particles is high

Classification of laboratory activities

- Smear preparation and staining: [Dirty activity]
- Processing samples for Xpert MTB/RIF testing, and inoculating cartridges: [Dirty activity]
- Microscopic examination of stained smears: [Clean activity]
- Loading cartridges into the GeneXpert instrument: [Clean activity]
- Record keeping and storage: [Clean activity]

Safety practices: Airflow

- **Use of bench spaces:** The bench used to process specimens for direct sputum-smear microscopy or the Xpert MTB/RIF assay should be separate from areas where specimens are received and from areas where paperwork is completed and telephones are used.
- **Ventilation:** When appropriate microbiological techniques are used, direct smear testing and direct processing of specimens for the Xpert MTB/RIF assay may both be carried out on an open bench in an adequately ventilated area.

Safety practices: Adequate ventilation

- Adequate ventilation for TB laboratories is typically described as directional airflow with 6–12 air exchanges per hour (ACH)
- Directional airflow refers to air moving from clean areas across areas where aerosols may be generated (dirty areas) and then to the outside.

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PPE: Gloves

- Gloves are required for processing specimens for TB diagnosis.
- Use disposable powder-free gloves, is recommended for Xpert Mtb rif assay
- Wearing gloves may give technicians a false sense of safety:
  - ✓**Regular and thorough handwashing remains essential**
- To avoid contamination remove gloves before using computer terminals or telephones
- DO NOT reuse gloves
- DO NOT wear gloves outside the laboratory

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PPE: Laboratory coats

Laboratory coats are essential:

- ✓ Leave coats at the worksite
  - do not take coats home
- ✓ Fasten the laboratory coat when worn
- ✓ Use appropriate size and type
- ✓ DO NOT wear outside of the laboratory
- ✓ Launder at least weekly, and after any overt contamination (do not take the coat home); disinfect before laundering.

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PPE: Respirators

- N95 and FFP2 respirators effectively filter out >94-95% of particles ≥0.3-0.4 µm in diameter.
- **Respirators** must be fitted to the face! (Use the FIT-TEST)

Respirators protect the wearer from inhaling droplet nuclei (they protect against inhalation).

- **Surgical masks** do not protect the wearer against inhaling infectious aerosols.

Surgical masks prevent microorganisms spreading from the wearer (they protect others from exhalation)

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Disinfectants

- A disinfectant is a chemical or mixture of chemicals used to kill microorganisms.
- Disinfectants are usually applied to surfaces or inanimate objects.
- Disinfectants may be used before autoclaving for pre-decontamination treatment.

NOTE: Because of the specific cell-wall structure of TB bacilli, they are resistant to most standard disinfectants – that is, quaternary ammonium compounds are ineffective.

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Disinfectants

- Select disinfectants that are effective against mycobacteria based on the material to be disinfected
  - ✓ **PHENOL** 2-5% in deionized water is highly irritating, and caution must be used in preparation. It is preferable to use phenolic derivatives:
    - Decontaminate equipment, surfaces and items or liquids before disposal (wear gloves)
    - Prepare the solution daily and leave in contact with the surface for at least 15 minutes to ensure decontamination.
  - ✓ **CHLORINE** (sodium hypochlorite, or bleach with 0.72% active chlorine) is an irritant, and is corrosive to metals and plastics:
    - It is a general purpose disinfectant; also can be used to soak contaminated items
    - Allow at least 15 minutes to ensure decontamination
    - Prepare daily and store in a well-ventilated area (toxic gas). Do not autoclave.
  - ✓ **ALCOHOL** 70% leaves no residue but is volatile and flammable (keep far from open flames):
    - Use as a disinfectant on skin (follow by washing with soap) and work surfaces (including metals).
  - ✓ **PERACETIC ACID leaves** no residue, but is stable for only 48 hours after preparation:
    - Rapid action against all microorganisms.

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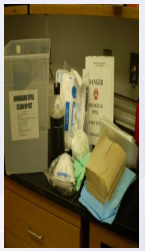
Spill kit

- All laboratories handling samples for TB diagnostic testing should have a spill kit containing:
  - Instructions (SOPs) for cleaning up spills
  - A large biohazard bag (autoclavable)
  - Suitable tuberculocidal disinfectant, such as hypochlorite (freshly prepared) or phenol-derivatives, stored in opaque bottles
  - Laboratory gowns (disposable) and goggles
  - Box of gloves (different sizes)
  - Respirators (N95 or FFP2)
  - Paper towels, cotton wool or absorbent cloths
  - Soap and chloramine tablets
  - Dustpan
  - Sharps container
  - "DO NOT ENTER" sign.



- Check the contents of the spill kit regularly and replace items after use or when they have expired.

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Spill clean-up procedures

Spill outside the BSC (major event) (1 of 2)

- Immediately vacate and secure the laboratory, and inform the laboratory manager/supervisor.
- Leave the laboratory's ventilation or exhaust systems **on**, including in the BSC.
- Do not re-enter the laboratory for at least 1 hour (post DO NOT ENTER signs).
- Before re-entering the laboratory, **put on clean gloves, a clean laboratory coat and a respirator**.
- Cover the spill (or spills) with cloths or absorbent paper, and soak the paper with a suitable disinfectant; apply the disinfectant concentrically, from the outer margin towards the centre of the spill.
- Allow sufficient time for the disinfectant to act (at least 30-60 minutes) before disposing of any material.

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Spill clean-up procedures

- Spill within the BSC (1 of 2)
  - Cover the spill area with cloths or absorbent paper, and apply a suitable disinfectant concentrically – that is, from the outer margin towards the centre of the spill:
    - Any equipment or material that has been splashed must be cleaned (including the interior surfaces and walls of the BSC, or safety buckets)
    - Do not use bleach to disinfect metal parts (it is corrosive).
  - Allow sufficient time for the disinfectant to act (30-60 minutes) before disposing of any material.

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Waste disposal

- At the end of each day, seal contaminated material (such as used sputum containers, transfer pipettes and used cartridges) in a biohazard bag, and autoclave or incinerate or bury it as soon as possible
  - ✓Warning: incinerating plastics can release toxins that are harmful to breathe
- Decontaminate transfer pipettes using an appropriate disinfectant prior to disposal.

All used materials should be considered to be contaminated!

Integrated Curriculum

Module 3: IPC

Objectives:

By the end of this Module, the participants will be able to:

- Describe the elements of TB IPC Plan
- Describe TB IPC Procedures and practices in facilities
- Describe the various interventions aimed at promoting IPC
- Describe how IPC will be monitored

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Elements of a TB IC plan—national or facility

- Responsible authority
- List highest risk settings and how defined
- Recommended set of IC measures
- Policies
- Human resource development
- Advocacy, communication, social mobilization
- Monitoring and evaluation indicators
- Budget

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All Precautions for Inpatient Settings Laboratories

Administrative Controls	Environmental Controls	Respiratory Protection Controls
Lab-specific risk assessment and IC plan Biosafety level (BSL) 2 for non-aerosol-producing procedures Annual HCW *M. tuberculosis* testing in med. and high-risk settings	Handle specimens suspected to contain *M. tuberculosis* and aerosol-producing procedures in class I or II biological safety cabinet (BSC).	Lab specific based on risk assessment At least N95. Use if aerosol-producing procedures performed outside BSC

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Monitor infection control Practices

- What gets measured gets done.
- Examples
  - ✓Measure laboratory turn-around time for sputum specimens.
  - ✓Have a staff member observe specific IC practices daily for one week.
  - ✓Keep track of number of health workers in the facility who develop TB during 6 month period

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Module 4: Available TB laboratory diagnostics

Objectives

By the end of the course the participant will be able to:

- Describe the biological characteristics of MTB
- Have knowledge on the current laboratory diagnostic techniques
- Demonstrate knowledge and use of each diagnostic techniques
- Understand how to interpret TB laboratory tests
  - Smear
  - Xpert MTB/RIF
  - Culture
  - Drug susceptibility test
  - Understand Xpert MTB/RIF algorithm
  - Understand SOPs for Xpert MTB/RIF testing

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Mycobacterium Tuberculosis bacteria

- TB is caused by the bacterial species *Mycobacterium tuberculosis* and occasionally by other species belonging to the TB complex (*M. bovis*, *M. africanum, M. canettii*)
- Members of the TB complex are also known as tubercule bacilli
- Laboratory methods for detection and diagnosis of TB
  - ✓ AFB Microscopy
  - ✓ Culture for detection and identification of TB
  - ✓ Drug susceptibility testing
  - ✓ Molecular and new technologies

Integrated Curriculum

TB diagnosis, treatment monitoring and Surveillance

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Diagnosis

- Smear Microscopy –ZN/FM
- GeneXpert
- Chest X-ray (for smear negative TB)

Surveillance

- Molecular tests e.g LPA,Xpert MTB/RIF
- TB Culture
- Drug Susceptibility Test (DST)

Treatment monitoring

- Smear Microscopy
- TB Culture
- Supportive PMDT investigation
  - ❖ LFT's
  - ❖ UEC's

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Trends on new tests and has WHO policies have reduced TAT since 2007

Year	Technology	Turnaround time	Sensitivity gain
Before 2007	Ziehl-Neelsen microscopy; solid culture	<1 day, though often batched 30-60 days	Baseline
2007	Liquid culture/DST; rapid speciation	15-30 days	+10% compared with Löwenstein-Jensen solid culture
2009	LED-based fluorescence microscopy	<1 day, though often batched	+10% compared with Ziehl-Neelsen microscopy
Endorsed 2010, updated 2013	Xpert MTB/RIF	<2 hours	+40% compared with Ziehl-Neelsen microscopy

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Smear Microscopy

- Microscopy is recommended for ALL levels of laboratories (that is, peripheral and higher levels).
- Microscopy has limited sensitivity, which is further reduced in HIV-co infected individuals
- Microscopy is required to monitor responses to anti-TB therapy.
- WHO recommends that in all settings LED fluorescence microscopy should be phased in to replace conventional bright-field microscopy and Ziehl-Neelsen staining

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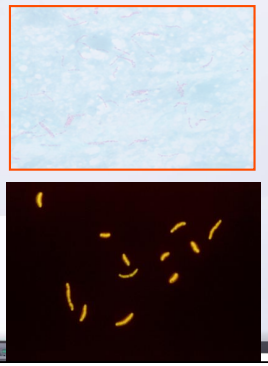
AFB Microscopy-ZN/FM stain

- Mycobacteria are called Acid-Fast Bacilli (AFB) due to their microscopic appearance after decolorizing.
- Organisms appear red on a blue background



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Why take a skin smear for leprosy diagnosis?

- To confirm a diagnosis of skin smear-positive multibacillary leprosy in a presumptive patients
- To help diagnose multibacillary relapse in a patient who has previously been treated
- To help with the classification of new patients

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Xpert MTB/RIF assay

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Molecular Diagnostic Tests and GeneXpert

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Molecular diagnostic tests

- Gene expert – detects R resistance
- Line Probe Assay
  - Genotype MTBDR assay (hain lifescince)- detects both R and H resistance

XpertMTB/RIF

- Automated machine that uses a polymerase chain reaction (PCR) to break apart and identify strips of DNA
- Tests for the presence of *Mycobacteria Tb.* genes as well as the genes associated with Rifampicin (RIF) resistance
- Can be used on raw (unprocessed) sputum
- Results available in 2 hours

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Indications for GeneXpert in Kenya

- **Low risk for DR TB**

All presumptive TB cases who are not in the high risk group including:

- People Living with HIV with TB symptoms
- Children <15 years with TB symptoms
- All presumptive TB cases with a negative smear microscopy result

- **High risk for DR TB**
- Previously treated TB patients: treatment failures, relapses, treatment after loss to follow up
- Drug Resistant TB patient contacts
- TB patients with a positive smear result at month 2 or month 5 of TB treatment
- Patient who develops TB symptoms while on IPT or has had previous IPT exposure
- Healthcare Workers with TB symptoms
- Prisoners with TB symptoms
- Refugees with TB symptoms

- **GeneXpert test is the preferred first test for TB diagnosis and identification of rifampicin resistance in all presumptive TB cases***
- **Patients diagnosed using geneXpert should be followed up using smear microscopy**
- **In situations where geneXpert is not available, smear microscopy may be used for initial TB diagnosis and concurrently, a sample specimen sent for geneXpert test.**

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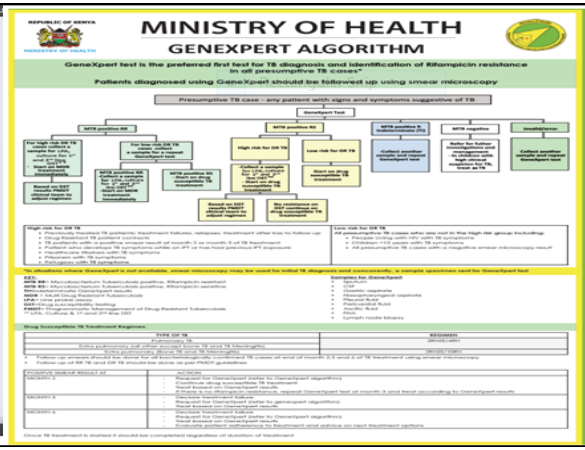

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Limitations of Gene Xpert

- Currently test sensitivity for Rifampicin only
- Not validated for processing specimen other than sputum
- Not used for DRTB follow-up monitoring
- Expensive
- Short expiry of cartilages (usually one year shelf-life)
- Requires electricity

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Possible Xpert Results

1. T =MTB detected, Rifampicin resistance not detected;
2. RR =MTB detected, Rifampicin resistance detected;
3. N = MTB not detected;
4. TI = MTB detected, Rifampicin resistance indeterminate
5. I = Invalid/error
6. No result

Inconclusive results repeat GeneXpert

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Managing Discordant results

1. Smear-Neg microscopy vs. MTB detected by Xpert
   - Will be common
   - RIF Resistance detected –
     - ✓collect sample for culture & DST ,
     - ✓Start treatment with cat iv
   - RIF resistance not detected –
     - ✓collect sample for culture & DST for the surveillance group
     - ✓Start treatment with cat 1
     - ✓RIF resistance indeterminate- repeat GeneXpert but emphasize on (quality sample) proper sample collection
2. Smear-pos microscopy vs. MTB not detected by Xpert
   - Will be rare
   - Lab error
   - Repeat both sputum microscopy and Gene Xpert
   - Consider Non Tuberculous Mycobacteria

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Managing Discordant results cont..

3. RIF-resistance detected by Xpert vs. not detected by culture/DST (Discordant Xpert & Culture & DST results)
   - Repeat Gene Xpert
   - continue MDR TB regimen
   - Clinical team discussion (County and National)
   - Inform PMDT coordinator and NTRL/Kisian lab person for sequencing

✓ **NB: Culture/DST should not be used to confirm / reject GeneXpert results**

✓ **NB. Gene Xpert is still the preferred 1st line test for diagnosis of TB in HIV+ patients where available**

✓ **In case sputum microscopy was done prior to or in addition to genexpert, discordant results should be interpreted as above**

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Module 5: Quality assurance/ quality control

- At the end of this module, participants will be able to:
  - Define Quality assurance and control
  - Establish the key indicators to monitor in QA/QC
  - Demonstrate understanding on the role of QA in results acceptability & reproducibility
  - Document the necessary measures to develop proper QA systems
  - Role of EQA in QA/QC

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Quality Assurance/Control definitions

- Quality assurance (QA) is a *system* designed to continuously improve the reliability and efficiency of laboratory services.
- This system includes, quality control, external quality assessment, quality improvement.
- Quality control (QC), a systematic internal monitoring of working practices, technical procedures, equipment and materials, including quality of stains.

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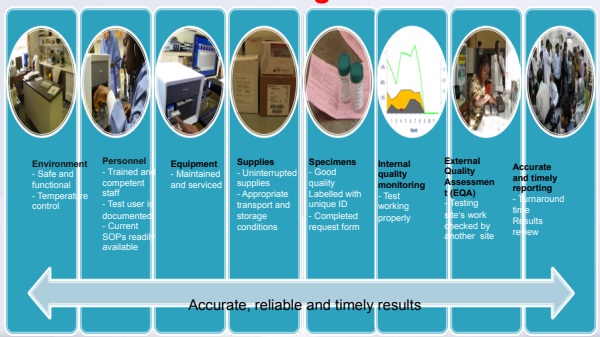
Key Components of Quality Assurance Program



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EQA and Proficiency testing (PT)

- External quality assurance (EQA)
  - A process that allows participant laboratories to assess their capabilities by comparing their results with those of other laboratories in the network through panel testing and blinded rechecking.
  - EQA also includes on-site evaluation of the laboratory to review quality of performance and should include on-site re-reading of smears.
  - EQA is an expansion of the proficiency testing as described by IUATLD.
- Proficiency testing performance (PT)
  - AFB smear microscopy
  - Culture
  - Drug susceptibility testing

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QA/QC monitored indicators

- Recovery rate of MTB
  - Percentage of MTB / total number of specimens
- Contamination rate (specimen, solid, liquid)
- Percentage of specimens reported as smear positive
  - distribution of smear grades (actual/scanty, 1+, 2+, 3+)
- Correlation between positive smears and positive cultures
- Percentage of negative smears resulting in positive cultures
- Turn-around time of AFB smear, culture and DST results
- Proficiency testing performance (AFB microscopy, culture, drug susceptibility testing)
- Percentage of Mtb positive with/out Rif, error rates, indeterminate

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Tuberculosis Culture and DST

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Mycobacterium tuberculosis complex - Characteristics

- Mycobacterium tuberculosis Complex (typical) consists of; *M tuberculosis, M. bovis, M. africanum , M. Microtti and M. Canetti, M. pinnipedii, M. caprae*
  - Acid-alcohol resistant bacilli
  - Resistant to cold, freezing and desiccation
  - Very sensitive to heat, sunlight, and UV radiation
  - Strictly aerobic (depends on Oxygen and pH of 7.4).
  - Polyvalent behaviour, depending on medium
  - Very slow division capacity

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M tuberculosis Complex progression

- M. *tuberculosis complex* takes 16-24 hrs. to divide (60 times slower than *S. aureus)*
- Slow and insidious Clinical Presentation
- Excessive delay to consult the health care
- Very late diagnosis
- Long period of contagiousness prior to diagnosis

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Rapid Tests for DR-TB

- Conventional drug susceptibility takes 4-8 weeks for results, however
  - Xpert Mtb rif PCR takes 2hrs – Mtb rif resistance (presumptive cases)
  - Line Probe assay takes 48hrs, both INH and rif resistant
  - Liquid culture (MGIT) takes 42 days

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Culture for detection and identification of TB

- **Culture more sensitive than microscopy**
  - Can detect as few as 10 – 100 viable bacteria / ml
  - Important for HIV+ individuals who often have low bacillary loads in sputum specimens
- **Processing of sputum prior to culture**
  - Digestion of mucus
  - Decontamination of normal flora
  - Concentration by centrifugation
- **Inoculation of liquid and solid media**
  - Detection of growth
  - Characteristic cording following growth in liquid medium
  - Confirm ID of AFB as *M. tuberculosis* – conventional and newer methods
  - Solid 14 days
  - Liquid 7 days

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Growth detection on LJs

- Supports growth of most mycobacteria
  - Growth can be quantified,
  - Colony morphology and pigmentation can be seen
- It is less likely to become contaminated during preparation and inoculation
- Contamination usually involves the total surface of the medium so it is easily seen

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Growth detection in liquid media

- This is an automated growth detection method
- Benefits:
  - Shorter turnaround time
  - Greater sensitivity
  - Fully automated formats
- Challenges:
  - Higher isolation rate of NTM
  - Higher contamination rate

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Antigen detection assays for ID

- MTBC secrete soluble protein MPB64 into media when growing
  - MPT64 and MPB64 differ by a one amino acid change resulting in a silent mutation
  - Protein is specific to the MTBC
- 3 assays
  - Capilia
    - Detects MTBC specific protein MPB64
  - SD Bioline
    - Detects MTBC specific protein MPT64
  - Becton Dickinson TBc ID
    - Detects MTBC specific MPT64
    - LPA
      Molecular testing (MTBC Kit)

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DST

- 1st line
- SIRE- Takes 5-15 day
- Pyrazinamide 5-21 Days

- 2nd line
- Moxifloxacin,Ofloxacin,Amikacin,Kanamycin, Capreomycin,Cyclocyrine,Ethionamide and PAS

Module 1 - Tuberculosis

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Advantages of culture

- Detects small numbers of organisms (as few as 10 bacilli)
- Confirms diagnosis of TB in HIV+ patients
- Allows species identification
- Allows drug susceptibility testing and DR surveillance
- Allows epidemiological studies

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Limitations of TB culture

- Slow growth of MTB: long turn-around-time
- Expensive, limited number of labs
- Essential Needs
  - Adherence to strict biosafety procedures
  - Adequate infrastructure: facility, electricity, water
  - Training of qualified staff
  - Equipment: proper use and maintenance
  - Continuous supply of media and reagents
  - Specimen transport system
  - Quality management (appropriate organisms, organized workflow)

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Disadvantages of conventional DST

- Conventional drug susceptibility testing is slow, generally takes 4-6 weeks for results
- Delay in diagnosis of MDR-TB:
  - ✓Increased mortality
  - ✓Patients improperly treated until results are ready
  - ✓Further resistance can occur
  - ✓Patients continue to spread resistant strain

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To Note

- Once TB is diagnosed, a patient should be classified based on the following:
  1. HIV status
  2. Anatomical location
  3. History of previous treatment
  4. Drug sensitivity pattern

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Kenya Lung health Training Course

TUBERCULOSIS

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TREATMENT OF TB

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The aim of TB treatment

Main aims of TB treatment:

1. Cure patients, prevent suffering and death from TB
2. Prevent long-term complications or sequelae of TB
3. Prevent relapse of the TB disease
4. Prevent transmission of the TB infection
5. Prevent the development of drug resistant TB

Basic Principles of TB treatment:

1. Never use single drugs
2. Always use drugs in combinations –using Fixed Dose Combinations (FDCs)
3. Drug dosage is based on weight
4. Drug intake should be directly observed
5. Ensure the entire treatment is taken as recommended

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Before initiating treatment

- Classify patients according to the following classifications;
  1. HIV status
  2. Anatomical site
  3. History of previous treatment
  4. Drug resistance pattern
- The regimen, duration of treatment, follow up investigations and adjunct medications and investigations is based on the above

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Classification based on anatomical sites

Classification	Definition
Pulmonary TB(PTB)	Any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree. This exclude pleural effusion
Extra pulmonary TB (EPTB)	Any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lung parenchyma, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges.

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Classification based on history of previous TB treatment (patient registration group)

Classification	Definition
New patients	Patient who has never been treated for TB or has taken anti-TB drugs for less than 1 month.
Previously treated patients	Patient who has received 1 month or more of anti-TB drugs in the past. They are further classified by the outcome of their most recent course of treatment as follows: **a)Relapse patients;** previously treated for TB, declared cured or treatment completed at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection) b) **Treatment after failure patients;** previously treated for TB and whose treatment failed at the end of their most recent course of treatment c) **Treatment after loss to follow-up patients;** previously treated for TB, and declared lost to follow-up at the end of their most recent course of treatment. (These were previously known as return after default patients.)
Patients with unknown previous TB treatment history do not fit into any of the categories listed above	

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Classification based on HIV status

HIV-positive TB patient	Any bacteriologically confirmed or clinically diagnosed case of TB who has a positive result from HIV testing conducted at the time of TB diagnosis or other documented evidence of enrolment in HIV care, such as enrolment in the pre-ART register or in the ART register once ART has been started
HIV-negative TB patient	Any bacteriologically confirmed or clinically diagnosed case of TB who has a negative result from HIV testing conducted at the time of TB diagnosis. Any HIV-negative TB patient subsequently found to be HIV-positive should be reclassified accordingly
HIV status unknown TB patient	Any bacteriologically confirmed or clinically diagnosed case of TB who has no result of HIV testing and no other documented evidence of enrolment in HIV care. If the patient's HIV status is subsequently determined, he or she should be reclassified accordingly

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Classification based on drug resistance, based on Drug susceptibility testing

Monoresistance	Resistance to one first-line anti-TB drug only.
Multidrug resistance	Resistance to at least both isoniazid and rifampicin
Extensive drug resistance	Resistance to any fluoroquinolone and to at least one of three second-line injectable drugs (capreomycin, kanamycin and amikacin), in addition to multidrug resistance
Rifampicin resistance	Resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to rifampicin, whether monoresistance, multidrug resistance, polydrug resistance or extensive drug resistance

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First line anti TB drugs

- These are drugs that are prescribed for the treatment of drug sensitive TB
- 1st line treatment is given to all drug sensitive new patients, relapse, previous failures, and return after default depending on DST results
- The first line drugs include;
  1. Rifampicin
  2. Isoniazid
  3. Pyrazinamide
  4. Ethambutol

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Properties of Individual anti TB drugs

Drug	Mechanism of action	Target bacilli	Media	Compartment it works in
Isoniazid(H)	Bactericidal after 24 hours. High potency: kills >90% bacilli in first few days of treatment.	Rapid and intermediate growing bacilli	Alkaline and acid media.	Intracellular and extracellular
Rifampicin(R)	Bactericidal within 1 hour. High potency. Most effective sterilizing agent.	All populations including dormant bacilli.	Alkaline and acid media.	Intracellular and extracellular
Pyrazinamide (Z)	Bactericidal with a low potency. Achieves its sterilizing action within 2-3 months.	Slow growing bacilli	Acid medium.	Intracellular bacilli only (macrophages)
Ethambutol (E)	Bacteriostatic. Low potency. Minimises the emergence of drug resistance.	All bacterial populations.	Alkaline and acid media.	Intracellular and extracellular

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Fixed Dose Combinations (FDC)

Advantages of using FDCs:

1. Reduced risk of resistance developing to the drugs in the event of missed doses
2. Reduction of pill burden
3. Fewer medication errors
4. Fewer prescription errors

Disadvantages of FDCs include:

1. Reduced bioavailability of some drugs
2. Flexibility in obtaining an optimal dose of some agents

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Anti TB regimen for use by both adult and children

	Intensive phase	Continuation phase
All forms of TB **except** TB Meningitis and osteo-articular TB	2 RHZE	4 RH
TB Meningitis and osteo-articular TB	2 RHZE	10 RH

- Directly Observed Therapy (DOT) should be provided using a treatment supporter who is acceptable and accountable to the patient and to the health system

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Adult dosage of anti-TB drugs according to body weight

Drug	Recommended dose in mg/kg	Range in mg/kg	Maximum dose
Isoniazid	5	5-10	300mg
Rifampicin	10	10-15	600mg
Pyrazinamide	35	30-40	1.5g
Ethambutol	20	15-25	1.6g

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FDC treatment dosage for adults

FDC Dosages	Formulation	30-39kg	40-54 kg	Over 55 kg
Rifampicin 150 mg + Isoniazid 75 mg + Pyrazinamide 400 mg + Ethambutol 275 mg	4-FDC tablet RHZE	2	3	4
Rifampicin 150 mg + Isoniazid 75mg	2-FDC tablet RH	2	3	4

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Pediatric dosage of anti-TB drugs according to body weight

Drug	Recommended dose in mg/kg	Range in mg/kg	Maximum dose
Isoniazid	5	5-10	300mg
Rifampicin	10	10-15	600mg
Pyrazinamide	35	30-40	1.5g
Ethambutol	20	15-25	1.6g

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FDC treatment dosage for children (5-20kg)

	Intensive phase (2RHZE)			Continuation phase (4RH)	
Weight (kg)	No. of tablets of RHZ in mg (60/30/150)	No. of tablets of RH in mg (60/60)	Ethambutol in mg (100)	No. of tablets of RH in mg (60/60)	No. of tablets of RH in mg (60/60)
5-7	1	1	1	1	1
8-14	2	1	2	2	1
15-20	3	2	3	3	2

FDC treatment dosage for children (21-30kg)

	Intensive phase (2 months RHZE)		Continuation phase (4 months RH)	
Weight band (kg)	No. of adult tablets of RHZE (150/75/400/275mg)	No. of paediatric tablets of RH (60/60mg)	No. of adult tablets of RH (150/75mg)	No. of paediatric tablets of RH (60/60mg)
21-30	2	2	2	2

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Dosage of pyridoxine

Weight (kg)	Dose of pyridoxine (available in both 25mg and 50mg tablets)
1-13.9 kg	12.5mg
14-25 kg	25mg
>25 kg	50mg

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Points to note

- Monthly monitoring of weight should be done and recorded in the patients TB record card and doses adjusted accordingly
- No trial of therapy should be done to minimize emergence of drug resistance
- Children above 30kg should be treated as adults
- All patients taking anti-TBs should also receive daily pyridoxine to reduce the risk of developing peripheral neuropathy
- However, lack of pyridoxine should hinder TB therapy

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Additional management decisions

a) Hospitalization

1. Severe forms of PTB and EPTB Severe malnutrition for nutritional rehabilitation
2. Signs of severe pneumonia (i.e. chest in-drawing)
3. Other co-morbidities e.g. severe anemia
4. Social or logistic reasons to ensure adherence
5. Severe adverse reactions such as hepatotoxicity

b)Steroid therapy should be offered in the following cases;

1. TB meningitis
2. PTB with respiratory distress
3. PTB with airway obstruction by hilar lymph nodes
4. Miliary TB
5. Pericardial effusion

Dosage of prednisone for adults and children

Dosage	Week 1-4	Week5-6	Week7
Adult and Children>30kg	1mg/kg (max 60mg)	0.5mg/kg	0.25mg/kg
Children < 30kg	1-2mg/kg (max 60mg)	0.5-1mg/kg	0.25-0.5 mg/kg

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Treatment outcome definitions

- The new treatment outcome definitions make a clear distinction between two types of patients:
  1. Patients treated for drug-susceptible TB
  2. Patients treated for drug-resistant TB using second-line treatment
     - Defined as combination chemotherapy for drug-resistant tuberculosis which includes drugs other than those in Group 1
- The two groups are mutually exclusive
- Patients found to have drug-resistant TB and placed on secondline treatment are removed from the drug-susceptible TB outcome cohort
- This means that management of the standard TB register and of the second-line TB treatment register needs to be coordinated to ensure proper accounting of the outcomes of treatment

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Treatment outcomes for Drug sensitiveTB patients

Outcome	Definition
Cured	A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear or culture negative in the last month of treatment and on at least one previous occasion
Treatment completed	A TB patient who completed treatment without evidence of failure BUT with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable
Treatment success	The sum of cured and treatment completed. This is calculated based on bacteriologically confirmed cases
Treatment failed	A TB patient whose sputum smear or culture is positive at month 5 or later during treatment
Died	A TB patient who dies for any reason before starting or during the course of treatment
Lost to follow-up	A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more
Not evaluated	A TB patient for whom no treatment outcome is assigned. This includes cases "transferred out" to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit

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Complications of PTB

1) Spontaneous Pneumothorax

- Presence of air in the pleural cavity resulting to impairment of oxygenation and ventilation
- Medical emergency
- Results from rupture of a TB cavity adjacent to the pleura
- May be associated with formation of pus in the pleural space (empyema) leading to a pyopneumothorax
- Presentation:
  - Acute shortness of breath
  - Chest pain
- Management:
  - The patient should be admitted

2)Bronchiectasis

- Chronic lung disease often secondary to an infectious process that results in the abnormal and permanent distortion of one or more of the conducting brochi or airways
- Presentation
  - Cough
  - Copious amounts of sputum which is mainly greenish, blood stained and foul smelling
  - Hemoptysis
- Management:
  - chest physiotherapy which involves postural drainage to improve drainage of respiratory secretions
- Infective exacerbations will require antibiotics.
- Broad spectrum antibiotics like amoxycillin-clavulanate, Metronidazole or clindamycin for anaerobic infection.
- Antipseudomonal antibiotic like ciprofloxacin, 3rd generation cephalosporin (Ceftazidime) should be used when colonization with *Pseudomonas* is suspected.
- If hemoptysis is severe and life threatening, patients should be admitted to hospital for more specialized treatment

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Complications of PTB...cont'd

3) Fibrosis of the lungs

- Sequelae of extensive tuberculous disease
- In severe terminal cases, long term oxygen therapy may be required
- Patients should be referred for review and specialised care by a physician

4) Lung abscess

- Seen in patients with extensive damage to the lungs after tuberculosis
- Antibiotic treatment is given aided by the results of a pus culture-sensitivity test
- Surgical intervention may also be necessary

Aspergilloma

- Result from colonization of tuberculous cavities or bronchiectatic lesions with the fungus *Aspergilus*
- Presentation
  - Recurrent or persistent haemoptysis in patient previously treated for TB.
  - Malaise
  - Fever
  - Chest x-ray shows a cavity with an air crescent (halo) around it
  - High levels of specific immunoglobulin G against Aspergillus in blood (Confirmatory test)
- The only effective treatment is surgical removal of the aspergilloma

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Module 4

Management NON-TUBERCULOUS MYCOBACTERIUM (NTM)

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Epidemiology

- Non Tuberculous Mycobacterium are free living organisms-found in air, water, soil, from where they cause infection
  - May also be spread to humans from domestic and wild animals
  - Person to person spread has not been documented
- Common in the immune-compromised
- Local anecdotal data report an incidence of 5-10% of MDRTB sputum culture specimen isolates
- There are more than 150 species

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NTM

- The clinically significant mycobacteria other than Mycobacterium associated with lung disease include;
  - *M. avium Complex (MAC)*
  - *M. kansasii*
  - *M. abscesus*
  - *M. malmoense*
  - *M. szulgai*
  - *M. fortuitum*
  - *M. xenopi*

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Morphology

- All mycobacteria share the characteristic of "acid-fastness," i.e., after staining with carbol-fuchsin or auramine-rhodamine, they do not decolorize with acidified alcohol
- Thus, the common term acid-fast bacilli (AFB) are essentially synonymous with mycobacteria
- Microscopy therefore, is less useful in distinguishing between the various types of mycobacteria

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NTM: Associated risk factors and clinical presentation

Associated Risk Factors

1. Immunosuppression
2. Smoking
3. Patients poorly responding to first and second line Anti-TB Therapy
4. Previously treated TB patients
5. Presence of underlying lung disease

Clinical presentation

- Very similar to PTB-impossible to distinguish clinically
- Symptoms thus may include:
  - Chronic cough - dry, productive or hemoptysis
  - Fever
  - Night sweats
  - Weight loss-wasting
- Suspect atypical organisms in patients with history of previous TB treatment (with adherence), with no or poor resolution of symptoms

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NTM: Investigations

- Sputum smear exam and mantoux test may be positive in both MTB and NTM infection
- Genexpert will detect MTB **BUT WILL NOT** detect NTM
  - Therefore, in patients with positive AFB sputum smear and a negative GeneXpert result for MTB, consider NTM and obtain a sample for culture
- Chest xray and other imaging modalities may not distinguish between MTB and NTM infection
- **Culture** is the gold standard for detection and differentiation of MTB from NTM
- Every attempt should be made to obtain a sample for culture when NTM is suspected

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Modalities used to distinguish between the mycobacteria species include

- **Culture:**
  - Appearance on culture media: There are differences in color and sensitivity to light
  - Time to produce positive cultures; Different mycobacteria may be classified into rapidly growing and slow growing mycobacteria
- **Molecular:**
  - Line probe assay
  - Nucleic acid hybridization probes
  - PCR methods
- **High performance liquid chromatography**

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Management of NTM

Mycobacterium species	Drugs to be used	Duration
Mycobacterium Avium complex	**Nodular/bronchiectactic disease:** Clarithromycin1gm/Azithromycin 500mg, Rifampin 600 mg and Ethambutol 15-25mg/kg, thrice weekly or daily, +/-amikacin/streptomycin in the first 2-3 months **In HIV co-infection:** Substitute rifampicin with rifabutin, daily clarithromycin or azithromycin with ethambutol. Add streptomycin/amikacin if no response **Prophylaxis for all with low CD4 count less than 50**: Clarithromycin 1g daily or azithromycin 1g weekly OR a fluoroquinolone if macrolide resistant MAC	-Treat until culture negative on therapy for 1 year -In HIV give prophylaxis till CD4 above 100
M. Fortuitum	• **Any 2 of the following drugs**: Amikacin, fluoroquinolones, sulfonamides, imipenems, linezolid, cefoxitin or clarithromycin • **Debridement** of cutaneous ,lung or other foci of infection and removal of implants	-6-12 months, until cultures are negative
M. malmoense	• Not very responsive to treatment • Clarithromycin, rifampicin and ethambutol had better response and less mortality	-At least 2yrs

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Management of NTM

Mycobacterium species	Drugs to be used	Duration
M. Abscessus	• Extremely difficult to eradicate- **Multidrug regimens** (that include clarithromycin 1g/day and intermittent courses 2 or more drugs of the following drugs: amikacin, imipenem, cefoxitin, tigecycline, fluoroquinolones, doxycycline or linezolid) is recommended may cause symptomatic improvement and disease regression. • Surgical resection of localized disease combined with multidrug clarithromycin-based therapy offers the best chance for cure of this disease.	-4-8 weeks of IV drugs then 6-12 months of per oral (P.O) regimen -Treat until sputum is culture negative
M. Kansasii	• Drug susceptible strains- **RHZE** (use conventional anti-TB doses) • Rifampicin resistant isolates-use any 2 of clarithromycin(1st option) or a fluoroquinolone (if macrolide resistance noted), sulfamethoxazole or streptomycin and ethambutol	-Until sputum cultures negative for more than 6 months
M. szulgai	• Responds to treatment • Combinations of rifampicin, ethambutol and clarithromycin	-Until cultures are negative

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Summary

- There are many different species of mycobacteria and most cause chronic debilitating lung disease
- A high index of clinical suspicion is needed to pick atypical mycobacterial infections, particularly in patients with pre-existing lung disease and in those not responding to anti-TBs

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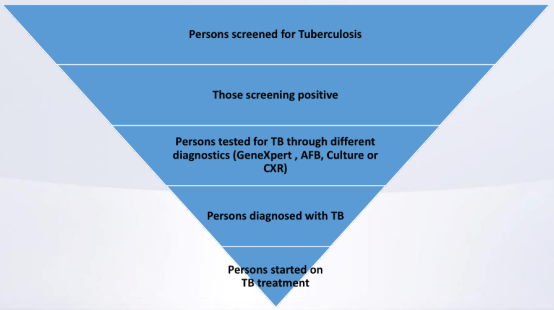
Cascade of Intensive Case Finding to Increase Case detection of tuberculosis



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Module 7

TB and HIV

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Introduction

- **Interaction of HIV with TB**
  1. Increased lifetime risk of TB from 5-10% to 50%
  2. Increased rate of progression of new TB infections to disease
  3. Increased risk of recurrence of previously treated TB
  4. Increased risk of death from TB
  5. Increased risk of adverse reactions to anti-TB drugs
  6. Increased stigma to the two diseases

- **Interaction of TB with HIV**
  1. Rapid progression of HIV disease
  2. TB is the leading cause of HIV-related morbidity
  3. TB is a leading cause of mortality among PLHIV
     - one-third of all AIDS related deaths are due to TB
  4. Increasing TB cases among PLHIV enhances the risk of TB transmission in the community regardless of their HIV status

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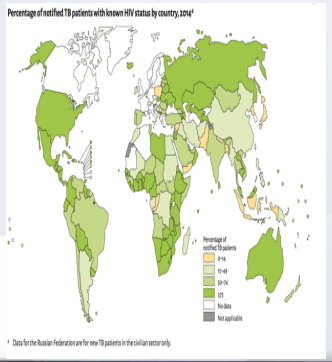
Global TB/HIV trends

In 2015,

- 55% of notified TB cases Globally had a documented HIV test result compared to 81% in Africa,
- TB/HIV co-infection highest (31%) in Africa, 11% Globally
- 78% were on ART Globally
- 910 000 people living with HIV were treated with isoniazid preventive therapy were in 2015.



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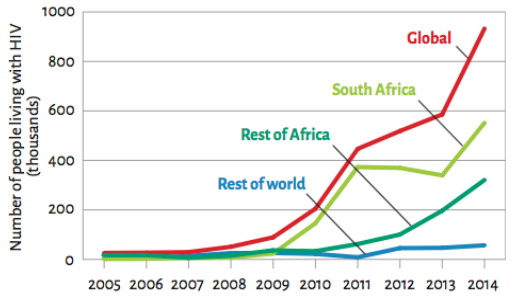
Provision of isoniazid preventive therapy (IPT) to people living with HIV, 2005–2014



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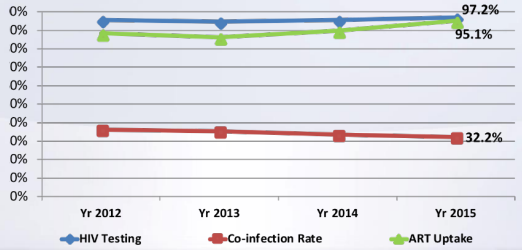
Kenya TB/HIV epidemiology

- Cases Notified 2015: 81,523
- Kenya's HIV prevalence is: 5.6%
- 32% of TB patients were infected with HIV in 2015



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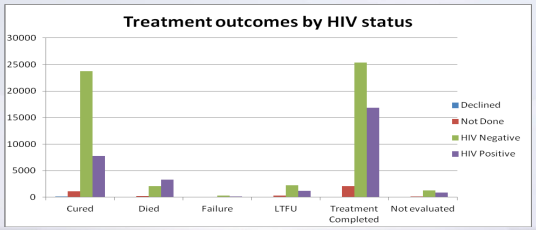
Treatment Outcomes

In 2014,

- Globally 75% Success rate among HIV + compared to 83% among all TB cases
- Insert Kenyan Data



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TB/ HIV collaborative activities

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Collaborative TB/HIV activities

Objective/ Activity	Implementer
A. Establish the mechanism for collaboration 1. TB/HIV coordinating bodies 2. HIV surveillance among TB patient 3. TB/HIV planning 4. TB/HIV monitoring and evaluation	**TB and HIV Programs**
B. To decrease the burden of TB in PLHIV- Three Is 1. Intensified TB case finding 2. Isoniazid preventive therapy 3. TB infection control in health care and other settings	**HIV program**
C. To decrease the burden of HIV in TB patients 1. HIV testing and counselling 2. HIV prevention 3. Cotrimoxazole preventive therapy 4. HIV/AIDS care and support 5. Antiretroviral therapy to TB/HIV co-infected patients	**TB program**

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TB/HIV collaborative activities

- The strong interaction between TB and HIV led to TB/HIV collaborative activities.
- These include;
  - IPC
  - ICF
  - IPT
  - Integration of TB and HIV services
  - Immediate initiation of cART

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Intensive Case Finding (ICF)

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Definition of ICF:

"Intensified case finding comprises screening for symptoms and signs of tuberculosis in settings where HIV-infected people are concentrated."

Interim Policy on Collaborative TB/HIV Activities, WHO 2004

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When do you carry out ICF?

•At HIV diagnosis

- During all HIV clinic appointment

Symptoms screened for include;

Adult	Children
Cough	Cough
Fever	Fever
Weight loss	Failure to thrive/poor weight gain
Night sweats	Lethargy/less playfulness
	Contact with any TB case

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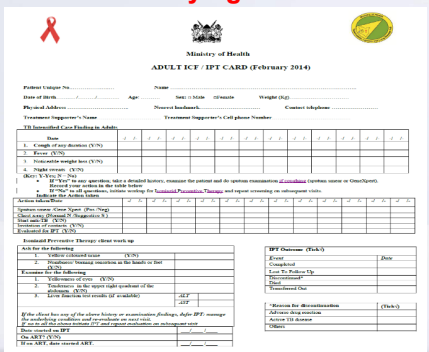
Tools for carrying out ICF: Adult



Ministry of Health

ADULT ICF / IPT CARD (February 2014)

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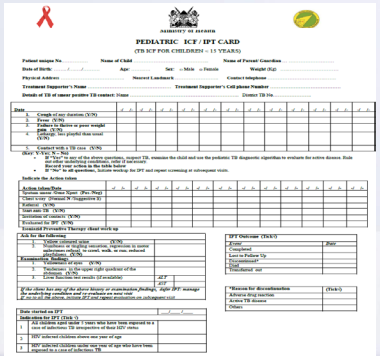
Tools for carrying out ICF: Children



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PEDIATRIC ICF / IPT CARD

(TB ICF FOR CHILDREN < 15 YEARS)

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Isoniazid Preventive Therapy

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Introduction

- IPT is given to treat latent infection and reduces TB reactivation beyond the duration of IPT use (up to 2 years)
- IPT reduces risk of TB occurrence by between 33% to 64%.
- If given after TB treatment, IPT reduces risk of TB recurrence by 82%
- ART alone reduces TB incidence by 70-90%[2-4] , and TB mortality by at least 50% [5] .
- IPT when given with ART, reduces risk for TB by *89%* [6] , and reduces the risk for mortality by 74% [10] in TST positive

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Indications for IPT

1. All PLHIV aged 1 and above who screen negative for TB using the ICF tool, **regardless of CD4 count, WHO stage and ART status**
2. All children under 5 years **irrespective of HIV status** who had recent close contact (past 12 months) of sputum positive TB case
3. Prisoners, irrespective of HIV status

Note:

- Past history of TB and current pregnancy are not contraindications for starting isoniazid preventive therapy
- IPT can be started at any time after successful completion of TB treatment
- IPT has not been shown to increase the risk of developing isoniazid-resistant TB

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Contraindications for IPT

1.Active TB disease

2.Active hepatitis (acute or chronic)

3.Symptoms of peripheral neuropathy (Numbness or tingling sensation, regression in motor milestones refusal to crawl, walk, run or reduced playfulness).

4.Contacts of Drug Resistant TB (DRTB)

NB.

- If the client has any of the above contraindications, defer IPT: manage the underlying condition and re-evaluate on next visit.
- Avoid alcohol consumption due to increased risk of hepatotoxicity

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INH and Pyridoxine dosing

- **Isoniazid is given for 6 months at a dose of 10mg/kg, up to a maximum of 300mg. .**
- **If available, pyridoxine should be given alongside Isoniazid to reduce the risk of peripheral neuropathy**

Dose of INH for IPT

Weight range (kg)	Dose in mg	Number of 100mg INH tablets	Number of 300mg (Adult) tablet
<5	50	½ tablet	-
5.1-9.9	100	1 tablet	-
10-13.9	150	1 ½ tablet	½ tablet
14-19.9	200	2 tablets	-
20-24.9	250	2 ½ tablets	-
>25	300	3 tablets	1 tablet
Adults	300	-	1 tablet

Dose of pyridoxine during IPT

Weight (kg)	Number of tablets of pyridoxine (50mg)
1-13.9 kg	Quarter tablet daily
14-25 kg	Half a tablet daily
>25 kg	One tablet daily
Adults	One tablet daily

All children on IPT should have their weight taken at every visit and INH dosage adjusted appropriately

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Patient monitoring and follow up and education

Patient follow up

- Before IPT is initiated, adherence counseling must be conducted a**t each clinic visit, patients on IPT should;**
  - Have adherence messages reinforced
  - Be screened for active TB during each clinic visit using the intensive case finding (ICF) card
  - Should have their ICF cards and IPT register updated at every visit and outcome documented on completion or discontinuation of therapy
  - Monitored for INH adverse events at every visit and outcome of ADR screening updated on back of ICF card

Patient education

- Patients should be advised to return immediately if they develop :-
  - Fever
  - Loss of appetite
  - Dark urine,
  - Jaundice
  - Rash
  - Persistent tingling and numbness of hands and feet
  - Consistent fatigue or weakness lasting more than 3 days
  - Abdominal pain
  - Nausea
  - Vomiting
  - Cough
  - Night sweats
  - Chest pain or difficulty in breathing
  - Reduced playfulness

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Patient Monitoring tools

- The ICF/IPT card should be used for conducting ICF (front) for patients on IPT at every visit.
- At every clinic visit this card should be used to screen for the symptoms of INH ADRs (hepatotoxicity, rash, peripheral neuropathy) and documented appropriately (back)
- Adherence should also be recorded on the monitoring (back) section of the ICF/IPT card.

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Adult ICF/IPT card (back)- IPT monitoring

IPT due date	Date collected IPT	Wt (kg)	Hepatotoxicity? (vomiting, right upper quadrant abdominal pain, yellow urine or eyes)		Peripheral Neuropathy Does client have any of the following in the limbs? Numbness, tingling or burning sensation		Does the patient have Rash?		Adherence Measurement Good = missed < 2 doses / month Fair = missed 2-4 doses / month Bad = missed ≥5 doses / month	
			Yes (state action taken)	No	Yes (state action taken)	No	Yes (state action taken)	No	Good Or Fair	Bad (state action taken) e.g. decision made to stop IPT, adherence counseling, etc)
Eg 4/5/15	4/5/15	55kg		no		no		no	Fair	

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Pediatric ICF/IPT card (back)-IPT monitoring

IPT due date	Date collected IPT	Wgt (kg)and actual dose of INH in mg	Hepatotoxicity (Signs & symptoms) vomiting, persistent irritability, abdominal, RUQ pain, yellow urine or eyes)		Peripheral Neuropathy (Signs & symptoms) (Older child – numbness, tingling, Younger child- regression in motor milestones refusal to crawl, walk, run)		Does the patient have a Rash?		Adherence Measurement Good = missed < 2 doses / month Fair = missed 2 – 4 doses / month Bad = missed ≥5 doses / month	
			Yes (state action taken)	No	Yes (state action taken)	No	Yes (state action taken)	No	Good or Fair	Bad (state action taken)
E.g 2/04/15	2/04/15	13kg		No		No		No	Good	

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Management of ADRs-Hepatitis

- If a patient on IPT presents with signs and symptoms of hepatitis; (yellowness of eyes, RUQ pains, vomiting etc)

Management;

- Check for other causes of hepatitis ; Test for Hepatitis B surface antigen (HBsAg) and hepatitis C virus (HCV).
- Check LFTs
- If liver enzymes < 3x with symptoms, or <5 times normal without symptoms, continue INH but monitor LFTs every week.
- If liver enzymes are **> 3x with symptoms**, or **>5 times normal without symptoms STOP** INH and repeat liver function tests weekly.
- Consult further.

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Management of ADRs-Peripheral neuropathy

- If patient develops signs of peripheral neuropathy(numbness, tingling sensations etc)

Management

- administer pyridoxine at **100mg** with close monitoring
- If patient develops **motor** symptoms, stop INH
- For rash, monitor closely.
- If worsens, temporarily stop INH
- If rash is severe, or associated with reddening or peeling of mucus membranes, (Steven Johnson Syndrome) - **stop INH** immediately and admit

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Management of patients developing TB while on IPT

- If a patient screens +ve during ICF, **gene Xpert** is the preferred test for diagnosis of TB if available
- If not available, conduct sputum microscopy and CXR if sputum is negative
- DST and culture should also be conducted for all patients who develop TB while on INH
- If drug susceptible or resistant TB is identified treat as per national guidelines
- If EPTB is suspected during IPT, investigate and manage as per national guidelines

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Management of defaulters or those discontinued from IPT

Scenario	Action
If patient had discontinued INH for less than 1 month	Conduct adherence counseling, Conduct ICF and if asymptomatic Continue from where they left off Ensure they have completed a **6 month course**
If a patient had taken INH for less than 1 month in total and discontinued for any reason (like toxicity or loss to follow up)	Conduct adherence counseling, Address reasons for discontinuation Conduct ICF and if asymptomatic Restart INH afresh Ensure they have completed a **6 month course**
If patient had discontinued INH for more than 1 month but less than 3 months	Conduct adherence counseling, Conduct ICF and if asymptomatic Restart INH Ensure they complete a **6 month course within a 9 month period**
If patient discontinued for more than 3 months, or had discontinued more than once	Do not re-initiate IPT

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Follow up after completion of IPT

- ICF should be conducted at every clinic visit for PLHIV who have completed IPT
- For contacts of PTB+ patients who completed IPT, efforts should be made to call patients' guardians for ICF every 6 months after completion to update their status (i.e no TB, suspect, TB case)
- 12, 18, and 24 month TB status should be updated in the IPT register
- Should patients screen positive (TB ICF) after completing IPT, manage according to national guidelines.

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IPT, newborns and BCG

- If a baby is born to a sputum +ve mother, assess the newborn for TB.
- Non-specific features suggestive of neonatal TB include;
  - Fever
  - Low birth weight
  - Hepato-splenomegally, -irritability
  - Feeding intolerance (symptoms of neonatal sepsis)
- If the child has none of the above, give IPT for 6 months
- Withhold BCG until 2 weeks after completion of IPT

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Commodity management for IPT

- Facilities to order and receive an initial 6 months supply of INH for initiating patients identified
- The INH refill TCA to align with ARVs TCA refill schedule i.e. if client is dispensed 2 months of ARVs then they receive 2 months of INH
- Revised ART LMIS tools i.e. DAR ARVs and OIs, F-CDRR and F-MAPS to be used to document consumption and reporting in the CCC where INH for HIV positive population will be dispensed.
- Dispensing of INH to the HIV positive clients will be at the CCCs and for the TB exposed HIV negative clients will be at the TB clinic.
- Dispensing for the TB negative children exposed to TB to be documented in TB-DAR
- ADRs of patients on INH be reported using the usual PV tools (yellow form)
- Receiving and storage of INH to follow the same procedure as for ARVs i.e. received by the pharmacist, and stored along with ARVs and other OI medicines in the drug store
- The TB clinic will source INH 100mg stocks from the health facility pharmacy periodically and will document quantities dispensed on the DAR

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Monitoring & Evaluation: Documentation

Screening

- All PLHIV, children <5 exposed to smear positive TB and prisoners shall be screened for TB using **ICF/IPT tool**.

IPT Initiation.

- The IPT /ICF card shall be updated by the clinician at the start of IPT and at every visit.
- The facility M&E staff (data clerk) will record all PLHIVs started on IPT in the CCC IPT register, and at every subsequent visit made for IPT refills.
- The TB clinician/nurse will record all children under the age of 5 started on IPT in the TB clinic' s IPT register, and at every subsequent visit made for IPT refills.

The IPT registers will be recorded such;

- Serially record all patients in the IPT register beginning each calendar year, (*the number should indicate a serial number and year e.g. 1/15).*
- Indicate the IPT serial number in the ICF/IPT tool and the MOH 258(appointment card) for PLHIV and ICF/IPT card for children < 5 exposed to smear positive TB.
- At the end of every month, draw a line to close the month and summarize the month as per criteria provided at the bottom of the IPT register (*Total started on IPT during the month disaggregated by age < 15 and 15+).*
- The Facility serial numbers in the IPT register shall be continued in the following month.
- For Each Month, Identify the cohort 12 months since the IPT start date and Indicate their 12 months outcomes. (*Use the codes provided at the bottom of the register)*
- New serial numbers shall be initiated in the beginning of the following calendar year.

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Reporting

- At the end of the reporting period CCC data clerk,
  - To tally the entries in DAR and IPT register using the **MOH C&T tally sheet**
  - The Totals from tally sheet shall be transferred to **MOH 731**
- At the end of reporting period in TB clinic
  - SCTLC to document all *< 5 exposed to smear +ve TB who received IPT in reporting period, report monthly totals to TIBU*
  - HCW at the TB clinic to summarize the monthly IPT totals and transfer the totals **to MOH 711**

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Management of TB/HIV co infected patients

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Provider Initiated Testing and Counseling (PITC)

- This is HIV testing **initiated by a health worker** as part of the diagnostic work up for patients who present with symptoms or signs that could be attributable to HIV disease. This will offer an entry point for all TB patients to quality and comprehensive treatment and care.
- Sites for PITC will depend on several factors within the institution including but not limited to workload, space for testing and human resources available.
- Ideally all TB patients should be counseled tested within the TB (chest) clinic to ensure integrated services.

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Cotrimoxazole preventive therapy (CPT)

- Cotrimoxazole preventive therapy (CPT) reduces mortality among TB patients with HIV irrespective of CD4 count.
- CPT should be provided to all TB/HIV co infected individuals (unless contraindicated).
- All patients should be monitored for side effects including rash and gastrointestinal disturbance.
- Cotrimoxazole should be withdrawn whenever moderate to severe reactions occur.

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Dose of cotrimoxazole for CPT

Weight in kg	Cotrimoxazole syrup (...mg per ml)	480 mg (Single Strength) tablet	960 mg (Double strength) tablet
1.0 - 4.9	2.5mls	¼ tab	-
5.0 - 8.9	5mls	½ tab	¼ tab
9.0 - 16.9	10mls	1 tab	½ tab
17.0 - 30.9	15mls	2 tab	1 tab
>30.9 (adults and adolescents)		2 tab	1 tab

Dapsone is recommended in patients allergic to Cotrimoxazole(CTX) and is used only in patients with WHO stage 4 disease and /or those with a CD4 <200 cells /mm3.

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Dapsone preventive therapy

- Dapsone should be discontinued;
  - when the CD4 has been greater than 200 cells /mm3 for adults and children >5 years for at least 6 months
  - the CD4% has been greater than the age specific threshold for severe immunodeficiency in the young children for at least 6 months
- **Dose for Dapsone**
- Dapsone is available as 25mg and 100 mg tablets.
- Children: 2mg / kg once daily (maximum dose 100mg)
- Adults: 100mg once daily

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Use of ART among TB/HIV co-infected

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Treatment of TB/HIV co infected patients

- The principles of treatment of tuberculosis in HIV-infected patients are similar to those in HIV-negative TB patients, and the same regimens should be used in both groups.
- Response to TB treatment may be slower in PLHIV.
- All PLHIV co-infected with TB should receive co-trimoxazole prophylaxis as well as antiretroviral therapy.
- Nutritional support is often needed for patients with low BMI
- The management of PLHIV co infected with TB/HIV should be integrated so that all family members are counseled and tested for HIV, screened for TB and managed appropriately.
- ARVs should be initiated within **2-8 weeks** of starting anti-TB therapy.

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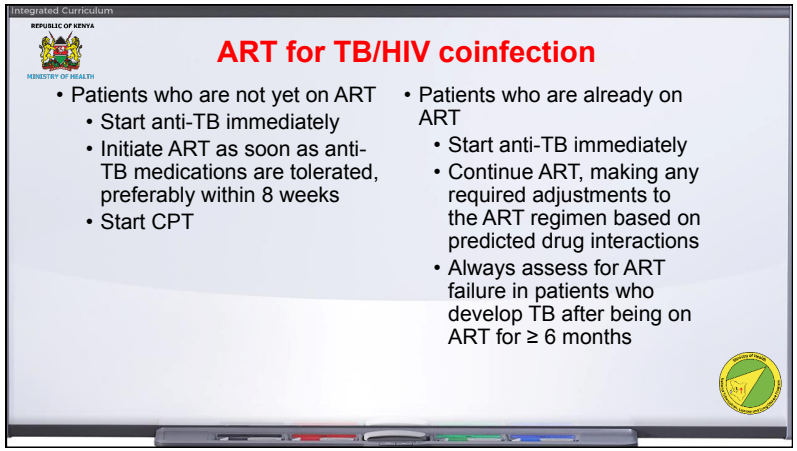
Immune re-constitution inflammatory syndrome (IRIS)

- This is a paradoxical deterioration after initial improvement following treatment initiation.
- It is seen during the initial weeks of TB treatment with initial worsening of symptoms due to immune re-constitution.
- **Management:** Continue anti-TB therapy: give non-steroidal anti-inflammatory drugs until severe symptoms subside.
- Give prednisone at **2mg/kg** once daily for 4 weeks, and then taper down over 2 weeks**(1mg/kg for7days, then 0.5mg/kg for 7 days)**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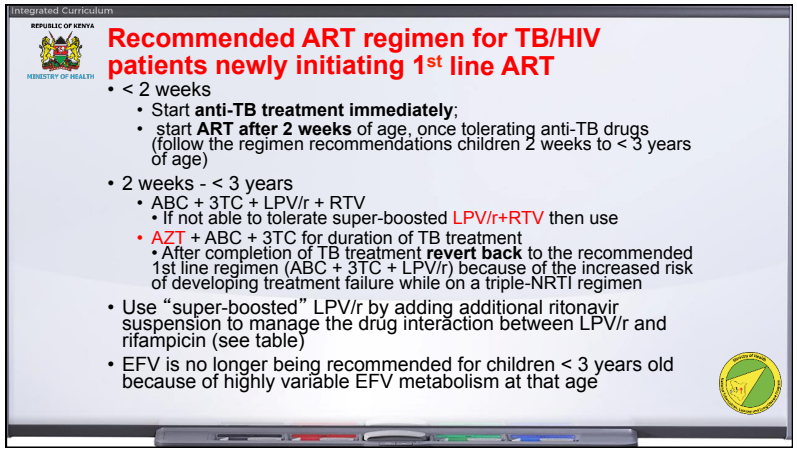
ART for TB/HIV coinfection
• Patients who are not yet on ART
• Start anti-TB immediately
• Initiate ART as soon as anti-TB medications are tolerated, preferably within 8 weeks
• Start CPT
• Patients who are already on ART
• Start anti-TB immediately
• Continue ART, making any required adjustments to the ART regimen based on predicted drug interactions
• Always assess for ART failure in patients who develop TB after being on ART for ≥ 6 months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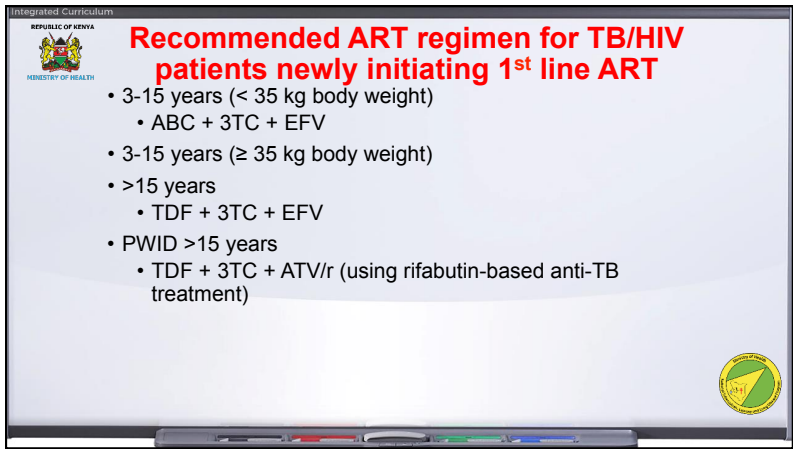
Recommended ART regimen for TB/HIV patients newly initiating 1st line ART
• < 2 weeks
• Start anti-TB treatment immediately;
• start ART after 2 weeks of age, once tolerating anti-TB drugs (follow the regimen recommendations children 2 weeks to < 3 years of age)
• 2 weeks - < 3 years
• ABC + 3TC + LPV/r + RTV
• If not able to tolerate super-boosted LPV/r+RTV then use
• AZT + ABC + 3TC for duration of TB treatment
• After completion of TB treatment revert back to the recommended 1st line regimen (ABC + 3TC + LPV/r) because of the increased risk of developing treatment failure while on a triple-NRTI regimen
• Use "super-boosted" LPV/r by adding additional ritonavir suspension to manage the drug interaction between LPV/r and rifampicin (see table)
• EFV is no longer being recommended for children < 3 years old because of highly variable EFV metabolism at that age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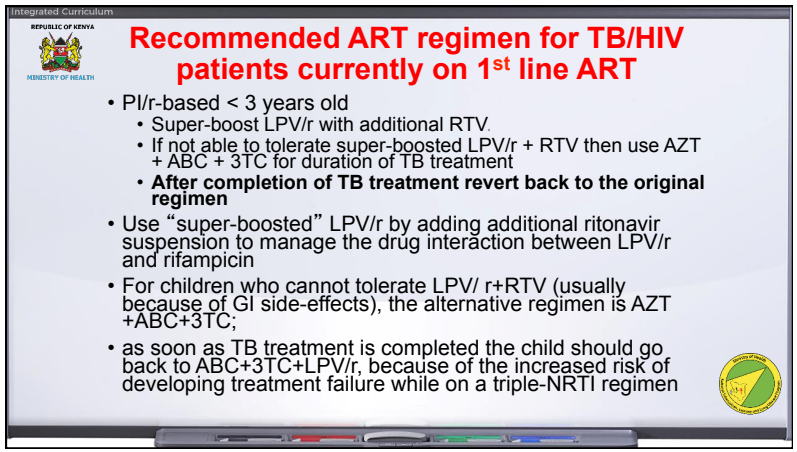
MINISTRY OF HEALTH
Recommended ART regimen for TB/HIV patients newly initiating 1st line ART
• 3-15 years (< 35 kg body weight)
• ABC + 3TC + EFV
• 3-15 years (≥ 35 kg body weight)
• >15 years
• TDF + 3TC + EFV
• PWID >15 years
• TDF + 3TC + ATV/r (using rifabutin-based anti-TB treatment)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Recommended ART regimen for TB/HIV patients currently on 1st line ART
• PI/r-based < 3 years old
• Super-boost LPV/r with additional RTV.
• If not able to tolerate super-boosted LPV/r + RTV then use AZT + ABC + 3TC for duration of TB treatment
• After completion of TB treatment revert back to the original regimen
• Use "super-boosted" LPV/r by adding additional ritonavir suspension to manage the drug interaction between LPV/r and rifampicin
• For children who cannot tolerate LPV/ r+RTV (usually because of GI side-effects), the alternative regimen is AZT +ABC+3TC;
• as soon as TB treatment is completed the child should go back to ABC+3TC+LPV/r, because of the increased risk of developing treatment failure while on a triple-NRTI regimen

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Recommended ART regimen for TB/HIV patients currently on 1st line ART

- PI/r-based 3 years – 15 years (weight < 35kg)
  - Switch to EFV. If EFV cannot be used, super- boost LPV/r with additional RTV to a ratio of 1:1
- PI/r-based 3-15 years (≥ 35 kg body weight) & (> 15 years any weight)
  - Continue PI/r; use rifabutin for anti-TB treatment
- EFV-based Any age
  - Continue same regimen
- NVP-based* < 3 years old
  - Switch to AZT + ABC + 3TC **(as soon as TB treatment is completed switch back or original regimen)**
- NVP-based* ≥ 3 years old
  - Switch to EFV
    - ***Guidelines recommend LPV/r for children < 3 years, however some children < 3 years maybe on NVP due to LPV/r toxicity**

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Ritonavir Dosing for Super-Boosting LPV/r in Children Taking Rifampin

Weight Range (kg)	Lopinavir/ritonavir (LPV/r)		Additional dosing of ritonavir for children taking rifampin
	Twice Daily	Twice Daily	Twice Daily
	Lopinavir/ ritonavir 80/20mg/ml solution	Lopinavir/ ritonavir 200/50mg tablets	Ritonavir liquid (80mg/ml, in 90 ml bottle) Ritonavir dose is adjusted to nearest mark for the ease of measurement
3 - 5.9	1 ml	-	1 ml
6 - 9.9	1.5 ml	-	1 ml
10 - 14.9	2 ml	-	1.5 ml
14 - 19.9	2.5 ml	1 tab twice daily	2 ml
20 - 24.9	3 ml	1 tab twice daily	2.5 ml
25 - 34.9	4 ml	2 tab in am & 1 tab in pm	4 ml in am & 2 ml in pm

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Recommended ART regimen for TB/HIV patients currently on 1st line ART

- Always assess for HIV treatment failure in patients who develop TB after being on ART for ≥ 6 months 2.
- For patients on 2nd line ART, subsequent regimens, or nonstandard drugs such at RAL or DTG who require regimen change because of TB treatment, consult the Regional or National HIV Clinical TWG **(ulizanascop@gmail.com)**
- NRTIs in the patient's current regimen do not require any adjustments with anti-TB treatment

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Integration of TB/HIV services

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Benefits and modes of integrating TB/HIV services

Benefits

1. To offer a **one stop shop** for TB and HIV services
2. To increase enrollment into HIV care and treatment services for TB / HIV co-infected patients
3. To **increase ART uptake** among the TB / HIV co-infected patients
4. To **improve adherence** to treatment for co-infected patients with resultant reduction in defaulter rates

Models

1. Complete integration
2. Partial integration
3. Strengthened referral linkages

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Complete Integration Model

- **Services offered in the Completely Integrated Clinic**
  1. Base line tests: Haemogram, ALT, CD4 and Creatinine
  2. Adherence counseling
  3. Nutritional counseling
  4. Anti-TB medication
  5. ARVs
  6. OI medication e.g CPT and others

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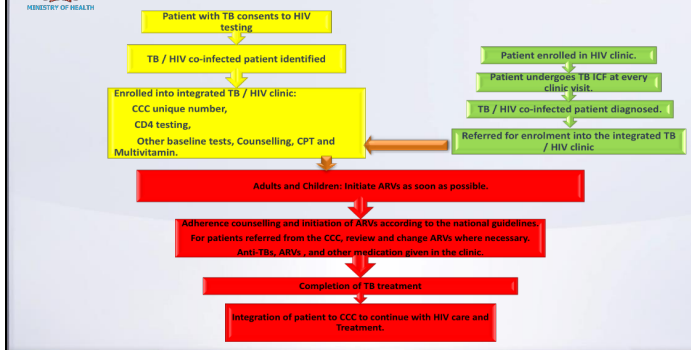
Complete Integration Model



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County coordination of TB/HIV activities

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Coordinating County and Sub county TB/HIV activities

- Practical steps to planning the implementation of TB/HIV collaborative activities at the sub-county

Sub county situation analysis

- This includes analysis of the TB/HIV services:
  - Collection of TB/HIV baseline statistics
  - The identification of risk groups for TB and HIV infection
  - A survey of existing sub county TB and HIV/AIDS service providers
  - A survey of existing stakeholders in the area
- This will be the responsibility of the sub-county Health Management Team (sCHMT) in consultation with the SCTLC and SCASCO.
- Sources of information include:
  - HMIS
  - Sub county TB register
  - Laboratory, ward and OPD registers
  - Surveillance results if they exist
  - Morbidity and mortality records.

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Coordinating County and Sub county TB/ HIV activities..cont'd

- Situational analysis should include description of groups within the sub county considered to be at special risk of TB and/or HIV infection e. g. PLHIV and support groups, prisoners, CSW, IDU's and migrants.
- A list of service providers should be included with an assessment of their:
  - Target population/catchment area
  - Number of clients/patients using service
  - Gender and ages of patients/clients
  - HIV status of patients/clients
  - Drugs available for HIV care at different clinical service providers
- Trends of service use over time should also be collected, the list includes:
  - Who is doing what and where in TB and HIV care provision.
  - Identification of gaps in the package of prevention and care for HIV and TB within the sub county
  - Identification of underserved populations

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Establishing a TB/HIV coordinating committees

- A Committee with all the relevant TB and HIV/AIDS care and support stakeholders invited to participate.
- Terms of reference and reporting structure for the group should be defined.
- This committee should be meeting regularly for effective networking and collaborative activities.
- A chairperson and secretary should be elected at formation.
  - chair should preferably come from non-government stakeholders within the sub county
  - secretary should be from the Ministry of Health.
- **Purpose** of committees; To ensure proper implementation, coordination and supervision of TB/HIV collaborative activities.

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Supporting the staff

- Constant support supervision by the committee is mandatory.
- Sub county TB/HIV committees should invest time and resources in training and motivating TB/HIV service providers as new activities are planned and implemented within the sub county.
- Other activities to support the staff include:
  - Regular meetings to maintain and update the skills of the service providers
  - Confidential staff support meetings where staff can share their own emotional responses to the occupational stress
  - Regular supervision with supportive and constructive feedback to health care providers
  - Exchange visits with care providers in other sub-counties and Health facilities
  - Strategies to reduce the risk of TB and HIV in health staff

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Monitoring and evaluation

- There should be quarterly collection of data on service use. This will allow changes in the sub county TB/HIV service performance to be monitored.
- Indicators for new activities should also be monitored and reported quarterly.
- Six monthly and yearly evaluations should be undertaken including quarterly meetings where lessons learned can be exchanged.

- ***Documenting the process***
- The coordinator of the sub county collaborative activities should be responsible for documenting the process of planning and implementing collaborative TB/HIV activities including the resources required.

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TB IN CHILDREN

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Objectives

- To understand epidemiology of TB in children
- To describe common clinical presentations of TB in children & use them to make a diagnosis
- To develop a structured approach to the management of TB and/or TB-HIV co-infection in a child
- To develop a structured approach in the handling of child contacts of adults with Pulmonary TB

In this context, a child refers to a person age 0 to 14 years

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Introduction

- The burden of TB in children is an important indicator of ongoing transmission within the community
- TB is an important cause of illness and death in children
- It is important to understand what factors put a child at risk of TB infection
- Once infected, other factors put a child at risk of progressing to TB disease and mortality
- The HIV epidemic has increased the burden of child TB and the clinical challenges in its management

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Child TB cases- Kenya 2015

Category	Number/%
Total TB cases	81,518
Total child cases	8.5%
Tested for HIV	94%
HIV positive	27%
CPT uptake	99%
ART uptake	95%

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Child TB trends

Year	Total TB cases	Child TB cases	% of total cases that are child TB cases
2013	90,692	8,649	9.5%
2014	90,091	8,517	9.5%
2015	81,518	6,968	8.5%

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Treatment outcomes

- Treatment Success Rate (No. Cured + Completed treatment)
  - < 5 years of age - **89.9 %**
  - 6-14 years of age - **89.4%**
- Mortality
  - < 5 years of age - **5.2%**
  - 6-14 years of age - **4.6%**

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Pathogens found in lungs from autopsy studies of African children

Causes of pneumonia	HIV-infected N=473	HIV-uninfected N=338	Total N=811
Bacterial	238 (50%)	132 (39%)	370 (46%)
PcP	145 (31%)	11 (3%)	156 (19%)
CMV	121 (26%)	7 (2%)	128 (16%)
M.tuberculosis	**50 (11%)**	**27 (8%)**	**77 (9%)**
Co-infection	98 (21%)	5 (1.5%)	103 (13%)

Combined data from 7 autopsy studies from five TB endemic countries shows that tuberculosis is a common diagnosis in children dying with lung disease including HIV-uninfected children

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TB Infection in children

- The source of infection for most children is an infectious adult or adolescent within their proximity, usually in the household
- Other contacts include those in school, and other minders
- A child may remain with latent TB for years and still be well
- A positive tuberculin skin test (TST) where available would be the only evidence of infection.

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Risk factors for TB infection and disease in children

For TB infection

- Contact with source case
  - –Closeness of contact
  - –Duration of contact
- **Source case**
  - –Smear positivity
  - –Cavities on CXR
- **Increased exposure**
  - –Living in high TB endemic communities
  - –Children of families living with HIV

For TB disease

- Young age
  - –Especially 0-2 years
- **HIV infection**
  - –Risk of infection and disease
- **Other immunosuppression**
  - –Malnutrition
  - –Post-measles
- **Not BCG vaccinated**
  - –Risk of disseminated disease

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Primary TB disease

- If the immune system cannot keep the bacilli under control, they multiply rapidly.
- They may spread through the lymphatics or the blood stream to the rest of the body.
- This leads to TB disease. It is **primary TB disease.**

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Progression from Primary Infection to Active TB Disease

Active TB disease may then develop from progression of the primary complex as follows:

- Hilar LN compressing bronchi (respiratory distress, wheeze, collapse lobe)
- Bronchial spread to parenchymal lung (TB pneumonia)
- Parenchymal lesions spread to pleura (pleural effusion)
- Lymphatic and / or haematogenous spread to other tissues in the body (commonly meningitis and miliary TB)

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Secondary TB disease

- Without treatment, approximately 5% of children infected with M. tuberculosis will develop disease in the first year or 2 after infection, and another 5% will develop disease later in life.
- Progression of the latent infection to disease is **secondary TB disease.**

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Older Child: Reactivation TB disease

- Years after primary infection dormant TB bacilli in the primary infection site in the lungs reactivate and multiply
- This can progress to secondary TB disease
- It occurs in older children who present with adult-like TB with cavitation, segmental or lobar consolidation

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Risk factors for Progression to Active TB disease in children

- Young age
  - Especially 0-2 years
- HIV infection
  - Risk of infection and disease
- Other immunosuppression
  - Malnutrition
  - Post-measles, other immunosuppressive conditions e.g. diabetes, malignancy
  - Immunosuppressive therapy
- Not BCG vaccinated
  - Risk of severe or disseminated disease
- Recent infection with M. tuberculosis (within the last 2 years)
- History of poorly treated previous TB

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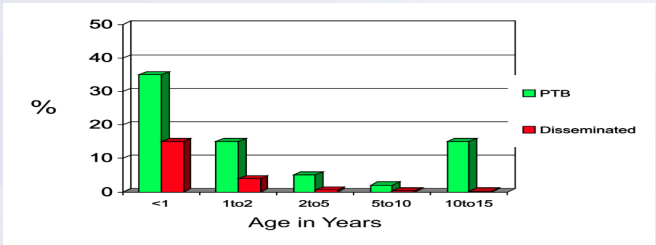
Young Age as a Risk Factor for TB disease



- Most cases occur in young children (<5years)
- Most disease occurs within 2 years after exposure/infection
  - The majority within 1 year

Age-specific risk for progression to active TB disease in Immune Competent Children

Age at Primary Infection	Total % Progressing to TB disease
< 1 year	50
1–2 years	20 – 30
2–5 years	5
5–10 years	2
>10 years	10 – 20

Immuno-suppression as a risk factor for TB disease

Various immune-suppressed children are at high risk of progressing to TB disease due to the inability of their immune system to prevent multiplication of the TB bacilli. Examples include:

- HIV (the lower the CD4 the higher the risk)
- Malnutrition
- Post-measles (depressed cell mediated immunity for months after measles)
- Children with malignancies
- Chronic diseases requiring long term steroid treatment

HIV as a Risk Factor for TB Disease

HIV epidemic

↓

Large increase in TB cases in HIV+ young adults

↓

Increased No. of TB infected HIV exposed children

↓

Increased no. Of HIV+ children with active TB disease

Diagnosis in children

- **The diagnosis of TB can be made with confidence in the majority of children using careful clinical assessment**
- It may be difficult to confirm diagnosis of TB in many children but it is usually not so difficult to make a clinical diagnosis of TB in a child
- Even though microbiological diagnosis is not always feasible, all efforts should be made to get a specimen for bacteriological confirmation of TB.
- A trial treatment with anti-TB drugs is **NOT RECOMMENDED** as a method of diagnosing TB in children.

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Recommended approach to diagnose TB in children

1. **Careful history**
   - includes history of TB contact
   - symptoms suggestive of TB
2. **Clinical examination**
   - includes growth assessment
3. **Tuberculin skin test**
4. **Bacteriological confirmation whenever possible**
5. **Investigations relevant for suspected PTB or suspected EPTB**
6. **HIV testing**

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History of contact

- **History of contact with an adolescent or adult with proven or suspected TB**
  - Close contact is defined as living in the same household as or in frequent contact with smear positive PTB index case
  - Ask about anyone in the household/dormitory/classroom/ school transport with chronic cough. If present request assessment of that person for possible TB
  - Most children will develop TB within one year of exposure

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History of symptoms

- The commonest symptoms associated with TB include:
  - Progressive and non-remitting cough for more than 2 weeks
  - Fever for more than 2 weeks
  - Lethargy /reduced playfulness /less active for more than 2 weeks
  - Weight loss, no weight gain or poor weight gain(failure to thrive)
  - Specific signs and symptoms depending on the site of extra-pulmonary TB

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Physical examination

- Examination of the respiratory system may reveal features of a respiratory infection
- In some cases, there may be atypical clinical presentations of PTB
- A normal respiratory clinical finding does not rule out PTB

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Atypical clinical presentations of PTB

Acute severe pneumonia

- Presents with respiratory distress and crackles
- Occurs especially in infants and HIV-infected children
- Suspect PTB if response to antibiotic therapy is poor. If child is HIV infected also suspect other HIV-related lung disease e.g. PCP

Wheeze

- Asymmetrical and persistent wheeze can be caused by airway compression due to enlarged tuberculous hilar lymph nodes
- Suspect PTB when wheeze is **asymmetrical, persistent and non-responsive to bronchodilator therapy**

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Investigations for TB diagnosis

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Bacteriological investigations*		
Laboratory test	**Target**	**Purpose**
MTB/Rif GeneXpert	• The first line test for all presumptive or suspected TB in Infants, children and adolescents • Surveillance for Drug Resistant TB among children previously treated for TB , child contacts of DRTB patients, refugees, prisones, children not improving on first line TB treatment	For diagnosis of TB To determine rifampicin susceptibility Done for child specimens of sputum, CSF, Gastric aspirate, Nasopharyngeal aspirates, Pleural fluid, Pericardial fluid, Ascitic fluid, FNA
Smear microscopy (Fluorescent and Light microscopy)	Infants, children and adolescents with presumptive Pulmonary TB	Only used in situations where Xpert is not accesible Monitoring smear positive and/or gene xpert positive TB patients on treatment at months 2, 5 and 6

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Radiological investigations		
X-ray	Chest Xray for all infants, children and adolescents with presumptive TB Xrays of the affected bone, joint, spine as appropriate	Diagnosis of TB and EPTB in all children where xray services are available For children obtain Anteroposterior and lateral CXR views
Ultrasound	Abdominal ultrasound Chest ultrasound	Diagnosis of abdominal TB Detection of pleural effusion
CT Scan or MRI	Head CT, Chest CT as needed MRI of the abdomen, head, chest or spine as needed	Evaluation of severe or complicated cases

Immunologic Tests		
Tuberculin skin test	Children	Useful test to detect TB exposure in children and support presumptive clinical diagnosis in situations where there is no obvious close TB contact to the child
Interferon gamma reaction assay (IGRA)	Children	Similar role to TST but more expensive.
Whenever possible try to make a bacteriological diagnosis of TB in infants and older children by obtaining specimens and sending them for Gene Xpert (preferred first line test), AFB microscopy or TB culture.		

**This includes tests that detect the TB bacillus or its antigens*

Adjunct tests for use in selected situations

Laboratory Test	Target	Purpose
Line Probe Assay (LPA)	Children who are: • MTB positive rifampicin sensitive, and are at high risk for DRTB • MTB positive rifampicin resistant, and are either high or low risk for DRTB	To determine if isoniazid resistance is present
Culture and DST	Children who are: • Eligible for LPA should also have a culture and DST requested • Children with clinically suspected TB whose Xpert is negative • Children who are on treatment for TB who are failing to respond to therapy	To diagnose TB To determine the drug sensitivity pattern To diagnose infections with non-tuberculous mycobacteria
Histology	All presumptive extra-pulmonary TB where FNA is indeterminant	Tissue diagnosis in suspected EPTB e.g TB adenitis

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Investigations

GeneXpert

- This is the preferred test for diagnosis of TB among children
- It is done for Sputum, gastric aspirate, CSF and bronchial secretion specimens
- Specimens from children who cannot expectorate can be obtained through a gastric aspirate

Sputum microscopy

- Where GeneXpert is not available, the sputum specimen can be evaluated using sputum microscopy.

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Investigations…..2

- **Chest Xray**
- TB may present with diffuse disease in younger children and an adult-like cavitary picture in older children.
- Radiological features suggestive of PTB will include:
  - Persistent lung opacification especially if focal
  - Enlarged hilar or subcarinal lymph nodes. In children below 6 years of age, mediastinal widening may be due to the thymus gland
  - Diffuse micronodular infiltrates (miliary pattern)
  - Pleural effusions
  - Upper lobe opacification with or without cavities especially in adolescents

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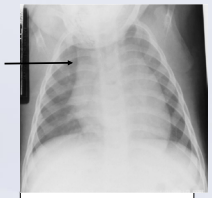
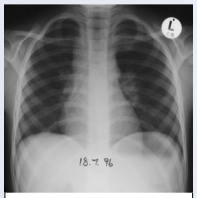
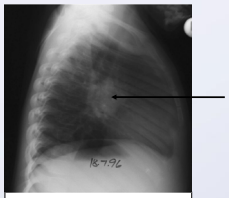
Pictures suggestive of Pulmonary TB



Common cause for a widened mediastinum in a young child is a large thymus which causes the sail sign on the chest radiograph (see arrow).



Suspected hilar and paratracheal lymph gland enlargement. The diagnosis can be made with more certainty when a lateral chest radiograph is examined as well



Massive hilar lymph gland enlargement visible on the lateral chest radiograph. The arrow indicates the hilar lymph glands.

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Mantoux test

- A positive Mantoux test is evidence that one is infected with M. Tuberculosis, but does not necessarily indicate disease
- Correct technique of administering, reading and interpretation of Mantoux text is very important
- Mantoux is positive if induration is:
  - ≥10mm in a well-nourished, HIV negative child
  - ≥5mm in a malnourished, or HIV infected child
- A negative Mantoux does not rule out TB (especially in the HIV positive or malnourished child).

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ALGORITHM FOR DIAGNOSIS OF TUBERCULOSIS IN CHILDREN

History of presenting illness	For all children presenting to a health facility ask for the following suggestive symptoms: **Cough, fever, poor weight gain, lethargy or reduced playfulness** Suspect TB if child has **two or more** of these suggestive symptoms. Ask for history of contact with adult/adolescent with chronic cough or TB within the last **2 years**
Physical examination	Examine the child and check for: •Temperature > 37.5 (fever) •Weight (to confirm poor weight gain, weight loss) - check growth monitoring curve) •Respiratory rate (fast breathing) •Respiratory system examination – any abnormal findings Examine other systems for abnormal signs suggestive of extra-pulmonary TB
Investigations	Obtain specimen* for Xpert MTB/RIF (and culture when indicated**) Do a chest Xray (where available) Do a Mantoux test*** (where available) Do a HIV test Do other tests to diagnose extra-pulmonary TB where suspected

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ALGORITHM FOR DIAGNOSIS OF TUBERCULOSIS IN CHILDREN….2

Diagnosis	**Bacteriologically confirmed TB**: Diagnose if specimen is positive for MTB	**Make a Clinical Diagnosis of PTB if**: *Child has **two or more** of the following suggestive symptoms:* •Persistent cough, fever, poor weight gain, lethargy *PLUS **two or more** of the following:* •Positive contact, abnormal respiratory signs, abnormal CXR, positive Mantoux **Note:** If child has clinical signs suggestive of EPTB, refer to EPTB diagnostic table
Treatment	**Treat for TB as follows:** •All children with **bacteriologically confirmed TB** •All children with a **clinical diagnosis of TB** NB: Children who do not have an Xpert result; or their Xpert result is negative **but** they have clinical signs and symptoms suggestive of TB should be treated for TB *All forms of TB (Except TB meningitis, bone and joint TB): **Treat for 6 months (2 RHZE / 4 RH)*** *TB meningitis, bone and joint TB: **Treat for 12 months (2 RHZE/ 10 RH)***	

*Specimen may include: Expectorated sputum (child > 5 years), induced sputum, nasopharyngeal aspirate and gastric aspirate.
Attempt to obtain specimen in every child

*** This may include IGRA in facilities where it is available

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Simplified Clinical TB Diagnosis

Having taken history and done a physical examination, the health worker may at this point make a clinical diagnosis of PTB in the child and make decisions on treatment

Presence of 2 or more of the following symptoms
Cough >2weeks
Weight loss or poor weight gain
Persistent fever and/or night sweats>2weeks
Fatigue, reduced playfulness, less active
PLUS
Presence of 2 or more of the following:
Positive contact history
Respiratory signs
CXR suggestive of PTB(where available)
Positive Mantoux test(where available)
Then PTB is likely, and treatment is justified

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Extra-Pulmonary Tuberculosis (EPTB)

- Extra pulmonary TB is common in children and presentation varies with age
- Symptoms are usually persistent and progressive with the most common form being TB lymphadenitis
- Clinical assessment in all cases of EPTB should consider time lapse from exposure to disease
  - shorter for young children with disseminated disease
  - longer for other forms that present in school-aged children

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Treatment of Tuberculosis in children

- **Children usually have paucibacillary disease**
- **Children develop extra-pulmonary TB (EPTB) more often than do adults**
- **Severe and disseminated TB (e.g., TB meningitis and miliary TB) occur especially in young children (less than 3 years old)**
- **Treatment outcomes in children are generally good even in the HIV infected provided treatment is started promptly. However, response to treatment in this category may be slow**

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Principles of TB treatment in children

- Children generally tolerate the anti-TB drugs better than adults
- Dosages are calculated according to weight (not age)
- Weight is important for monitoring treatment response
- Streptomycin is no longer recommended as first-line therapy in children

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Standard Operating Procedures for Treatment

- Classify the case of child TB before starting treatment into pulmonary or extrapulmonary TB
- Record the TB diagnostic category, treatment regimen and date anti-TB treatment was started on road-to-health book as well as on TB treatment card and facility TB register
- A caregiver should be identified as the DOT supporter for all ages including older children. Educate the DOT supporter on anti-TB regimen and adherence
- Take the child's weight at each visit and record
- Calculate drug dosages at every visit according to the child's current weight (note that children gain weight while receiving anti-TB treatment)
- Once treatment is started it must be completed; **"trial of TB treatment" should never be used as a diagnostic tool**

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RECOMMENDED TB TREATMENT REGIMEN

TB disease category	Recommended regimen	
	Intensive phase	**Continuation phase**
All forms of TB except TB meningitis, bone and joint TB (osteoarticular TB)	2˚ RHZE	4 RH
TB meningitis Osteoarticular TB	2 RHZE	10 RH
Drug resistant TB	Refer to a DRTB specialist	

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Use of Ethambutol in children

- Ethambutol is now recommended as fourth drug in intensive phase of first-line regimens and can be safely used at recommended dosages in all ages
- The risk of toxicity is negligible for children of any age when Ethambutol is used at recommended dosages of **20(15-25) mg/kg/day**
- Dosage **should not exceed 25mg/kg/day**
- Risk of toxicity is dose-related

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DOSAGES FOR A CHILD WEIGHING UP TO 3.9 KG

Weight bands (Kg)	Number of tablets				
	Intensive Phase			Continuation Phase	
	RHZ (75/50/150mg)	E(100mg)	How to reconstitute the medicines	RH(75/50mg)	How to reconstitute the medicines
Less than 2 Kg	¼	¼	Dissolve **one (1)** tablet of RHZ in **20 ml** of safe drinking water. Once fully dissolved, add the completely crushed **one (1)** tablet of Ethambutol and give **5ml (1/4)** of this solution	¼	Dissolve **one (1)** tablet of RH in **20 ml** of safe drinking water. Once fully dissolved, give **5ml (1/4)** of this solution
2 – 2.9	½	½	Dissolve **one (1)** tablet of RHZ in **20 ml** of safe drinking water. Once fully dissolved, add the completely crushed **one (1)** tablet of Ethambutol and give **10ml (1/2)** of this solution	½	Dissolve **one (1)** tablet of RH in **20 ml** of safe drinking water. Once fully dissolved, give **10ml (1/2)** of this solution
3 – 3.9	¾	¾	Dissolve **one (1)** tablet of RHZ in **20 ml** of safe drinking water. Once fully dissolved, add the completely crushed **one (1)** tablet of Ethambutol and give **15ml (3/4)** of this solution	¾	Dissolve **one (1)** tablet of RH in **20 ml** of safe drinking water. Once fully dissolved, give **15ml (3/4)** of this solution

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Dosage For Paediatric TB Treatment (Improved Formulations)

	Number of Tablets		
	Intensive Phase		Continuation Phase
Weight Bands (Kgs)	RHZ (75/50/150mg)	E(100mg)	RH(75/50mg)
4 - 7.9	1	1	1
8 - 11.9	2	2	2
12 - 15.9	3	3	3
16 - 24.9	4	4	4
25 kg and above	Use adult dosages and preparations		

CHILD ABOVE 25KG: ADULT DRUG FORMULATION DOSAGE TABLE

	Number of Tablets	
	Intensive Phase	Continuation Phase
Weight Bands (Kgs)	RHZE (150/75/400/275mg)	RH(150/75mg)
25 – 39.9	2	2
40 – 54.9	3	3
55kg and above	4	4

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Pyridoxine Dosing for Children on TB Treatment

Weight (Kgs)	Dose in mg	Number of 25mg tablets	Number of 50mg tablets
<5	6.25 mg	Half a tablet 3 TIMES PER WEEK	Not suitable for young infant
5.0 – 7.9	12.5 mg	Half a tablet daily	Half of 50mg tablet 3 TIMES PER WEEK
8.0 – 14.9	25 mg	One tablet daily	Half of 50mg tablet daily
15.0 kg and above	50 mg	Two tablets daily	One 50mg tablet daily

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Follow-up of a child on anti-TB Therapy

- This is a critical part of effective TB treatment
- Patients visit the health facility weekly during intensive phase and every two weeks during continuation phase
- During the visit, the child should be assessed for:
  - Adherence
  - Drug toxicity
  - **Weight gain**
  - Improvement of symptoms
- Sputum should be taken for AFBs at months 2, 5 and 6 for those who were bacteriologically confirmed at the beginning of treatment

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At every follow up visit:

- Weigh the child. Document the weight and adjust dosage if necessary
- Explain and emphasize to care-giver and child why they must take the full course of treatment even if they are feeling better (adherence counseling)
- Note risk factors for poor adherence such as long distance to health facility, lack of/transport costs, orphan (especially if mother has died) or primary care-giver unwell and adolescents, TB/HIV co-morbidity
- Explain that anti-TB drugs in children are well tolerated and safe
- CXR is not required in follow-up if the child is responding well to anti-TB treatment. If a child had an abnormal CXR at diagnosis, a repeat is done at the end of TB treatment

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Poor response to treatment

- Most children with TB will start to show signs of improvement within 4 – 8 weeks of anti-TB treatment
- Weight gain is a sensitive indicator of good response to treatment
- Children not responding to TB treatment after one month should be reassessed for causes of the poor response and possible drug resistance. **TB treatment should however not be stopped**

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Causes of poor response to treatment

- Poor adherence; this is the commonest cause. If uncertain, a child can have health care worker DOT at the health facility
- HIV infection
- Wrong diagnosis
- Other concurrent chronic lung diseases
- Under-dosage of drugs
- Resistant form of TB
- Complications e.g. neurological complications, bronchiectasis e.t.c.

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Treatment failure

- This is considered if
  - There is no symptom resolution or symptoms are getting worse
  - There is continued weight loss
  - If smear positive at baseline and remains smear positive up to 5 months
- Always confirm that adherence is good. If uncertain, a child can have health care worker DOT at the health facility
- Refer children with suspected treatment failure for further assessment

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ADR	PRESENTATION	LIKELY DRUG	MANAGEMENT
Hepatitis	-Nausea and vomiting if mild -Jaundice & tender hepatomegally if severe	INH, RIF, PZA	Stop the anti-TB drugs immediately and refer to hospital
Peripheral neuropathy	-Worse in malnutrition and TB/HIV co-infection -Tingling, numbness, weakness or **reduced playfulness**	INH	Supplemental pyridoxine
Optic neuritis	Reduced vision, blue-green color blindness	EMB	**Ensure correct EMB dose** Stop Ethambutol Refer for further management
Rash	-Mild -Severe (involves mucous membranes)	INH, RIF, PZA, EMB	Mild-give antihistamines Severe. Stop anti-TBs and refer

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In-patient treatment

- The following categories of children with TB should be treated as in-patients
  - Severe forms of PTB and EPTB (e.g. Spinal TB) for further investigation and initial management
  - TB meningitis
  - Severe malnutrition for nutritional rehabilitation
  - Signs of severe pneumonia(i.e. chest in-drawing)
  - Other co-morbidities e.g. severe anaemia
  - Social or logistic reasons to ensure adherence
  - Severe adverse reactions such as hepatotoxicity

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Steroid therapy

- This should be given in the following situations:
  - TB meningitis
  - PTB with respiratory distress
  - PTB with airway obstruction by hilar lymph nodes
  - Severe Milliary TB
  - Pericardial effusion
- Give prednisone at **2mg/kg** once daily for 4 weeks, and then taper down over 2 weeks **(1mg/kg for 7 days, then 0.5mg/kg for 7 days)**

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Referral of children with TB

- **This should be considered if:**
  - Child has severe disease
  - Diagnosis is uncertain
  - Necessity for HIV-related care e.g. to commence ART
  - Failure to respond to treatment despite good adherence

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IPT in children

Provide Isoniazid preventive therapy (IPT) for the following high risk

children in whom signs or symptoms of TB disease have been ruled out:

- All children aged under 5 years who have been exposed to a case of infectious TB irrespective of their HIV status
- All HIV infected children above one year
- HIV infected children under one year of age who have been exposed to a case of infectious TB

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IPT in children….2

- Follow up of a child on IPT is monthly
- If TB disease develops in the course of IPT, stop IPT and treat for TB
- All children on IPT should receive pyridoxine at **12.5mg daily**

Note: **INH preventive therapy should NOT be given to children exposed to an adult with proven MDR/XDR TB. The children should instead be followed up for signs of active TB disease and managed appropriately**

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Dose of Isoniazid (INH) for Isoniazid Preventive Therapy (IPT) in children

Weight (kg)	Daily Dose in mg	Number of 100 mg tablets
<5	50	½
5.1 – 9.9	100	1
10-13.9	150	1½
14-19.9	200	2
20-24.9	250	2½
>25	300	3*

*For children more than 25 kg, one can use 1 adult tablet of INH (300mg) once daily.
All children on IPT should also receive pyridoxine at 12.5mg/day.

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Follow up for children on IPT

- Children on IPT should receive monthly follow up
- During each follow up visit:
  - Give adherence counseling
  - Screen for TB disease i.e. persistent cough, fever, lethargy, poor weight gain
  - Monitor INH adverse effects
  - Update the patient details in the IPT register

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Introduction to TB/HIV in children

- HIV infection is one of the risk factors associated with development of Tuberculosis in children
- HIV infected children may have multiple and concurrent opportunistic lung infections that clinically present like TB, thus making the diagnosis of TB in a HIV infected child more difficult
- The ARVs and anti-TB drugs have potentially significant drug-drug interactions as well as overlapping toxicities
- Therefore comprehensive approach to management of both TB and HIV is critical

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HIV testing in children

Population	Recommendations
HIV testing and counseling of infants and children aged less than 18 months	•HIV exposure status of all infants should be established at the 6-week immunization visit or at first contact thereafter, using maternal medical information •Conduct HIV antibody testing for mother or children less than 18 months of age and of unknown status to establish their HIV exposure status •All HIV-exposed infants should be offered routine DNA PCR testing at the 6-week immunization visit, or at the earliest opportunity for infants seen after 6 weeks of age •Infants with an initial positive HIV DNA PCR results should be presumed to be HIV infected and started on ART in line with national guidelines
HIV testing and counseling of children older than 18 months	•Conduct HIV testing and counseling for all children presenting to the health facility irrespective of reason for their visit to the health facility •Conduct HIV testing and counseling for all children of HIV infected adults as soon as possible, within one month of confirming the HIV positive status of the adult
HIV testing and counseling of adolescents	•Conduct HIV testing and counseling for all adolescents including key populations presenting to the health facility irrespective of reason for their visit to the health facility •All adolescents identified HIV positive should be linked to prevention, care and treatment services •All adolescents should be counseled about the potential benefits and risks of disclosure of their HIV status and empowered and supported to determine if, when, how and to whom to disclose •For sexually active adolescents with partners, HIV testing and counseling should be offered to their partners and Children

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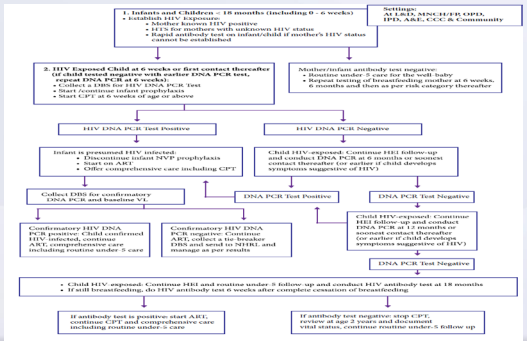
Algorithm for Early Infant Diagnosis of HIV



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Presumptive Diagnosis of HIV in children <18 months while awaiting DNA PCR Results

Child < 18months of age; HIV antibody test positive and symptomatic with:
2 or more of the following:
- Oral candidiasis/thrush
- Severe pneumonia
- Severe sepsis

OR, any of the following
- Any WHO Clinical Stage 4 condition
- Recent maternal death or advanced HIV disease in mother
- Child's CD4 < 20%

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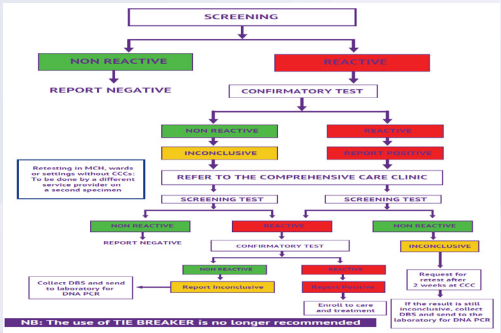
HIV Testing Services Algorithm for the child >18 months



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Diagnosis of TB in HIV

- HIV test should be routine in the assessment of a child with suspected TB
- Note that excluding HIV infection decreases the number of alternative diagnoses because chronic or persistent lung disease is common in HIV-infected children
- The approach to diagnosis of TB (PTB and EPTB) is similar in the HIV-infected child as for the HIV-uninfected child
- Diagnostic challenges are greater because co-infection with HIV reduces the specificity of the typical and clinical and radiological features of TB
- Samples should be taken for Xpert MTB/RIF whenever possible
- Symptomatic screening for TB should be routine for all HIV-infected children including upon HIV diagnosis and commencement of ART

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Differential diagnosis of chronic respiratory symptoms in HIV infected children

Differential Diagnosis	Clinical features
Recurrent pneumonia	Recurrent episodes of cough, fever and fast breathing that usually respond to antibiotics
Lymphoid Interstitial Pneumonitis	Slow onset cough associated with generalized symmetrical lymphadenopathy, finger clubbing, parotid enlargement. Nutritional status variable, mild hypoxia, CXR: diffuse reticulonodular pattern andbilateral perihilaradenopathy
Pneumocystis Jirovecii Pneumonia	Common cause of acute severe pneumonia, severe hypoxia especially in infants. Unusual after 1 year CXR: diffuse interstitial infiltration, hyperinflation
Tuberculosis	Persistent respiratory symptoms not responding to antibiotics. Often poor nutritional status; positive TB contact especially in younger children CXR: focal abnormalities and peri hilar adenopathy
Bronchiectasis	Cough, productive of purulent sputum, halitosis, finger clubbing, seen in older children. CXR: honeycombing usually of lower lobes Complicates recurrent bacterial pneumonia, LIP or TB
Mixed infection	Common problem: LIP, bacterial pneumonia, Consider TB when there is poor response to first-line empiric management
Kaposi' s sarcoma	Uncommon Characteristic lesions on skin or palate

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Treatment of TB in HIV

- Principles of TB treatment in HIV-infected children are similar to those in HIV-negative children
- The same regimens should be used as those used in HIV negative children
- Response to TB treatment may be slow in PLWHA
- Nutritional support is often needed for children with TB/HIV
- The management of children with TB/HIV should be integrated so that all family members are counseled and tested for HIV, screened for TB and managed appropriately

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CPT in TB/HIV co-infected children

- Cotrimoxazole reduces mortality among children infected with HIV
- All children with TB/HIV should be initiated on Cotrimoxazole as soon as possible
- The duration of treatment is usually life-long with a once daily dosing
- The children should be monitored for side effects
- CPT should be discontinued if a child develops severe adverse reactions

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Screening for Child Contacts of Known TB Cases

- Young children living in close contact with an index case of smear positive pulmonary TB are at a high risk of TB infection and disease
- The risk of developing disease after infection is much greater for malnourished children, children under 5 years and HIV infected children

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Screening for Child Contacts of Known TB Cases….2

- The main purpose of child contact screening is to:
  - Identify symptomatic children (i.e. children of any age with undiagnosed TB disease) and treat them for TB
  - Provide Isoniazid preventive therapy (IPT) for the high risk children who have no signs or symptoms of TB disease
- A clinical assessment is sufficient to decide whether the contact is well or symptomatic

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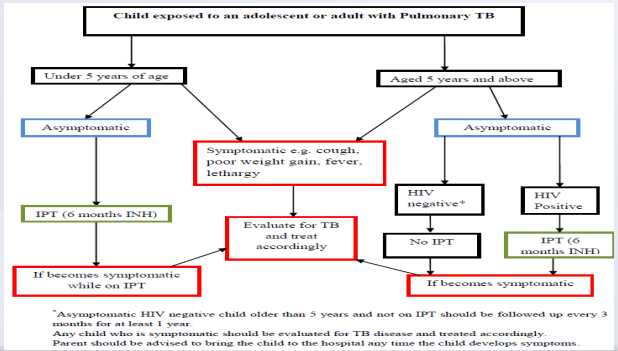
Management of child exposed to PTB



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Child contact known to be HIV-infected

- If the child contact is HIV-infected and asymptomatic for TB, then IPT should be considered for all ages, including those 5 years and older
- As with other contacts, active disease should be ruled out before providing HIV-infected children with IPT
- HIV infected children who have symptoms should be carefully evaluated for TB, and if found to have TB should be started on TB treatment

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Suspected HIV infection of source case

- If the index case is a parent and is HIV infected, their children may be at risk of both TB and HIV infection
- It is important to counsel and test for HIV as we screen for TB infection in all the contacts

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Child contacts of infectious MDR-TB cases

- MDR TB child contacts should receive careful clinical follow-up for a period of at least 2 years
- **If active disease develops, prompt initiation of treatment of the child with a regimen designed to treat MDR-TB is recommended**
- The regimen is usually based on the resistance pattern of the MDR TB index case
- The use of second-line drugs for chemoprophylaxis in MDR-TB contacts is currently not recommended

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IPT in children

- Provide Isoniazid preventive therapy (IPT) for the high risk children who have no signs or symptoms of TB disease i.e.
  - All children aged under 5 years who have been exposed to a case of infectious TB irrespective of their HIV status
  - All HIV infected children above one year
  - HIV infected children under one year of age who have been exposed to a case of infectious TB
- **All children on IPT should receive pyridoxine at 12.5mg daily**
- **INH preventive therapy should NOT be given to children exposed to an adult with proven MDR/XDR TB.** The children should instead be followed up for signs of active TB disease and managed appropriately

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Follow up of children on IPT

- Children on IPT are followed up monthly until they complete their IPT. Thereafter, they are evaluated every three months for up to one year
- During every follow-up visit, evaluate the child for:
  - Signs and symptoms of TB
  - Adverse drug reactions to INH
  - Weight increase
- Adjust the INH dose appropriately if the child gains weight and moves to the next treatment band

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Management of a baby born to a Mother with PTB

- A newborn infant has a high risk of infection/disease from a mother with smear-positive pulmonary TB if the mother is diagnosed with TB in pregnancy
- Upon delivery, the placenta and the baby should be evaluated for evidence of congenital TB infection
- The neonate should be screened for TB
- Those that are symptomatic should be treated for TB
- Those without active TB disease should be on IPT for 6 months

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Signs and symptoms of neonatal TB disease

- Fever
- Feed intolerance
- Poor weight gain
- Hepato-splenomegally
- Irritability

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BCG vaccination

- It offers protection against the more severe types of TB such as Milliary TB and TB meningitis
- All children should be given the BCG vaccine as soon as possible after birth EXCEPT in the following due to the risk of disseminated BCG disease:
  - Children with suspected TB infection at birth
  - Children with symptomatic HIV infection at birth
  - Congenital immunodeficiency syndrome

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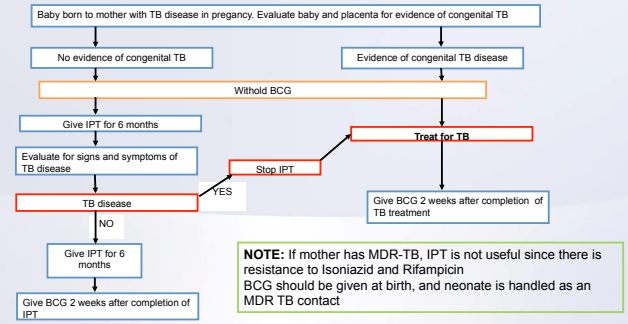
BCG in newborns exposed to TB



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Complications of BCG vaccination

- Develop in 1-2% of children following BCG vaccination
- They include:
  - Local abscesses at the injection site
  - Secondary bacterial infections
  - Suppurative adenitis in the regional axillary lymph node
  - Local keloid formation
  - Disseminated BCG disease. Consider it if axillary node enlargement is on the same side as BCG in a HIV- positive infant and treat as TB
- Most reactions will resolve spontaneously over a few months and do not require specific treatment

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Gastric aspiration

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Requirements

- 2 people (one doing the test and an assistant)
- Gloves
- Nasogastric tube (usually 10 French or larger)
- 5, 10, 20 or 30 cm3 syringe, with appropriate connector for the nasogastric tube
- litmus paper specimen container
- Pen (to label specimens)
- Laboratory requisition forms
- Sterile water or normal saline (0.9% NaCl) Sodium bicarbonate solution
- (8%) Alcohol/chlorhexidine
- The procedure can be carried out as:
- An inpatient: first thing in the morning when the child wakes up, at the child' s bedside or in a procedure room on the ward (if one is available)
- An outpatient . The child should have fasted for at least 4 hours (infants for 3 hours) before the procedure

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Procedure for GA

- Find an assistant to help
- Prepare all equipment before starting the procedure
- Position the child on his or her back or side. The assistant should help to hold the child
- Measure the distance between the nose and stomach, to estimate distance that will be required to insert the tube into the stomach
- Attach a syringe to the nasogastric tube
- Gently insert the nasogastric tube through the nose and advance it into the stomach
- Withdraw (aspirate) gastric contents (2–5 ml) using the syringe attached to the nasogastric tube
- To check that the position of the tube is correct, test the gastric contents with litmus paper or by pushing some air (e.g. 3–5 ml) from the syringe into the stomach and listening with a stethoscope over the stomach

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Procedure for GA……2

- If no fluid is aspirated, insert 5–10 ml sterile water or normal saline and attempt to aspirate again
- If still unsuccessful, attempt this again (even if the nasogastric tube is in an incorrect position and water or normal saline is inserted into the airways, the risk of adverse events is still very small)
- **Do not repeat more than three times**
- Withdraw the gastric contents (ideally at least 5–10 ml)
- Transfer gastric fluid from the syringe into a sterile container (sputum collection cup)
- Add an equal volume of sodium bicarbonate solution to the specimen (in order to neutralize the acidic gastric contents and so prevent destruction of tubercle bacilli)

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After the procedure

- 1. Wipe the specimen container with alcohol/chlorhexidine to prevent cross-infection and label the container.
- 2. Fill out the laboratory requisition forms.
- 3. Transport the specimen (in a cool box) to the laboratory for processing as soon as possible (within 4 hours).
- 4. If it is likely to take more than 4 hours for the specimens to be transported, place them in the refrigerator (4–8 °C) and store until transported.
- 5. Give the child his or her usual food.

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Safety

- Gastric aspiration is generally not an aerosol-generating procedure and can safely be performed at the child's bedside or in a routine procedure room

Contraindications

- Children not fasting for at least 4 hours (3 hours for infants) prior to the procedure
- Children with a low platelet count or bleeding tendency

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Mantoux testing

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Requirements

- A firm, well-lit surface
- A vial of tuberculin
- A single-dose disposable tuberculin syringe
- A quarter or a half inch 27-gauge needle with a short bevel
- A ruler with millimeter (mm) measurements
- 2x2 gauze pads or cotton balls
- Alcohol swabs
- A puncture-resistant sharps disposal container
- Record-keeping forms for the patient and provider
- A pen

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Preparing the patient

Discuss with the patient:

- Why the skin test is given
- What is involved in the procedure
- When the patient should return for the test to be read
- If a patient can't return within the 72-hour time period, do not administer the test. Instead, schedule another time

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Preparing the injection and injection site

- Place forearm palm-side up on a firm, well-lit surface
- Locate injection site 5–10 cm (2–4 inches) below elbow joint
- Select an area free of any barriers to placing and reading the skin test
- Clean the area with an alcohol swab by circling from the center of the site outward
- Allow the site to dry completely before the injection
- Confirm that the vial contains tuberculin PPD-S (5 TU per 0.1 ml) and its expiration date
- Write the date and your initials on the label to indicate when the vial was opened and who opened it
- Fill the syringe with 0.1 ml tuberculin

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Injecting the tuberculin

- TST is an intradermal injection
- With the needle bevel against the patient's skin, insert it slowly at a 5 - 15 degree angle with the needle bevel facing up
- Advance the needle bevel approximately 3 mm so that the entire bevel is covered and lies just under the skin
- Release the stretched skin and hold the syringe in place on the forearm
- Slowly inject the tuberculin solution
- You should feel fairly firm resistance as the tuberculin enters the skin
- A tense, pale wheal that's 6 to 10 mm in diameter appears over the needle bevel. If not, repeat the injection at a site at least 5 cm (2 inches) away from the original site
- Remove the needle without pressing or massaging the area
- Discard the used syringe immediately in the designated puncture-resistant container
- In case a drop of blood appears at the injection site, lightly blot the blood away with a gauze pad or cotton ball
- Do not cover the site with an adhesive bandage because the adhesive could cause irritation and interfere with the test
- Immediately and thoroughly wash your hands

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After the injection

- Write the date and the time the test was administered, the name and manufacturer of the injected solution, the lot number, the tuberculin dose administered, the expiration date, the forearm or alternative site in which the injection was given, the site location if you repeat the test, the name of the person who administered the test, and the reason for giving the skin test
- **Remind the patient to return.**
- Explain how to care for the injection site after the test
- Return the tuberculin vial to the refrigerator, or other cooling container

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Reading and interpretation

- The results should be read 72 hours after administration
- Visually inspect injection site under good light and on a firm surface
- Use fingertips to find the margins of induration which is a hard, dense, raised formation
- Mark induration and measure across the forearm; from the thumb side of the arm to the little finger side of the arm or vice versa.
- Place "0" of ruler line on the inside-left edge of the induration
- Read ruler line on the inside-right edge of the induration (use lower measurement if between two gradations on mm scale)
- Record the measurement in millimeters
- If no induration, record as 0 mm
- Do not record as "positive" or "negative"

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Interpretation

TST interpretation depends on two factors:

- Diameter of the induration
- Person's risk of being infected with TB and risk of progression to disease if infected

- Mantoux is positive if induration is:
  - 10mm in a well-nourished, HIV negative child
  - 5mm in a malnourished, or HIV infected child
- A negative mantoux does not rule out TB infection or disease (especially in the HIV positive or malnourished child)

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Module 8

TB in special populations

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TB AND DIABETES

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Epidemiology of Diabetes

- In 2013, the International Diabetes Federation (IDF) estimated that 387 million people worldwide were living with diabetes, of whom 46.3% were undiagnosed.
- The prevalence of diabetes was 8.3% worldwide with 77% occurring in low and middle income countries with 4.9 million deaths in 2014.
- There were 775,200 cases of diabetes in Kenya in 2014 and the estimated prevalence among the adult population (20-79 years) in Kenya is 3.6%.

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How diabetes affect TB/ How TB affects diabetes

How diabetes affect TB

- Diabetes **triples** the risk of developing active tuberculosis (TB) due to reduced immunity.
- Changes the sensitivity and specificity of conventional TB diagnostic algorithms.
- Diabetes can worsen the clinical course of TB
- Diabetes may also adversely affect TB treatment outcomes; it may increase the time to sputum culture conversion, increases the risk of death and the risk of TB relapse
- There is some evidence that diabetes may also accelerate the emergence of drug-resistant TB, especially multidrug-resistant among those receiving TB treatment
- Diabetes may interfere with the activity of certain anti-TB medicines

How TB affects diabetes

- worsen glycemic control in existing diabetes
- TB medications may interfere with the treatment of diabetes through drug interactions

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TB and Diabetes co-morbidities

- TB and DM preventive messages should be given in both care settings as patient education and CMEs to the facility staff.
- IPT is **NOT** recommended as a method of preventing TB in DM patients (studies have shown that there may not be any additional benefit to this and it may worsen peripheral neuropathy associated with DM).
- Improved collaborative activities would improve care and prevention of diabetes.
- Under-diagnosis of the disease is common, and could be improved by screening people with TB for diabetes.
- Management of diabetes must be optimized in general, and in particular during TB disease, as during all types of infections.

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TB and Diabetes co-morbidities

- Improved management of diabetes could build on the successes of the DOTS strategy, emphasizing ;
  - support to patients and supervision of their treatment;
  - standardized protocols,
  - a reliable supply of quality-assured medicines,
  - regular monitoring and evaluation, and
  - management and administrative procedures
  - as well as political commitment.

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TB/DM collaborative activities

- The objectives of those collaborative activities are;

1. Set up means of coordinating diabetes and TB activities
2. Detect and manage TB in patients with diabetes
3. Detect and manage diabetes in patients with TB
4. Ensure TB infection control in health-care settings where diabetes is managed

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1. Setting up means of coordinating diabetes and TB activities

- TB/DM activities will ride on existing TB/HIV coordinating bodies that are already established.
- These will be established at national level, county, sub county and facility level.
- The purpose of the coordinating bodies will be to coordinate, strengthen and increase ownership of all TB/DM activities alongside TB/HIV activities.
- Additionally these teams will be tasked to address commodity issues, data quality issues, and to Identify and address any existing training gaps in different administrative levels.

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2. Detecting and managing TB in patients with diabetes

- TB screening will be conducted for diabetic patients at every visit using the National TB ICF/IPT symptom-screening tool
- This should be recorded in the individual patients TB ICF/IPT symptom-screening card and aggregated in the National presumptive TB register
- Sputum smear microscopy should be used to investigate the patient for TB or genexpert where available.
- Other appropriate investigations like radiography and culture may be conducted.
- Healthcare workers in the diabetes clinic will provide DOTs TB treatment as per the National guidelines
- Upon completion of TB treatment, patients with diabetes will be referred back to a specialist diabetes clinic for continued diabetes chronic care and management

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3. Detecting and managing diabetes in patients with TB

- All TB patients co-morbid with DM will be treated with the same standard regimen
- All attempts should be made to ensure glycemic control is optimum during TB treatment.
- This may include regular random and fasting sugar monitoring at every clinical visit, and as often as possible based on glycemic control
- Sputum monitoring of co-morbid TB/DM patients will be conducted as is the case for TB patients without DM

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4. Ensure TB infection control in health-care settings where diabetes is managed

- In diabetes clinics, where the risk of TB is higher than in the general population, the risk of transmitting TB is increased, and the consequence of transmission is more severe for a person with diabetes.
- As is commonly practiced within the TB settings, Infection Prevention and Control interventions need to be strengthened and implemented including;
  1.administrative,
  2.environmental
  3.respiratory measures

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TB IN PREGNANCY AND LACTATION

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TB in pregnancy

- In 2011, it was estimated that more than 200,000 cases of active tuberculosis occurred among pregnant women globally; the greatest burdens were in Africa and Southeast Asia.
- TB in pregnancy however, can present insidiously, since symptoms of malaise and fatigue may be attributed to pregnancy rather than disease, therefore during pregnancy it can be difficult to recognize weight loss
- Pregnant women with active TB disease should be treated as soon as the diagnosis of TB has been made with the standard 6 month regimen 2RHZE/4RH.
- Anti-TBs are not dangerous in pregnancy and are compatible with breast feeding.
- Adherence to anti-TBs will cure tuberculosis, and prevent spreading tuberculosis to the unborn child as well as the household.
- Identification and treatment of maternal TB is the best way of preventing TB in the newborn.
- There is no significant increase in malformations for infants born to infected mothers and there is also **no indication for therapeutic abortion**

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Peri-natal Tuberculosis and Lactation

- Breast feeding should be continued during anti-TB therapy as the excretion of these drugs through breast milk is minimal and does not affect neonates and infants.
- These trace amounts of anti-TB in breast milk are however not enough to treat or prevent TB in the neonate, and children born to mothers with TB must therefore be evaluated for TB as well
- If diagnosed among neonates, TB should be treated using the standard treatment regimens

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TB prophylaxis among neonates and infants

- Neonates born to mothers with active TB who screen negative for TB should be offered Isoniazid Preventive Therapy (IPT) prophylaxis
- BCG is then offered 2 weeks after completion of the 6 month course of IPT
- Though extremely rare, intrauterine transmission of TB may occur
- Once a baby is born to a mother with active TB disease, or an infant has close contact with active TB disease, evaluation of the newborn should be undertaken.

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Evaluation for clinical features of peri-natal TB in newborns

- A neonate may present with symptoms of TB at birth or delayed until eight weeks of age.
- Symptoms are usually non specific and may include;
  - Respiratory distress
  - Fever
  - Hepato-splenomegaly
  - Irritability, poor feeding and lethargy
  - Lymphadenopathy
  - Failure to thrive
  - Jaundice

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Where TB is diagnosed

- If neonatal TB is suspected, conduct gastric aspirates for sputum gene Xpert, Chest x-ray, and lumbar puncture where indicated.
- On confirmation of TB, initiate anti TBs, using the standard 6 month regimen (2RHZE/4RH). Adjust the dosage of anti-TBs based on the weight of child.
- Give pyridoxine alongside anti TBs .
- Breastfeeding should be continued until the child is 6 months. BCG for neonates on anti-TBs should be withheld until 2 weeks after completion of the anti-TBs

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TB IN PRISON

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Introduction

- TB in prisons is a major public health problem in many settings, particularly in countries with a high incidence of TB.
- In Kenya, the TB notification rate in prisons is 10 times higher than in the general population.
- The situation is worsened by the emergence and spread of drug-resistant TB, particularly multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB .

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Management of TB among prisoners

- All presumptive TB cases (i.e screen positive) within the prison population should be investigated using GeneXpert as the preferred confirmatory test
- Treatment should be administered under the direct observation of health care staff
- All TB patients should be tested for HIV, and those testing positive initiated on CPT and ART immediately
- IPC measures should be observed to reduce transmission
- Upon transfer or release from the prison, prisoners on treatment should be referred using the referral forms to a facility for continuity of care

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TB and Alcohol Abuse

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Alcohol abuse among TB patients

- All TB patients must be asked about history of alcohol use to identify alcohol abusers
- Harmful drinking habits and or alcohol dependence could negatively impact TB treatment outcomes.
- Alcohol abuse should be recorded in the TB patient record card in order for the HCW to manage an abusive patients accordingly.

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Management of alcohol abuse among TB patients

- Identify the risks and discuss the consequences of alcohol abuse
- Provide medical advice on the benefits and consequences of alcohol abuse
- Solicit patient commitment to reducing / stopping alcohol use
- Identify goals e.g. reduced drinking and eventual abstinence
- Give advice and encouragement to stop drinking
- Provide educational materials on alcohol cessation and abstinence.
- Screen for other co-morbidities particularly liver and kidney dysfunction

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TB and tobacco use

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Tobacco abuse among TB patients

- All TB patients should be evaluated for smoking and tobacco use.
- Identify smokers among new TB patients and enquire on duration of smoking, number of cigarettes smoked per day including previous history of smoking.
- This should be recorded in the TB patient treatment card for management and follow up.

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Management of Tobacco abuse among TB patients

- Discourage smoking by offering counseling and education on the dangers of smoking to themselves and others in their vicinity
- Explain that cessation will improve the patient's chances of getting cured; preventing TB related death and not spreading TB infection at home
- Positive benefits on smoking cessation should be highlighted such as saving money, gaining weight and health; protecting family members from the effects of second hand smoke and improved physical performance
- Address any barriers they may have to quitting smoking
- A smoking cessation plan with set timelines should be drawn out together with the patient who is willing to quit smoking
- Assess the progress of the smoking cessation plan at every appointment and record this in the TB patient record card

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Module 6

Drug Resistant (DR-TB)

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Introduction to DR-TB

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Objectives

At the end of the module the participants will:

1. Have an overview of DR-TB
2. Understand the definitions used
3. Be able to Classify DR-TB
4. Be able to make a diagnosis of DR-TB

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Epidemiology

- Globally, it is estimated that 480 000 cases developed MDR TB in 2014.
- An estimated 3.3% of new cases and 20% of previously treated cases have MDR-TB.
- Annually, about 150 000 die due to this form of tuberculosis
- About 9% of MDR-TB cases have XDR-TB
- In Kenya- an estimated 0.7% of new cases and 2.1% of previously treated TB cases are MDR TB

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REPUBLIC OF KENYA

MINISTRY OF HEALTH

Drug Resistance

- Occurs when bacteria with naturally occurring resistant mutations are selected by inadequate therapy of a specific antibiotic.
- This means the bacteria with resistant mutations are not killed or inhibited by this antibiotic.
- Clinically manifested by disease progression despite treatment, failure to achieve negative sputum or cultures, and/or treatment failure

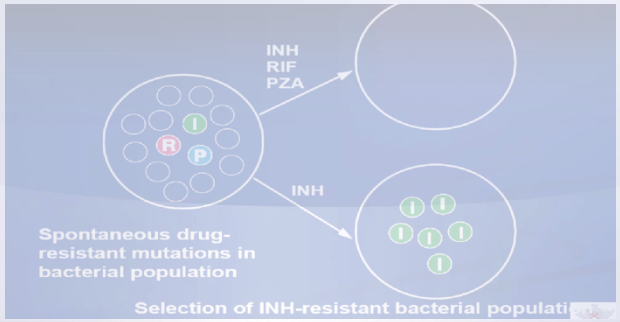
Causes of Drug Resistance

- There are two principal pathways leading to the development of active drug-resistant TB:
  - initial drug resistance
  - Primary
  - Acquired (secondary) drug resistance
- Primary resistance is as a result of an infection with a resistant strain
- Acquired drug resistance is the result of inadequate, incomplete or poor treatment quality that allows the selection of mutant resistant strain

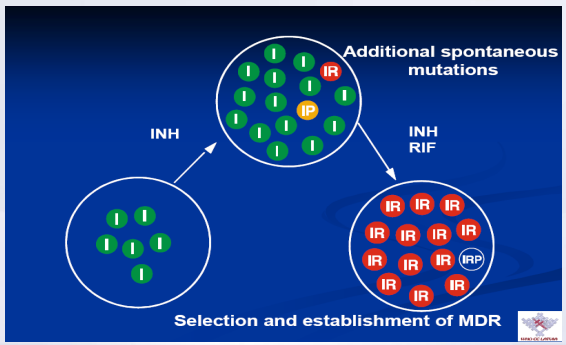
Causes of Acquired DR-TB

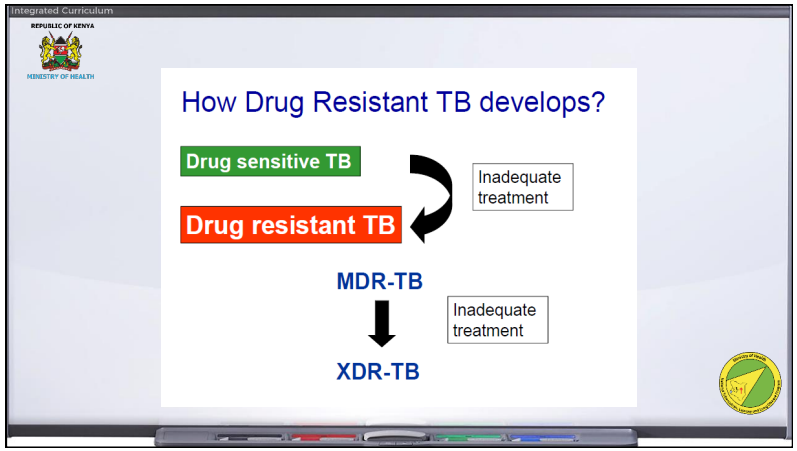
Health care provider factors	Drugs	Patients factors
• Absence of guidelines	•Inadequate supply	•Poor adherence or poor DOT
•Non compliance to guidelines	•Poor quality	•Lack of information
•Inadequate training	•Poor storage conditions	•Lack of transportation
•Poor or no treatment monitoring	• Wrong dose or combination	•Adverse effects
•Poorly organized or funded TB control programmes	•Poor regulations of medicines	•Social barriers
	•Unavailability of certain medicines	•Malabsorption

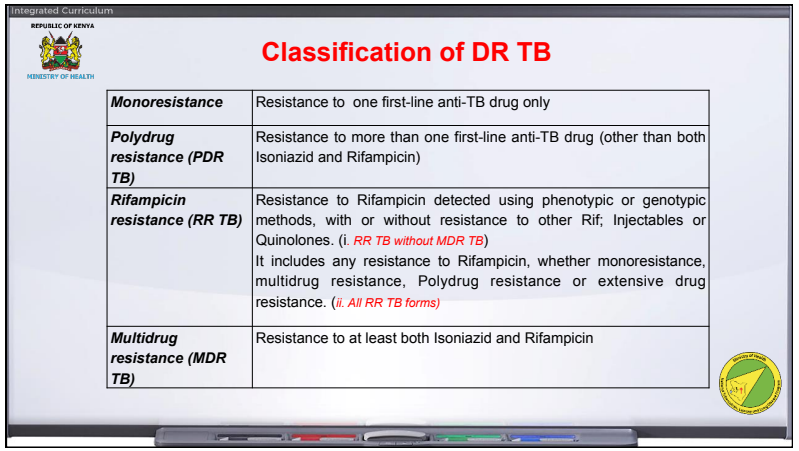
Development of Resistance: Selection of resistance

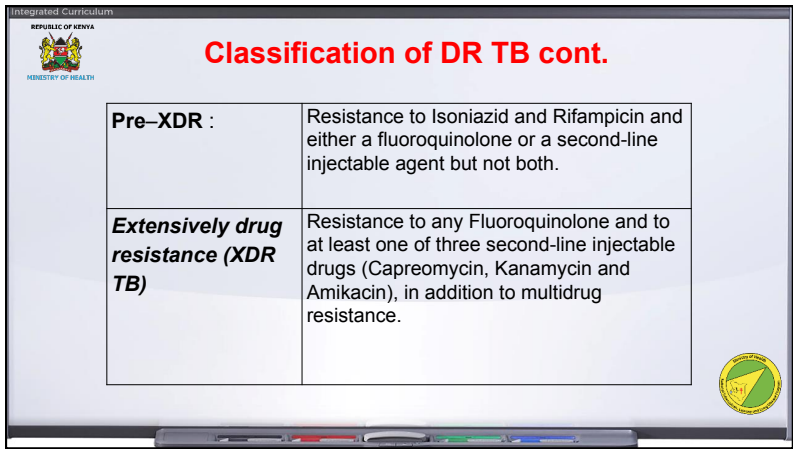


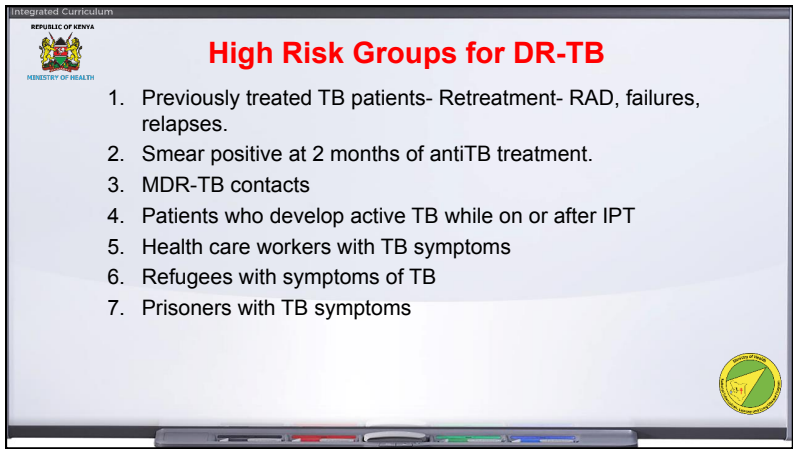
Amplification of resistance

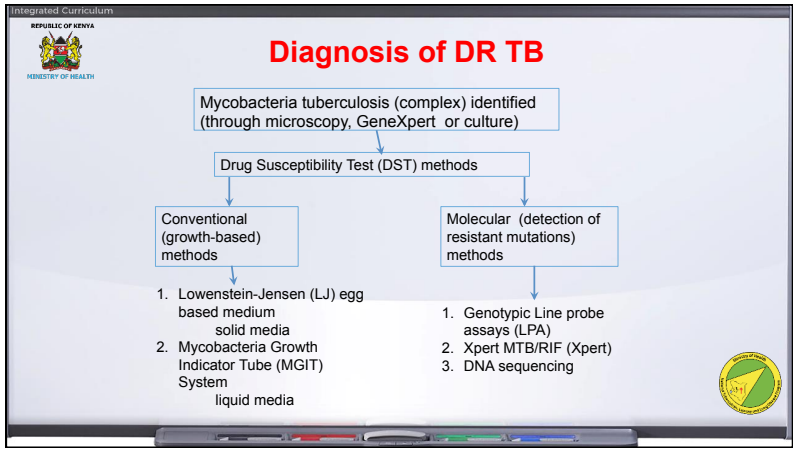



Integrated Curriculum
How Drug Resistant TB develops?
Drug sensitive TB
Inadequate treatment
Drug resistant TB
MDR-TB
Inadequate treatment
XDR-TB


Integrated Curriculum
Classification of DR TB
Monoresistance
Resistance to one first-line anti-TB drug only
Polydrug resistance (PDR TB)
Resistance to more than one first-line anti-TB drug (other than both Isoniazid and Rifampicin)
Rifampicin resistance (RR TB)
Resistance to Rifampicin detected using phenotypic or genotypic methods, with or without resistance to other Rif; Injectables or Quinolones. (i. RR TB without MDR TB)
It includes any resistance to Rifampicin, whether monoresistance, multidrug resistance, Polydrug resistance or extensive drug resistance. (ii. All RR TB forms)
Multidrug resistance (MDR TB)
Resistance to at least both Isoniazid and Rifampicin


Integrated Curriculum
Classification of DR TB cont.
Pre–XDR :
Resistance to Isoniazid and Rifampicin and either a fluoroquinolone or a second-line injectable agent but not both.
Extensively drug resistance (XDR TB)
Resistance to any Fluoroquinolone and to at least one of three second-line injectable drugs (Capreomycin, Kanamycin and Amikacin), in addition to multidrug resistance.


Integrated Curriculum
High Risk Groups for DR-TB
1. Previously treated TB patients- Retreatment- RAD, failures, relapses.
2. Smear positive at 2 months of antiTB treatment.
3. MDR-TB contacts
4. Patients who develop active TB while on or after IPT
5. Health care workers with TB symptoms
6. Refugees with symptoms of TB
7. Prisoners with TB symptoms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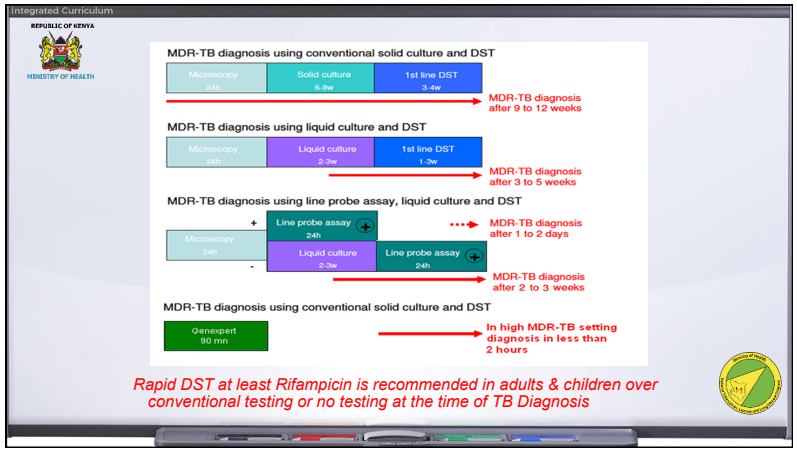
Diagnosis of DR TB
Mycobacteria tuberculosis (complex) identified (through microscopy, GeneXpert or culture)
Drug Susceptibility Test (DST) methods
Conventional (growth-based) methods
Molecular (detection of resistant mutations) methods
1. Lowenstein-Jensen (LJ) egg based medium solid media
2. Mycobacteria Growth Indicator Tube (MGIT) System liquid media
1. Genotypic Line probe assays (LPA)
2. Xpert MTB/RIF (Xpert)
3. DNA sequencing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MDR-TB diagnosis using conventional solid culture and DST
Microscopy 24h
Solid culture 6-8w
1st line DST 3-4w
MDR-TB diagnosis after 9 to 12 weeks
MDR-TB diagnosis using liquid culture and DST
Microscopy 24h
Liquid culture 2-3w
1st line DST 1-3w
MDR-TB diagnosis after 3 to 5 weeks
MDR-TB diagnosis using line probe assay, liquid culture and DST
+
Line probe assay 24h
MDR-TB diagnosis after 1 to 2 days
Microscopy 24h
-
Liquid culture 2-3w
Line probe assay 24h
MDR-TB diagnosis after 2 to 3 weeks
MDR-TB diagnosis using conventional solid culture and DST
Genexpert 90 mn
In high MDR-TB setting diagnosis in less than 2 hours
Rapid DST at least Rifampicin is recommended in adults & children over conventional testing or no testing at the time of TB Diagnosis


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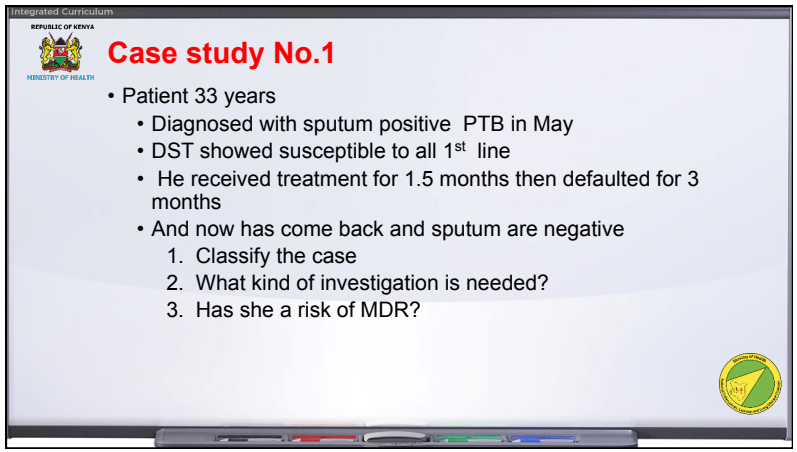
Case Studies on classification and diagnosis of DR-TB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Case study No.1
• Patient 33 years
• Diagnosed with sputum positive PTB in May
• DST showed susceptible to all 1st line
• He received treatment for 1.5 months then defaulted for 3 months
• And now has come back and sputum are negative
1. Classify the case
2. What kind of investigation is needed?
3. Has she a risk of MDR?

Integrated Curriculum

Case study No.2

- Patient 50 years
  - Alcohol abuser
  - TB diagnosed first time
  - Smear positive
  - He has chronic pancreatitis, diabetes and frequent diarrhea
  - Treatment with 1st line poorly tolerated
  - Sputum still positive at 2 months
  - DST shows susceptibility to 1st line
  - At month 5, still sputum positive, DST shows resistant to R and H
    1. Classify the case
    2. What may be the cause of resistance in this patient?

Integrated Curriculum

Case study No.3

- Patient 42 years
  - Completed TB treatment 2 years ago
  - Has come back with a cough
  - Sputum positive on microscopy
  - GeneXpert reports RR
  - Culture reports not yet received
    1. Classify the resistance pattern

Integrated Curriculum

Case study No. 4

- Patient 20 years
  - RSOn TB treatment
  - Sputum positive at month 5
  - GeneXpert reports RS
  - Culture reports resistance to H, Z , E
    1. Classify the resistance pattern

Integrated Curriculum

Case study No.6

- Patient 28 years
  - On MDR TB treatment
  - Culture converted at month 3
  - Positive at month 5 and 6
  - DST reports resistance to FQ
    1. Classify the resistance pattern
    2. What may be the cause of Resistance?

Integrated Curriculum

SUMMARY

- Definitive diagnosis of drug-resistant TB requires the detection of Mycobacterium tuberculosis bacteria and determination of resistance to anti-TB drugs using GeneXpert, LPA (HAIN) and culture and DST respectively.
- Different patterns of Drug resistant TB exist (Mono, Poly, RR, MDR, Pre-XDR and XDR)

Integrated Curriculum

Patient Work Up for DR-TB

Integrated Curriculum

Objectives

- At the end of the session the participant should be able to:
  - Describe the evaluation of patients before starting a drug resistant TB regimen
  - Describe the role of the PMDT clinical team

Integrated Curriculum

Pre-treatment Evaluation

- Confirm diagnosis of DR-TB
- Education and counselling with the patient
- Obtain a thorough history and perform a physical exam
- Obtain informed treatment consent
- Conduct a home visit and carry out an infection control assessment, family counselling, IPC education and contact screening
- Drugs to cater for a full course of treatment should be available
- Establish a DR TB management clinical team
  - * Treatment will be started once the above conditions are met

Integrated Curriculum

Counseling

- Discuss the following:
  - Causes of TB/DR TB
  - Mode of Transmission
  - Duration and administration of treatment
  - Importance of adherence
  - Adverse Drug Reactions
  - Importance of HIV and pregnancy testing
  - Infection Prevention and control
  - Nutrition and psychosocial support services available
  - Willingness to enroll in a nearby facility

Integrated Curriculum

Initial Evaluation of DR TB patients

A. History

1. Demographic Data
2. TB History
   - Date of previous TB diagnosis, type of TB, start and end dates of treatment, history of HIV co-infection (date of diagnosis, treatment regimen and date of ART initiation), Microscopy, culture and DST results, Adverse effects & complications
3. Past Medical and social History
   - LMP & method of contraception, Previous and current co-morbidities, use of medication, Alcohol, drug & tobacco use among others
4. DR TB Contacts
   - Treatment history of contacts, Current status, DST data

Integrated Curriculum

Initial Evaluation of DR TB patients

B. Physical Examination

1. Vital signs, calculate BMI and Z-scores for children
2. General examination looking for signs of advanced disease or extra-pulmonary disease

C. Radiological/Laboratory/ Clinical Tests

- Baseline chest X-Ray,
- Lab Tests including HIV test, pregnancy test, renal function and liver function tests
- Audiometry (hearing test),
- ECG .

Integrated Curriculum

DR-TB Management Clinical Teams

Composition:

- CTLC , CASCO, Clinician (Physician/MO) , SCTLC, SCASCO, Pharmacist , DOT Nurse, Social Worker, Public Health Officer, Nutritionist, Laboratory Technologist

Roles:

- Overall responsibility of managing DR TB in their regions
- Recommend initiation of treatment and discharge
- Follow up and review complex cases as need arises
- Co-ordinate referrals of DR TB patients to and from their counties
- Ensuring adequate and consistent commodity supply in their regions

** The clinical team should meet at least once a month to discuss the progress and challenges during the course of treatment*

The clinical team must also review patients every 2 weeks for month 1, then monthly while on intensive phase and quarterly while on continuation phase

Integrated Curriculum

Summary

- All DR-TB patients will be subjected to a pre-treatment evaluation & counselling session
- DR-TB patient's will be managed by a PMDT team
- All DR-TB patients will receive treatment as DOTS
- Carry out and document clinical and laboratory tests

Integrated Curriculum

Principles of DR-TB Treatment

Integrated Curriculum

Objectives

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

1. Describe Treatment models for DR-TB
2. Identify second line anti-TB drugs for management of DR-TB
3. Familiarise with the DR-TB treatment regimens
4. Understand DR-TB patient follow up
5. Familiarise with the DR-TB treatment outcomes

Integrated Curriculum

Treatment delivery models

Isolation	Ambulatory Facility based	Ambulatory Community based
Preferred for: • Refugees • Complications necessitating admission • Mobile populations / Nomadic • Non-adherence • Very sick patient	· Patient lives nearby. Will take less than 1-2 hours to travel to the facility · General condition of the patient is stable	· Patient lives far from the facility. · General condition of the patient is stable

All the above may also be selected based on mdr tb management clinical team's decision

Integrated Curriculum

Principles of MDR/RR treatment

- When designing a DR-TB regimen, the following should be considered:
  - Must have at least 5 drugs
  - Include Pyrazinamide
  - Include an injectable
  - Include a quinolone
  - Drug resistance pattern
  - Previous patient treatment history

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Multi-drug Resistant TB (MDR-TB) & RR TB

First-line: ~~INH~~ (H), ~~RIF~~ (R), EMB (E), PZA (Z)

Second-line: Injectable — SM, KM, AMK, CM; Quinolone — OFLOX, CIPRO, MOXI; Other 2nd-line — ETO/PTO, CS, PAS

Third-line: Other agents — Bedaquiline, Delaminid, Linezolid, AMX/CLV, Clofazimine, Clarithromycin, Carbapenems

- Resistant to the most effective first-line drugs (H & R)
- Requires 20 to 24 months of treatment given under DOTs
- Use Standardized regimen : 8 months Km-Pto-Lfx-Cs-Z / 12 months Pto-Lfx-Cs-Z

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Treatment Phases

- Injectable phase should last at least 8 months
  - Switch to continuation phase only when three most recent consecutive culture results taken at least 30 days apart, remain culture negative during the intensive phase
- Continuation phase should last at least 12 months

* ***Repeat first and second line DST for patients who remain sputum smear or culture positive at month 3 and 6 or in case of culture reversion***

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Management of Mono and Poly drug Resistant TB

First-line: ~~INH~~ (H), RIF (R), ~~EMB~~ (E), PZA (Z)

Second-line: Injectable — SM, KM, AMK, CM; Quinolone — OFLOX, CIPRO, MOXI; Other 2nd-line — ETO/PTO, CS, PAS

Third-line: Other agents — Bedaquiline, Delaminid, Linezolid, AMX/CLV, Clofazimine, Clarithromycin, Carbapenems

- Resistance to either one (mono) or more than one (poly) 1st line anti-TB drugs other than both INH and RIF

* ***Different resistant patterns will require unique treatment regimen based on DST results***

Integrated Curriculum

Regimens

Pattern of Drug Resistance	Regimen	Duration
Rifampicin Resistance	8 Km-Lfx-Cs-Pto-Z/12 Lfx-Cs-Pto-Z	20months
Isoniazid **and** Ethambutol **and** Pyrazinamide ± streptomycin	3 Km-Lfx-R-Z/15 LFX-R-Z	15 months
Isoniazid **and** Pyrazinamide	3 Km-Lfx-R-Z/15 LFX-R-Z	15 months
Isoniazid **and** Ethambutol	3 Km-Lfx-R-Z/15 LFX-R-Z	15 months
Isoniazid ± Streptomycin	R/Z/E/Lfx	9 months

Streptomycin Monoresistance should be treated with drug susceptible regimen and registered in the drug susceptible TB register (TB 4)

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Management of XDR TB

- XDR-TB is a public health emergency - requires prompt diagnosis and treatment, appropriate isolation, and aggressive contact tracing
- XDR-TB is a curable disease
- Suspect XDR-TB in patients who are:
  - Failure on 2nd line TB treatment
  - Close contact of a known XDR-TB
  - HIV +ve individuals in high MDR TB prevalent

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Extra-drug Resistant TB (XDR-TB)

First-line: ~~H~~, ~~R~~, EMB (E), PZA (Z)

Second-line:
- Injectable: ~~KM~~, AMK, CM
- Quinolone: ~~OFLOX~~, ~~LVFLOX~~, MOXI
- Other 2nd-line: ETO/PTO, CS, PAS

Third-line — Other agents: Bedaquiline, Delaminid, Linezolid, AMX/CLV, Clofazimine, Clarithromycin, Carbapenems

- Resistance to any flouroquinolone & any 2nd line injectable, in addition to Rifampicin and Isoniazid
- All XDR-TB patients should receive an individualized treatment regimen based on the second line DST results
- Bedaquiline & Delaminid will be used after guidance from the National DR TB clinical team

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Table 6. Medicines recommended for the treatment of RR-TB and MDR-TB[a]

Group A. Fluoroquinolones[b]		Levofloxacin	Lfx
		Moxifloxacin	Mfx
		Gatifloxacin	Gfx
Group B. Second-line injectable agents		Amikacin	Am
		Capreomycin	Cm
		Kanamycin	Km
		(Streptomycin)[c]	(S)
Group C. Other core second-line agents[b]		Ethionamide / prothionamide	Eto / Pto
		Cycloserine / terizidone	Cs / Trd
		Linezolid	Lzd
		Clofazimine	Cfz
Group D. Add-on agents (not part of the core MDR-TB regimen)	**D1**	Pyrazinamide	Z
		Ethambutol	E
		High-dose isoniazid	H[h]
	D2	Bedaquiline	Bdq
		Delamanid	Dlm
	D3	*p*-aminosalicylic acid	PAS
		Imipenem–cilastatin[d]	Ipm
		Meropenem[d]	Mpm
		Amoxicillin-clavulanate[d]	Amx-Clv
		(Thioacetazone)[e]	(T)

Extensively-drug Resistant TB (XDR-TB)

- Resistance to any flouroquinolone & any 2nd line injectable, in addition to Rifampicin and Isoniazid
- All XDR-TB patients should receive an individualized treatment regimen based on the second line DST results
- Bedaquiline & Delamanid will be used after guidance from the National DR TB clinical team

Bedaquilline and Delamanid

- Novel agents developed to treat MDR-TB
- Conditionally approved for use
- Increased rates of cure
- Need to monitor patients with regular ECGs

Indications for Bedaquiline & Delamanid

1. Pre-XDR and XDR TB patients
2. In MDR TB, when group 4 drugs are compromised or severely toxic
3. Severe intolerance to second line injectable
4. Contraindications to any second line drugs
5. Patient who have failed an MDR-TB regimen

How to Construct an individualised MDR-TB Treatment Regimen

- In 20 month regimen
- Select
  - one drug (I) GRP A:
  - One drug from GRP B: and
  - 2 Drugs From GRP C
  - then Z from D1

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Monitoring of Treatment

- All doses of DR-TB medicines will be directly observed daily by a Health Care Worker
- At every DOT encounter:
  - Inquire about side effects or any other problems
  - Patients should be observed swallowing each dose of medication and monitor for 30 minutes
  - If a patient vomits, repeat the dose
- Patient shall be seen by a clinician:
  - **During the intensive phase**: Every two weeks in the first month of treatment and then monthly. Daily if the patient is hospitalized.
  - **During the continuation phase**: Every 3 months and when called upon by the DOT worker

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Clinical and Lab follow up

Month	Baseline	1	2	3	4	5	6	7	8	9	10	11	12	15	18	21
Clinical review	X	Every 2 weeks	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Audiometry	X	X	X	X	X	X	X	X	X							
Weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Height	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Smear	X	X	X	X	X	X	X	X	X	X	X	X	X	Monthly till treatment completion		
Culture	X	X	X	X	X	X	X	X	X	X	X	X	X	Monthly till treatment completion		
1st line DST	X						X									
2nd line DST	X			X			X									
LFTs (AST, ALT, Bilirubin)	X	X	X	X			X			X			X	X	X	
Creatinine Potassium, Magnesium	X	X	X	X	X	X	X	X	X							
Full Hemogram	X			X			X						X		X	
CD4	X						X						X		X	
RBS	X															
Pregnancy Test	X															
CXR	X						X						X		X	
TSH	X		X				X						X			
ECG (Bdq)	X	X	X	X	X	X	X	X	X	X						

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DR TB Treatment failure

- Suspect treatment failure when:
  - Clinical condition deteriorates
  - Persistently positive smears or a positive culture (up to month 6 for MDR TB and 3 months for PDR TB)
  - Reversion to culture or smear positive after they have been negative

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Managing DR TB Treatment failure

- Convene a clinical management meeting
- Assess for adherence
- Confirm regimen and dosages
- Assess for co-morbidities e.g. chronic diarrhoea, HIV , diabetes , malignancies e.t.c.
- Review all DST reports and repeat 1st and 2nd line DST

*__DO NOT__ add single drugs to the failing regimen

** Redesign the regimen based on resistant pattern and patient history

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Definitions

- **Conversion (to negative):** This is when two consecutive cultures, taken at least 30 days apart, are found to be negative. The specimen collection date of the first negative Culture is used as the date of conversion

- **Reversion (to positive):** This is when two consecutive cultures taken at least 30 days apart, after an initial negative are found to be positive
  - ❖ For the purpose of defining Treatment failure, reversion is considered only when it occurs in the continuation phase.

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Treatment Outcomes

Cured	DRTB patient who completes treatment with three or more consecutive negative cultures taken at least 30 days apart after the intensive phase.
Treatment completed	DRTB patient who has completed Treatment as recommended Without evidence of failure BUT no record that three or more Consecutive cultures taken at least 30 days apart are negative after the intensive phase.
Death	A patient who dies from any cause while on DR-TB treatment.
Loss to Follow Ups	A patient who interrupts DR-TB treatment for two or more consecutive months.
Treatment failure:	Treatment terminated or need for permanent regimen change of at least two anti-TB drugs because of: • Lack of conversion by end of the intensive phase; or • Bacteriological reversion in the continuation phase after conversion to negative • Evidence of additional acquired resistance to FQ or injectable drugs; or Adverse drug reactions
Transfer out:	A patient who has been transferred to a reporting unit in another County and for whom the treatment outcome is unknown.
Not evaluated	A patient for whom no treatment outcome assigned. (This includes cases "transferred out" to another treatment unit and whose treatment outcome is unknown).
Treatment success	The sum of Cured and Treatment completed.

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Shorter MDR TB Regimen

- 'Bangladesh' Regimen – 90% cure rates
- Adopted in countries across Western and Southern Africa
- Regimen
  - **Intensive phase -** ***4-6(Km, Mfx, Pto, Cfz, High-dose-I, E, Z)***
  - **+**
  - **Continuation Phase -** ***5(/Mfx, Cfz, E, Z)***

- Will be adopted in Kenya in July 2017

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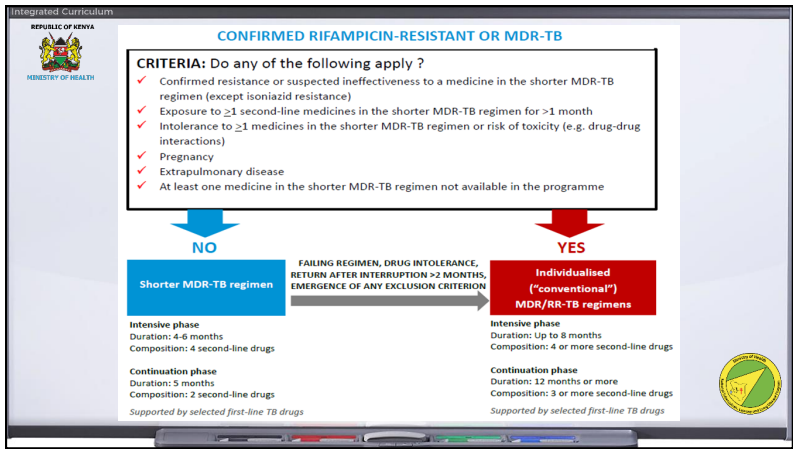

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Remember

- The best chance to cure the patient is the first chance

- ***Give the best possible treatment the first time (do not "save" good drugs to use later)***

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Management of DR-TB in special Populations

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Objectives:

- **By the end of this unit the participant will be able to manage;**
  - DR -TB in contacts
  - DR-TB in Children
  - DR-TB in Pregnancy and Breastfeeding
  - DR-TB/HIV co-infection
  - DR-TB in Diabetes, Renal and Liver Disease

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Management of DRTB Contacts

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Definition of contacts

- Close contacts of DR-TB patients are people living in the same household, or spending many hours a day together with the patient in the same indoor living space.
- The available data indicate that close contacts of DR-TB patients who develop active TB most commonly have drug-resistant disease.
- Contact investigation of DR-TB should be given high priority

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Contact Investigation

- The prevalent burden of active TB among close contacts of MDR-TB cases represents a backlog of untreated, chronic MDR-TB disease and intra-household transmission.
- Prevalent cases identified through contact investigation could be source cases rather than secondary cases

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Managing Contacts(Adults & Children)

- Do contact invitation/tracing
- Evaluate for active disease
  - Thorough history taking
  - Physical examination

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Managing contacts cont.

- If active disease present or symptomatic
  - Do GeneXpert
    - Start DR-TB treatment based on resistance pattern of index case as you await DST results
    - Follow the GeneXpert algorithm for further guidance

**Every effort should be made to confirm DR TB by culture and DST in children. However, children with active TB may be smear and culture negative posing a challenge in confirming a diagnosis of MDR or XDR*

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Managing contacts cont.

- If no evidence of active TB or asymptomatic, continue 3 monthly symptom based screening until 12 months after index patient completes treatment
- If symptoms persist and culture is negative, consult with the clinical team and carry out further investigations e.g. Bronchoscopy

Children with active TB who are household contacts of a confirmed MDR-TB or XDR-TB patient should be considered to have DR-TB, even if smear and culture are negative.

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Chemoprophylaxis

- WHO does not recommend universal use of SLDs for chemoprophylaxis among contacts
- Child contacts of smear positive MDRTB patients should NOT receive IPT

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Summary

- Contacts of MDR-TB patients are likely to be infected with MDR-TB, but the probability varies in different settings.
- Careful follow-up of contacts of MDR-TB is mandatory to determine if active disease develops.
- Contact follow-up schedule: Initial, 3months, 6months, 12months and 24 months. The contacts should be encouraged to report immediately any symptoms in between the scheduled screening visits

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DR-TB in Children

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Case Study

- **A mother who has been on treatment for MDR-TB for 9 months**
  - Has been smear- and culture-negative for 6 months
  - She brings her child to the health centre for evaluation. The child is 14 months old and weighs 6.9 kg
  - She had BCG at birth and now presents with 4 months of failure to thrive, poor appetite and intermittent low grade fever for 3 months
  - Tuberculin (PPD) skin testing is 16 mm, and chest radiography reveals hilar adenopathy but no infiltrates
  - There are no other known TB contacts
  - TB was first diagnosed in the mother shortly after giving birth to the child; she is a patient who had both Category I and II treatment failure

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Case Study

- **Her resistance pattern from the start of treatment for DR-TB is: Resistance to:**
  - H,R,Z,E,S;Susceptible to Amk-Cm-Ofx
  - DST of PAS, Eto and Cs were not done because the laboratory cannot guarantee reproducibility of these agents
- **Question**
  - What advice and regimen do you prescribe for the child?

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Multidrug-resistant TB in Children

- Mainly due to transmission from a MDR-TB source case

Suspect MDR-TB in a child if:

- A DR TB contact
- Is a contact of a previously treated TB case
- A child with TB not responding to 1st line therapy despite adherence
- a child previously treated for TB present with recurrent disease.
- If the community in which the child resides (or had resided) has a high prevalence of drug-resistant tuberculosis.

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Diagnosis of DR TB in children

- Bacteriologic confirmation of TB is more difficult in children
  - Children have lower bacillary load. Hence the majority of children do not have positive smears or cultures.
  - Diagnosis is based on clinical and radiographic findings.
  - The line between infection and sickness is not always readily apparent.
- Aggressive methods (e.g. induced sputum, gastric aspirate, bronchoscopy) may be used to obtain samples from children.
- Often there is no culture to perform DST.

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Principles of DR TB treatment in children

- Regimen ,DOTs plus and follow up is similar to adults.
- Empiric treatment using source regimen for DR-TB should be initiated promptly
- Drug dosages should be based on body weight
- In culture-negative children with DR-TB, clinical criteria can be used to determine response to therapy and the duration of the intensive and continuation phases.
- The DR-TB clinical teams should be involved in decisions made about paediatric cases.
- The benefit of fluoroquinolone far outweighs the risk, and should be part of every DR-TB regimen.
- Counsel the child's caregiver at every visit, to provide support, advice about adverse events and the importance of compliance and completion of treatment

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Summary

- Transmission
  - usually occurs at the household level
  - Leads to primary cases in children
- Try as much as possible to get bacteriological confirmation
- Higher rate of disseminated and extrapulmonary cases
- Treat as per the DST of the source case

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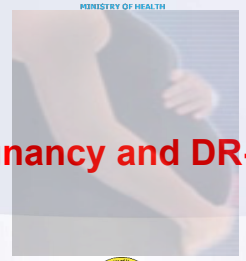
Pregnancy and DR-TB



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Managing MDR TB in pregnancy

- If an MDR patient is pregnant, evaluate gestational age and severity of the drug-resistant TB.
- Discuss the risks and benefits of treatment with the primary goal of smear conversion to protect the health of the mother and child, both before and after birth.

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Approach to DR TB in pregnancy

1. Start treatment of drug resistance in second trimester or sooner if condition of patient is severe.
   - The decision to postpone the start of treatment should be agreed by both patient and doctor after analysis of the risks and benefits
2. Avoid injectable agents (Aminoglycosides -due to toxic effects to the developing foetal ear). Capreomycin has a lower risk of ototoxicity and is the drug of choice if an injectable agent cannot be avoided
3. Avoid Eto&Pto and instead use PAS. Eto/Pto can increase the risk of nausea and vomiting associated with pregnancy, and teratogenic effects have been observed in animal studies.

**** Pregnancy is not a contraindication to the treatment of MDR-TB***

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DR TB and Breastfeeding

- Infant formula should be substituted for breast milk because small quantities of the drugs will be passed into the milk
- Clinicians and parents should agree to breastfeeding when the formula is not a feasible option
- The mother and her baby should not be completely separated, the care of the infant should be left to family members if the mother is sputum smear positive until she becomes sputum smear negative
- The mother should be provided with an N-95 respirator if close infant – mother contact cannot be avoided or a surgical mask if no N-95 mask, until she converts

****Breastfeeding mothers should receive full course of DR TB treatment***

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DR-TB/HIV Co-management

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Challenges in Treatment of DR-TB in HIV-infected patients

- High number of drugs per day administered over prolonged periods
- Overlap or additive of adverse reactions
- Immune reconstitution syndromes may occur
- Higher mortality

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Potential overlying and additive toxicities of ART and anti-tuberculosis therapy

TOXICITY	ANTIRETROVIRAL AGENT	ANTITUBERCULOSIS AGENT
Peripheral neuropathy	**D4T, ddI, ddC**	**Lzd, Cs, H,** Amino glycosides, Eto/Pto, E
Central nervous system (CNS) toxicity	**EFV**	**Cs,** H, Eto/Pto, Fluoroquinolones
Nephrotoxicity	TDF	Aminoglycosides, Cm
Depression	**EFV**	**Cs,** Fluoroquinolones, H, Eto/Pto
Headache	**AZT, EFV**	**Cs**
Nausea and vomiting	**RTV, D4T,** NVP, and most others	**Eto/Pto, PAS, H, E, Z** and others

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Diabetes Mellitus, Liver & Renal insufficiency in DR TB

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Diabetes and DR TB

- **Medical follow-up**: Diabetes must be managed closely throughout treatment through a clinical team every month.
- Diabetes mellitus may potentiate the adverse effects of anti-TB drugs
  - Commonly Renal dysfunction and peripheral neuropathy
  - Eto/Pto may make it more difficult to control insulin levels hence may require increase d dose of insulin.

•**Creatinine and potassium** should be monitored weekly for the first month and then at least monthly thereafter because the injectables cause nephrotoxicity. For deranged results, seek physician.

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Renal Insufficiency and DR-TB

- Renal insufficiency complicates the management of TB disease because some anti-TB drugs are cleared by the kidneys.
- Alteration in dosing of anti-TB drugs is commonly necessary in patients with renal insufficiency (renal clearance of < 30 ml/ min) or end-stage renal disease (ESRD) requiring hemodialysis

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Drug	Frequency	Recommended dose and frequency for patients with Creatinine clearance < 30 ml/min or for patients receiving haemo-dialysis
Isoniazid	No change	300mg once daily or 900mg 3* wk.
Rifampicin	No change	600 mg once daily
Pyrazinamide	Yes	25-35 mg/kg/dose 3 * wk.
Ethambutol	Yes	15-25 mg/kg 3* wk.
Ofloxacin	Yes	600-800mg/dose 3 * wk.
Levofloxacin	Yes	750-1000mg/dose 3 * week
Moxifloxacin	No change	400mg once daily
Cycloserine	Yes	250mg OD or 500mg 3* wk.
Prothionamide	No change	15-20mg/kg/day
Para Aminosalicilic acid	No change	4g/dose twice daily
Capreomycin	Yes	12-15 mg/kg/dose 2 or 3 * wk.
Kanamycin	Yes	12-15 mg/kg/dose 2 or 3 * wk.
Amikacin	Yes	12-15 mg/kg/dose 2 or 3 * wk.
Clofazimine	No change	200-300mg daily
Amoxicillin/Clavulanate	Yes	1g based on amoxicillin component daily

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Liver Disease and DR-TB

- The treatment of DR-TB disease in patients with unstable or advanced liver disease is problematic for several reasons:
  - The likelihood of drug-induced hepatitis is greater;
  - The implications of drug-induced hepatitis for patients with marginal hepatic reserve are potentially serious, even life-threatening; and
  - Fluctuations in the indicators of liver function related to the pre-existing liver disease can confound monitoring for drug-induced hepatitis

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Management of adverse drug effects to Second line Anti-TB drugs

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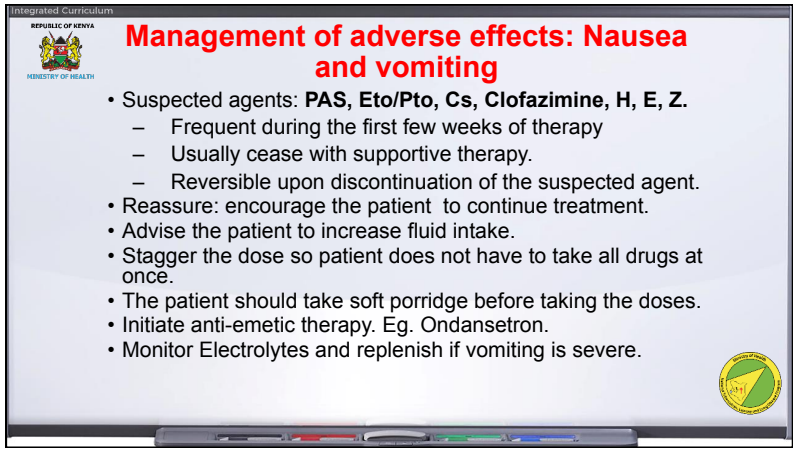
Objectives

At the end of this unit, the participants will be familiar with:

1. Practical approach to address adverse reactions
   Be familiar with adverse reactions
   Monitoring in a systematic manner
   Patients education and support
2. Management of adverse reactions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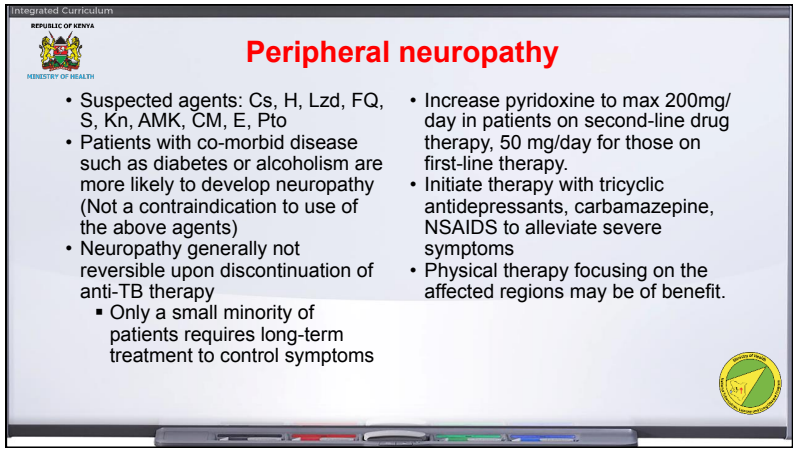
Management of adverse effects: Nausea and vomiting
• Suspected agents: PAS, Eto/Pto, Cs, Clofazimine, H, E, Z.
– Frequent during the first few weeks of therapy
– Usually cease with supportive therapy.
– Reversible upon discontinuation of the suspected agent.
• Reassure: encourage the patient to continue treatment.
• Advise the patient to increase fluid intake.
• Stagger the dose so patient does not have to take all drugs at once.
• The patient should take soft porridge before taking the doses.
• Initiate anti-emetic therapy. Eg. Ondansetron.
• Monitor Electrolytes and replenish if vomiting is severe.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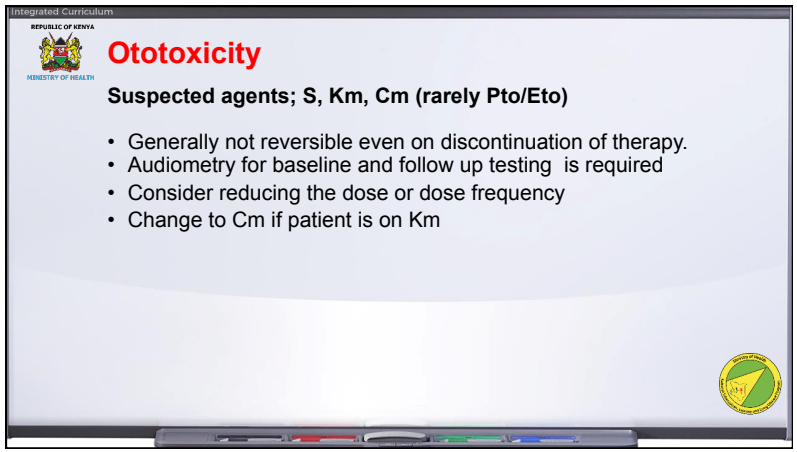
Peripheral neuropathy
• Suspected agents: Cs, H, Lzd, FQ, S, Kn, AMK, CM, E, Pto
• Patients with co-morbid disease such as diabetes or alcoholism are more likely to develop neuropathy (Not a contraindication to use of the above agents)
• Neuropathy generally not reversible upon discontinuation of anti-TB therapy
▪ Only a small minority of patients requires long-term treatment to control symptoms
• Increase pyridoxine to max 200mg/ day in patients on second-line drug therapy, 50 mg/day for those on first-line therapy.
• Initiate therapy with tricyclic antidepressants, carbamazepine, NSAIDS to alleviate severe symptoms
• Physical therapy focusing on the affected regions may be of benefit.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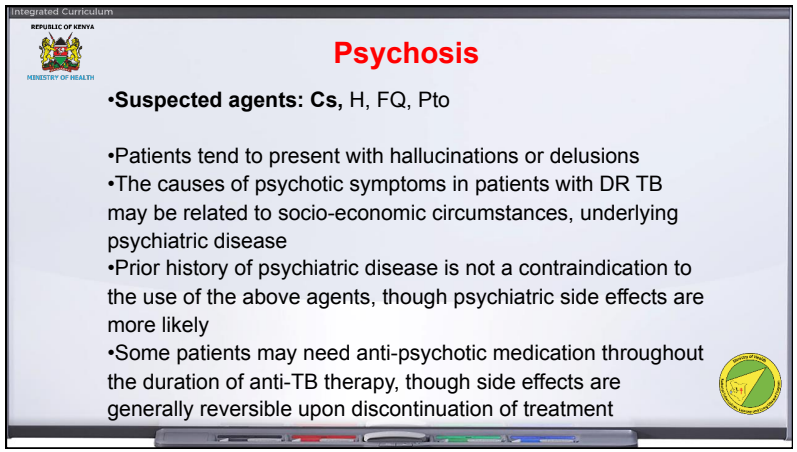
Ototoxicity
Suspected agents; S, Km, Cm (rarely Pto/Eto)
• Generally not reversible even on discontinuation of therapy.
• Audiometry for baseline and follow up testing is required
• Consider reducing the dose or dose frequency
• Change to Cm if patient is on Km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Psychosis
•Suspected agents: Cs, H, FQ, Pto
•Patients tend to present with hallucinations or delusions
•The causes of psychotic symptoms in patients with DR TB may be related to socio-economic circumstances, underlying psychiatric disease
•Prior history of psychiatric disease is not a contraindication to the use of the above agents, though psychiatric side effects are more likely
•Some patients may need anti-psychotic medication throughout the duration of anti-TB therapy, though side effects are generally reversible upon discontinuation of treatment

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Management of Psychosis

- Initiate anti-psychotic agents; Haloperidol (Serenase) coadministered with benzhexol (Artane) to prevent extra-pyramidal side-effects
- Stop Cycloseresine. Re-introduce at lower doses once psychotic symptoms have improved.
- Some patients will not be able to tolerate the re-introduction of Cycloseresine and should be replaced with PAS.

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Hepatitis

- Suspected agents: Z, R, H, Pto/Eto, PAS, E, FQ

- Generally reversible upon discontinuation of suspected agent.
- History of prior hepatitis should be carefully analyzed to determine most likely causative agent.

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Management of Hepatitis

- Exclude chronic viral hepatitis and alcohol induced hepatitis in those with elevated LFTs
- Avoid pyrazinamide in those with pre-existing liver disease
- Drug induced hepatitis usually occurs between 3-8 months

  - If liver enzymes are elevated but less than 5 times normal, continue anti-TB therapy. Do LFTs each week.
  - If liver enzymes greater than 5 times normal, stop all anti-TB medications. Repeat LFTs weekly. Re- introduce treatment once the LFTs are normal.

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Hypothyroidism

- Suspected agents: PAS, Pto / Eto (particularly when given in combination)

- Monitor TSH during treatment and if suggestive symptoms
  - TSH level is greater than 10 → symptomatic hypothyroidism is likely → therapy should be given.
  - Administer oral levothyroxine 50-100 mcg/day
- *Hypothyroidism is reversible upon discontinuation of PAS and/or Eto, i.e., the TSH level normalizes after 2-3 months.*

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Renal Failure

Suspected agents: S, Km, Am, Cm

- Renal impairment may be permanent following treatment with the above agents
- Suggested management strategies
  1) Rule out other causes of nephropathy.
  2) Follow serum creatinine and electrolytes closely.
  3) Discontinue suspected agent
  4) Consider switching injectable agent to Cm

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Arthralgia

Suspected agents: Z, FQs

- Symptoms of arthralgia diminish over time even without intervention

1) Consider initiating therapy with non-steroidal anti-inflammatory drugs (ibuprofen 400-800 mg TDS)

2) Initiate exercise regimen

3) In severe cases Pyrazinamide can be discontinued and substituted.

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Diarrhea

- Suspected agents: PAS, Pto / Eto
- Real diarrhoea?
  - Stool is truly watery
  - More than three or four times a day.
- Mild diarrhoea:
- Severe diarrhea, particularly if accompanied by bloody stools, severe abdominal pain, or fever greater than 38.5 °C:
  - Consider other causes such as acute bacterial enteritis, or pseudo-membranous colitis related to flouro-quinolone

- Management
  - Check electrolytes
  - Give rehydration salts
  - For severe diarrhea
    - Loperamide 4 mg by mouth initially
    - Follow with 2 mg after each loose stool
    - Maximum of 10 mg per 24 hours
    - Encourage fluid intake.

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Electrolyte loss

- **Suspected agents: Cm, Km, Amk, S, PAS, (rarely Pto / Eto)**
- Consider other potential causes of electrolyte deficiency, treat if necessary:
  - Vomiting
  - Diarrhoea
  - Endocrinopathy

- Electrolyte abnormalities are typically reversible with discontinuation of therapy
- Untreated hypomagnesaemia may lead to a syndrome of "resistance" to correction of hypokalemia

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Management of Electrolyte loss

- Measure serum electrolytes:
  - Before treatment
  - Monthly thereafter beginning 7-10 days after the baseline specimen is collected
- Clinical signs of electrolyte derangement (i.e., muscle weakness, cardiac arrhythmias) should prompt immediate testing

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Electrolyte loss

- Mild-to-moderate hypokalemia (i.e., 2.5 < K < 3.5 mEq/L, asymptomatic) and mild hypomagnesaemia (1.4 < Mg < 1.8 mg/dl, asymptomatic):
  - Treated with oral supplements (40-80 mEq potassium chloride, 420-840 mg magnesium Sulphate)
  - Repeat monitoring in 24-48 hours.
- Where it is not possible to measure magnesium:
  - If a patient has hypokalemia it should be assumed that he also has some degree of hypomagnesaemia

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Potassium Replacement

Potassium level meq/L	Dose KCl in meq	Frequency of monitoring (sooner if patient has vomiting/diarrhoea)
Above 3.6	None	Monthly
3.4-3.6	20-40	monthly
3.0-3.3	60	weekly
2.7-2.9	80	One to 2 days
2.4-2.6	80-120	daily
2.0-2.3	10meq/hr IV and 80 P.O every 6-24 hrs	Hourly after infusion until serum K^+ is > 2.8 meq/L
< 2	10 meq/hr IV and 100 P.O every 6 hours	Hourly after infusion until serum K^+ is > 2.8 meq/L. Consider withholding injectable until > 2.4

Admission advised if K+ is <2.6 or with ECG changes

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Depression

Suspected agents; Cs, FQ and H. But usually due to socio-economic circumstances associated with treatment.

- Depressive symptoms may fluctuate during therapy.
- Prior history of depression may increase the risk of developing depression during treatment but is not a contraindication to use of the above agents.

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Management of Depression

- Address socio-economic conditions if possible.
  - Supportive counseling
  - Intensive psychological therapy
  - Emotional support
  - Group therapy
- If necessary initiate anti depressant medication.
- Consider lowering the dose or discontinuing the suspected agent

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QT Prolongation

Suspected agents: Bdq, Dlm, Cfz, Mfx

Can lead to fatal arrhythmias. QTc interval must be closely monitored for patients on Bdq or Dlm.
Electrolyte disturbances can contribute and K+ and Mg2+ level should be check regularly and replaced.

If QTc 450-500ms - Weekly ECGs
If QTc>500ms - Stop all QT prolonging drugs. Discussion with national TB programme.

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In conclusion

- Substantial adverse reactions in the treatment of MDR-TB, may require removal of drugs, replacement of drugs and, in some cases, stopping treatment
- The proportion of MDR-TB patients defaulted is substantial, likely related to adverse reactions, large number of drugs used, and long duration of treatment
- Designing MDR-TB Regimens should take adverse reactions and the possibility of defaulting into account
- Health workers should be trained to indentify and manage adverse reactions in a efficient manner

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Kenya Lung health Training Course

TUBERCULOSIS

MODULE 4: LEPROSY

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Kenya Lung health Training Course

Leprosy

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Objectives

By the end of this unit, the participants will be able to ;

1. Understand current trends of Leprosy
2. Understand its pathophysiology
3. Understand how to diagnose, manage and prevent leprosy

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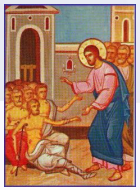
What is Leprosy?

- World's oldest recorded disease
- It is a chronic infectious disease
- Characterized by lesions of the peripheral nerve, skin, and mucus membrane of the URT



Every year last Sunday of January is World Leprosy Day

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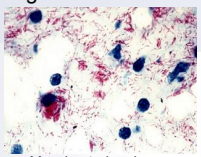
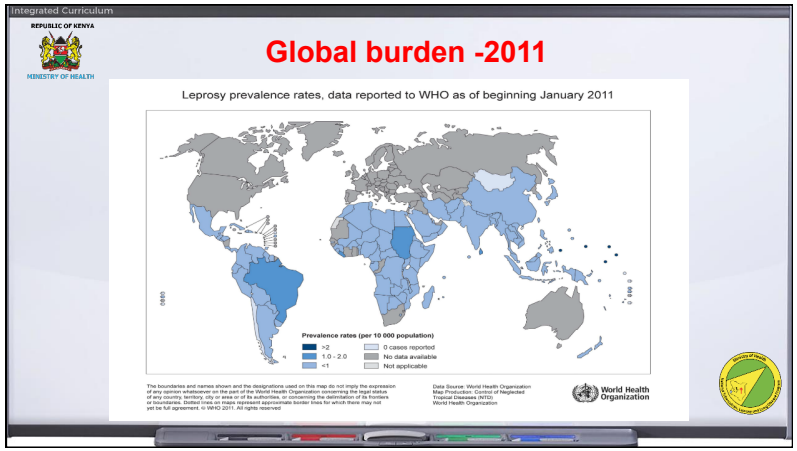
What causes it?

- *Mycobacterium leprae*
- Rod Shaped acid fast bacilli
- Discovered by Norwegian scientist Hammer Hansen in 1873
- It multiplies slowly (12 to 20 days into 2 through binary fusion)
- Takes long for the disease to manifest



Mycobacterium leprae

Hammer Hansen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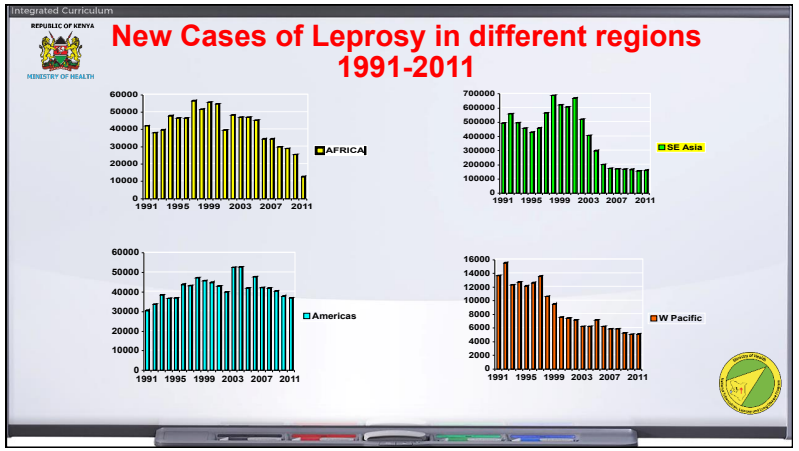
Global burden -2011
Leprosy prevalence rates, data reported to WHO as of beginning January 2011
Prevalence rates (per 10 000 population)
>2
1.0 - 2.0
<1
0 cases reported
No data available
Not applicable
World Health Organization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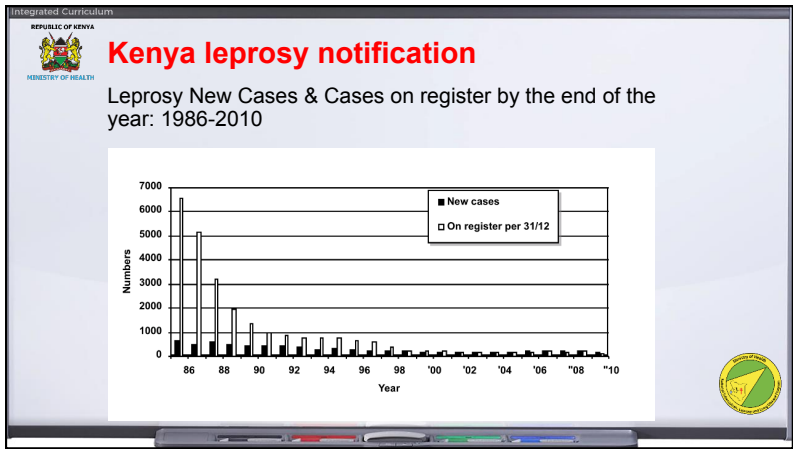
New Cases of Leprosy in different regions 1991-2011
AFRICA
SE Asia
Americas
W Pacific
1991 1995 1999 2003 2007 2011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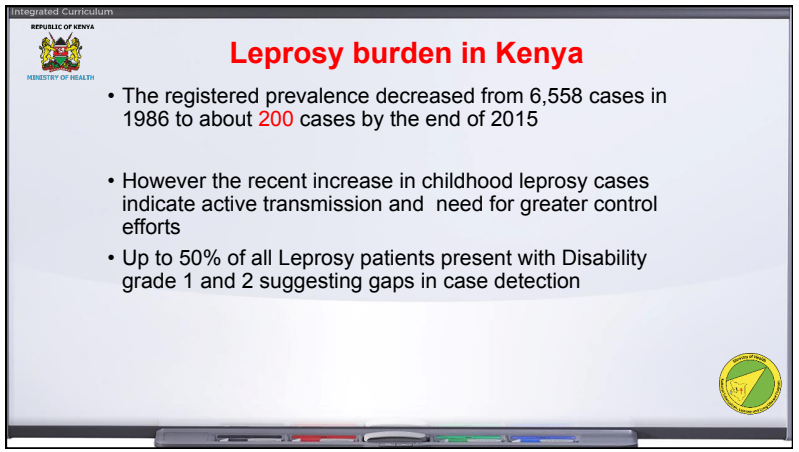
Kenya leprosy notification
Leprosy New Cases & Cases on register by the end of the year: 1986-2010
New cases
On register per 31/12
Numbers
Year
86 88 90 92 94 96 98 '00 '02 '04 '06 '08 "10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Leprosy burden in Kenya
• The registered prevalence decreased from 6,558 cases in 1986 to about 200 cases by the end of 2015
• However the recent increase in childhood leprosy cases indicate active transmission and need for greater control efforts
• Up to 50% of all Leprosy patients present with Disability grade 1 and 2 suggesting gaps in case detection

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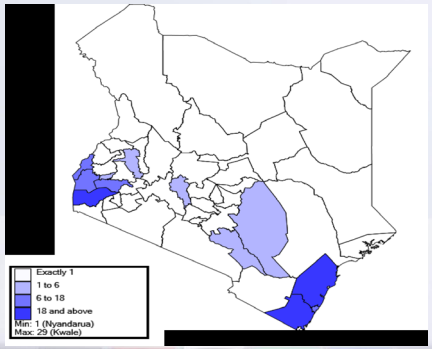
Leprosy case notification 2015



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Natural host

- Armadillos -are the only known natural hosts
- Humans

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Mode of transmission and incubation period of leprosy

Mode of transmission

- Droplet infection.
  - The source of infection is leprosy patient.
  - It is transmitted when the patient is
    - coughing,
    - Sneezing
      - there should be long-term contact with patient.

Incubation period

- The incubation period from infection to clinical manifestations is variable.
- It is shorter for PB disease (in the order of 2–5 years)
- than for MB (in the order of 5–10 years and sometimes much longer)

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Who is at risk?

- It can affect all ages and both sexes
- 95% of people who are exposed do not develop disease

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Pathophysiology

- Leprosy bacilli invades the cooler areas of the body(skin and mucus membranes) and the peripheral nerves
- Presence of bacilli and the Immune reaction to leprosy destroys tissues in these areas

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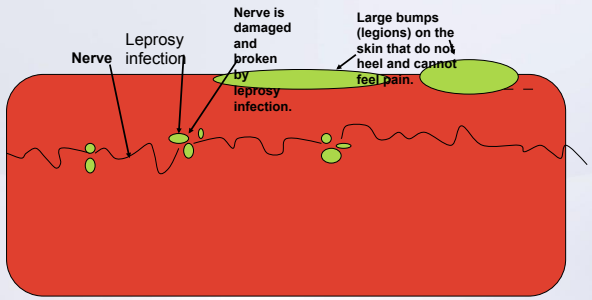
How the human body is affected by Leprosy



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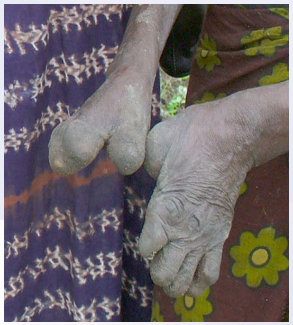
PATHOPHYSIOLOGY

- Leprosy antibody antigen reaction complexes block capillaries leading to cell death to affected areas
- Cartilage & affected cells get absorbed back into the body, causing fingers, toes, ears and noses to disappear



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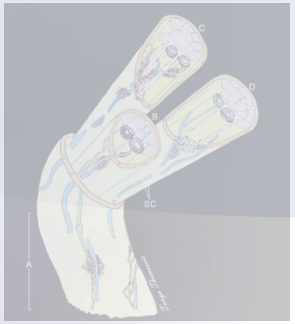
MINISTRY OF HEALTH

Mechanism of Nerve Damage

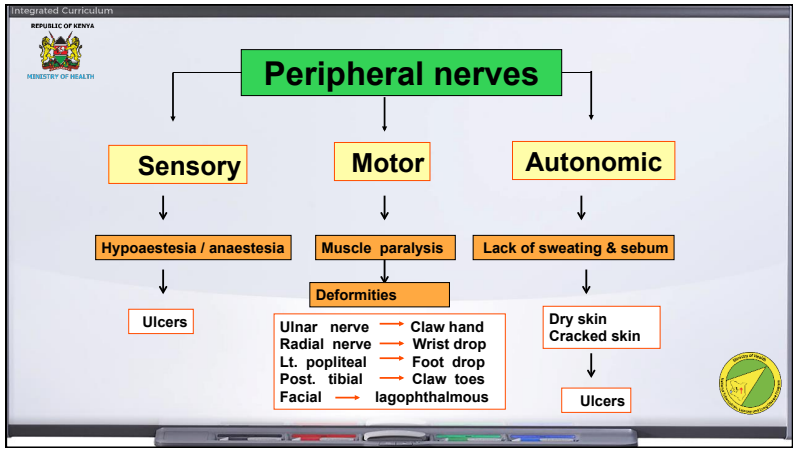


1.Entry Through Blood Vessels

2.Inflammatory Response

3.Demyelination

Scollard, DM et al. 2006. "The continuing challenges of leprosy." Clinical microbiology reviews 19, no. 2: 338-81.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MINISTRY OF HEALTH
Peripheral nerves
Sensory
Motor
Autonomic
Hypoaestesia / anaestesia
Muscle paralysis
Lack of sweating & sebum
Deformities
Ulcers
Ulnar nerve → Claw hand
Radial nerve → Wrist drop
Lt. popliteal → Foot drop
Post. tibial → Claw toes
Facial → lagophthalmous
Dry skin
Cracked skin
Ulcers


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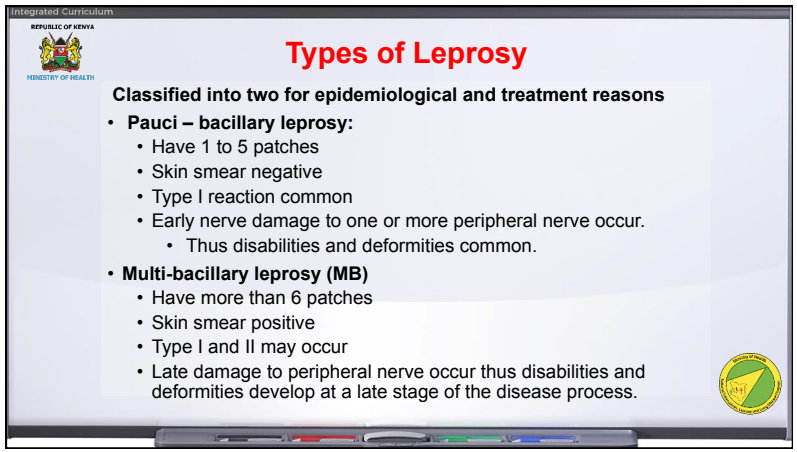
MINISTRY OF HEALTH
Signs and symptoms of leprosy
When to suspect leprosy
• Burning sensation in the skin
• Pale patches on the skin with loss of sensation
• Numbness and tingling the feet and/or hands
• Weakness of the eyelids, hands or feet
• Tender nerves
• Painless wounds or burns, swellings, especially on the face and ear lobes
• Large painless bumps on the skin that do not feel pain or heal for weeks or months
• Disappearance of eyebrows or eyelashes (madarosis)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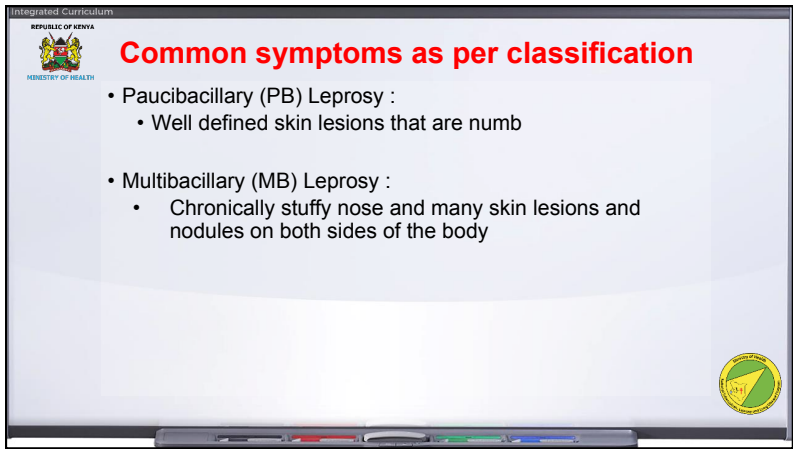
Types of Leprosy
Classified into two for epidemiological and treatment reasons
• Pauci – bacillary leprosy:
• Have 1 to 5 patches
• Skin smear negative
• Type I reaction common
• Early nerve damage to one or more peripheral nerve occur.
• Thus disabilities and deformities common.
• Multi-bacillary leprosy (MB)
• Have more than 6 patches
• Skin smear positive
• Type I and II may occur
• Late damage to peripheral nerve occur thus disabilities and deformities develop at a late stage of the disease process.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Common symptoms as per classification
• Paucibacillary (PB) Leprosy :
• Well defined skin lesions that are numb
• Multibacillary (MB) Leprosy :
• Chronically stuffy nose and many skin lesions and nodules on both sides of the body

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The Cardinal signs of Leprosy (WHO)

- A diagnosis of leprosy is made if one of the following signs is positive:
  - Skin patch with loss of sensation
  - One or more enlarged nerves
  - The presence of leprosy bacilli

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DIAGNOSIS

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1st cardinal sign: hypo pigmented patch with loss of sensation

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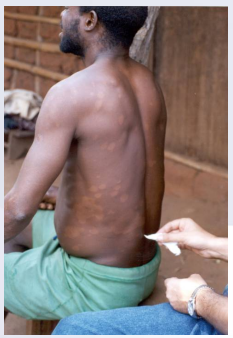
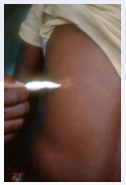
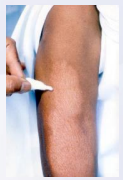
Testing for loss of sensation



1. Explain
2. Demonstrate
3. Test when the patient comprehends fully





Courtesy of B. Naafs

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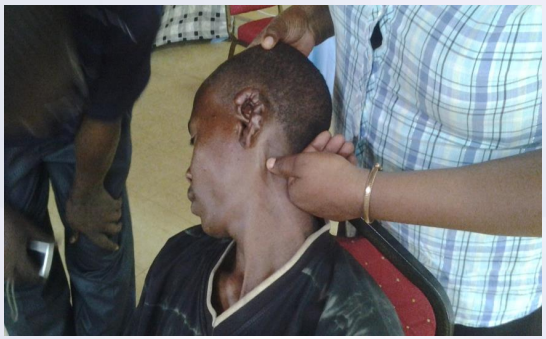
Other signs :Nodules on the ears



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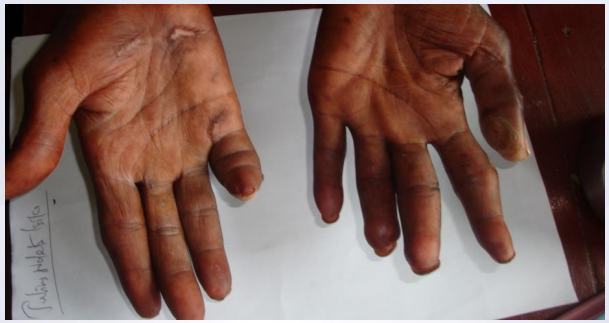
Scars , wasting and dryness of the palms



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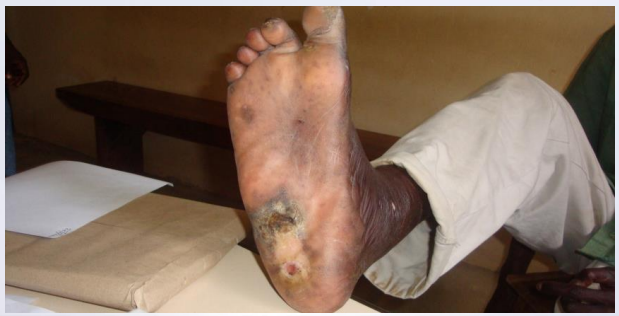
Chronic painless wound on the planter aspect of a newly diagnosed client



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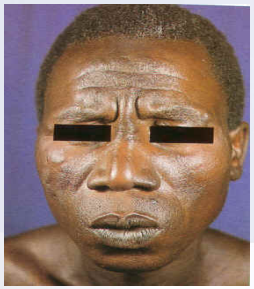
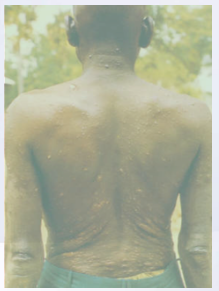


Diffuse Infiltration Of The Face With Loss Of Eye Brows With A Skin Smear Of 6+



MB LEPROSY(MUTIPLE SKIN LESSIONS)

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Second cardinal sign

- One or more enlarged nerves

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Examination of nerves

- Peripheral nerves may be thin or large, soft or hard, tender or painful, at sites of predilection;
- Record size "–" or "+" or "++" is adequate;
- Record pain or tenderness.
- Record texture as normal, soft, firm or hard.
- Be gentle, look at the patient's face as you palpate nerves; he will wince if they are tender. (Hastings R, 1985)

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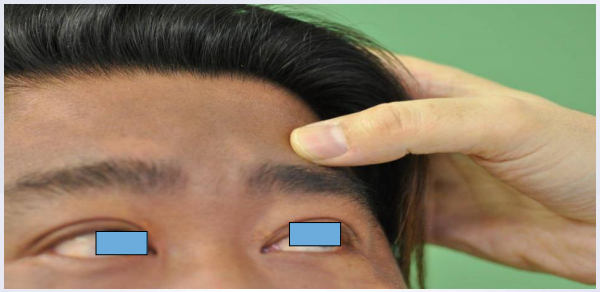
Supra orbital nerve



Palpation of the supraorbital nerve

Courtesy of S. Noto

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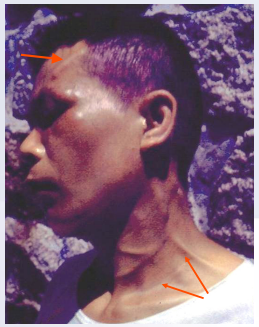
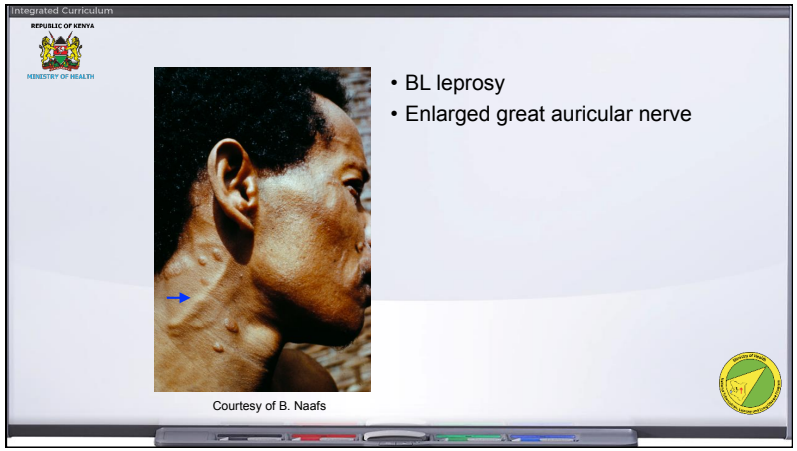
Cervical plexus, and branch of the supra-orbital nerve



Courtesy of Grace Warren

- Large cervical plexus and branch of the supra-orbital nerve associated with small lesions beside the eye.
- Leprosy patient in Hong Kong.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• BL leprosy
• Enlarged great auricular nerve
Courtesy of B. Naafs


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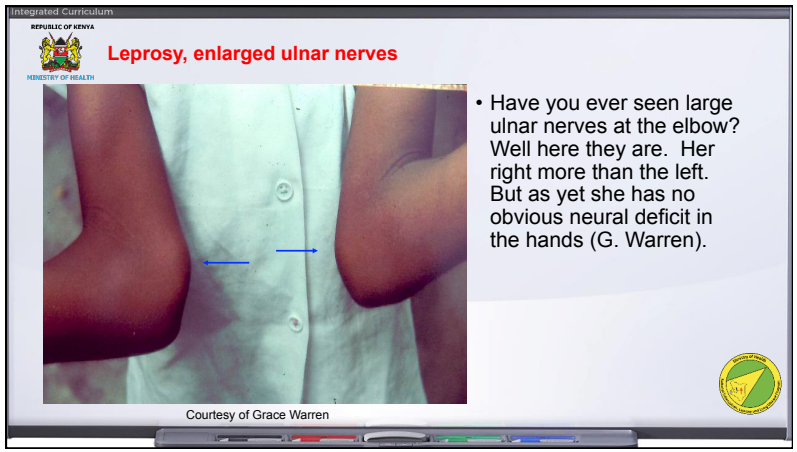
Ulnar nerve
Palpation of the left ulnar nerve
Courtesy of S. Noto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Leprosy, enlarged ulnar nerves
• Have you ever seen large ulnar nerves at the elbow? Well here they are. Her right more than the left. But as yet she has no obvious neural deficit in the hands (G. Warren).
Courtesy of Grace Warren


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Radial cutaneous nerve
Palpation of the radial cutaneous nerve
Courtesy of B. Naafs

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The 3rd cardinal sign of leprosy

"Positive slit-skin smear"

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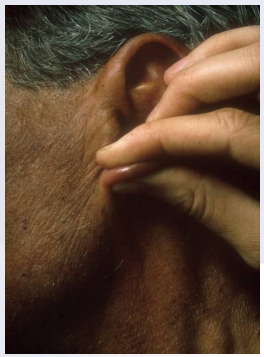

Courtesy of B. Naafs

- **The slit and scrape method**
- Technique of smear-taking from the
- ear lobe

Warning:
The use of gloves is advised

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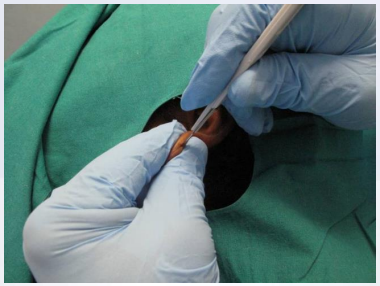
The slit and scrape method Technique of smear-taking from the ear lobe



Courtesy of E Nunzi and A Clapasson

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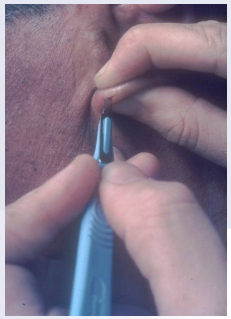

Courtesy of B. Naafs

The slit and scrape method

- **Blade is then turned through 90 degrees**

Warning: the use of gloves is advised


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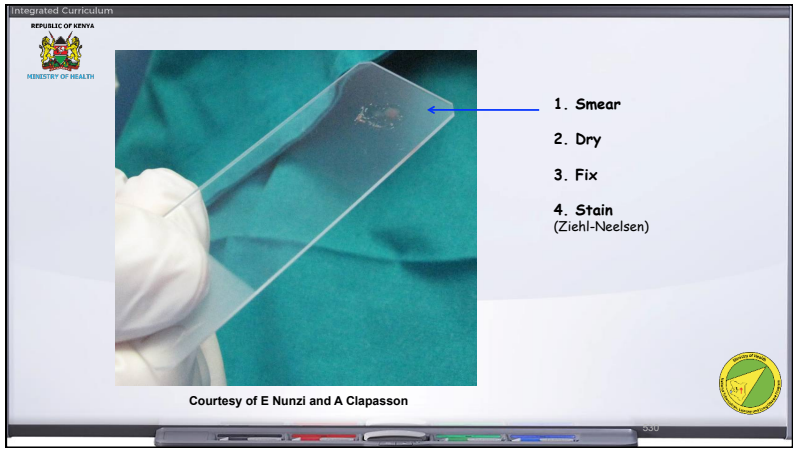
MINISTRY OF HEALTH
Technique of smear-taking
Courtesy of E Nunzi and A Clapasson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MINISTRY OF HEALTH
1. Smear
2. Dry
3. Fix
4. Stain
(Ziehl-Neelsen)
Courtesy of E Nunzi and A Clapasson


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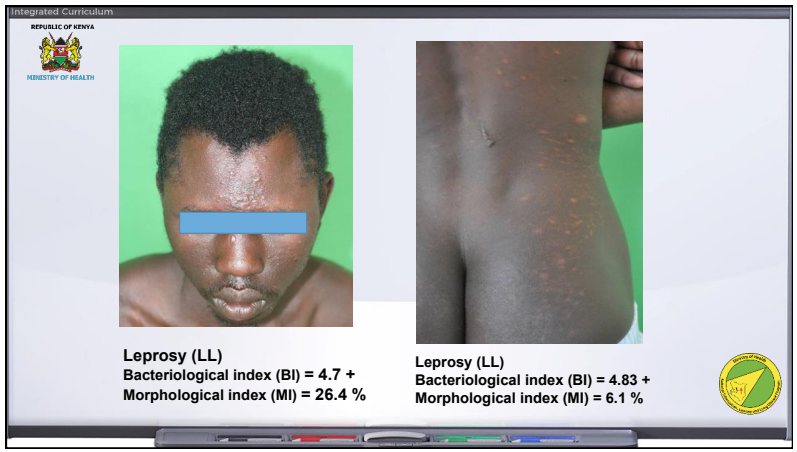
MINISTRY OF HEALTH
Morphology
S
F
G
Courtesy of A Clapasson
Solid (S)
Granular (G)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Leprosy (LL)
Bacteriological index (BI) = 4.7 +
Morphological index (MI) = 26.4 %
Leprosy (LL)
Bacteriological index (BI) = 4.83 +
Morphological index (MI) = 6.1 %

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Goals of Treatment

Major goals of treatments are:

1.Administer adequate treatment

2.Stop transmission

3.prevent disabilities

4.Rehabilitate patients

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Steps to start multidrug therapy (MDT)

- Classify as PB or MB leprosy
- Inform the patient about the disease
- Explain the MDT blister pack - show drugs to be taken once a month and every day
- Explain possible side effects (e.g. darkening of skin) and possible complications and when they must return to the health centre
- Ask the patient when it is convenient for him/her to come back to the health centre. Give enough MDT blister packs to last until the next visit.
- Fill out the patient treatment card

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Multi Drug Therapy

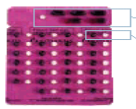
PB adult blister pack

PB adult treatment:

Once a month: Day 1
– 2 capsules of rifampicin (300 mg X 2)
– 1 tablet of dapsone (100 mg)

Once a day: Days 2–28
– 1 tablet of dapsone (100 mg)

Full course: 6 blister packs



MB adult blister pack

MB adult treatment:

Once a month: Day 1
– 2 capsules of rifampicin (300 mg X 2)
– 3 capsules of clofazimine (100mg X 3)
– 1 tablet of dapsone (100 mg)

Once a day: Days 2–28
– 1 capsule of clofazimine (50 mg)
– 1 tablet of dapsone (100 mg)

Full course: 12 blister packs

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PB child blister pack

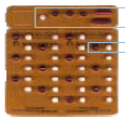
PB child treatment (10–14 years):

Once a month: Day 1
– 2 capsules of rifampicin (300 mg+150 mg)
– 1 tablet of dapsone (50 mg)

Once a day: Days 2–28
– 1 tablet of dapsone (50 mg)

Full course: 6 blister packs

For children younger than 10, the dose must be adjusted according to body weight.



MB child blister pack

MB child treatment (10–14 years):

Once a month: Day 1
– 2 capsules of rifampicin (300 mg+150 mg)
– 3 capsules of clofazimine (50 mg X 3)
– 1 tablet of dapsone (50 mg)

Once a day: Days 2–28
– 1 capsule of clofazimine every other day (50 mg)
– 1 tablet of dapsone (50 mg)

Full course: 12 blister packs

For children younger than 10, the dose must be adjusted according to body weight.

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Side effects: Clofazimine (Laprene)

- **Gastro intestinal disturbances:-** nausea, vomiting, abdominal pains
  - Give drugs after meal.
- **Red skin/eyes** – The patient has no complaints at all apart from the cosmetic effect.
  - Harmless, reassure the patient.

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Side effects: Dapsone:

- **Slighting itching -** treat symptomatically with anti-**histamine**
- **Anaemia -** Investigate for other causes of anaemia, refer to medical officer or DTLC for further management.
- **Exfoliative darmatitis -** The skin is itchy, and letter peals off. Patient is very ill, stop drugs immediately and refer the patient to medical officer or DTLC or nearest hospital.
- **Fixed drug reaction -** stop drugs. The eruption will slowly clear after stopping.

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Side effects: Rifampicine:

- **Red urine** – Harmless, no action needed; re-assure the patient.
- **Symptoms as for severe flu** – Treat symptomatically and reduce the dosage to half until the symptoms have disappeared.
- **Jaundice** – Stop all drugs immediately and refer patient to a medical officer or DTLC
- **Anaemia** – Investigate for other causes of anaemia
  - Refer to medical officer or the DTLC

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Leprosy complications

- There are two types of reactions (They occur to 30-50% 0f patient prior, during and after leprosy treatment)
  - Reversal reaction (or type I reactions)
  - Erythema nodosum leprosum (Type II reaction
- **Reversal reaction (RR), Type I reaction**
  - It occurs in both MB and PB leprosy
  - Suspect reversal reaction when you observe the following
  - Acute or sub-acute redness and swelling of one or more skin patches.
  - Edema of hands, feet or face
  - Acute or sub-acute pain, swelling tenderness of peripheral nerves; combined with acute or slowly developing loss of sensation and weakness in the area innervated by the affected peripheral nerve.
- **Silent neuritis**
  - Type of reversal reaction, which is a symptomatic, nerve function deteriorates slowly and goes unnoticed by the patient. It can only be detected by doing regular at least quarterly – assessments of sensation and muscle function.
  - Sensation and motor function

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Management of type I reaction

- Patient should be treated with anti-inflammatory drugs like, asprine, indocid in mild cases, or high doses prednisolone in severe cases for up to six month; i.e.
- Tabs prednisone 40 mg OD x 2/52
- Tabs prednisone 30 mg OD x 2/52
- Tabs prednisone 20mg OD x 2/52
- Tabs prednisone 15mg OD x 2/52
- Tabs prednisone 10 mg OD x 2/52
- Tabs prednisone 5 mg OD x 2/52

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Suspect ENL reaction with

- A history of sudden onset
- The appearance of red, tender nodules in the skin.
- They remain for about three days then disappears and crop up again in other places
- Mild to high fever
  - Painful red eye with loss of vision
  - Painful swollen testicles
  - Tender nerves
  - Other organs: -
    - Swollen tender lymph nods and joints – Splenomegally and hepatomegally

When to suspect severe form of ENL:

•Temperature higher than 38.5°C
•Red painful eyes
•Painful swollen testicles
•Ulcerating skin nodules
•Severe arthritis,
•Lymphadenitis
•Severe nerve pains.

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Management of ENL Reaction

- **Mild ENL**:- Give analgesics – paracetamol, Indocid, normally patients improves within a week, if no improvement refer to medical Officer or DTLC.
- **Severe ENL** – Refer as an emergency to the DTLC. The patient should be treated with prednsolon and clofazimine for 4-6 weeks on average. This reaction may re-occur repeatedly. Patient can be hospitalized or be treated on an ambulatory basis.

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Clofazimine use in reactions treatment

- Treatment with Clofazimine should start with 100 mg three times a day for a maximum of 12 weeks, with the dose then tapering to 100 mg twice a day for 12 weeks and to 100 mg once a day for 12–24 weeks.
- Management of ENL reaction with Clofazimine alone is indicated in cases of severe ENL when the use of corticosteroids is contraindicated.
- Treatment with Clofazimine should follow the same guidelines as when it is used in combination with prednisolone.
- Total duration of treatment with high-dose Clofazimine should not exceed 12 months.

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The eye in leprosy

- The eye is affected in leprosy in 2 main ways: direct bacillary invasion & leprosy reactions.
- Direct bacillary invasion: leads to a leproma, and exposure keratitis..
- Bacillary invasion of the cornea: leads to vascularization of the cornea resulting in opacities and blindness.
- *Management*: initiation of MDT.

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Involvement of the ophthalmic division of the (5th.) trigeminal nerve

↓

Corneal sensation imparment

↓

Patients ignore injuries

↓

keratitis, conjunctivitis and ulcers

↑

Unable to close the eye (unbliking stare)

↑

Lagophthalmos

↑

Involvment of zygomatic & temporal braches of the (7th.) facial nerve.

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Complications of the eye

Lagophthalmos:

•The patient is unable to close the eyelids due to weakness of the muscles, which close the eyelids. – Patient does not blink properly and the cornea is usually insensitive.

•If these muscles are very week, the eye may water continuously.

•The cornea is at risk of drying out and is exposed to foreign bodies, which adhere to it, without the patient noticing them patient may go blind on affected eye.

Management:

•**Mild –** Exercise (physiotherapy)

•**Severe** – Surgery – Tarrsoraphy – reduction of palpabrae fissure

•Temporalis muscle transfer to create artificial blink

- Pad eyes at night
- Use tear substitute if eye is dry e.g. 1% chlorbutamol

•

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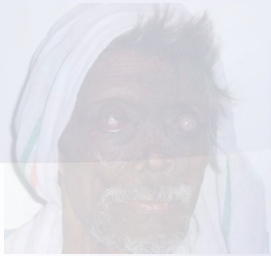
Complication of the eyes

• Lagophthalmos

• Cataracts



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Complications of the eye

Red eye – It is an emergency; it is a serious sign in leprosy patient especially if combined with lagopthalmos. It needs carefully examination and often referral.

- It may be caused by: -
- - Foreign body:
- - E.g. hair, insets, piece of grit etc; causing irritation and redness – inspect and remove foreign body. Apply topical eye antibiotics and pad for 2 days.

Keratitis:

- Inflammation of the cornea, caused by infection by bacteria or virus, often enhanced by drying out particularly in patients with logopthalmos
- Treat with antibiotics topical and systemic, refer patient to eye specialist.

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Complications of the eye

- **Acute Iridocyclitis**
- Inflammation of iris and cilliary body, which is a result of type II reaction in an MB Leprosy patient. It is characterized by:
- - Acute red eye
- - Loss of vision
- - Pin-point pupils not reacting to light
- - Photophobia
- **Management** – Start patient on atropine eye ointment TDS and apply eye pad. Then refer patient immediately.

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Foot Problems among Leprosy Patients

- Common problems are:-
  - Plantar ulceration
  - Foot drop
  - Fixed deformities of feet and toes
  - Tarsal disorganization.
- PLANTAR ULCERATION:--
  - Found in 10% of patients
  - Manifestation of sensorimotor deficit
  - Mostly in front part of sole in MTP joint
  - Augmented by infection through fissures and paralysis of feet muscles(which counter the stress while walking)

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Foot care in a leprosy patient

1. Management:--
   - Absolute bed rest and elevate foot
   - Soap soaking/ eusol bath, irrigation, dressing
   - Remove slough or other draining procedures
   - Start antibiotics
   - Protective foot wearing
2. Prevention:--

Protective footwear:-(type depends on state of foot)

- *Feet with only sensory loss* (no muscle paralysis), footwear should have tough outer sole, should not rub against toes. Eg using automobile tyre side pieces.

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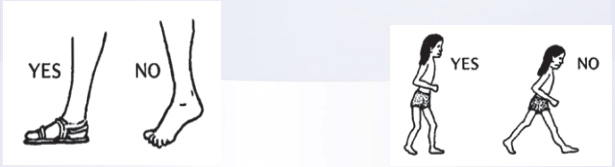
Cont…

- Any footwear can reduce the pressure up to 25%
- Appropriate footwear should have outer sole of 15-18mm thick and soft inner sole 18-22mm.
- Iron nails and buckles are to be avoided.
- Raja Model is most suitable one.



learn to take short steps

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-Female models -Male models

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Cont...

- *Insensitive feet*(with intrinsic muscle paralysis):-
- These require a resilient, non collapsing, shock absorbing insole that will dampen the impact during walking
- Microcellular rubber is most suitable.

<u>Foot Care Practices:</u>--

- Similar to those done for hand
  - Soaking, scrubbing and smearing routine
  - Corn and callosities are removed carefully
  - Identify 'safe limits' of walking

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Foot drop

- About 1-2% of leprosy patients develop due to damage to lateral popliteal nerve.
- Paralysis of anterior muscles give rise to foot drop characteristic 'stepping gait' occurs in which ball of foot instead of heel hits the ground
- Inversion foot leads to overloading on outer part

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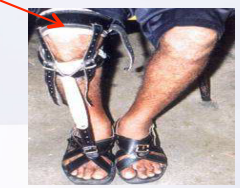
Cont…

- Splinting of knee - this allows rest to inflamed nerve and result in quicker healing.
- Dropped foot should be supported to hasten recovery.

Splint



- Stretching calf muscles: as in foot drop these are not used while walking so contracture may develop.

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Deformities grading

HANDS AND FEET

- Grade 0: no anaesthesia, no visible deformity or damage.
- Grade 1: anaesthesia present, but no visible deformity or damage.
- Grade 2: visible deformity or damage present

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Deformity grading – EYES

- Grade 0: no eye problem due to leprosy; no evidence of visual loss.
- Grade 1: eye problems due to leprosy present, but vision not severely affected as a result of these (vision: 6/60 or better; can count fingers at 6 m).
- Grade 2: severe visual impairment (vision: worse than 6/60; inability to count fingers at 6 m) also includes lagophthalmos, iridocyclitis and corneal opacities.

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Factors complicating Management of leprosy

- People with the disease are stigmatized
- The patches in pauci-bacillery patient sometimes only disappear years after MDT has been stopped, patient may therefore not understand why treatment is stopped.
- Leprosy reaction with complications such as paresis, paralysis or blindness can occur months or year after a patient is declared cured.
- Leprosy disabilities are often irreversible.
- Even with MDT the treatment period is still quite long. (6 month to 1 yr)

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Information to patients About the disease

- Caused by a bacteria
- Affects skin and sometimes nerves
- Progresses slowly
- Easy to diagnose and cure
- Lead normal life, do not change life style

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Information to patients about the treatment

- MDT will cure you completely
- MDT is free of cost
- MDT is available in all health centres
- MDT should be taken as advised (regular, full course)
- If you have problem or questions contact your health centre

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Information to patients

- To take the drugs after a meal or in the evening just before going to bed if he feels nausea after ingesting them
- To inform the staff at the clinic if they intend to travel or move to another area
- Tablets given are to be taken daily at the same time.
- Drugs to be collected from the clinic every four weeks
- Leprosy reaction can still develop after M.D.T. the reaction should not be treated with a new course of MDT but other drugs will be used to treat them

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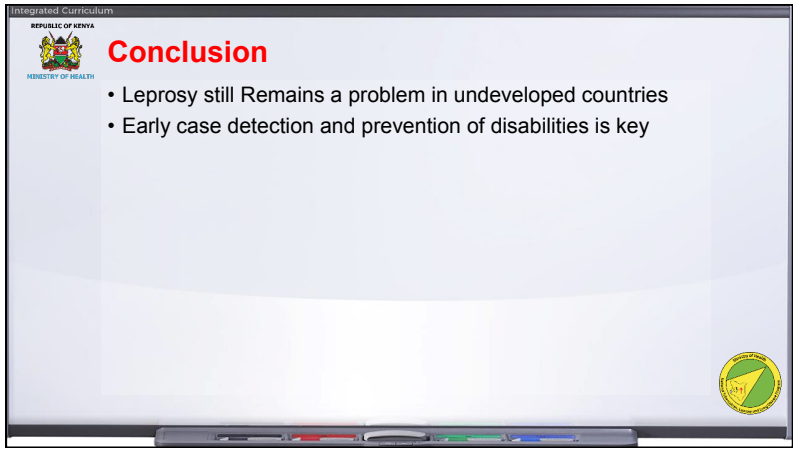
Information to patients About possible problems

- Skin discoloration due to clofazimine
- Urine discoloration due to rifampicin
- When to report to the clinic as soon as he notices;-
  - sudden weakness of muscles
  - one or both of his eyes are red and painful.
  - pain in one of his limb
  - the appearance of red, swollen tender nodules in the skin.
  - And as soon as patches have started to become red and swollen again.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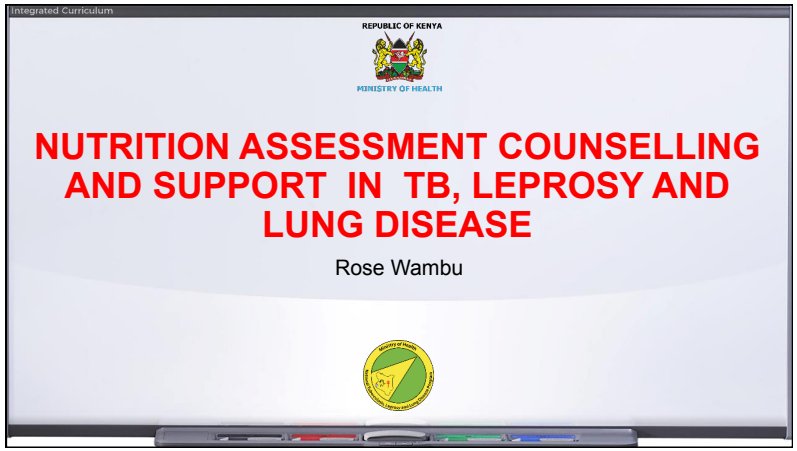
Conclusion
• Leprosy still Remains a problem in undeveloped countries
• Early case detection and prevention of disabilities is key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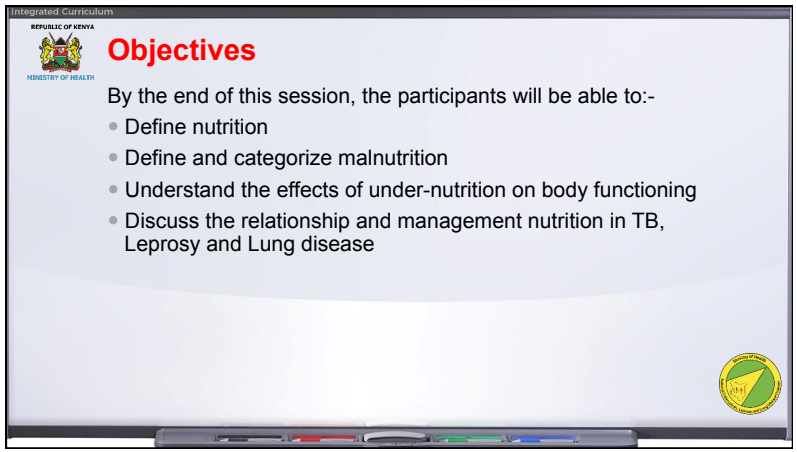
NUTRITION ASSESSMENT COUNSELLING AND SUPPORT IN TB, LEPROSY AND LUNG DISEASE
Rose Wambu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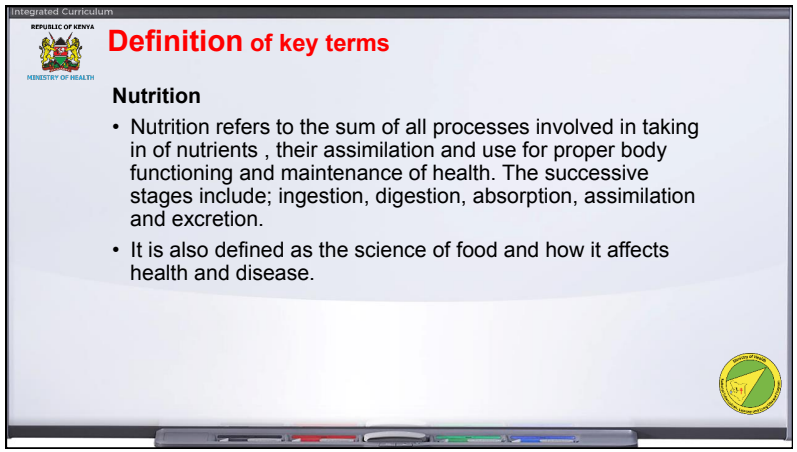
Objectives
By the end of this session, the participants will be able to:-
Define nutrition
Define and categorize malnutrition
Understand the effects of under-nutrition on body functioning
Discuss the relationship and management nutrition in TB, Leprosy and Lung disease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Definition of key terms
Nutrition
• Nutrition refers to the sum of all processes involved in taking in of nutrients , their assimilation and use for proper body functioning and maintenance of health. The successive stages include; ingestion, digestion, absorption, assimilation and excretion.
• It is also defined as the science of food and how it affects health and disease.

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Malnutrition

Malnutrition is a state in which the physical function of an individual is impaired to the point where he/she can no longer maintain adequate bodily performance process such as growth, pregnancy , lactation, physical work , resting and recovering from disease.

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Nutrients

These are defined as chemical substances that provide nourishment and affect the nutritive and metabolic processes of the body.

They are divided into two;

•Macro nutrients - required in large amounts

•micro nutrients – required in small amounts

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Five key aspects of Nutrition

- Food availability and accessibility
- Food intake
- Digestion and absorption
- Metabolism and utilization
- Excretion of extra components of food, toxins and waste

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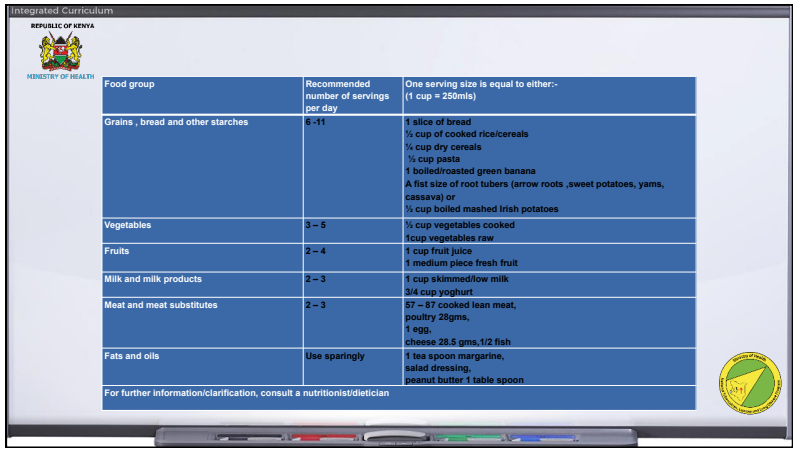
Nutritional Requirements

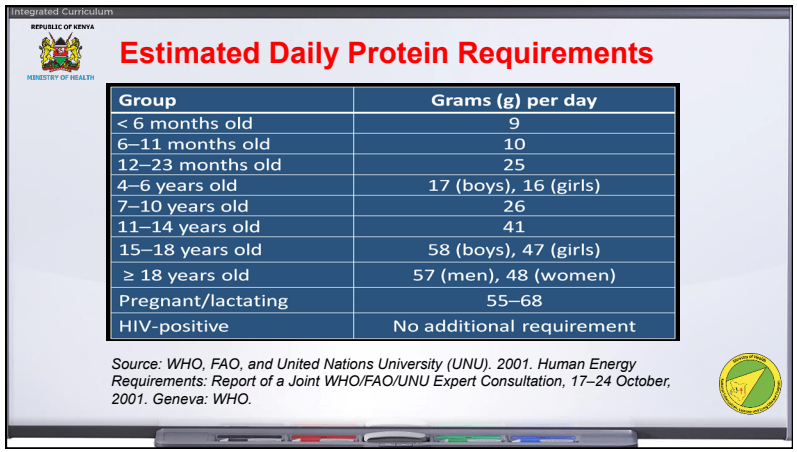
1. **Macronutrients**
   - Carbohydrates
   - Protein
   - Lipids

2. **Micronutrients**
   - Vitamins A,B,C,D,E
   - Minerals- Iron, zinc, selenium, calcium

3. **Others**
   - Fibre /Roughage
   - Water: At least 8 glasses/day

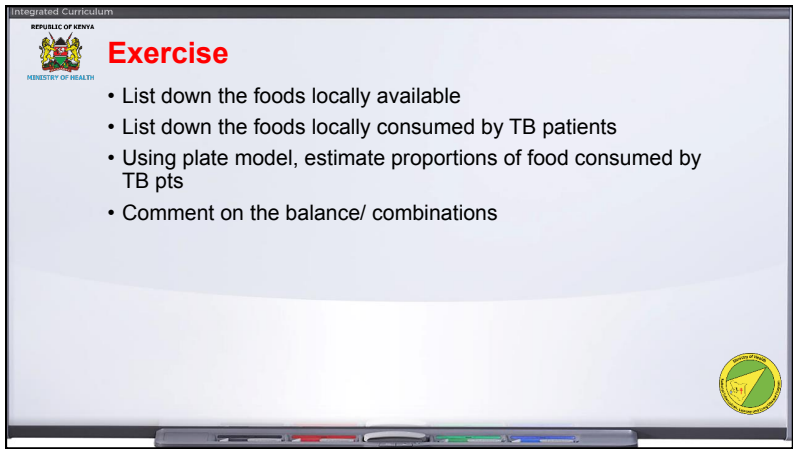


Food group	Recommended number of servings per day	One serving size is equal to either:- (1 cup = 250mls)
Grains , bread and other starches	6 -11	1 slice of bread ½ cup of cooked rice/cereals ¼ cup dry cereals ½ cup pasta 1 boiled/roasted green banana A fist size of root tubers (arrow roots ,sweet potatoes, yams, cassava) or ½ cup boiled mashed Irish potatoes
Vegetables	3 – 5	½ cup vegetables cooked 1cup vegetables raw
Fruits	2 – 4	1 cup fruit juice 1 medium piece fresh fruit
Milk and milk products	2 – 3	1 cup skimmed/low milk 3/4 cup yoghurt
Meat and meat substitutes	2 – 3	57 – 87 cooked lean meat, poultry 28gms, 1 egg, cheese 28.5 gms,1/2 fish
Fats and oils	Use sparingly	1 tea spoon margarine, salad dressing, peanut butter 1 table spoon
For further information/clarification, consult a nutritionist/dietician		



Group	Grams (g) per day
< 6 months old	9
6–11 months old	10
12–23 months old	25
4–6 years old	17 (boys), 16 (girls)
7–10 years old	26
11–14 years old	41
15–18 years old	58 (boys), 47 (girls)
≥ 18 years old	57 (men), 48 (women)
Pregnant/lactating	55–68
HIV-positive	No additional requirement

Source: WHO, FAO, and United Nations University (UNU). 2001. Human Energy Requirements: Report of a Joint WHO/FAO/UNU Expert Consultation, 17–24 October, 2001. Geneva: WHO.



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Categories of Malnutrition

- **Acute malnutrition** is caused by a decrease in food consumption and/or illness, resulting in bilateral pitting oedema or **wasting** . It is further categorized in to Severe Acute Malnutrition (SAM) and Moderate Acute Malnutrition (MAM)
- **Chronic malnutrition** is caused by prolonged or repeated episodes of undernutrition starting before birth, resulting in stunting. **Stunting** is defined by low height-for-age.
- **Underweight** is a composite form of undernutrition which includes elements of stunting and wasting. Underweight is defined by low weight-for-age.
- **Micronutrient deficiencies** are a result of reduced micronutrient intake and/or absorption. The most common forms of micronutrient deficiencies are related to iron, vitamin A, and iodine.

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The objectives of nutrition in Tuberculosis, leprosy and lung disease are;

- To prevent and correct malnutrition
- Reduce the effects of medication on patients
- To improve and maintain the nutritional status of patients
- Promote adherence
- To promote drug efficacy
- Restoring fat-free mass in chronic obstructive pulmonary disease.

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Relationship between nutrition and leprosy and lung diseases

- Pulmonary diseases with nutrition implications include TB, COPD, Asthma, Pneumonia, bronchitis, among others.
- Poor nutrition status in lung disease has been related to adverse effects that may contribute to complications and increased mortality.
- In lung disease, resting energy expenditure (REE) is 15-20% above the normal values for adults and 25-50% for infants. Therefore need for increased energy intake

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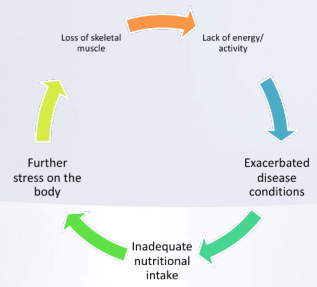
Relationship between nutrition and leprosy and lung diseases



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Relationship between TB and Malnutrition

- Malnutrition weakens the immune system and predisposes people to develop TB as much as any other infectious disease.
- Active TB leads to malnutrition. TB patients frequently suffer from a loss of weight and appetite and consequently present a low body mass index and skin fold thickness.
- It has long been recognized that TB is linked to poverty and malnutrition (Debatable)

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How TB affect Nutrition

- There's a 13% increase in basal metabolic rate (BMR) change with every 1 degree Celsius rise in body temperature.
- The adipose and glycogen stores normally decrease due to increase in energy expenditure.
- There is reduced absorption of minerals, vitamins, proteins and increase in nitrogen breakdown leading to low immunity.

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....How TB affects Nutrition

- Due to the high fever, there is loss of body fluids - sweating and urination during the acute phase. Electrolyte loss nitrogen break down
- Due to loss of appetite and anorexia during illness, there is reduced food intake and depletion of body stores.
- Mal-absorption due to the high metabolic rate leads to malnutrition and wasting.

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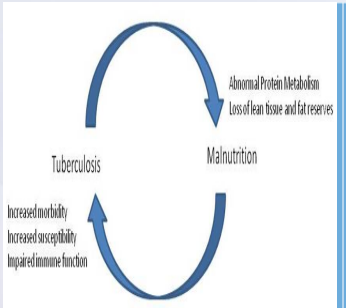
Relationship between TB and Malnutrition



- **TB affects the metabolism of important nutrients such as protein and some micronutrients. Malnutrition on the other hand limits cell mediated immunity and increases susceptibility to infection.**
- **Nutritional status is one of the most important determinants of resistance to infection.**
- **Malnutrition increases the risk of developing TB and the vice versa.**
- **Malnutrition as well as TB Weakens immune system & increases disease burden in an individual**
- **In both there is increased nutrient requirements**

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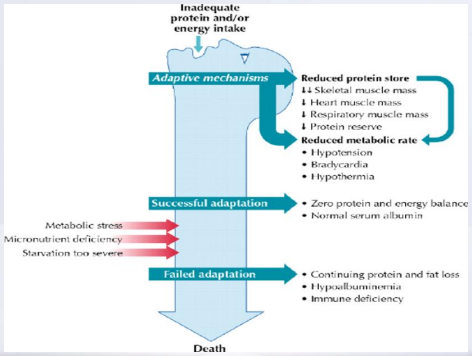
Pathophysiology of undernutrition



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Consequences of malnutrition

- Reduced access to food due to morbidity/low productivity
- Less activity, less lung function and less heart function
- Serum protein levels can affect airway function and diffusing capacity of lungs
- Cachexia also affects lung function
- Decreased cough and inability to mobilize secretions
- High likelihood of progression from latent infection to active disease
- Increased risk of mortality
- Diminished pharmacal-dynamic effectiveness of anti-mycobacterium drug regimen
- Impair the protective efficacy of Bacillus Calmette-Guerin (BCG)
- Delayed and prolonged wound healing
- Progressed disabilities

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Role of nutrition

Optimal Nutrition enhances:

- Growth, development, replacement and repair of cells and tissues.
- Helps chemical processes such as digestion, metabolism, assimilation and excretion
- Restores and protects the integrity of the immune system.
- Prevent wasting and other forms of malnutrition micronutrient included.
- Delay HIV progression.
- Improve drug efficacy
- Optimize cellular activity and tissue/organ function by providing sufficient amounts that meets daily body requirement

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UNIT 2

NUTRITION ASSESSMENT COUNSELLING AND SUPPORT

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NACS

Nutrition assessment counseling and support (NACS) aims to establish routine nutrition assessment as an integral component of facility- and community-based health care providers to deliver nutrition-specific services. It links clients to nutrition-sensitive interventions provided by the health, agriculture, food security, social protection, education and rural development sectors.

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NUTRITION ASSESSMENT

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Objectives

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

- Define nutrition assessment
- Explain the importance of nutritional assessment.
- Discuss the methods of nutrition assessment.
- Carry out accurate nutritional assessment.
- Be able to interpret nutritional assessment data

Nutrition in tuberculosis 591

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Step I: Nutritional assessment

- Obtaining, verifying and interpreting data in order to identify existing or potential problems
- Judging a person's nutritional status, situation, and vulnerability to poor nutrition by taking measurements and/or asking questions.
- It leads to problem diagnosis and helps to design appropriate plan of care or interventions.
- It generates the information needed for a comprehensive approach to nutrition intervention
- Based on results, patients can be referred for specialized care if/ when necessary.

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Why is nutritional assessment critical

To identify clients with specific nutrition needs (nutritional care/support, dietary/nutrient supplements, medical treatment, referral for further assessment)

- To measure changes in nutritional status so as to inform optimal approaches, motivate clients to continue practices, and understand program impacts.
- To identify nutritional problems and infections early for timely interventions and so prevent deterioration.
- Design a nutrition plan of care that will prevent or minimize malnutrition
- To evaluate efficacy of nutritional care on regular basis
- To inform drug dosage prescription
- To enable individualized diet prescriptions.

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Nutrition assessment methods

- Anthropometric measurements
- Biochemical assessments
- Clinical assessment (signs of deficiencies)
- Dietary (24 hour recall, food diary,)
- Economic and social status
- Functional

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Anthropometric assessment

This is the measurement of body size ,weight and proportions.

Anthropometric measurements include:

–Weight/Height
–Circumferences – waist, hip, MUAC, head
–Skin fold thickness.

The following nutrition indicators can be computed from the above measurement

- Weight (% change over time)
- BMI (for adults) and weight-for-height/age (for children)
- Waist/hip ratio
- Body surface area

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Measuring weight

- Weight should be taken using a functional medical scale which should be calibrated before starting. If a UNI scale, standardize with a known weight after 100 weights.
- Place the scale on a flat even surface
- Zero the weighing scale (i.e. make sure the arrow is on 0)
- Ensure that the weighing scale is at eye level
- Before taking weight ensure client is on light clothing or the child, take all his/her clothes off
- All patients should have their weight taken and recorded immediately

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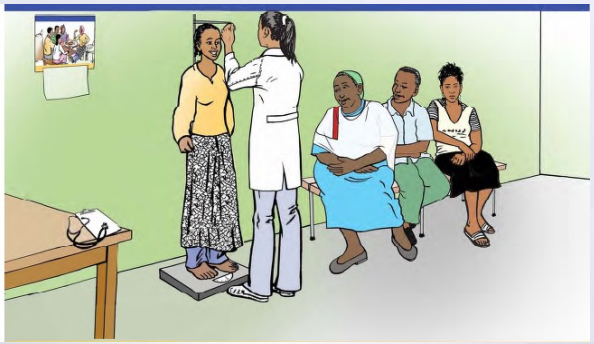
Measuring weight and height



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Measuring height

- Make sure the measuring rod of the stadiometer is straight.
- Make sure the patient is barefoot.
- Ask the patient to stand with heels together, arms to the side, legs straight, shoulders relaxed. Heels, buttocks, scapulae (shoulder blades), and back of the head should be against the vertical board of the stadiometer.
- Just before the measurement is taken, ask the patient to inhale deeply, hold the breath, and keep an erect posture ("stand up tall") while you lower the headboard onto the highest point of the head with enough pressure to compress the hair.
- Read the measurement to the nearest 1 cm and keep your eye level with the headboard to avoid errors.

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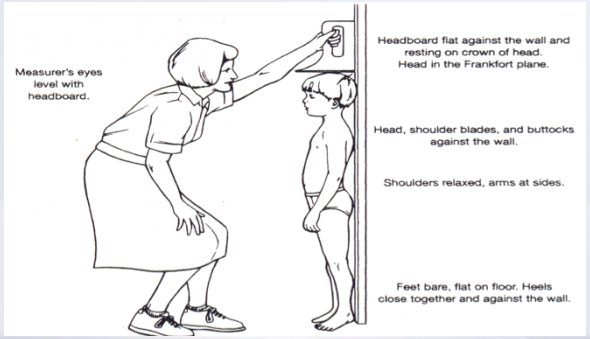
Measuring height cont.



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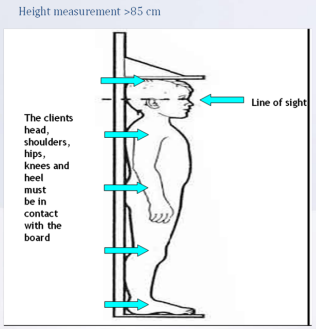
How to measure height in both adults and children



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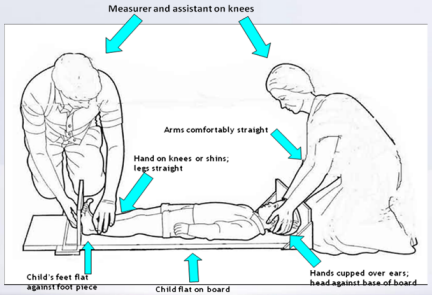
How to measure length in children

Height measurement <85 cm



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Computation of Adult BMI

- Weight in kg (to the nearest 100 g, e.g., 77.5)
- Divide by the square of height in meters (taken at nearest centimeter and converted to meters)

$$\text{BMI} = \frac{\text{Weight (kg)}}{(\text{height in meters})^2}$$

- BMI is expressed in kg/m^2 (though the units are often not indicated

NB

Children 5 -17yrs- use BMI for age expressed in z scores using reference charts

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Adults' BMI Classification

	Condition
≥30	Obese
25.0-29.9	Overweight
18.5–24.9	Normal BMI
16.0–18.5	Moderate acute malnutrition
<16.0	Severe acute malnutrition

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Children Z -Score Classification

W/H level	**Condition**
<80% or <-2Z Score	Moderate acute malnutrition without medical complications
<70% or <-3Z Score	Severe acute malnutrition without medical complications
<70% or <-3Z Score	Severe acute malnutrition with medical complications
W/H level	Condition

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Mid-Upper Arm Circumference

- Circumference of the left upper arm measured at the mid-point between the tip of the shoulder and the tip of the elbow, taken with the arm hanging down. Relatively independent of height.
- Measure of muscle mass and subcutaneous fat stores
- Potentially suited to screening for admissions to feeding centres during emergencies.
- Applied well to bed-ridden clients.

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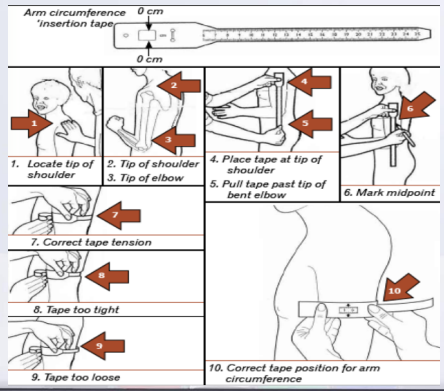

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Waist circumference

- Is an indicator of intra-abdominal fatness and a good indicator of abdominal fat
- A high waist circumference is associated with an increased risk for type 2 diabetes, high cholesterol, high blood pressure and cardiovascular disease.
- Indicators of risk
  - –Men: Waist Circumference Greater than or equal to 102cm
  - –Women: Waist Circumference Greater than or equal to 88cm

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Waist-hip Ratio

- This is a way of measuring where body fat is stored.
- A high waist-to-hip ratio indicates an increased risk of obesity-related health problems.
  - –Waist-to-hip ratio is calculated by dividing the measured waist circumference by the measured hip circumference.

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Waist-hip Ratio

- Waist = waist-to-hip ratio (WHR)
  Hip

Indicators of risk

- Women: WHR Greater than 0.85
- Men: WHR Greater than 1.0

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Group work

Exercise 20 min

In groups

- Take your weights, height, MUAC
- Take your waist and Hip circumference and calculate your W/H ratio
- Calculate your BMI
- What action will you take considering your BMI?

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Biochemical assessment

Complements anthropometric assessments by:

- Better informing decisions for management
- Providing clear grading of patient nutritional status

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Biochemical assessment with nutrition implication

- Kidney function test
- Liver function test
- Blood glucose
- Haemoglobin levels
- Electrolytes
- Cholesterol levels

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Clinical assessment

This involves physical observation/ judgement, Signs of nutrient deficiencies like visible wasting, hair changes, oedema, skin changes

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Clinical assessment

Body part or system	Signs/Symptoms	Possible deficiency
Hair	Lackluster, Thinness, sparseness, dryness, dyspigentation, easy pluckability, texture change	Proteins, protein-energy, Zinc, copper biotin.
Face	Paleness, Moon face (swollen), Greasy scaling around nostrils (nasolabial)	Riboflavin, Niacin, Pyridoxine, Iron
Eyes	Pale white eyes and eyelid lining (pale conjunctivae), Redness and fissuring of eyelid corners dullness and dryness (corneal or conjunctival xerosis), redness, lesions of conjunctivae (Bitot's spots)	Iron, folate, vitamin A, C, B2 B_6 and B_{12}
Mouth	Angular redness, lesions or scars at the corners of the mouth (stomatitis), swelling and redness of lips and mouth (cheilosis)	Riboflavin Niacin pyridoxine iron
Tongue	Smoothness, slickness (filiform papillary atrophy), beefiness, redness, pain (glossitis), swollen, magenta color	Niacin, pyridoxine, riboflavin, vitamin B_{12} folate, iron

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Clinical assessment

Body part or system	Signs/Symptoms	Possible deficiency
Gums	Swelling, sponginess, bleeding, receding	Vitamin C
Skin	Dryness, scaling, lightening of skin color often centrally on the face (diffuse pigentation), rough, gooseflesh skin (follicular hyperkeratosis), small skin hemorrhages (petechiae), excessive bruising, hyper pigented patches that may peel off, leaving superficial ulcers or hypo pigented skin (flaky paint dermatosis), oedema, delayed wound healing.	Vitamin A, C and K, Zinc, essential fatty acids, protein, Niacin.
Nails	Spoon-shape (kiolonychia), pale, brittle, ridged.	Iron
Glands	Enlarged thyroid or parotid	Protein, iodine
Musculoskeletal system	Bowlegs knock knees, enlarged joints, hemorrhages, muscle and fat wasting.	Protein-energy, Vitamin D and C, Calcium
Neurological system	Mental confusion, irritability, psychomotor changes, motor weakness, sensory loss	Thiamin, Riboflavin and Vitamin B12

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Dietary Assessment

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Dietary history

- Obtaining a diet history involves interviewing the client on the past and/or current food practices
- Measuring/estimating adequacy of the food consumed (variety, amount, frequency, with whom, sources of food, preparation)

What to assess

-Total energy and nutrient intake
-Macro- and micronutrient intake
-Water and fluid intake
-Eating habits
-Drug and alcohol intake
-Food preparation methods
-Factors hindering food intake

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Tools and methods of collecting diet history

1. Food record diaries
2. 24 hour recall
3. Food frequency
4. Diet diversity

- Appetite assessment

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Assessment cont…

Economic and social status

• Includes the assessment of food security, source of income, number of household members and social support

Functional

•Functionality of body parts assess the energy levels- (ability to prepare or consume meals and mobility) lethargy and disability.

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Session 2

NUTRITION DIAGNOSIS

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Objectives

By the end of this session participants should be able to

- Define nutrition diagnosis
- List the components of nutrition diagnosis
- Make a diagnosis using cut off points

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NUTRITION DIAGNOSIS

- The purpose of Nutrition diagnosis is to identify and label and describe an actual occurrence, risk of, or potential for developing a nutrition related problem.
- Nutrition diagnosis uses a standardized language to describe nutrition problems consistently so that they are clear within and outside the profession
- the language enhances communication and documentation of nutrition care and it will provide a minimum data set and common data elements

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Components of a Nutrition diagnosis

1. Problem (Diagnostic Label)
2. Etiology (Cause/Contributing Risk Factors
3. Signs/Symptoms (Defining Characteristics

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Nutrition Diagnostic Statement (PES)

- A nutrition diagnostic statement is written in a PES format that states the Problem (P), the Etiology (E), and the Signs & Symptoms (S).
- Example of PES statement for a TB patient would be:
- Reduced food intake related to side effects of drugs as evidenced by weight loss and client reported history

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Assessment diagnosis and classification of malnutrition in adults

ASSESS				
HISTORY	**LOOK AND FEEL**	**CRITERIA**	**CLASSIFICATION**	**TREATMENT/CARE**
Ask client or refer to records: 1. Has the client lost weight in the past month/since the last visit? 2. Has the client had: – Active TB (on treatment)? – Another chronic OI or malignancy (e.g., oesophageal infections)? – Mouth sores/oral thrush? 3. Has the client's body composition/fat distribution changed noticeably? – Thinning of limbs and face? – Fat distribution on limbs, breasts, stomach, back? 4. Has the client had: – Nausea and vomiting? – Persistent fatigue? – Poor appetite?	1. If client has oedema on both legs or base of the spine, rule out pre-eclampsia, kidney problems, elephantiasis, heart failure, and wet beriberi (vitamin B1 deficiency with oedema) 2. Measure client's weight (kg) and height (cm) 3. Compute BMI $\frac{\text{Weight (kg)}}{\text{Height (m}^2\text{)}}$ 4. Measure MUAC for pregnant women, women up to 6 months post-partum, and adults who cannot stand straight 5. Examine for conditions that cause secondary malnutrition 6. Look for complications and danger signs (anaemia, severe dehydration, active TB, severe bilateral oedema)	**Adults (non-pregnant and non-post-partum)** BMI: < 16 If can't measure BMI, MUAC: < 19 cm **OR** Bilateral pitting oedema (both feet or legs are swollen, and the skin remains indented when pressed with a finger) **Pregnant women and women up to 6 months post-partum** MUAC: < 21 cm or < 23 cm with weight loss	**SAM with complications** (fever, hypothermia, severe anaemia or dehydration, vomiting, bilateral oedema +++) **or** no appetite	**Inpatient treatment** Follow Nutrition Care Plan for SAM in Inpatient care
			SAM with appetite and no complications BMI: < 16 **or** MUAC: < 19 cm and no danger signs	**Outpatient treatment** Follow Nutrition Care Plan for SAM in Outpatient Care
		Adults (non-pregnant and non-post-partum) BMI: ≥ 16.0 to < 18.5 MUAC: ≥ 19.0 to < 21.0 cm **Pregnant women and women up to 6 months post-partum** Poor weight gain MUAC: ≥ 21 to < 23 cm	**Moderate/mild malnutrition** **Significant weight loss**	**Follow Nutrition Care Plan for MAM**
		Adults (non-pregnant and non-post-partum) BMI: ≥ 18.5 to 24.9 MUAC: ≥ 21.0 cm **Pregnant and post-partum women (up to 6 months)** MUAC: ≥ 23 cm	**Normal**	**Follow Nutrition Care Plan for Normal Nutritional Status**

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Assessment, diagnosis and classification of malnutrition in children

ASSESS				
ASK	**LOOK AND FEEL**	**CRITERIA**	**CLASSIFICATION**	**TREATMENT/CARE**
Ask mother or caregiver or refer to records: 1. Has the child lost weight in the past month/since the last visit? 2. Has the child had: a. A cough for more than 21 days? (This may be a result of HIV-related chronic lung disease, such as lymphocytic interstitial pneumonia or bronchiectasis) b. Active TB (on treatment)? c. Diarrhoea (three or more stools per days)? d. Another chronic OI or malignancy?	**1. Look for severe visible wasting:** – Loss of muscle bulk on arms, shoulders, buttocks, and thighs, with visible rib outlines – Sagging skin on buttocks **2. Check for oedema** (swelling) in both feet **3. Weigh the child** **4. Measure MUAC** **5. If MUAC measurement is not possible, then measure weight-for-age and look at the shape of the curve on the growth chart** – Has the child lost weight since the last visit? (Measure again to confirm current weight) – Is the growth curve flattening? – Is the child gaining weight?	**Bilateral pitting oedema** (both feet and/or legs are swollen, and the skin remains indented when pressed with the thumb) **OR** MUAC: 6–59 months: < 11.5 cm 5–9 years: < 13.5 cm 10–14 years: < 16.0 cm 15–17 years: < 17.5 cm **AND** Appetite test (pass or fail)	**SAM** **Bilateral oedema +++, marasmic kwashiorkor** **With no appetite or with medical complication** (anorexia, intractable vomiting, convulsions, no alertness, lethargy, lower respiratory tract infection, high fever, severe anaemia or dehydration, hypoglycaemia, hypothermia) **With appetite and without medical complication** Clinical wellness Alertness Caregiver able/willing to manage SAM at home and return to clinic every 14 days	**Inpatient treatment** **Follow Nutrition Care Plan for SAM in Inpatient Care** **Outpatient treatment** **Follow Nutrition Care Plan for SAM in Outpatient Care**
		MUAC: 6–59 months: ≥ 11.5 to < 12.5 cm 5–9 years: ≥ 13.5 to < 14.5 cm 10–14 years: ≥ 16.0 to < 18.5 cm 15–17 years: ≥17.5 to < 19.5 cm	**MAM** **Poor weight gain**	**Follow Nutrition Care Plan for MAM**
		Weight gain parallel to or higher than median growth curve MUAC: 6–59 months: ≥ 12.5 cm 5–9 years: ≥ 14.5 cm 10–14 years: ≥ 18.5 cm 15–17 years: ≥ 19.5 cm	**Normal** **Growing appropriately**	**Follow Nutrition Care Plan for Normal Nutritional Status**

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Changes in weight over time

Change of weight is also used as a measure of nutritional status

Unintentional decrease in weight	Issue and action in the TB clinic
>5% in 2–3 months	Associated with increased risk of hospitalization -Dietary (and food security) assessment to ensure adequate intake; -Address infections -Nutritional counselling as necessary
≥10% in 2–3 months	Associated with 5-fold or more risk of death compared with no weight change -Rehabilitation depending on BMI status, -Address infections -Address eating problems

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Session 3: Nutrition interventions

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Nutrition Intervention

An intervention is a specific set of activities and associated materials used to address the problem. Nutrition interventions are purposefully planned actions designed with the intent of changing a nutrition-related behavior, risk factor, environmental condition, or aspect of health status for an individual, target group, or the community at large.

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Nutrition Intervention Components

1. Selecting,
2. Plan the nutrition intervention
3. Implement the nutrition intervention

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Step 3: Nutrition Intervention

Components of Nutrition Intervention

1. Select nutrition intervention

Prioritize the nutrition diagnoses based on severity of the problem

2. Plan nutrition intervention
   - Identify ideal goals and expected outcomes
   - Select intervention strategies
   - Consult evidence based guides for practice, other national developed guidelines

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3.Implement the intervention

Collaborate with other health care professionals

Implementing the nutrition intervention
- Communicate the plan of nutrition care,
- Carry out the plan of nutrition care,
- Continue with data collection
- modify the plan of care as needed

Ensure quality implementation of the care by:
- Individualizing the intervention to the setting and client
- Follow up and verify that implementation is occurring and needs are being met
- Revise strategies as changes in Nutrition in Tuberclosis.

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Nutrition intervention

Four categories of nutrition interventions:
- Nutrition education (E)
- Nutrition counseling (C)
- Food and/or nutrient delivery (ND)
  - Nutrient requirements for TB
  - Food by prescription
  - Enteral and parenteral nutrition support
- Rehabilitation.

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Interventions

Intervention	What to consider
NUTRITION EDUCATION Provision of information and educational materials designed to improve health status, dietary habits and physical activity habits.	Critical nutrition points (CNPs) • *Assist the TB patient at nutritional risk in achieving a positive change in food habits.* • *Improve nutritional status and* • *Prevent nutrition related problems through optimal use of the supplemental foods and other nutritious foods.* • *Monthly assessments especially weight.* • *Increase food intake* • *Sanitation, food hygiene and water safety.* • *Positive living behaviors* • *Physical activity.* • *Drink safe, clean water 8 glasses a day.* • *Manage food drug interactions.* • *Provide micro nutrient supplement* • Follow-up and closely monitor the patient.
NUTRITION COUNSELING Should be patient-centered	Areas for counseling • *Weight management* • *Drug reaction* • *Adherence* • *Dual infection increase or reduce intake* • *Relapse* • *Referral from community* • *Rehabilitation*

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Nutrients requirements

Nutrient	Normal (Kcals or grams)	Additional for TB patient	Food examples
Energy	2100Kcal	300-500Kcals	1 to 2 cups of enriched porridge
Proteins	0.8 g/ Kg Bwt	0.4- 0.7g/kgBwt	Milk ,Egg, nuts, pulses and meat
Fats	25 – 30% of total Kcals	Nil	Margarine, butter, vegetable oils,
Carbohydrates	55-60% of total Kcals	10-15% of total Kcals	Enriched porridge, Nduma, bread, sweet potatoes

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Requirement

Vitamins and minerals

- Vitamin A supplementation (every six months or as per the National Vitamin A supplementation schedule) and vitamin A rich foods.
- Patients on Isoniazid should ideally be supplemented with 25mg -50mg of pyridoxine B6 daily
- Other antioxidants Vitamin E, zinc and selenium neutralize free radicals and prevent the production of peroxides from lipids.
- Consider iron folic acid, supplementation depending on the haemoglobin level.

Water

- Drink at least 8 glasses or more of clean and safe water per day

Fiber

- Low fiber diet is recommended as the patient nutrient intake is impaired and they require high energy

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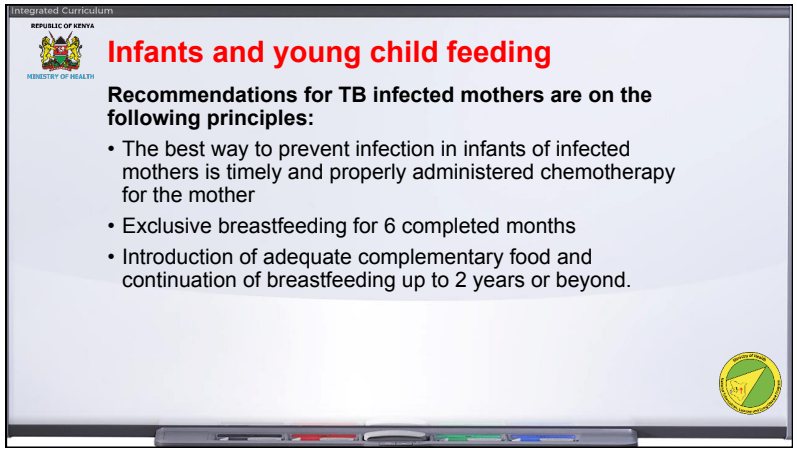
Recommended energy and Protein Requirements for women during pregnancy and Lactation in TB

PREGNANCY				Extra energy for women with TB and or HIV
	Energy requirements		Protein requirements	
	Total nutrient requirements	36-40 kcal/kg/day	0.8-1.0g/kg/day	20-30%
	First trimester0-12 Wks	+150 kcal/day	+0.7g/kg	20-30%
	Second trimester 13-27 Wks	+300 Kcal/day	+3.3g/kg/day	20-30%
	3rd trimester 28-40 Wks	+300 kcal/day	5.8g/kg/day	20-30%
LACTATION				
	Total nutrient requirements	+500 kcal/day	+20g/day	20-30%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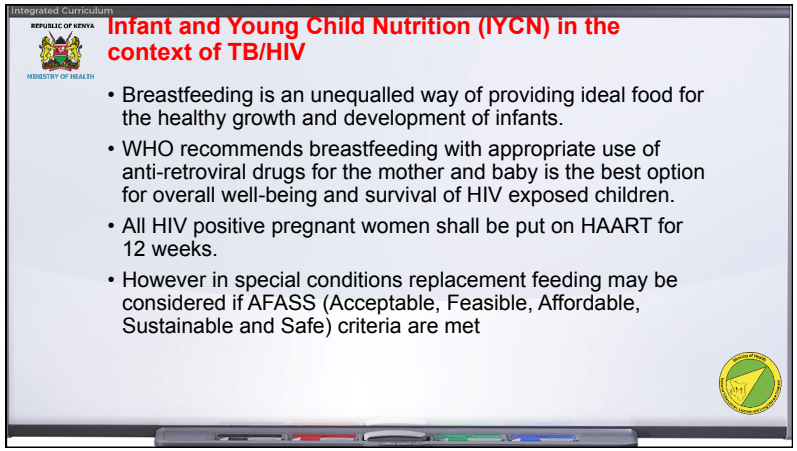
Infants and young child feeding
Recommendations for TB infected mothers are on the following principles:
• The best way to prevent infection in infants of infected mothers is timely and properly administered chemotherapy for the mother
• Exclusive breastfeeding for 6 completed months
• Introduction of adequate complementary food and continuation of breastfeeding up to 2 years or beyond.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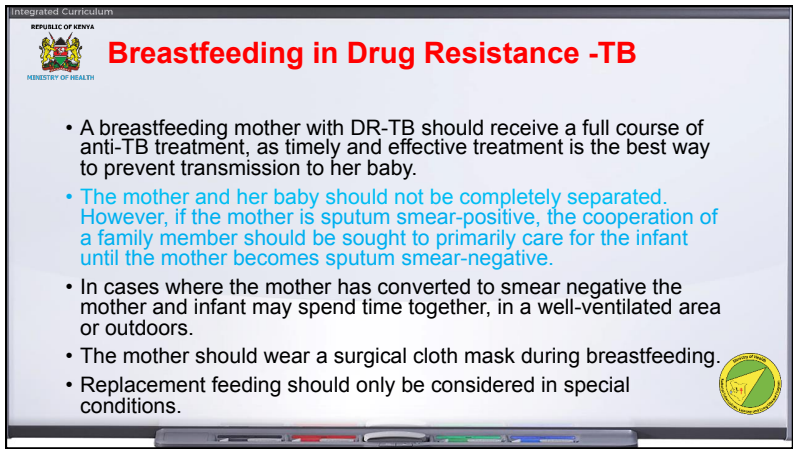
Infant and Young Child Nutrition (IYCN) in the context of TB/HIV
• Breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants.
• WHO recommends breastfeeding with appropriate use of anti-retroviral drugs for the mother and baby is the best option for overall well-being and survival of HIV exposed children.
• All HIV positive pregnant women shall be put on HAART for 12 weeks.
• However in special conditions replacement feeding may be considered if AFASS (Acceptable, Feasible, Affordable, Sustainable and Safe) criteria are met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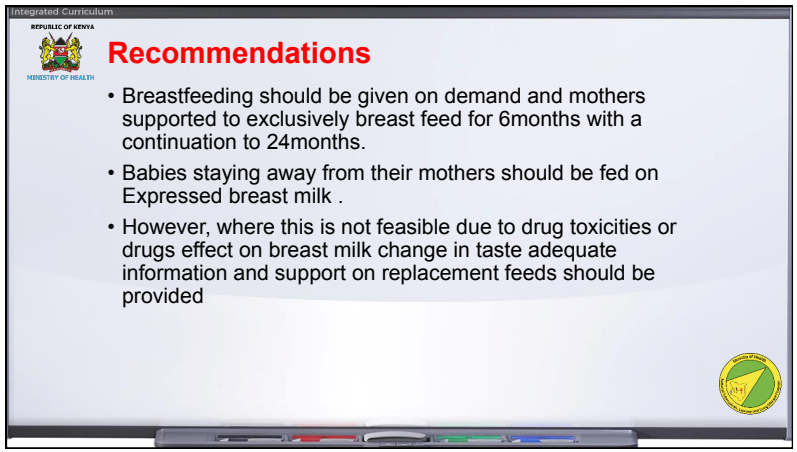
Breastfeeding in Drug Resistance -TB
• A breastfeeding mother with DR-TB should receive a full course of anti-TB treatment, as timely and effective treatment is the best way to prevent transmission to her baby.
• The mother and her baby should not be completely separated. However, if the mother is sputum smear-positive, the cooperation of a family member should be sought to primarily care for the infant until the mother becomes sputum smear-negative.
• In cases where the mother has converted to smear negative the mother and infant may spend time together, in a well-ventilated area or outdoors.
• The mother should wear a surgical cloth mask during breastfeeding.
• Replacement feeding should only be considered in special conditions.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Recommendations
• Breastfeeding should be given on demand and mothers supported to exclusively breast feed for 6months with a continuation to 24months.
• Babies staying away from their mothers should be fed on Expressed breast milk .
• However, where this is not feasible due to drug toxicities or drugs effect on breast milk change in taste adequate information and support on replacement feeds should be provided

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Complementary feeding

After six months all babies require complementary foods while breastfeeding continues for up to two years of age or beyond

Complementary feeds should be:

- timely
- adequate
- safe
- properly fed

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Key messages for complementary feeding

1. Breastfeeding for two years or longer helps a child to develop and grow strong and healthy.
2. Starting other foods in addition to breast milk at 6 completed months helps a child to grow well
3. Foods that are thick enough to stay in the spoon give more energy to the child.
4. Animal-source foods are especially good for children, to help them grow strong and lively
5. Peas, beans, lentils, nuts and seeds are also good for children
6. Dark-green leaves and yellow-coloured fruits and vegetables help a child to have healthy eyes and fewer infections
7. A growing child needs 2-4 meals a day plus 1-2 snacks if hungry :give a variety of foods.
8. A growing child needs increasing amounts of food.
9. A young child needs to learn to eat: encourage and give help…with lots of patience.
10. Encourage the child to drink and to eat during illness and provide extra food after illness to help them recover quickly.

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Feeding the Child Who is Ill

- Encourage the child to drink and to eat – with lots of patience
- Feed small amounts frequently
- Give foods that the child likes
- Give a variety of nutrient-rich foods
- Continue to breastfeed – often ill children breastfeed more frequently
- Vitamin A according to routine supplementation and disease target schedule

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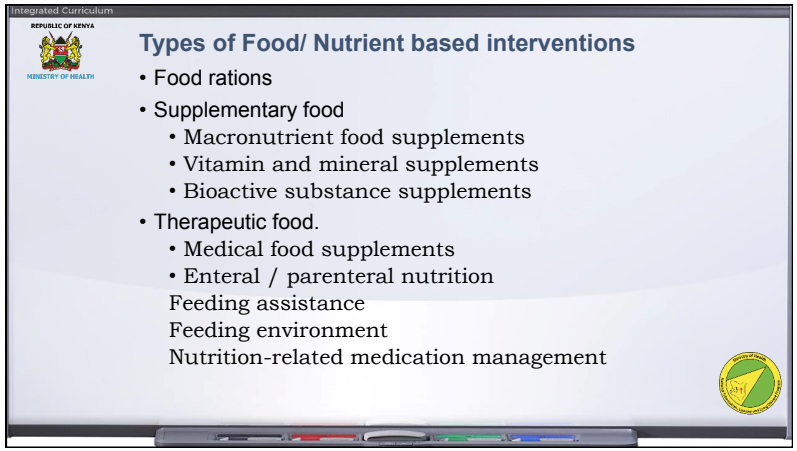
FOOD AND NUTRIENT BASED INTERVENTIONS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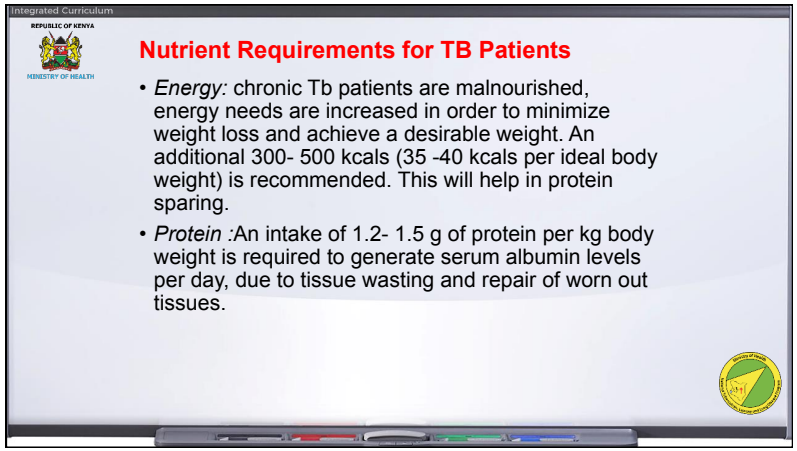
Types of Food/ Nutrient based interventions
• Food rations
• Supplementary food
• Macronutrient food supplements
• Vitamin and mineral supplements
• Bioactive substance supplements
• Therapeutic food.
• Medical food supplements
• Enteral / parenteral nutrition
Feeding assistance
Feeding environment
Nutrition-related medication management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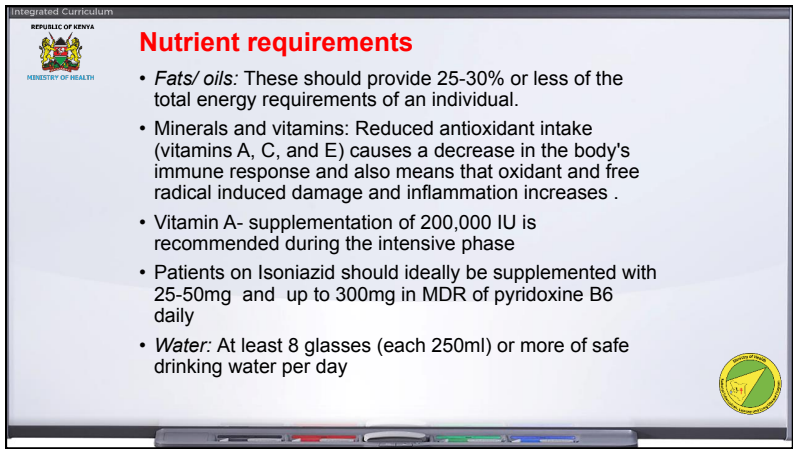
Nutrient Requirements for TB Patients
• Energy: chronic Tb patients are malnourished, energy needs are increased in order to minimize weight loss and achieve a desirable weight. An additional 300- 500 kcals (35 -40 kcals per ideal body weight) is recommended. This will help in protein sparing.
• Protein :An intake of 1.2- 1.5 g of protein per kg body weight is required to generate serum albumin levels per day, due to tissue wasting and repair of worn out tissues.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Nutrient requirements
• Fats/ oils: These should provide 25-30% or less of the total energy requirements of an individual.
• Minerals and vitamins: Reduced antioxidant intake (vitamins A, C, and E) causes a decrease in the body's immune response and also means that oxidant and free radical induced damage and inflammation increases .
• Vitamin A- supplementation of 200,000 IU is recommended during the intensive phase
• Patients on Isoniazid should ideally be supplemented with 25-50mg and up to 300mg in MDR of pyridoxine B6 daily
• Water: At least 8 glasses (each 250ml) or more of safe drinking water per day


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Management of Acute Malnutrition
Severe and Moderate Acute Malnutrition

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6 – 23 months

		Moderate Acute Malnutrition
Eligibility	• bilateral pitting Oedema + •Weight for Height less than – 3 z score •MUAC less than 11.5 cm •Passed appetite test	•Weight for Height less than – 2 •MUAC between 11.5 – 12.5 cm
Prescription	1. Nutrition counseling (care giver) 2. Sachets of RUTF per Kg. Bwt per week 3. Safe water solution	1. Nutrition counseling (care giver) 2. 100gms FBF per day 3. Ready to use supplementary feeds(RUSF) 1 Satchet per day
Treatment follow Up	•weekly – seven days	•Monthly (30 days)
Discharge	•Weight for height equal to – 1.0 Z score •No oedema •Passed appetite test	• Weight for height equal to – 1.0 Z score

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24 -59 Months

	Severe Acute Malnutrition	Moderate Acute Malnutrition
Eligibility	• bilateral pitting Oedema + •Weight for Height less than 3 z score •MUAC less than 11.5 cm •Passed appetite test	•Weight for Height less than – 2 z score •MUAC between 11.5 – 12 cm
Prescription	1. Nutrition counselling (care giver) 2. 21 – 35 sachets of RUTF per week	1. Nutrition counselling (care giver) 2. 200gms FBF – per day or 3. 2 Satchets RUSF per day
Discharge	•weekly – seven days	•Monthly (30 days)

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5 – 9 years

	Severe Acute Malnutrition	Moderate Acute Malnutrition
Eligibility	• bilateral pitting oedema + •BMI for Age less than – 3 Z score •MUAC less than 13.5 cm •Passed appetite test	•BMI for Age less than – 2 Z score •MUAC between 13.5 – 14.5 cm
Prescription	1. Nutrition counselling 2. 21 sachets of RUTF per week 3. 100gm FBF per day	1. Nutrition counselling 2. 200-300gms FBF – per day or 3. 2 Sachets RUSF per day
Treatment follow Up	•weekly – seven days	•Monthly (30 days)
Discharge	•BMI for Age equal or greater than – 3.0 Z score •No oedema for 10 days •Passed appetite test	• BMI for Age equal to or greater than – 1.0 Z score

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10 – 17 years

	Severe Acute Malnutrition	Moderate Acute Malnutrition
Eligibility	• bilateral pitting Oedema + •BMI for Age less than – 3 Z score •MUAC less than 16 cm •Passed appetite test	•BMI for Age less than – 2 Z score •MUAC between 16 – 18.5 cm
Prescription	1. Nutrition counselling 2. 21 sachets of RUTF per week 3. 200gms FBF per day	1. Nutrition counselling 2. 200-300gms FBF – per month or 3. 2 Sachets RUSF per day
Treatment follow Up	•weekly – seven days	•Monthly (30 days)
Discharge	•BMI for Age equal or greater than – 3.0 Z score •No Oedema for 10 days •Passed appetite test	• BMI for Age equal to or greater than – 1.0 Z score

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Adults 18 years & above

	Severe Acute Malnutrition	Moderate Acute Malnutrition
Eligibility	•Pitting Oedema + •BMI less than 16 kg/m^2 •MUAC less than 16 cm •MUAC 16 – 18.5 •Passed appetite test	•BMI 18.5 kg/m^2 •MUAC between 16 – 18.5 cm
Prescription	1. Nutrition counselling 2. 21 sachets of RUTF per week 3. 200gms FBF per day	1. Nutrition counselling 2. 200-300gms FBF – per day or 3. 2 Satchets RUSF per day
Treatment follow Up	•weekly (7 days)	•Monthly (30 days)
Discharge	•BMI equal to or greater than 16 kg/m^2 •No Oedema for 10 days •Passed appetite test	• BMI equal to or greater than 18.5 kg/m^2

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Pregnant or Postpartum mothers

	Severe Acute Malnutrition	Moderate Acute Malnutrition
Eligibility	• Bilateral pitting Oedema + • **BMI less than 20 kg/m^2 *** • MUAC less than 19cm • **Passed appetite test****	• MUAC between 19 – 23 cm Pregnancy ✓ **Observed low weight gain of < 1.3kg /month** Postpartum ✓ **Observed non intentional weight loss of > 0.7 kg/month and BMI < 20 kg/m^2**
Prescription	1. Nutrition counselling 2. 21 sachets of RUTF per week 3. 200gms FBF per day	1. Nutrition counselling 2. 200-300gm FBF –per day
Treatment follow Up	•Weekly (7 days)	•Monthly (30 days)
Discharge	•MUAC equal to or greater than 19 cm •No Oedema for 10 days •Passed appetite test •Observed weight gain of above 1 kg/month during pregnancy •Steady weight gain after 6 weeks &BMI > or = 20	• MUAC = or > 23 cm

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Nutritional management of patients with co-morbidities

Condition	Nutrition management
Diabetes	• For undernourished patients, therapeutic and supplemental food are used with caution; use of insulin and close monitor of blood sugar • Additional 200-500 Kcal (especially on patients on insulin) • Protein 1.2-1.5g/kg Bwt • Fats – 20g PUFA and MUFA • Supplementation of B6 • Vitamin A,C,E • Minerals zinc selenium, magnesium and calcium • Refer to diabetic clinic
Hyperthyroidism	• Treat the underlying cause • Use high calorie diet to meet the extra energy needs • Refer appropriately to medical/surgical clinic
Hypothyroidism	• Recommend iodine rich foods e.g. sea foods or iodine fortified salt • Refer appropriately
Hypertension	• Include foods high in potassium, magnesium, calcium and vitamin C • For undernourished patients give supplementary/therapeutic foods with caution • Refer to medical clinic
CVD	• Reduce salt intake to< 4g per day, an equivalent of (2400mg) sodium per day • Use a wide variety of fruits and vegetables • Refer appropriately

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UNIT 3
FOOD AND DRUG INTERACTIONS

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Food-drug interactions

By the end of this session, the participants will be able to:-

- Describe possible food and drug interactions and their management
- Identify possible linkages for appropriate/continued support

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Medication - Food interactions in TB therapy

- TB patients take several medications
- Medications can interact with each other and with food
- Medication - Food interactions should be addressed immediately to:
  - Prevent weight loss and malnutrition
  - Improve Drug efficacy
  - Improve client adherence to treatment

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Interaction between Drugs and Food/Nutrition

1. Food can affect drug efficacy.
2. Drugs can affect nutrient utilization.
3. Drug side effects can affect food consumption or nutrient absorption.
4. Combinations of certain drugs and foods can create unhealthy side effects.

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1. Food → Drug Efficacy

Affects

Examples

- Food reduces absorption of:
  - Aspirin (analgesic)
  - Isoniazid (Bananas, yorghut-yeast)
  - Rifampin
- A high fat meal:
  - Enhances the bioavailability of Tenofovir(ARV)
  - Reduces the absorption of Indinavir(ARV)

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2. Drugs → Nutrient Utilization

Affects

Examples

- Rifampicin increases vitamin D metabolism
- Isoniazid may decrease the absorption of calcium and phosphorus
- Isoniazid may cause pyridoxine deficiency.

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3. Drug Side Effects

Affect

Consumption /Absorption

Examples

- Metallic taste -
- Nausea/Vomiting
- Abdominal pain
- Anorexia
- Diarrhea
- Stomatitis

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4. Drug-Food Combinations

Cause

Unhealthy Side Effects

Examples

- Alcohol and Isoniazid can cause inflammation of the liver.

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Management of drug - Food Interactions

1. Offer drug-specific recommendations. e.g.
   - Separate timing of doses
   - Avoid/recommend appropriate foods
   - Consider change of drugs used
   - Adjust doses if needed
   - Query use of herbal/traditional medicine
2. Involve the client in finding solutions that address drug-food interactions

Side Effects related to TB drugs and food intake recommendations

Drug name	Food recommendation	Avoid	Possible side effects
Rifampicin	To be taken 1 hr before or 2 after food. 1 hr before antacids	alcohol	Nausea, vomiting, appetite loss
Isoniazid	Taken 1 hr before or 2 hrs after food. Give 10mg B_6 daily	Alcohol	Interferes with Hepatitis, Cutaneous hypersensitivity, Peripheral neuropathy
Ethambutol	May be taken with food	Avoid alcohol	Retrobulbar neuritis, Arthralgia
Streptomycin	Increase fluid intake		Taste changes, taste of food, nausea
Pyrazinamide	May be taken with food		Hepatitis, Nausea, Vomiting, Arthralgia
Ethionamide	Take with or after meals(Supplement with Vit B_6)	Alcohol	Abdominal discomforts, nausea
Ofloxacin	Take 2hrs before or after food	Antacids, milk products	Gastrointestinal reactions, Insomnia
Kanamycin (Km)	Can be taken without regard to food		Ototoxicity: hearing damage, vestibular, disturbance, Nephrotoxicity: deranged renal function test
Capreomycin	Increase fluid intake, take with foods high in potassium(bananas, avocados)		Ototoxicity: hearing damage, vestibular, disturbance, Nephrotoxicity: deranged renal function test
Para-aminosalicylic acid(PAS)	Take with or immediately after food. Increase fluid intake	Alcohol	Gastrointestinal reactions Dizziness, Headache, Depression, Memory loss
Cycloserine	Supplement with vitamin B_6	alcohol	Dizziness, Headache, Depression,

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Nutrition management in chronic respiratory diseases (lung diseases)

UNIT 4

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Objectives of Nutrition Interventions in Chronic Respiratory Diseases

- To equip health workers with knowledge on identification of nutritional risks and nutrition interventions for chronic respiratory diseases
- To discuss dietary recommendations for the prevention and management of chronic lung diseases
- To be able to Assess the nutrition status, classify patients and plan for appropriate interventions

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Aims of nutrition interventions in chronic respiratory diseases

- Provide adequate nourishment to the body and prevent malnutrition
- Boost the body's immune system
- Relieve the cough
- To aid expulsion of mucous
- Reduce severity of disease
- Reduce duration of disease
- Improve adherence to medication

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Nutrition management of coughs/ flu

- Intake of lemon juice with honey which is a traditional remedy for coughs is recommended
- Provide foods rich in Vitamin A as it is vital for healthy bronchial mucosa and helps relieve cough
- Provide foods rich in vitamin C as it boosts body' s immunity to effectively fight infections
- Reduce intake of salt as it may cause fluid retention in the respiratory system hence aggravate cough
- Reduce intake of dairy products as they may increase mucous production in the respiratory tract which can trigger or aggravate cough

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Nutrition management of bronchitis

- Use of mucolytics such as onions, leek and radishes is recommended
- Provide emollients such as okra, dates and figs as they soften and reduce inflammation in the respiratory mucosa
- Use of foods with antibiotic and antiseptic properties such as garlic and propolis is recommended as they combat bacteria and viruses that cause or aggravate bronchitis
- Encourage intake of lemon juice with honey which is a traditional remedy for coughs
- Provide foods which are rich in vitamin A as it is vital for healthy bronchial mucosa and helps relieve cough

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Nutrition management of asthma

- Provide antioxidants such as vitamins A, C and E as they enhance bronchial tubes' ability to withstand free radicals coming from environmental pollution
- Provide honey as it contains some pollen which can desensitize the body against environmental pollen
- Encourage consumption of onions. Onion is a bronchial dilator and antispasmodic which can relieve and prevent asthma attacks
- Reduce intake of food additives, salt, wine, beer and fish. Fish contains histamine which provokes all allergic reactions

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Foods that trigger asthma attack

- Eggs
- Cow's milk
- Peanuts
- Soy
- Wheat
- Fish
- Shrimp and other shellfish
- Salads & fresh fruits

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Food Preservatives and Asthma

- Food preservatives can also trigger an asthma attack. Additives, such as sodium bisulfite, potassium bisulfite, sodium metabisulfite, potassium metabisulfite, and sodium sulfite, are commonly used in food processing or preparation and can be found in foods such as:
  - Dried fruits or vegetables
  - Potatoes (packaged and some prepared)
  - Wine and beer
  - Bottled lime or lemon juice
  - Shrimp (fresh, frozen, or prepared)
  - Pickled foods

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Nutrition in COPD

- There is an increase in the energy needed for the work of breathing
- Unplanned weight loss from poor nutrition can further weaken the respiratory muscles
- Good nutrition helps prevent infections
- Poor nutrition can worsen COPD symptoms and decrease exercise tolerance

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Role of nutrition in COPD cont:

- Patients should take a lot of water 6-8 glasses unless the clinician recommends otherwise. This helps to keep mucus thin, making it easier for body to cough it up. Some people find it easier to fill a container full of their daily fluid requirement in the morning and spread it out during the day.

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Role of Nutrition in COPD cont: Decrease Sodium Intake

Reasons

- Eating too much salt causes fluid retention. Too much fluid can make breathing more difficult.
- To reduce sodium intake, patients should not add salt when cooking and should avoid the following

High sodium foods

- Cured smoked and canned meats, frankfurters, ham and salami
- Regular canned vegetables, soups and vegetable juices
- Salted snacks (nuts, crisps)
- Regular frozen meals
- Foods in brine (pickles, olives, Tuna)
- Regular processed cheeses
- Seasoned salt, meat tenderizer, MSG, soy sauce, barbeque sauce

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Role of micronutrients in COPD

Calcium

- Calcium helps with lung function, muscle contraction and blood clotting. It works with

Magnesium

- Two cups of milk can satisfy the daily adult need for calcium.
- Sources of Magnesium include, dark green vegetables, whole grains, beans, peas, lentils, tofu and some seafood. Chocolate and cocoa contains some

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Role of minerals in COPD

Potassium

- Required for muscle contractions. It is very important for the heart muscle.

Foods high in potassium include:

- Milk, yogurt, winter squash, tomatoes, apricots, cantaloupe, bananas, oranges, carrots,
- potatoes, raisins, spinach and dates.

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Meal sizes and frequencies for patients with COPD

- Small more frequent meals i.e. 4 meals plus 2 snacks (6 meals) that are energy dense help undernourished patients meet their caloric needs more efficiently.
- High fiber foods such as, vegetables, dried legumes, bran, whole grains, rice, cereals, pasta and fresh fruit aid in digestion by helping food move more easily through the digestive tract.

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Meal sizes and frequencies for patients with COPD cont:

- Patients with COPD should not over eat as this makes breathing more difficult. Consuming carbonated beverages like Soda or carbonated water or gas-producing foods such as beans, cauliflower or cabbage can also cause bloating. Eliminating these types of beverages and foods will ultimately allow for easier breathing.

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PHARMACOVIGILANCE
ENSURING SAFE USE OF MEDICINES

Integrated Curriculum

Objectives

By the end of this session participants will be able to

- Define pharmacovigilance, adverse drug reactions, and side effects
- Explain the rationale for Pharmacovigilance
- Discuss the roles and responsibilities of health care workers in pharmacovigilance
- Discuss the Guideline for the National Pharmacovigilance System in Kenya
- Discuss the tools for reporting in pharmacovigilance

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What do you see here? When did this happen first?

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Definition of Pharmacovigilance

"Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines, with the view to:

- Identifying new information about hazards, and
- Preventing harm to patients."

From:

- Greek *pharmakon* - drug
- Latin *vigilare* - to keep awake or alert, to keep watch

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What is an adverse drug reactions?

- A response to a medicine which is **noxious** and **unintended**, and which occurs at **doses normally used** in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function[1].

[1] *WHO Technical Report No 498 (1972)*

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What is a side effect?

- Any **unintended effect** of a pharmaceutical product occurring at **doses normally used** in humans, which is **related to the pharmacological properties of the medicine**

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Why Pharmacovigilance?

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Why Pharmacovigilance?

- To minimize harm
  - 'Drugs are double-edged weapons'
    - do good
    - do harm
- To control economic impact
  - ….Adverse reactions are a cost of modern medical therapy…..
    Goodman and Gilman, 1995

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Need and Importance of PV

- The information collected during the pre-marketing phase of a medicine is inevitably incomplete with regard to possible adverse reactions:
  - Tests in animals are insufficiently predictive of human safety
  - In clinical trials, patients are selected and limited in number, the conditions of use differ from those in clinical practice and the duration of trials is limited
  - Information about rare but serious ADRs, chronic toxicity, use in special groups (such as children, elderly or pregnancy) or medicine interactions is often incomplete or not available

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Need and Importance of PV

- Quality of medicines varies between companies in each country and between countries for the same product
- Distribution and use of medicines may vary (e.g. indications, dose, availability may all vary between countries)
- Genetics, diet, traditions of the people also vary
- Pharmaceutical quality and composition (especially excipients) of locally and internationally produced pharmaceutical products may differ

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Need and Importance of PV

- The use of herbal remedies, whose origin is obscure, may lead to toxicological problems, when used alone or in combination with other medicines.

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Burden of ADRs

Morbidity and Mortality

- Adverse Drug Reactions are one of the leading causes of morbidity and mortality.
- It has been estimated that approximately 2.9 - 5.6% of all hospital admissions are caused by ADRs
- As many as 35% of hospitalized patients experience an ADR during their hospital stay.[1]

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Burden of ADRs

- ADRs are one of the leading causes of morbidity and mortality.
- It has been estimated that they are the *4th –6th largest* cause of mortality in USA.
- *This situation is expected to be worse in developing countries!*

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Benefits of Pharmacovigilance

✓Prevention of medicine-related morbidity

✓Prevention of medicine-related mortality

✓ Minimize in-patient and out-patient morbidity

✓ Huge savings in healthcare costs

✓Better patient confidence and trust

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Influence of Pharmacovigilance on Medicines Regulation

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Medicine regulation

- Medicines regulation is governed by issues of **safety**, **quality** and **efficacy**
- Any concerns on the above can lead to regulatory actions
- Regulatory actions include:
  - Recall
  - Reschedule
  - Withdrawal
  - Policy change

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Recall

- A medicine or a particular batch may be removed from the market due to safety, quality and efficacy concerns.
- Recall can be voluntary or initiated by a regulatory authority
  NB: The Board must be informed of any market recalls
- Once the issues in question have been satisfactorily addressed by the Market authorization holder, the product can be re-introduced into the market

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Example of Recall

- In 2008, Kenya recalled batches of Duo-cotecxin® (antimalarial) due to presence of counterfeit packs
- In 2008, some paracetamol suspensions and syrups were recalled due to re-crystallization

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Rescheduling

- Medicines can be classified as
  - Human, Vet, Herbal
  - Prescription Only Medicine (POM), Pharmacy only (P), Over-the-counter (OTC)
  - Part I and Part II poison
  - Schedules
  - Groups
  - Others e.g. pharmacological, therapeutic and chemical
- At registration almost all medicines are POM (part I); subsequently may change to P or OTC (part II)
- Can also move in reverse (from P or OTC to POM)

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Example of Reschedule

- Most medicines were initially registered as “Prescription Only Medicines (POMs)” and on being found to be relatively safer in the wider population, they were rescheduled to “Over The Counter (OTC)” medicines.
  - Sulphonamide/Pyrimethamine anti-malarials in 1998 were POM and were rescheduled to OTC then to POM for Intermittent preventive treatment in pregnancy (IPTp).
  - Chloroquin was rescheduled from OTC to POM

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Withdrawal

- This involves **revocation**, **suspension** or **cancellation** of the marketing authorization by the Pharmacy and Poisons Board
- Mostly due safety concerns but can also be due to quality and efficacy

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Example of Withdrawal

- 2004 Vioxx® (Rofecoxib), a COX-II inhibitor was withdrawn due to increased risk of cardiovascular events
- Thalidomide tragedy…

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Policy Change

- Usually the last step in regulatory actions.
- May require extensive consultation as it may lead to change in treatment guidelines.
- Common practice in programs

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Example of Policy Change

- Removal of Inj. Streptomycin
- Change from HIV and AIDS patients using d4T to TDF due to toxicity

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SCOPE

PRODUCT DEVELOPMENT

↓

POST-MARKET SURVEILLANCE

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COMPONENTS OF PHARMACOVIGILANCE

These include:

- Product development
- Substandard medicines
- Medication error reporting
- Efficacy monitoring
- Off-label use of medicines

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COMPONENTS OF PHARMACOVIGILANCE

- Case reports of acute and chronic poisoning reports
- Assessment of medicine-related mortality
- Abuse and misuse of medicines reports
- Adverse interactions of medicines with chemicals, other medicines, and food reports

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New Areas in Pharmacovigilance

These include:

- Product development
- Substandard and counterfeit medicines
- Medication error reporting
- Efficacy monitoring
- Off-label use of medicines
- Case reports of acute and chronic poisoning
- Assessment of drug-related mortality
- Abuse and misuse of medicines reports
- Adverse interactions of medicines with chemicals, other medicines, and food reports

Healthcare Providers supporting Pharmacovigilance

- Pharmacists
- Pharmaceutical technologists
- Clinicians (Consultants, Medical Officers and Clinical Officers)
- Nursing Officers
- Laboratory technologists
- Records officers

Role of the Prescriber

Every medicine prescribed has *risk : benefit* relationship

The prescriber should:

- consider risk : benefit relationship of each medicine
- prescribe the safest medicine among those of similar efficacy
- explain to the patient the nature, purpose and risks associated with the treatment
- ensure that the patient consent is based on an adequate understanding of the likely risks and benefits
- Report all suspected ADRs

Role of the Nurse

- Collect important ADR related information that a patient may not reveal to a doctor
- Inform clinicians of concerns in a patient's vital signs and laboratory reports

Role of the Pharmacist

- Ensuring that medicines are used safely
- Prevention and early detection of suspected ADRs through involvement in patient care
- Review of treatment charts and medication counseling to alert patients of potential ADRs
- Collecting data on ADRs
- Educating other healthcare professionals about the prevention, detection and reporting of suspected ADRs.

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National Pharmacovigilance Guidelines and Tools

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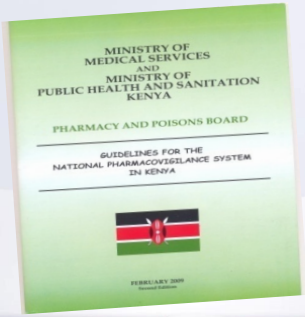
Guidelines for the National Pharmacovigilance System in Kenya



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Guideline contents

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- Introduction to ADRs and PV
- The proposed PV system in Kenya
- Reporting
- Flow of information
- Tools in PV
- ADR monitoring
- Roles and responsibilities
- Roll out and training
- Principles of efficient reporting
- Annexes and references

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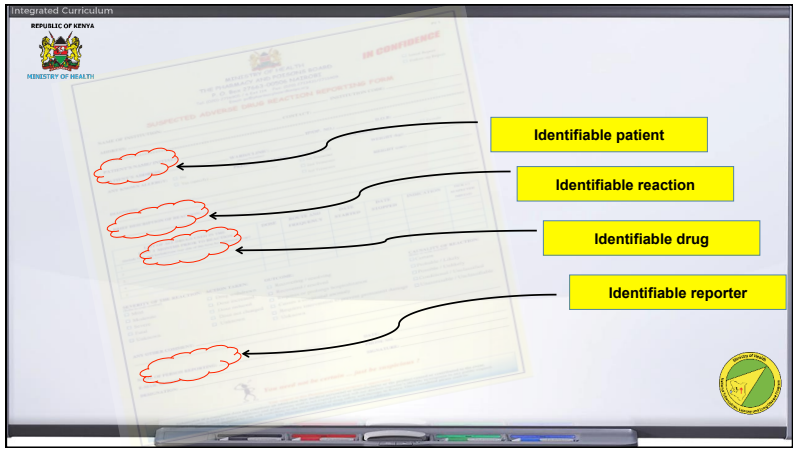
Tools

- Yellow form (PV 1) – Form for reporting suspected adverse drug reactions
- White card (PV 4)-Alert card
- Pink form (PV 6)- Form for reporting poor quality medicinal products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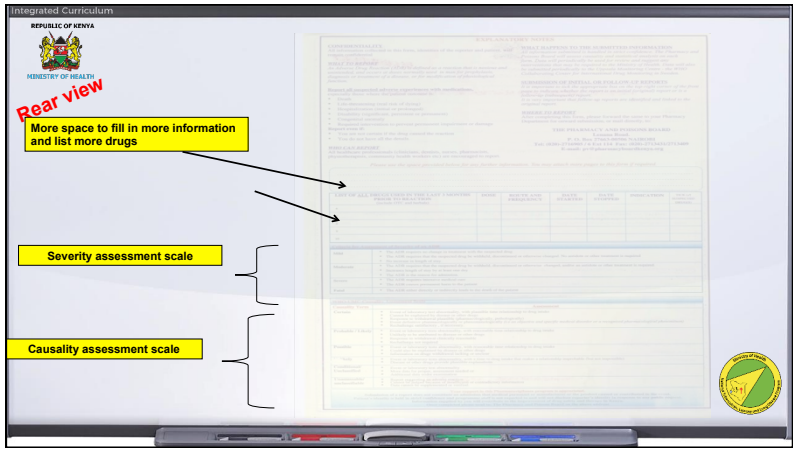
Identifiable patient
Identifiable reaction
Identifiable drug
Identifiable reporter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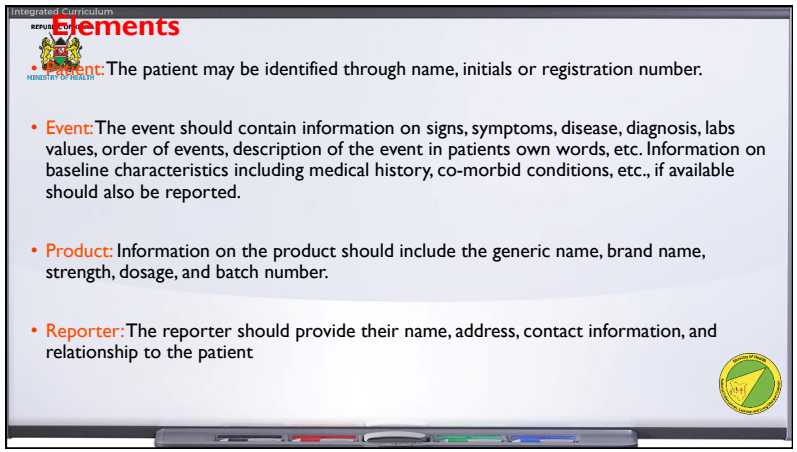
Rear view
More space to fill in more information and list more drugs
Severity assessment scale
Causality assessment scale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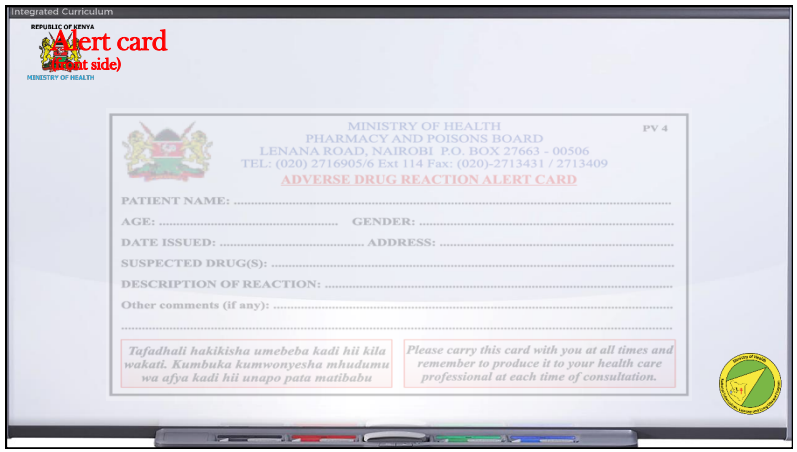
Elements
Patient: The patient may be identified through name, initials or registration number.
Event: The event should contain information on signs, symptoms, disease, diagnosis, labs values, order of events, description of the event in patients own words, etc. Information on baseline characteristics including medical history, co-morbid conditions, etc., if available should also be reported.
Product: Information on the product should include the generic name, brand name, strength, dosage, and batch number.
Reporter: The reporter should provide their name, address, contact information, and relationship to the patient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Alert card
(Front side)
MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
LENANA ROAD, NAIROBI P.O. BOX 27663 - 00506
TEL: (020) 2716905/6 Ext 114 Fax: (020)-2713431 / 2713409
PV 4
ADVERSE DRUG REACTION ALERT CARD
PATIENT NAME:
AGE:
GENDER:
DATE ISSUED:
ADDRESS:
SUSPECTED DRUG(S):
DESCRIPTION OF REACTION:
Other comments (if any):
Tafadhali hakikisha umebeba kadi hii kila wakati. Kumbuka kumwonyesha mhudumu wa afya kadi hii unapo pata matibabu
Please carry this card with you at all times and remember to produce it to your health care professional at each time of consultation.

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Alert card
(back side)

CRITERIA FOR ISSUE OF A PATIENT ALERT CARD

The criteria for issue of the Patient Alert Card is as follows:

The alert card is given to:

- Patients who are hypersensitive / allergic / intolerant to a particular drug
- Patients who develop a 'near-fatal' reaction to any particular drug
- Patients who had a drug- induced morbidity to any drug
- Patients who had hospital admission due to an ADR to any drug
- Patients who developed an ADR which caused increase in the health care expenditure

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PV 6 (PINK FORM)

FORM FOR REPORTING
POOR QUALITY
MEDICINAL PRODUCTS

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Pharmacovigilance in Kenya: Flow of Information

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What to report
- Suspected ADR
- Poor quality medicinal product

Who should report
- Patient
- Relatives
- Healthcare worker

When to report
- Fill the form - as soon as possible on suspicion
- Send the form - as soon as possible on completion

Where to send
- District pharmacist
- Designated official/organization
- PPB-department of pharmacovigilance

How to send
- Appointed courier
- Direct post
- Fax/Telephone/Email
- MoH system in existence

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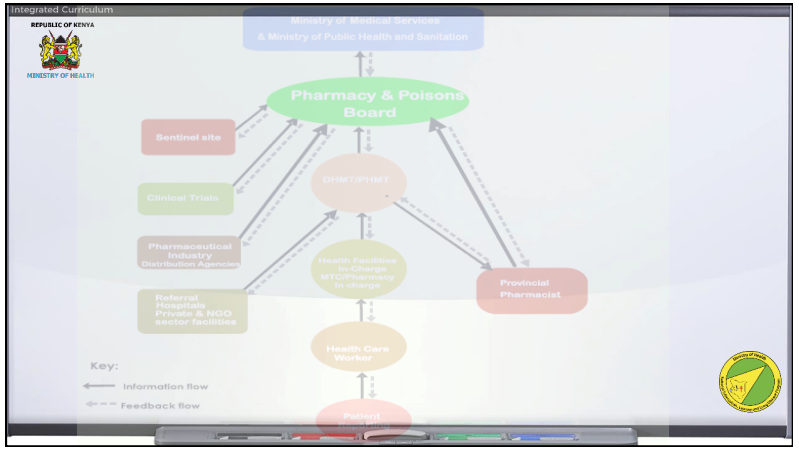

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Sources of Reporting tools

- PPB
- PPB website
- All health facilities

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Case study 1

ANM is a 32 year old male who comes to your facility complaining of dysphagia, cough, oral candidiasis and considerable weight loss. After several tests the patient is found to be eligible for ART and the clinical team decides to initiate him on d4T + 3TC + NVP and CTX for prophylaxis. 2 weeks later, patient prevents with SJS, diarrhea and excessive dehydration.

- Identify the problem in the above case
- Use the relevant tool (s) to enter and report the information

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Case study 2

- A consignment of Xmol (Paracetamol 120mg/5ml) is received at PPB dispensary in Koinange district on 10 June 2010 from KEMSA. The manufacturing date is 10 June 2009 and expiry date is June 2012. The batch number is X100 and the manufacturer is Koinange Pharma box 100 Koinange Kenya. 2 days after receiving it, you notice that the syrup appears to have glass like particles at the bottom and on comparing with the previous stock, the colour appears to be yellowish instead of pink. On examination, the product conforms with the labeling requirements

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Case Study 2 (cont'd)

- Identify the problem in the above case
- Use the relevant tool (s) to enter and report the information

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THANK YOU

The image cannot be displayed. Your computer may not have enough memory to open the image, or the image may have been corrupted. Restart your computer, and then open the file again. If the red x still appears, you may have to delete the image and then insert it again.

"You need not be certain…

Just be suspicious"

Report all SUSPECTED adverse drug reactions

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Kenya Lung health Training Course

MINISTRY OF HEALTH

TB INFECTION PREVENTION AND CONTROL

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Objectives

By the end of this session, the participants will be able to:

1. Understand the elements infection prevention and control in TB control
2. Clarify roles and responsibilities of health care workers and other stakeholders
3. Prioritize and initiate interventions for health-care facilities and other levels
4. Develop a TB infection prevention and control plan for their facilities.
5. Monitor and evaluate set targets for TB infection prevention and control at all levels

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Outline

1: Introduction to the course
2: Administrative controls
3: Environmental Controls
4: Respiratory protection
5: IPC in special situations

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Introduction

- Tuberculosis infection prevention and control (IPC) refers to a combination of measures aimed at minimizing the risk of TB transmission within populations
- It complements core interventions in TB and HIV control
- It is important because of :
  - Association of TB with HIV
  - Emergence of drug resistant TB (DR-TB)
  - Increased risk of transmission among contacts of TB patients, health care facilities and congregate settings

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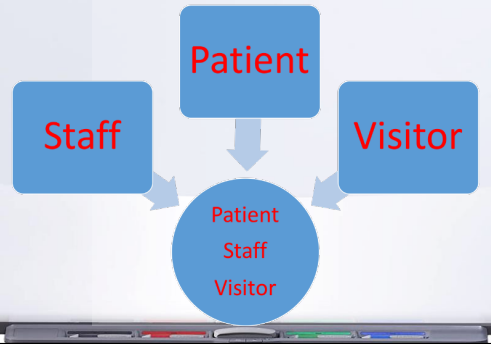
Who may infect who?



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IPC MEASURES

There are three levels of TB infection control measures:

1. Administrative control measures
2. Environmental control measures
3. Personal protective equipment

• POINTS TO REMEMBER

- Administrative measures are the most important of the three levels.
- Environmental control measures and personal protective equipment will not work in the absence of **solid administrative controls.**

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Levels of Infection control interventions

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Administrative control Measures

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Administrative control measures

Definition

Managerial or work practices that reduce the risk of TB transmission by preventing the generation of droplet nuclei and limiting exposure to droplet nuclei

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Administrative support for TB infection control

- **Administrative commitment** to implementation of TB infection control is necessary to ensure success of TB prevention efforts
- **An Infection Prevention and Control Committee** should be formed to coordinate activities amongst different facility services

** TB IPC is part of general Infection Control*

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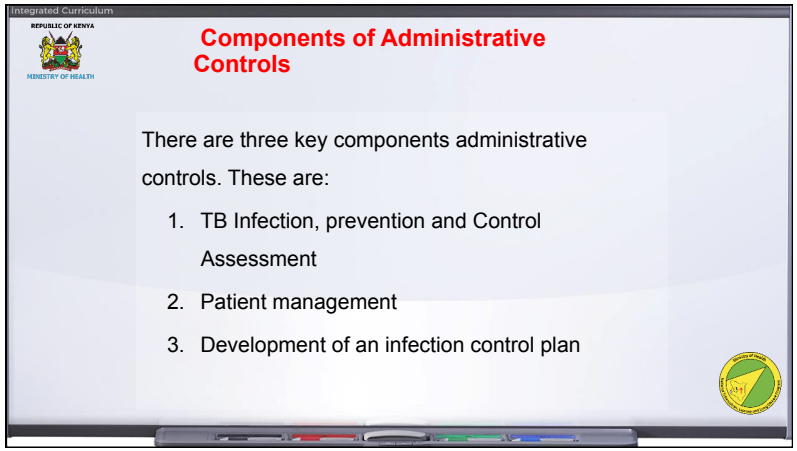
Functions of the IPC committee

1. Meet monthly and discuss:
   - Development of the TB Infection Control Plan
   - Quality of TB infection control in the facility
   - Staff training in TB infection control
   - Changes to ensure TB infection control is implemented
   - Finances and budgets that allow for implementation of infection control interventions
2. Conduct operational research on IPC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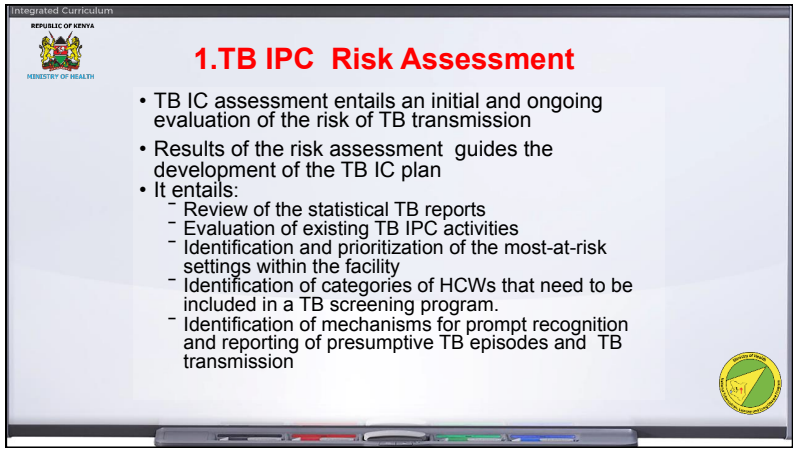
Components of Administrative Controls
There are three key components administrative controls. These are:
1. TB Infection, prevention and Control Assessment
2. Patient management
3. Development of an infection control plan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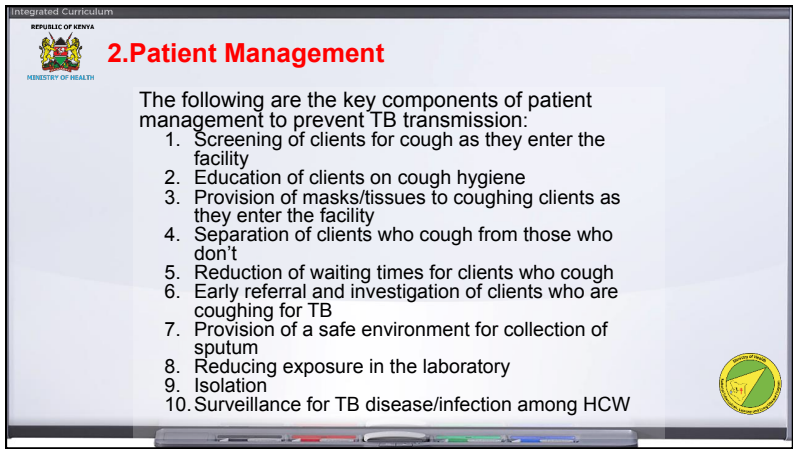
1.TB IPC Risk Assessment
• TB IC assessment entails an initial and ongoing evaluation of the risk of TB transmission
• Results of the risk assessment guides the development of the TB IC plan
• It entails:
- Review of the statistical TB reports
- Evaluation of existing TB IPC activities
- Identification and prioritization of the most-at-risk settings within the facility
- Identification of categories of HCWs that need to be included in a TB screening program.
- Identification of mechanisms for prompt recognition and reporting of presumptive TB episodes and TB transmission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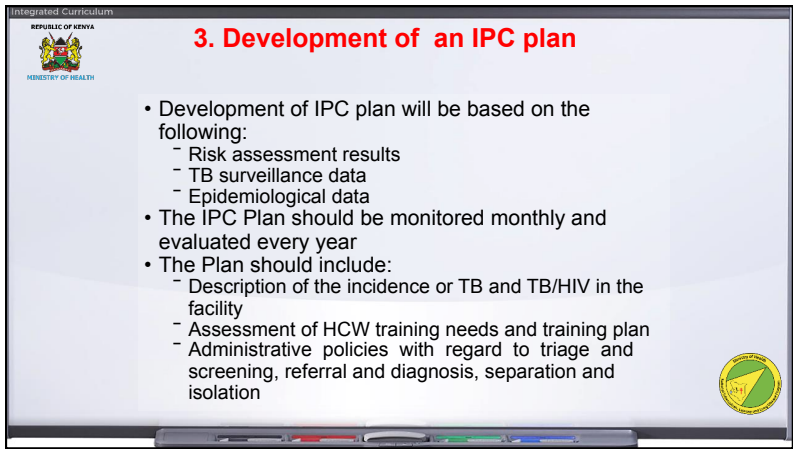
2.Patient Management
The following are the key components of patient management to prevent TB transmission:
1. Screening of clients for cough as they enter the facility
2. Education of clients on cough hygiene
3. Provision of masks/tissues to coughing clients as they enter the facility
4. Separation of clients who cough from those who don't
5. Reduction of waiting times for clients who cough
6. Early referral and investigation of clients who are coughing for TB
7. Provision of a safe environment for collection of sputum
8. Reducing exposure in the laboratory
9. Isolation
10. Surveillance for TB disease/infection among HCW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3. Development of an IPC plan
• Development of IPC plan will be based on the following:
- Risk assessment results
- TB surveillance data
- Epidemiological data
• The IPC Plan should be monitored monthly and evaluated every year
• The Plan should include:
- Description of the incidence or TB and TB/HIV in the facility
- Assessment of HCW training needs and training plan
- Administrative policies with regard to triage and screening, referral and diagnosis, separation and isolation

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Cont..

- Using and maintaining environmental controls
- Policy on the training and use of respiratory protection
- Area-specific infection control recommendations
- Description of roles and responsibilities for implementation and monitoring the infection control plan.
- Time-line and budget (e.g., material and personnel cos

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Group Work

- You are the Facility In charge for Health facility X. You need to develop a plan :
  - List and discuss the elements of the IPC plan
  - Assuming you have a plan, how do you implement it?
  - List and discuss the steps to implement it, including barriers and funding issues

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Environmental control Measures

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Environmental Control Measures

- **Definition**
  - These are measures that are used to reduce the concentration of droplet nuclei in the air
- The Principles of environmental controls, address five primary methods of employing technology in reducing TB risk. These are:
  - Facility design
  - Dilution
  - Filtration
  - Purification
  - Disinfection

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FACILITY DESIGN

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Facility Design

The design should take into consideration

1. Patient flow pattern:-
   - Minimizes congregate situations
   - Provide areas for segregation of potentially infectious patients
   - Provides isolation rooms/wards for infectious inpatients
   - Minimizes cross-infection
2. Maximize natural ventilation considering
   - Direction of prevailing winds
   - Placement and size of doors, windows, corridors
   - Promotes air-flow patterns to be from least infected (HCW) to most infected (patient)
3. Maximize availability of sunlight

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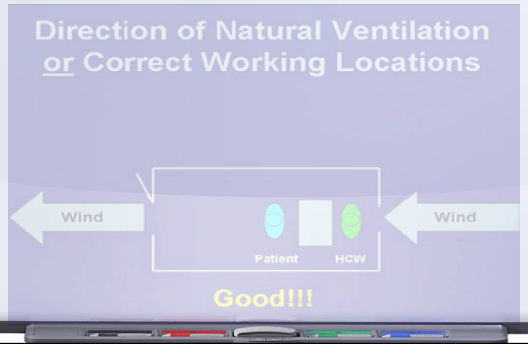
Clinic sitting arrangement



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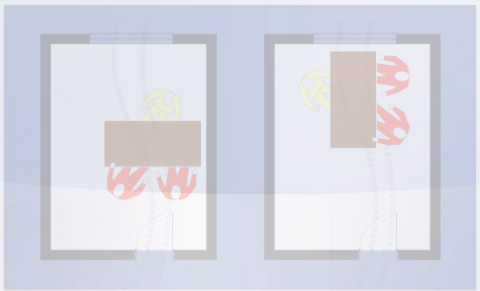
Sitting arrangement under natural ventilation



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TB Consultation Room Layout

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AIR DILUTION

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Air Dilution (ventilation)

- Reduces the concentration of MTB in a space by introducing clean air
- Dilution does not kill the MTB but reduces probability of transmission by dispersing the microbes to non-infectious concentrations.
- This is achieved by employing:
  - Natural ventilation
  - Mechanical ventilation
  - Mixed mode ventilation to achieve the desired dilution factors

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1. Natural ventilation

- Natural ventilation is created by use of external airflows generated by wind or differences in temperature
- Natural ventilation
  - ✓ relies on open doors and windows
  - ✓ it's unregulated in case of permanent openings.
  - ✓ the direction of wind may not be controlled nor change the flow of air.
- Natural air movement should be monitored since it can be used to determine the sitting arrangement in consultation rooms between patients and HCWs.

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Natural Ventilation

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Advantages	Disadvantages
– High ventilation rate	– Climate dependent
– Low installation cost	– No control over direction of contaminated air.
– Low maintenance cost or	– Noise pollution
– Maintenance free	– Privacy of consultation
– Applicable widely in settings where TB transmission is high	– Security
– No Space for machinery.	– Fire risk
	– Other diseases-malaria

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3. Mechanical ventilation

- Mechanical ventilation is created by use of mechanical devices that force air exchange and drive air flow
- Mechanical devices range from simple table, floor, window, ceiling fans and exhaust fans to more complex high tech. negative and positive pressure air handling units
- It works by generating **pressure** or **air flow** differentials to move air in a room or space
- To be effective, it is essential that:
  - ✓ All doors and windows are kept closed
  - ✓ A minimum of 12 ACH is maintained

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Types of mechanical ventilation

1. Local exhaust ventilation
   - Sputum booth
   - Biosafety cabinets (BSC)
   - Biosafety hoods or laminar flow cabinets
   - Patient tents
2. General ventilation for large areas and spaces
   - Air handling units
3. Mobile ventilation devices
   - Free standing circulation unit

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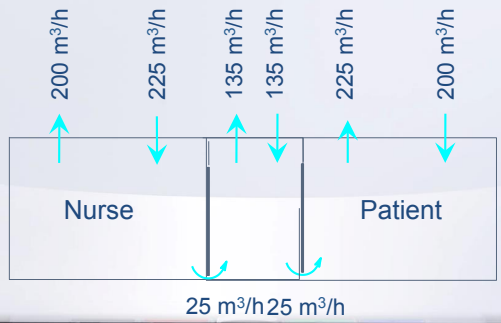
Air flow by negative pressure mechanism

- Negative pressure is a means of forcing air flow into a room by creating low pressure inside the room
- Negative pressure is achieved by exhausting air at a higher volumetric rate than the rate at which air is being supplied
- Negative pressure is necessary for achieving directional airflow (laminar airflow)
- The direction of airflow is controlled by creating a lower (negative) pressure in the area into which the flow of air is desired
- For air to flow from one area to another, the air pressure in the two areas must be different
- Air will flow from positive pressure areas (HCW area) to negative pressure areas (patient area)
- Negative pressure is the approximate air-pressure difference between two areas in a health-care setting

What is negative pressure



Air flow by negative pressure

- A room that is under negative pressure has a lower pressure than adjacent areas, which keeps air flowing from the adjacent rooms or areas into the room
- The following gadgets are used to ascertain negative pressure between rooms
  - Smoke tube
  - Velocity meter (velometer, vaneometer and anemometer)
  - Pressure sensor (Air flow balometer and manometer)

Application of negative and positive pressure

TYPICAL NEGATIVE PRESSURE SPACES

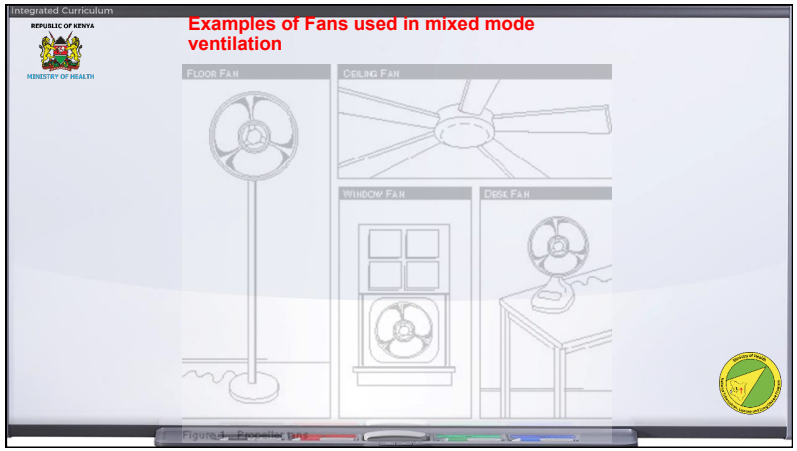
- Bronchoscopy rooms
- Labs
- ICU/HDU
- Autopsy Room
- Embalming Rooms
- Outpatient Settings
- TB wards
- Medical Offices
- Ambulances
- Dialysis Units
- Dental Care
- Infectious isolation rooms

TYPICAL POSITIVE PRESSURE SPACES

- Operating theatres
- Surgical Suites
- Preventive isolation rooms

3. Mixed-mode (hybrid) ventilation

- This ventilation combines the use of mechanical and natural ventilation
- It is done through the installation of an exhaust or supply fan to increase the rate of air changes in the room
- It is used in places where natural ventilation is not adequate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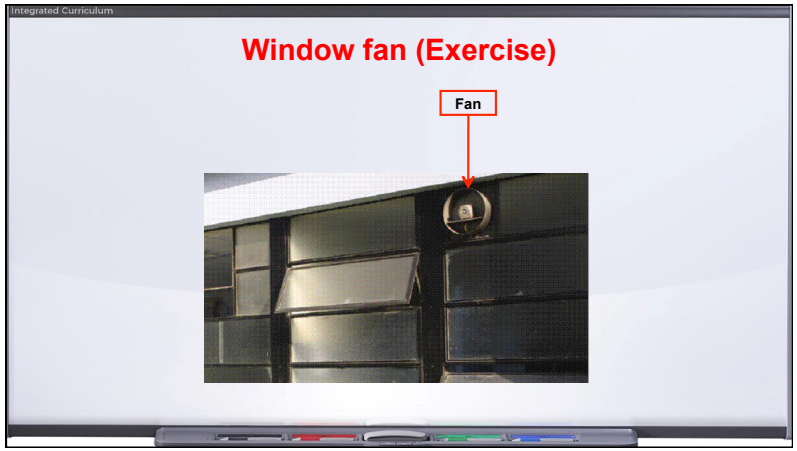
Examples of Fans used in mixed mode ventilation
FLOOR FAN
CEILING FAN
WINDOW FAN
DESK FAN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Window fan (Exercise)
Fan


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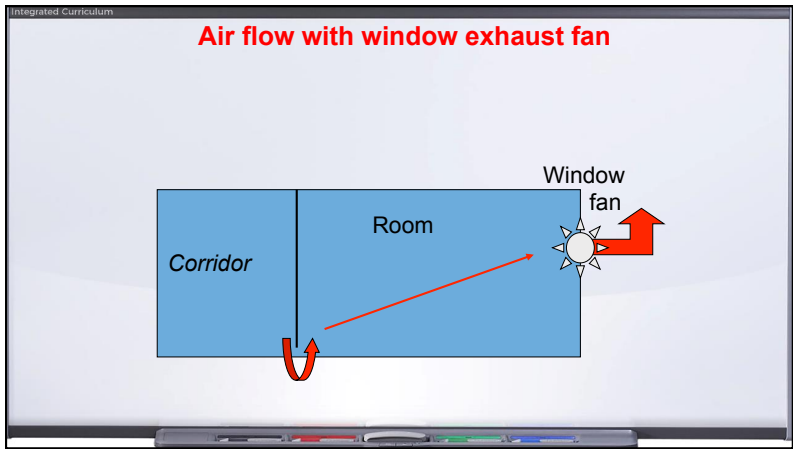
Where does the air go?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Air flow with window exhaust fan
Window fan
Room
Corridor

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3.FiLTRATION

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Filtration

- Filtration reduces the concentration of infectious organisms by passing fluid through a filtration media
- Does not kill the infectious organisms, but reduces their concentration
- Air is filtered by use of High Efficiency Particulate Air filter (HEPA) of 0.3 micron
- This traps bacteria, viruses, spores & dust achieving 99.97% clean air

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Types of filter media

1. Fiber
   - Cellulose
   - Polymeric
   - *Glass (best for hospital)*
2. Membranes
   - Cellulose esters
   - Nylon
   - Polycarbonate
3. Fabric
   - Cotton
   - Polyester
4. Foam
   - Polymeric
   - Active carbon
5. Granular bed
   - Sand
6. Sintered metal
   - Silver
   - Titanium
   - Nickel
7. Ceramic
   - Aluminum Oxide
   - Silicon carbide

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Room air cleaners

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4.PURIFICATION

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Purification

- Purification is the process of getting rid of impurities
- This involves the destruction of the infectious organisms
- The commonest method of air purification is use of Ultra-Violet Germicidal Irradiation (UVGI)

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ULTRAVIOLET GERMICIDAL IRRADIATION (UVGI)

- This method is employed in
  - In high-risk areas such as prisons and other very poorly ventilated areas of the health care facility
  - larger wards, TB clinic waiting areas or in-patient areas where TB patients gather together
  - Where use of natural and simple mechanical ventilation such as Ceiling or floor fans may not be feasible.
- UVGI provides a less expensive alternative to HEPA filtration and structural re-adjustment

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How much UVGI do we need to kill *M. tuberculosis*?

- TB bacilli are killed when exposed sufficiently to UV light
- The target is to destroy 90% of MTB colony formation
  - This is achieved by irradiating ultraviolet C (UVC) of density of at least 100 J/M^2 (this is the dosage or susceptibility level of MTB)
- This can be measured using a photometer or a radiometer

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Maintenance requirements

- UVGI lamps should cleaned on monthly basis to remove dust with 96% alcohol solution
- Lamps should not last more than 2 years as the UVGI output will fall below 20%
- Relative Humidity in air must not be above 65%

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Example of Upper room UVGI

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Upper Room UVGI Lamp

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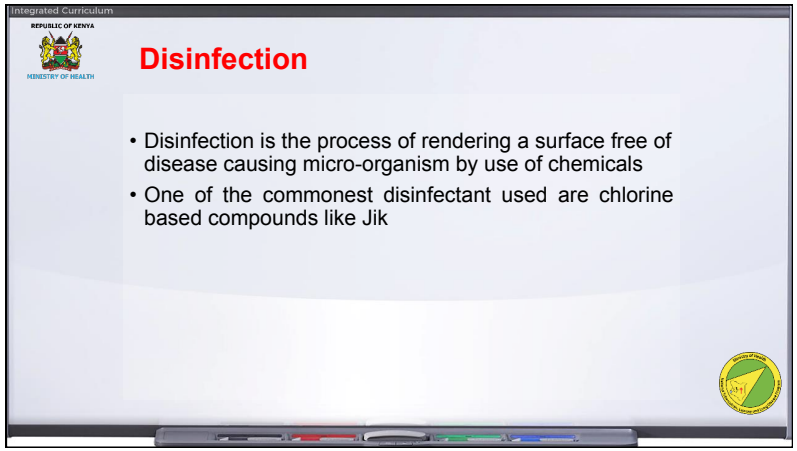
5.DISINFECTION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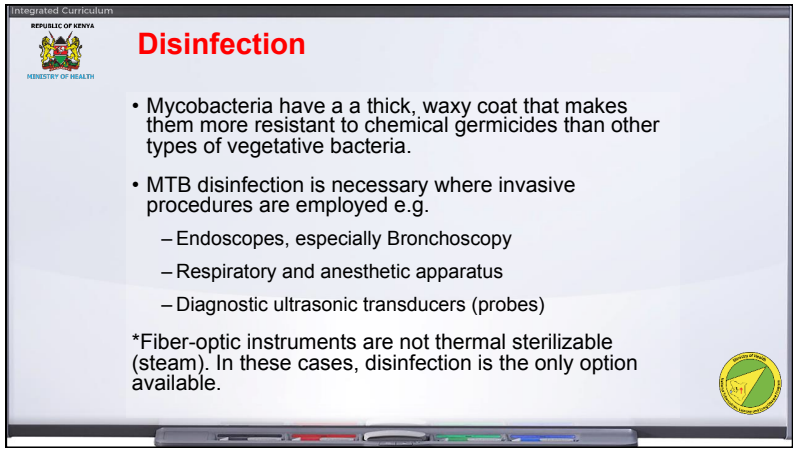
Disinfection
• Disinfection is the process of rendering a surface free of disease causing micro-organism by use of chemicals
• One of the commonest disinfectant used are chlorine based compounds like Jik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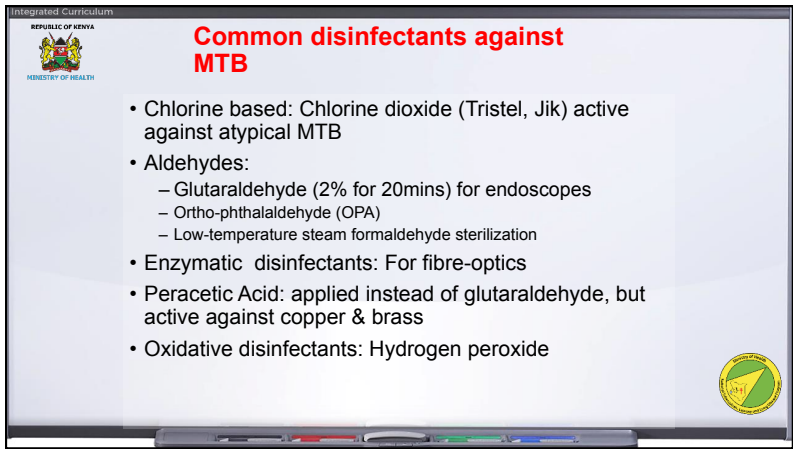
Disinfection
• Mycobacteria have a a thick, waxy coat that makes them more resistant to chemical germicides than other types of vegetative bacteria.
• MTB disinfection is necessary where invasive procedures are employed e.g.
– Endoscopes, especially Bronchoscopy
– Respiratory and anesthetic apparatus
– Diagnostic ultrasonic transducers (probes)
*Fiber-optic instruments are not thermal sterilizable (steam). In these cases, disinfection is the only option available.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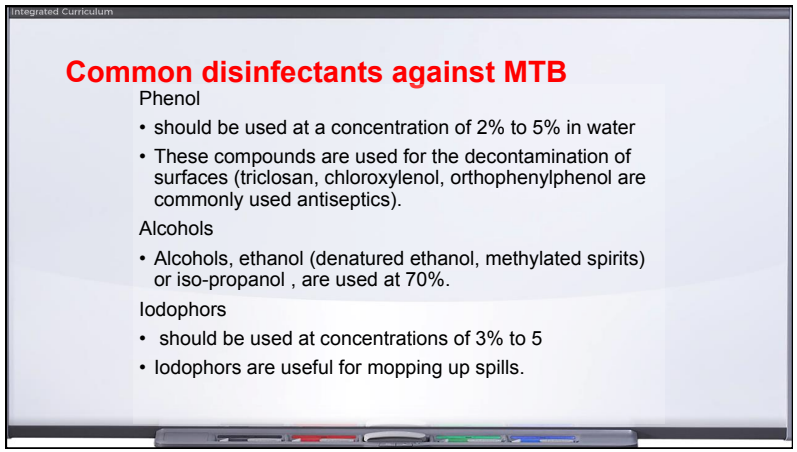
Common disinfectants against MTB
• Chlorine based: Chlorine dioxide (Tristel, Jik) active against atypical MTB
• Aldehydes:
– Glutaraldehyde (2% for 20mins) for endoscopes
– Ortho-phthalaldehyde (OPA)
– Low-temperature steam formaldehyde sterilization
• Enzymatic disinfectants: For fibre-optics
• Peracetic Acid: applied instead of glutaraldehyde, but active against copper & brass
• Oxidative disinfectants: Hydrogen peroxide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Common disinfectants against MTB
Phenol
• should be used at a concentration of 2% to 5% in water
• These compounds are used for the decontamination of surfaces (triclosan, chloroxylenol, orthophenylphenol are commonly used antiseptics).
Alcohols
• Alcohols, ethanol (denatured ethanol, methylated spirits) or iso-propanol , are used at 70%.
Iodophors
• should be used at concentrations of 3% to 5
• Iodophors are useful for mopping up spills.

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Common MTB sterilizers

- Hydrogen Peroxide: excellent when applied in a low temperature hydrogen peroxide plasma machine for half an hour
- Ethylene oxide: 24 hours in ethylene oxide sterilizer

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PRACTICAL
Measuring natural air change (Air Change per Hour -ach)

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Calculation of air changes per hour (ACH)

ACH= Average flowrate/ room volume

Average flowrate= __m^3 / hour

Room volume= __ m^3

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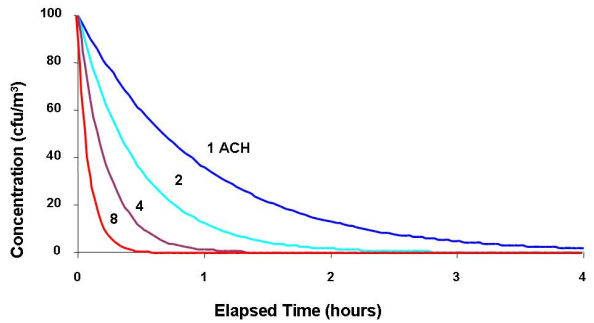
Air dilution



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Examples of ACH calculations

Room volume	Average air flowrate (Air volume x h)	ACH
4m x 4m x 2.5 m	m^3 x h	Flow/ volume
40 m^3	40	1
40 m^3	200	5
40 m^3	300	7.5
40 m^3	600	12

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ACH and time (in minutes) required for removal efficiences of 99% and 99.9% of airborne contaminants

ACH	99%	99.9%
2	138 min	207 min
4	69	104
6	46	69
12	23	35
15	18	28
20	14	21
50	6	8
400	<1	1

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Exercise: ACH calculation

- Window opening= 0.5 m high, 0.5 m wide
- Window area = 0.5 m x 0.5 m = 0.25 m^2
- Average air velocity through window= 1 m/s
- Average flow rate = Area window x average air velocity= 0.25 m^2 x 1 m/s x 3,600 s/h = 900 m^3/h
- Room dimensions= 3 m wide, 5 m deep, and 3 m high
- Room volume = 3 m x 5 m x 3 m = 45 m^3

- ACH = Average flow rate/ room volume=

=900 m^3/hour/45 m^3 = 20 ACH

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Group Exercise 1: ACH calculation of identified room

Working in Groups of 5

Requirements for the Exercise

- Tape measure
- Calculator
- Veneometre
- Watch/Timer
- Note Pad and Pen

Instructions

- Identify a room and take measurement
- Calculate ACH using the formula

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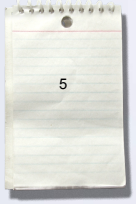
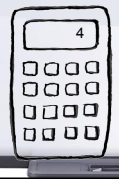
Tools you need to measure ACH



1. A tape measure
2. Vaneometer
3. Smoke tube
4. Calculator
5. Note pad



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PERSONAL PROTECTIVE EQUIPMENT/ RESPIRATORY PROTECTION

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Infection control interventions

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Personnel Protective Equipment: Masks

- Surgical masks reduce the spread of microorganisms from the wearer (protection from exhaled droplets)
- They do not provide protection to the wearer from inhaling small infectious aerosols

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Surgical masks (yes for patients)

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Surgical masks (not for staff)

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Personnel Protective Equipment: Respirators

N95 respirators effectively filter out ≥ 95% (98% for FFP3) of the particles ≥ 03 µm)

N95/ FFP2

FFP3

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WHO recommendations

- When used with administrative and environmental controls, particulate respirators may provide health care workers (HCW) additional protection from TB
- Respirators
  - Must meet or exceed standards
  - Be properly used
  - Be part of a training programme

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WHO recommends particulate respirators for HCWs:

- Caring for patients with confirmed or suspected infectious TB (in particular MDR-TB)
- Performing aerosol-generating procedures on infectious TB patients
  - Bronchoscopy, intubation, sputum induction
  - Use of high speed devices for lung surgery or autopsy

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Other types of respirators

- Negative pressure respirators
- Air-purifying respirators (APR)
- High Efficiency Particulate Air (HEPA) filter

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Negative pressure respirator

- A respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator

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Air-purifying respirator (APR)

A respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying elements

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Respirator Fitting

Practical demonstration of respirator fitting

- Get a respirator
- Check expiry date
- Check for any physical damage
- Read the manufacturer's/user instructions
- Fit the face mask
- Demonstrate storage of a respirator.

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Why is fit testing necessary?

- Ensure a proper seal between respirator and wearer
- Determine appropriate make/model
- Determine appropriate size

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When should fit testing be done?

Employees should pass a fit test:

- Prior to initial use
- Whenever a different respirator facepiece (size, type, model or make) is used
- Whenever changes in the worker's physical condition or job description that could affect respirator fit are noticed or reported

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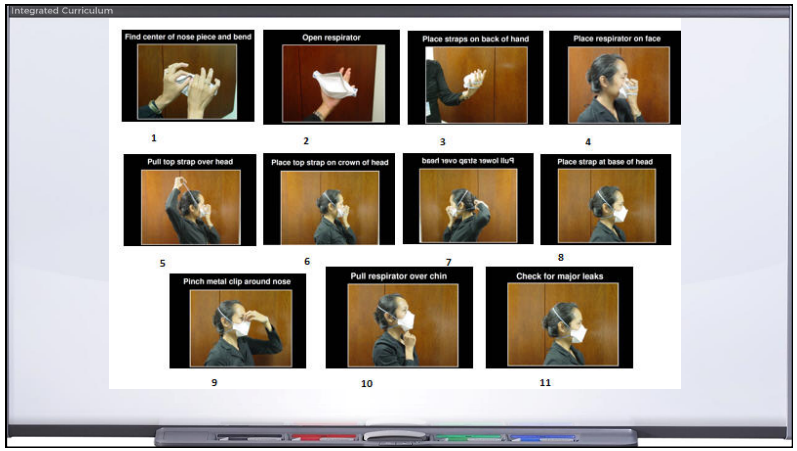
Sources of facepiece leakage

- Around facepiece/skin interface
- Through air-purifying element
- Through exhalation valve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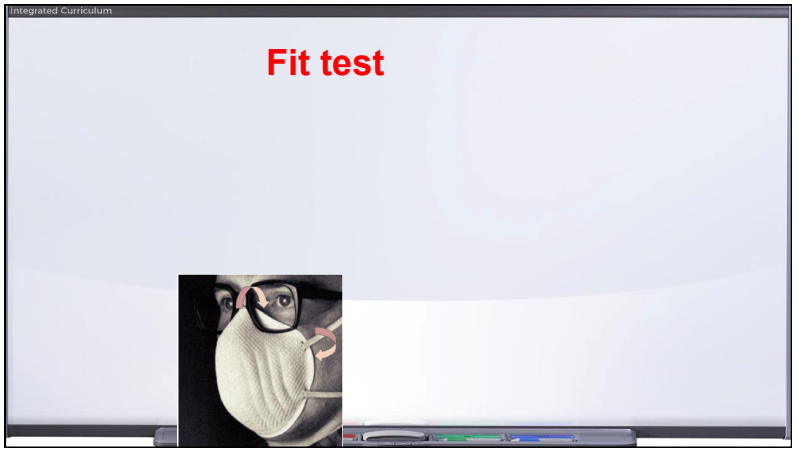
Find center of nose piece and bend
Open respirator
Place straps on back of hand
Place respirator on face
1
2
3
4
Pull top strap over head
Place top strap on crown of head
Place strap at base of head
5
6
7
8
Pinch metal clip around nose
Pull respirator over chin
Check for major leaks
9
10
11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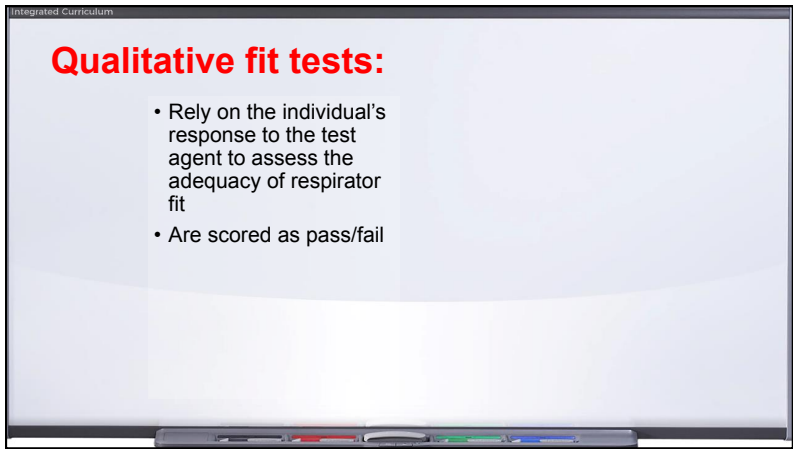
Fit test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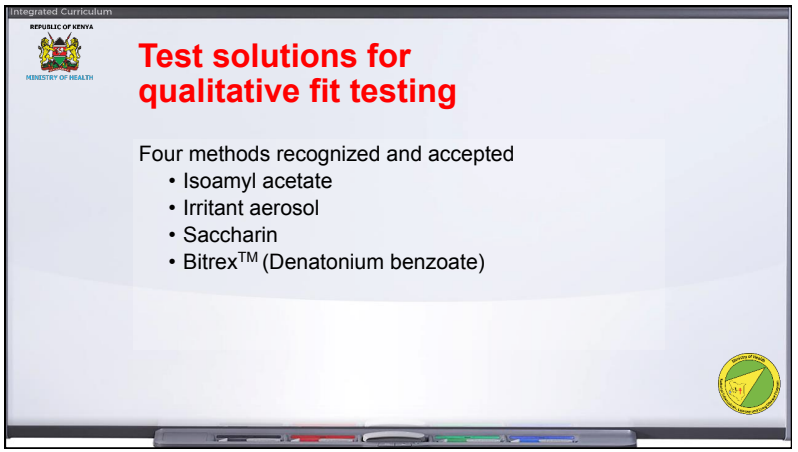
Qualitative fit tests:
• Rely on the individual's response to the test agent to assess the adequacy of respirator fit
• Are scored as pass/fail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Test solutions for qualitative fit testing
Four methods recognized and accepted
• Isoamyl acetate
• Irritant aerosol
• Saccharin
• Bitrex™ (Denatonium benzoate)

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Is this respirator put on properly?

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Factors contributing to poor fit

- Weight loss or gain
- Facial scarring
- Changes in dental configuration (dentures)
- Facial hair
- Cosmetic surgery
- Excessive makeup
- Mood of workers (smiling/ frowning)
- Body movements

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Care for respirators

- How do we take care of our respirators?
  - Decontamination?
  - Cleaning?
  - Storage?
- To take care of our respirators
  - Decontamination NO!
  - Cleaning NO!
  - Storage Clean & Dry place!
- Take care when re-using respirator – closely monitor service life
- Dispose respirator if you question its performance
- Do not share the respirator
- Follow the manufacturers instruction

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Reasons for disposal

Click to edit Master title style

- If wet
- If damaged
- If dirty

- Golden Rule

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Methods of disposal

- Burn and bury
- Incineration
- Autoclaving

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Exercise on Respiratory protection

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Exercise for participants

- Discuss and comment on the pictures given
- Discuss for 20 minutes then report the groups' comments to the plenary

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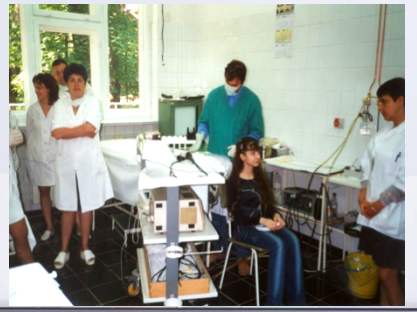
Brochoscopy room: What is wrong with this picture from infection prevention stand point?



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DOTS room: What is wrong with this picture from infection prevention stand point?

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KNH: Isolation MDR-TB tent

TB/HIV clinic

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Summary

- Surgical masks prevent infectious particles from being expelled by the wearer
- Respirators protect the health care worker from inhaling infectious particles
- When used with administrative and environmental controls, N95, FFP2 or FFP3 respirators provide additional protection when HCWs care for infectious TB patients
- Whenever respirators are used, a respirator programme is necessary

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•IPC IN SPECIAL SETTINGS

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Congregate settings

- Have a higher risk of TB infection because of
  - longer duration of potential exposure
  - crowded environment
  - poor ventilation
  - limited access to health care services
- These settings Include:

1. Prisons and remand cells:
   - All inmates should be screened for TB using PF10 tool at admission and after every 6 months
   - Prison and Remand cells should implement TB IC guidelines

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Cont…

2. Informal settlements (slums):
   - Conduct Community sensitizations on
   - Adequate ventilation
   - Early health seeking behavior
   - Conduct active TB screening, contact and defaulter tracing
3. Refugee and internally displaced persons (IDP) camps:
   - TB Screening at cross boarder points and camps
   - Do GeneXpert and Culture Drug Susceptibility Test to rule out Drug Resistant TB on symptomatic refugees
4. Learning institutions and security forces training camps
   - TB infection control should be incorporated in school health program and training camps

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Public services transport

- Advocacy and sensitization of relevant ministries and stakeholders on IPC is important
- Public Transport Users should ensure adequate ventilation by opening all the windows or applying mechanized ventilation
- Patients known to have potentially infectious TB should be advised not to travel on commercial aircraft until there is no longer a risk of transmitting infection to others

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Infection control and legal implication

- TB, MDR-TB patients and the community should be adequately educated on the importance of adhering to DOTs and DOTs Plus strategy.
- Patients who may refuse to adhere to the treatment will have to be managed according to the existing laws and guidelines.

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Basic Techniques in Managing TB

Commodities

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Objectives

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

- Describe the basic concepts of Tb commodity management especially for Gxpert consumables,FLD,SLD and nutritional commodities
- Use commodity management tools to ensure accountability of all commodities in the facility.
- Adequately report on TB commodities consumption.
- Use of available commodity planning tools to provide stock status alert

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Why Commodity Management

Commodity management is ensuring that the

- Right product,
- Of the right quality
- In Right quantities is delivered
- At Right time
- At Right place
- To the Right customer

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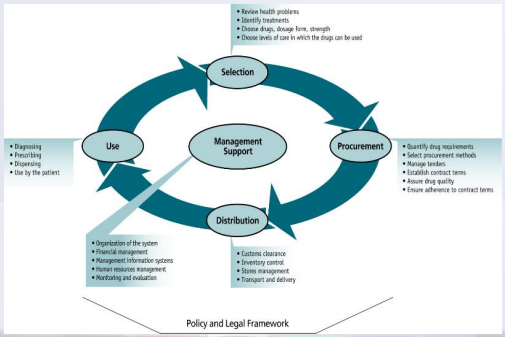
Commodity Management Cycle



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Quantification and Rational

Quantification:

- This is the process of estimating the quantities of medicines and other commodities needed for a specific period of time in order to ensure an uninterrupted supply.

Rationale:

- To ensure that there are sufficient quantities to meet clients' / patients' needs and avoid shortages/stock-outs.
- To avoid surpluses that may lead to over-stocking, expiries and/or wastage of commodities.
- To make informed procurement adjustments when faced with budgetary constraints

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Quantification methods used in TB commodities

Consumption method

The consumption based method uses historical data on the actual medicines dispensed to patients to calculate the quantity of medicines that will be needed in the future.

Morbidity method

The morbidity-based method uses data about diseases and the frequency of their occurrence in the population (incidence or prevalence) or the frequency of their presentation for treatment.

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FLOW OF LOGISTICS

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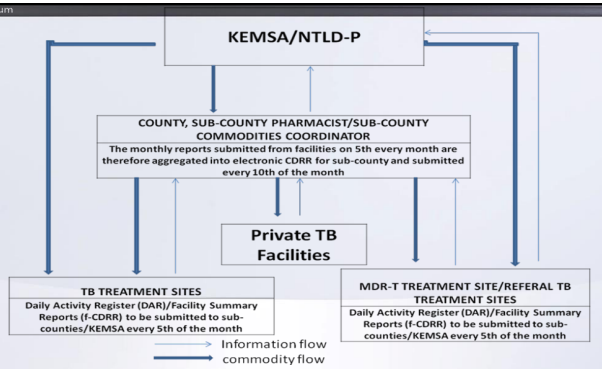

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Commodity Management at facility level

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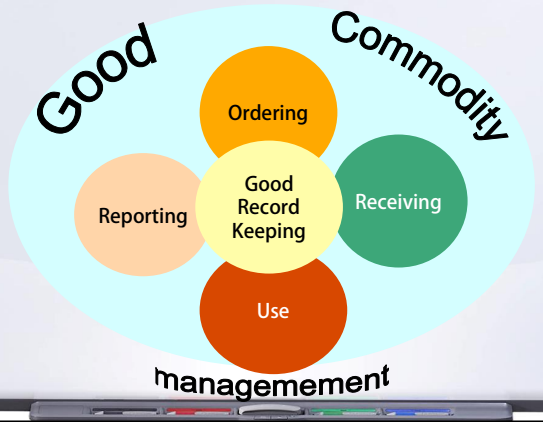

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How to order for commodities

- Orders are made to KEMSA on a monthly basis.
- Use the Facility consumption data report and request(FCDRR)
- Order an amount equivalent to 1 Months of stock plus One month safety stock.

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How to receive

- Commodities must be received within normal working hours.
- Check the number of boxes on the transporters delivery note
- Check the quantities received for each commodity against the KEMSA delivery note
- Note and report any discrepancies on the delivery if any

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How to receive

- Each consignment will come with a KEMSA Delivery Note, Invoice and Account Statement and transporter packing list
- Record any discrepancy/other problem (eg. wrong item, wrong quantity, damaged item etc)
- Always enter the received commodities in the BIN Card,

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Ensure that all the contents of the delivery are in good physical order:

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How to Receive

Bin Card

FORM S5	REPUBLIC OF KENYA	
BIN CARD		
ITEM CODE NO.	UNIT OF ISSUE	SERIAL NUMBER:
ITEM DESCRIPTION	STORAGE REQUIREMENTS	LEDGER CARD NO. .....
.....		LOCATION .....

Date	Issue / Receipt Voucher No.	Receipt	Issue	Balance	Initials	Date	Issue / Receipt Voucher No.	Receipt	Issue	Balance	Initials
	B/F From Card No.	B/F									
	C/F										

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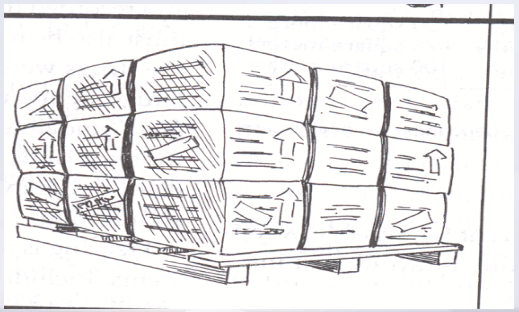
Storage: Good arrangement: Keep commodities off the floor, in cartons facing up. This allows easy cleaning and minimizes damage by water



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Storage: Good stock rotation

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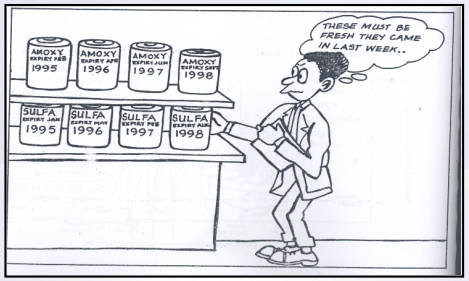
Storage: Good control &Stock Rotation (FEFO/FIFO)

Is this Health Worker using FEFO method?



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Storage: conditions, Temperature

- Store Commodities at Manufacturer's recommended conditions.
- Have Air conditioner if possible
- Should have the Max-Min thermometers
- Always follow the manufacturers instructions when storing commodities.

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Storage: Assured Security: Restricted Access

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Use

- During dispensing of TB medicines, All health workers must ensure they record the usage in the provided Daily activity Register for TB commodities.

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Rational Drug Use

- The rational use of medicines requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community (World Health Organization, 1988).

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Importance of Rational Drug Use

- Irrational medicine use can destroy the benefits of a good pharmaceutical management system and also reduce the therapeutic useful life of an effective medicine.
- Resources spent on procurement are lost if the correct drugs are not prescribed and dispensed to the correct patient.

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Factors affecting rational use of medicines

- **Diagnosis** - correct diagnosis based on parasitologically confirmed diagnosis
- **Prescribing** – prescribing /administering the recommended medicine based on the correct diagnosis
- **Dispensing** - correct dispensing (quantity, packaging and labeling) of the prescribed medicine.
- **Patient compliance** - patients' adherence to health worker and label instructions.

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Good Record keeping

Records to track stock levels and transactions:

- Inventory records

Other records:

- Temperature Log: To monitor temperature

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Stock keeping records

Level of Use	Inventory Record	Information
Receiving and storing commodities	•Delivery Notes •Bin cards/stock ledger	Confirmation of delivery and receipt of commodities
Issuing	Bin cards S11/S12	Issues to dispensing area or other facilities
Dispensing	Daily activity registers e.g. AL register and Tally sheets	Amount of commodities actually dispensed to patients
Reporting &Ordering	SORF , Health facility monthly summaries	The consumption/ dispensed to user data. Stock balances at end of each reporting period

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Why account for your commodities?

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Reasons for accounting for TB commodities

- To accurately determine your needs
- To avoid stock outs.
- To avoid expiries.
- To minimize wastage
- To prevent pilferage.
- To help sustain funding from partners

MODULE 8: ENGAGING COMMUNITIES, PATIENTS AND NON STATE ACTORS (NSA) IN TB, LEPROSY AND LUNG HEALTH CARE SERVICES

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Kenya Lung health Training Course

COMMUNITY ENGAGEMENT IN TB, LEPROSY AND ASTHMA ACTIVITIES

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COMMUNITY ENGAGEMENT

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Learning Objectives

At the end of this session the participant should be able to:

1. Explain what is community engagement and the rationale
2. Describe effective characteristics and tasks of various community players/stakeholders
3. Discuss effective implementation of community engagement
4. Describe how to identify a potential treatment supporters
5. Explain ENGAGE TB Approach
6. Explain patients rights and responsibilities
7. Describe Infection prevention and control at community level
8. Describe the process for monitoring community engagement

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What is Community Engagement?

- Community engagement involves trained and supervised community members who provide TB-DOTs, treatment support to patients and referral for TB, Leprosy and Asthma
- This support is provided outside of health facilities in homes, schools, places of worship among others.
- The purpose is to decentralize TB, leprosy and lung health services beyond health facilities and into the communities
  - does not replace health-facility DOTS
  - embraces primary health care approach of community engagement
  - makes TB, Leprosy and Asthma care more accessible to patients and their families

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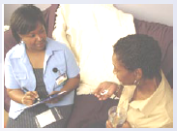
Rationale for Community Engagement

- Though diagnosed in clinics and hospitals, TB Leprosy and asthma thrives in the community
- Its important to link community action on TB Leprosy and asthma with the efforts of the health Care Worker.
- There is the need for an enhanced collaboration and coordination between the HCW, communities and Non State Actors.
- Non State Actors will contribute to the achievement of universal coverage and comprehensive care in TB, leprosy & Lung Health services.
- Attending daily TB services at health facility can be difficult for:
  - ✓ patients who are too sick
  - ✓ patients who live far away from the facility and therefore the need for community engagement.

Image Source: World Lung Foundation



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Community based approaches

Case identificaton and diagnosis	• Identification of signs and symptoms of TB, Leprosy and Asthma • Referral of presumptive cases of TB, Leprosy and Asthma • Collection and shipment of sputum for TB diagnosis to health facilities • Contact tracing for patients lost to follow up
Patient care and support	• Implementation of TB DOTs • Counsel and advice patients on Ambulatory services • Promote provision of social and livelihood support • Patient follow up to ensure completion of treatment
Infection prevention control	• Health education of the patient, family and community • Vaccination of children with BCG among others • Promote provision of IPT for children exposed to TB • Reverse referral or up down from facility to community- Home based care

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Link between facility and Community

Health care worker should;

- Ensure that every patient referred to facility as a presumptive TB, Asthma or Leprosy from the community is appropriately attended to.
- Ensure presumptive TB case reaching the facility are entered into the presumptive/ contact investigation register(where applicable)
- Probe for person referring the presumptive case to the facility especially those referred by CHVs
- Ensure active contact investigation of all cases who turn positive for the disease (TB, Leprosy).
- Assist all patients to identify appropriate treatment supporters

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Who is Eligible for Community Care?

Community care is optional however patients should be encouraged to embrace community approach

- Eligible patients include those
  - Who are very sick
  - Who live in remote areas away from the facility
  - Require DOT services

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What is needed to implement community engagement

- Collaboration and cooperation between NTLD-P, health facilities, communities, and NGOS
- Clear roles and guidelines for all service providers including community volunteers
- Education and counseling of patients and families
- Identification and training of community volunteers and CHEWs
- A effective system of supervision and monitoring of community volunteers /CHEWs

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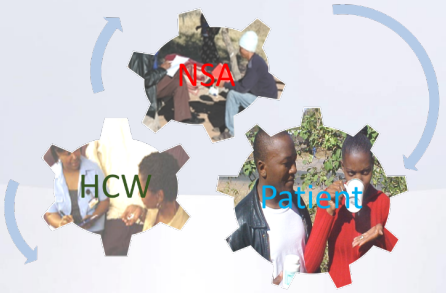
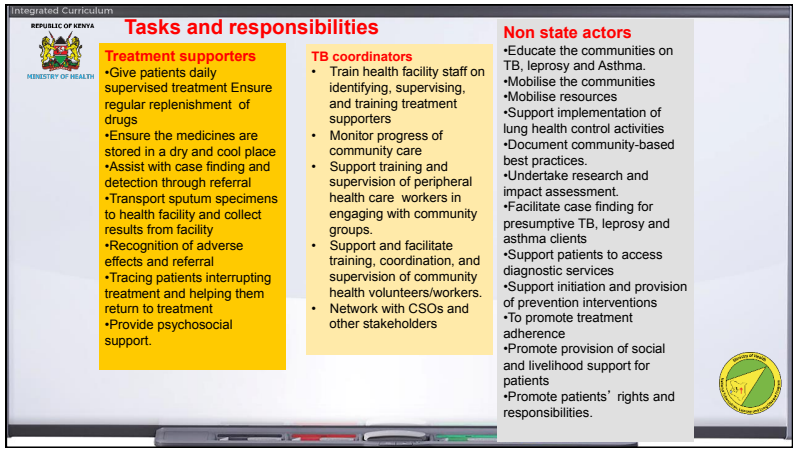
Tasks and responsibilities of different community players

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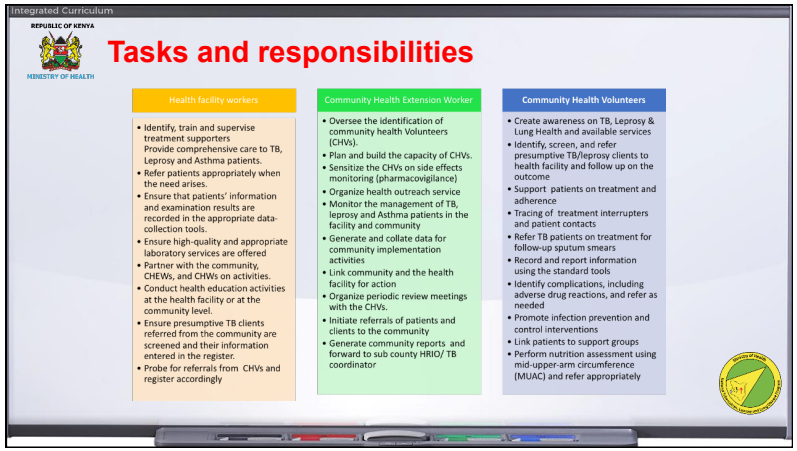
Tasks and responsibilities
Treatment supporters
•Give patients daily supervised treatment Ensure regular replenishment of drugs
•Ensure the medicines are stored in a dry and cool place
•Assist with case finding and detection through referral
•Transport sputum specimens to health facility and collect results from facility
•Recognition of adverse effects and referral
•Tracing patients interrupting treatment and helping them return to treatment
•Provide psychosocial support.
TB coordinators
• Train health facility staff on identifying, supervising, and training treatment supporters
• Monitor progress of community care
• Support training and supervision of peripheral health care workers in engaging with community groups.
• Support and facilitate training, coordination, and supervision of community health volunteers/workers.
• Network with CSOs and other stakeholders
Non state actors
•Educate the communities on TB, leprosy and Asthma.
•Mobilise the communities
•Mobilise resources
•Support implementation of lung health control activities
•Document community-based best practices.
•Undertake research and impact assessment.
•Facilitate case finding for presumptive TB, leprosy and asthma clients
•Support patients to access diagnostic services
•Support initiation and provision of prevention interventions
•To promote treatment adherence
•Promote provision of social and livelihood support for patients
•Promote patients' rights and responsibilities.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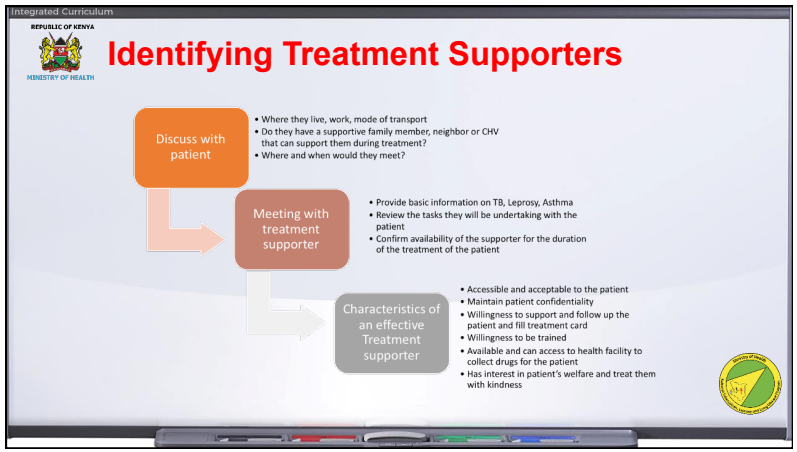
Tasks and responsibilities
Health facility workers
• Identify, train and supervise treatment supporters Provide comprehensive care to TB, Leprosy and Asthma patients.
• Refer patients appropriately when the need arises.
• Ensure that patients' information and examination results are recorded in the appropriate data-collection tools.
• Ensure high-quality and appropriate laboratory services are offered
• Partner with the community, CHEWs, and CHWs on activities.
• Conduct health education activities at the health facility or at the community level.
• Ensure presumptive TB clients referred from the community are screened and their information entered in the register.
• Probe for referrals from CHVs and register accordingly
Community Health Extension Worker
• Oversee the identification of community health Volunteers (CHVs).
• Plan and build the capacity of CHVs.
• Sensitize the CHVs on side effects monitoring (pharmacovigilance)
• Organize health outreach service
• Monitor the management of TB, leprosy and Asthma patients in the facility and community
• Generate and collate data for community implementation activities
• Link community and the health facility for action
• Organize periodic review meetings with the CHVs.
• Initiate referrals of patients and clients to the community
• Generate community reports and forward to sub county HRIO/ TB coordinator
Community Health Volunteers
• Create awareness on TB, Leprosy & Lung Health and available services
• Identify, screen, and refer presumptive TB/leprosy clients to health facility and follow up on the outcome
• Support patients on treatment and adherence
• Tracing of treatment interrupters and patient contacts
• Refer TB patients on treatment for follow-up sputum smears
• Record and report information using the standard tools
• Identify complications, including adverse drug reactions, and refer as needed
• Promote infection prevention and control interventions
• Link patients to support groups
• Perform nutrition assessment using mid-upper-arm circumference (MUAC) and refer appropriately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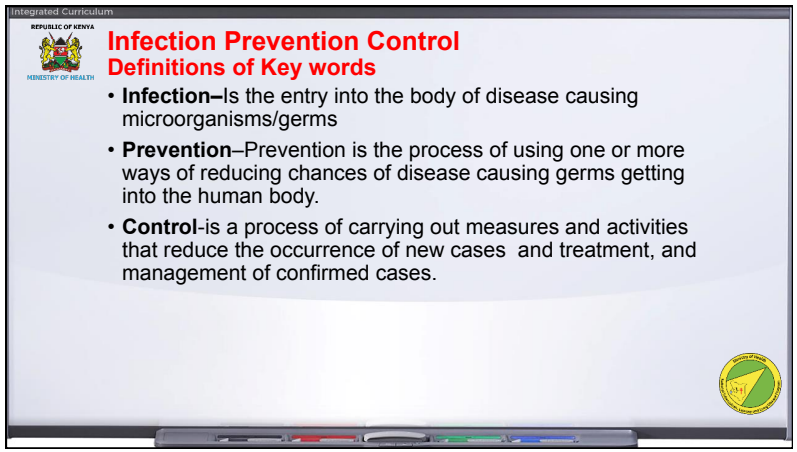
MINISTRY OF HEALTH
Identifying Treatment Supporters
Discuss with patient
• Where they live, work, mode of transport
• Do they have a supportive family member, neighbor or CHV that can support them during treatment?
• Where and when would they meet?
Meeting with treatment supporter
• Provide basic information on TB, Leprosy, Asthma
• Review the tasks they will be undertaking with the patient
• Confirm availability of the supporter for the duration of the treatment of the patient
Characteristics of an effective Treatment supporter
• Accessible and acceptable to the patient
• Maintain patient confidentiality
• Willingness to support and follow up the patient and fill treatment card
• Willingness to be trained
• Available and can access to health facility to collect drugs for the patient
• Has interest in patient's welfare and treat them with kindness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Infection Prevention Control
Definitions of Key words
• Infection–Is the entry into the body of disease causing microorganisms/germs
• Prevention–Prevention is the process of using one or more ways of reducing chances of disease causing germs getting into the human body.
• Control-is a process of carrying out measures and activities that reduce the occurrence of new cases and treatment, and management of confirmed cases.

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Implementation of IPC at community level

- Engage community leaders and representatives as champions for TB prevention activities, especially in areas with a high burden of TB and MDR or XDR TB.
- Create community awareness of the early signs and symptoms of TB, prompt treatment until cured and risk reduction strategies for the home (such as opening windows, sleeping away from the patient and using IPT for children and patients spend more time outdoors)
- Minimize stigma related to TB infection control measures such as the wearing of face masks.
- Be the role model for TB infection control.

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Implementation of IPC at community level

- Develop and display posters and other IEC materials that feature natural ventilation and cough hygiene.
- Train CHWs and TB treatment and adherence supporters on TB infection control and how to conduct home visits.
- Educate household members on TB infection control measures.
- Emphasize TB signs and symptoms, adherence to treatment and cough etiquette.

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Implementation of IPC at community level

- Conduct contact investigations of all household members and other close contacts who may have been exposed to the patient.
- Offer HIV testing and counseling to all household members.
- Offer preventive treatment if available. Pay special attention to children and household members who are HIV positive.
- Whenever possible, wear respirators while attending to MDR TB patients at home.
- Encourage household members and the person(s) with TB disease to participate in a facilitated support group if available.

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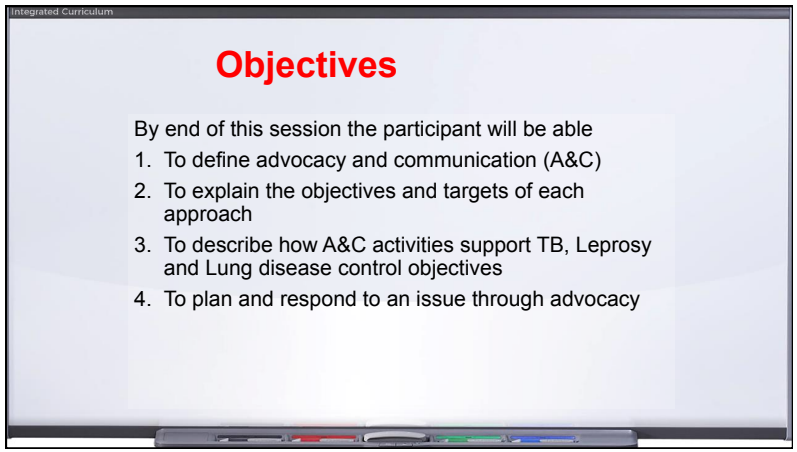
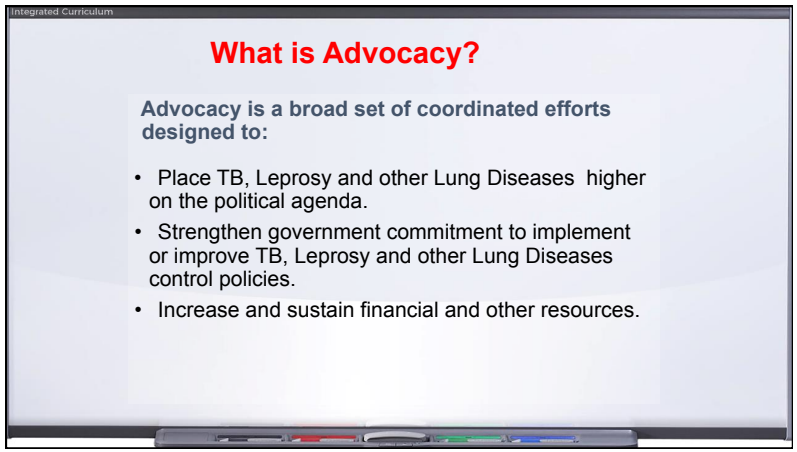
Summary IPC issues

- Cough hygiene
- Patient's knowledge of TB and HIV
- Vulnerability of the children
- Ventilation issues for the CHW's home visit (advice to open the windows)
- Standard interventions, such as health education
- Contact investigation on the children
- Relative risk of transmission in church and public transportation
- Patient counseling
- Social and spiritual needs of the patient vis a vis ventilation in e.g church
- IEC materials
- Adherence to treatment

MODULE 9: ADVOCACY AND COMMUNICATION





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POTENTIAL OF ADVOCACY

- Advocacy gives the opportunity to provide a bring a desired change. This means that advocacy has the potential to:-
  - solve a problem,
  - meet a need,
  - remove /bridge a gap
  - Improve the profile of an issue to catch the attention of decision makers

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Advocacy

Changes: Policies, programs, funding, political commitment, media coverage.

Targets: Decision-makers, community leaders, people with influence, media.

Activities/Approaches: Lobbying, Partnership meetings, Parliamentary debates, Political events, Official memoranda, Petitions & Letter/Email campaigns, engaging champions, peaceful street processions, policy briefs, media

Successes: Formulation/revision of relevant policies, better programs, more funding, more discussion of TB, Leprosy and other Lung Diseases among politicians, positive coverage of TB, Leprosy and other Lung Diseases in media.

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KEY ADVOCACY AREAS FOR NTLD-P

- **Raise the profile of TB, leprosy and lung diseases** through targeted public and private stakeholders and TB ambassadors/champions in order to influence relevant policy changes.
- Increase the visibility of TB messages to **raise awareness and debunk myths and misconceptions regarding TB, MDR-TB and XDR-TB.** These will be done through health-related events, such as World TB day, World Malaria Day, World Diabetes Day, Day of the African Child, Day for the Elderly, and Reproductive Health Day.
- **Increase resource allocation** to address TB, leprosy and lung diseases

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KEY ADVOCACY AREAS FOR NTLD-P

- **Promote screening for TB and lung diseases** to increase diagnosis and access to care and treatment.
- **Normalize TB and by so doing reduce stigma** associated with TB by promoting TB ambassadors, celebrity spokespersons, testimonials and public discourse on TB, Leprosy and Asthma
- **Increase disclosure of current and past TB and Leprosy patients** to increase treatment adherence and reduce stigma

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PLANNING FOR ADVOCACY ACTIVITIES

Key Steps: To achieve the desired goals in advocacy you must plan activities in a strategic way. You should:-

1. Research / gather evidence on the issues and set your objectives
   - Collect information
   - Search existing materials
   - Commission new research if needed
   - Find out as much as possible about the problem
   - Work out the evidence that will support your case
   - Show how people are affected by the problem
   - Use statistics to show the number of people affected

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Key Steps (continue)

2. **Identify your target audience**
   - Decide which are the main institution or individuals to be influenced (decision makers)
   - Spent time developing relationship with people who influence policy
3. **Identify allies**
   - Identify organization with similar objectives and plans as yours
   - Working as coalition will give your advocacy activities a broader base and stronger voice

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Key Steps (continue)

4. **Develop your message**
   - Highlight the problem and recommendation
   - A good advocacy message must be clear, to the point and easy to remember
   - You must repeat it frequently
6. **Plan how to deliver our message**
   - Identify messenger with high impact
   - You can deliver your message formally or informally depending on your audience
   - Review whether to use the media (invite the journalists to attend your workshop)
   - In some cases “quiet influencing” without involving the media may be more effective

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Key Steps (continue)

7. **Raise resources**
   - Draw a budget /mobilize resources
   - Cover all the component of advocacy
   - Advocacy has significant resources implications
   - A successful advocacy requires time and skills which need to be planned and budgeted for
8. **Monitoring and Evaluating impact**
   - Plan how you are to monitor and evaluate advocacy activities
   - This help you see what has worked
   - Help you in making reports to the development partners or central level

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Case study

In Sub county X, placing DOTS centers in rural health clinics helped improve patient adherence to treatment. However, funding for the intervention came to an end. To regain financial support, a number of local program staff and community advocates met with current donors to advocate for continued funding.

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Building Facts For Your Case

- Assess facts about TB in your own Sub county/County:
  - Show the severity of the situation or worsening trends
  - Show improvements in TB control through use of DOTS
  - Make TB epidemic relevant to important constituencies of socio-economic development
  - Show that TB control makes economic sense
  - Document current spending on the disease
  - Demonstrate that the DOTS strategy is feasible in your district/province/country
  - Note the benefits of DOTS for the health infrastructure and development
  - Demonstrate the consequences of inaction

Integrated Curriculum

Preparing advocacy Messages

- Show public concern and clearly articulate your message
- Recognize your target group
- Consider the context of your messaging e.g. political, cultural, economical and social determinants of health
- Recognize bureaucracy, budget and administration constraints

(Use different channels ('Insiders', Media, influential people and 'Outsiders' {activists})

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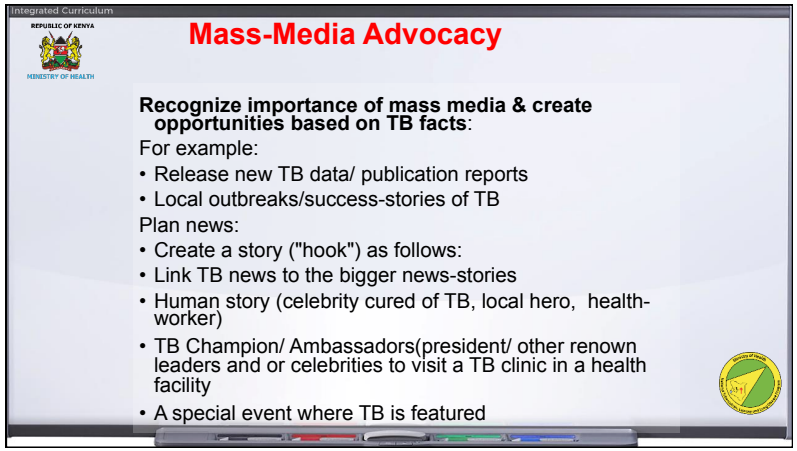
Seeking Stakeholders Support

- Identify stakeholders with similar objectives with yours
- Have a clear agenda and be focused on your subject matter,
- Have well-reasoned and seasoned arguments, supported with relevant data
- Powerful real-life stories
- Be clear about what you want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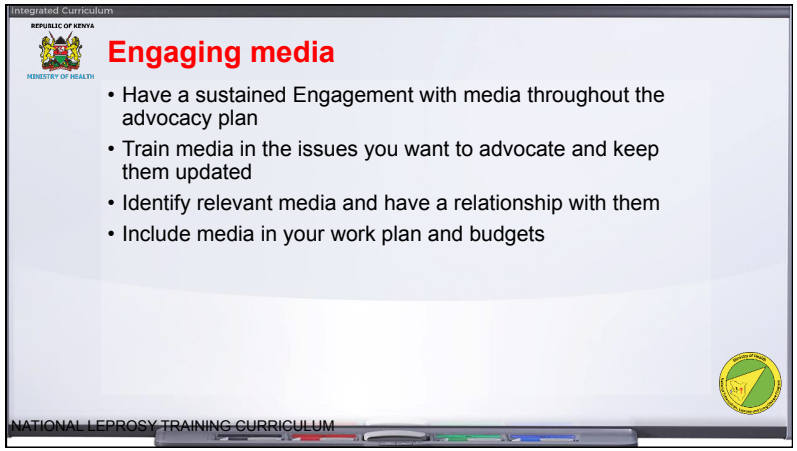
Mass-Media Advocacy
Recognize importance of mass media & create opportunities based on TB facts:
For example:
• Release new TB data/ publication reports
• Local outbreaks/success-stories of TB
Plan news:
• Create a story ("hook") as follows:
• Link TB news to the bigger news-stories
• Human story (celebrity cured of TB, local hero, health-worker)
• TB Champion/ Ambassadors(president/ other renown leaders and or celebrities to visit a TB clinic in a health facility
• A special event where TB is featured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Engaging media
• Have a sustained Engagement with media throughout the advocacy plan
• Train media in the issues you want to advocate and keep them updated
• Identify relevant media and have a relationship with them
• Include media in your work plan and budgets
NATIONAL LEPROSY TRAINING CURRICULUM


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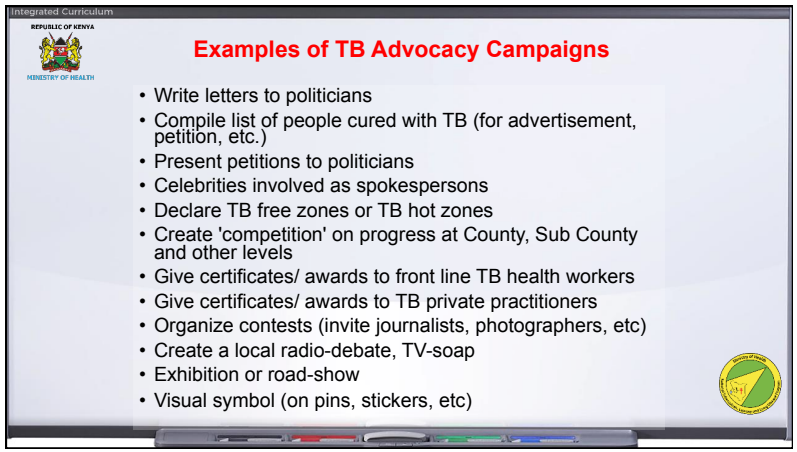
Advocacy opportunities
• TB campaigns
• National and International days
• TB conferences and health seminars
• Special national/ regional events such as political, religious, social/ cultural, sports, etc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Examples of TB Advocacy Campaigns
• Write letters to politicians
• Compile list of people cured with TB (for advertisement, petition, etc.)
• Present petitions to politicians
• Celebrities involved as spokespersons
• Declare TB free zones or TB hot zones
• Create 'competition' on progress at County, Sub County and other levels
• Give certificates/ awards to front line TB health workers
• Give certificates/ awards to TB private practitioners
• Organize contests (invite journalists, photographers, etc)
• Create a local radio-debate, TV-soap
• Exhibition or road-show
• Visual symbol (on pins, stickers, etc)

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Annual Calendar Events That Provide Opportunities For Advocacy

24th February: Anniversary of John Keats' death (Famous poet died from TB at age 25. Most TB deaths are still among ages 15-44)

8th March: International Women's Day (TB kills more women than all combined causes of maternal mortality)

24th March: World TB Day (The threat of TB; The effectiveness of DOTS)

7th April: World Health Day (TB leading killer of youths/ adults in dev. countries)

1st December: World AIDS Day (TB/HIV co-epidemic)

5th December: International Volunteer Day (DOTS volunteers)

10th December: 50th anniversary of the Human Rights Declaration (The threat of TB in prisons)

14th November : World Diabetes Day

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Religious Days

- ***Sabbath, Sunday, Christmas and Idd Fitr***

Use of local events at community level:

- **Barazas, Chamas, Food festivals, Bull fighting, donkey festivals**

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Module 2

COMMUNICATION

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Objectives for this session

By end of this session the participants should be able:-

- To explain what communication is
- To list the channels of communication and where they are applied
- To develop simple messages for various target groups
- To explain the communication strategies

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What is Communication?

Definition: it is the act or process of using words, signs, sound and behaviors to express or exchange information, ideas, thoughts, feeling etc to someone else and receive feed back.

Communication includes activities designed to:

1. Increase knowledge:
   - TB disease (symptoms, curability).
   - TB control services (prevention, diagnosis and treatment).

2. Change attitudes and behaviors:
   - Health providers
   - Clients (current, potential).
   - Community/Family members.

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Communication

Changes: knowledge, attitudes, behaviors.

Targets: patients, providers, communities, policymakers, opinion leaders, service providers, nongovernmental organizations.

Activities: use of information, education and communication materials (e.g. Brochures, posters), Media campaigns, Special events, health counseling, Trainings, presentations, Brand logos, promotional giveaways

Successes: improved knowledge and/or attitudes that lead to a new or different behavior (positive for TB control

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COMMUNICATION CHANNELS THAT CAN BE USED IN SENSITIZATION OF COMMUNITY

- Online Channels
  - Facebook
  - Twitter
  - Blogs
  - Website
  - WhatsApp
- Print Channels
  - Newspapers
  - Posters
- SMS
- Radio
- Television

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Message Content

- ***What*** *do* you want to achieve
- ***Why*** do you want to achieve it
- ***When*** would you like to achieve it
- ***Who*** will help you achieve it
- ***How*** do you propose to achieve it
- ***What*** actions would you like the audience to take

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Message Elements

- Content/Ideas
- Language
- Source/Messenger
- Format
- Time and Place

Keep
It
Short
Simple

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Different messages

Science

- Detailed and precise information
- Technical language
- Comprehensive arguments
- Objective and unbiased
- Building your case before conclusions
- Supporting evidence
- Academic acknowledgement
- Science focus

Media/ Advocacy

- Simple information
- Simple language
- Few messages
- Strong arguments based on fact
- Conclusions first
- Few facts and figures
- Illustrative and emotive-use consented personal stories of beneficiaries
- Quick action based on opportunities
- Celebrity/opinion leader support
- Political focus

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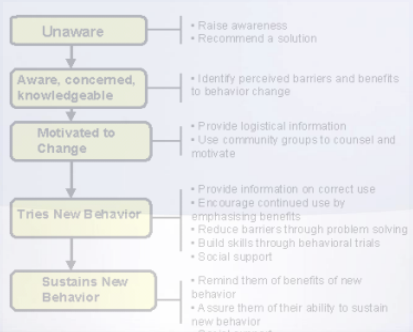
Communications Strategies



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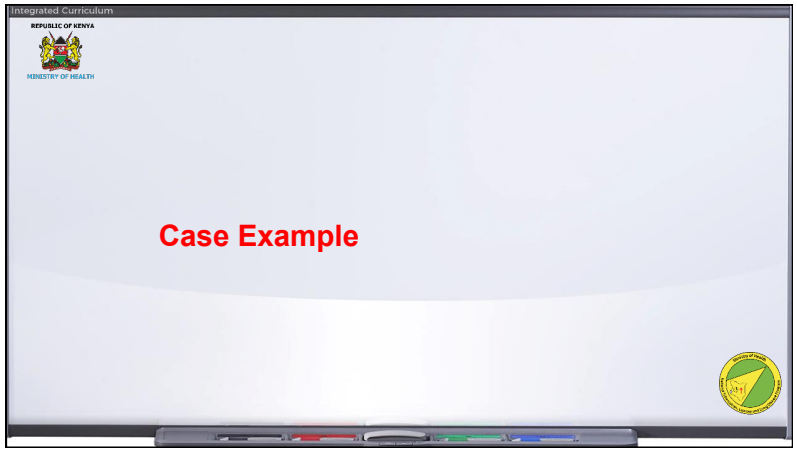
Best practices for effective communication

1. Build trust
2. Announce early
3. Be transparent
4. Respect public concerns
5. Plan in advance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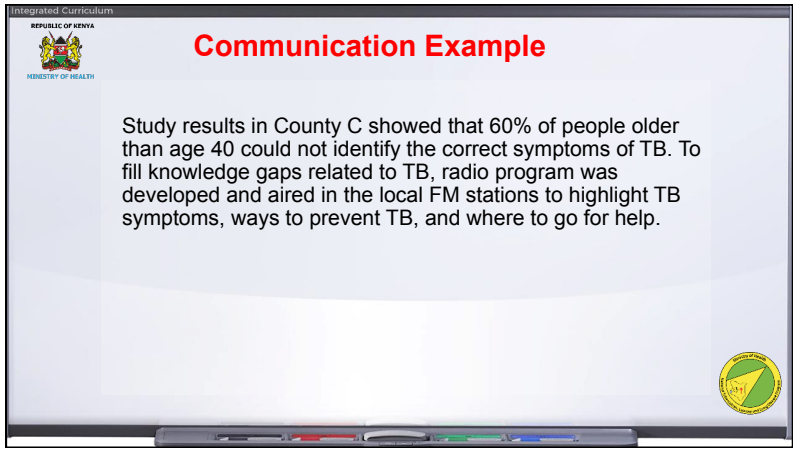
Case Example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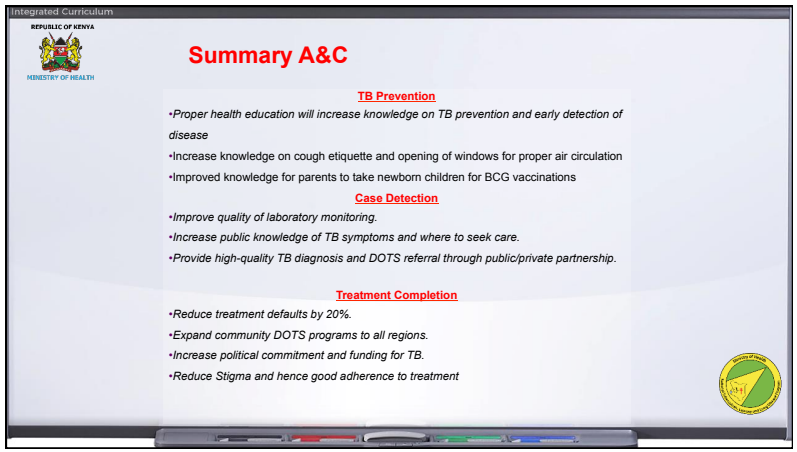
Communication Example
Study results in County C showed that 60% of people older than age 40 could not identify the correct symptoms of TB. To fill knowledge gaps related to TB, radio program was developed and aired in the local FM stations to highlight TB symptoms, ways to prevent TB, and where to go for help.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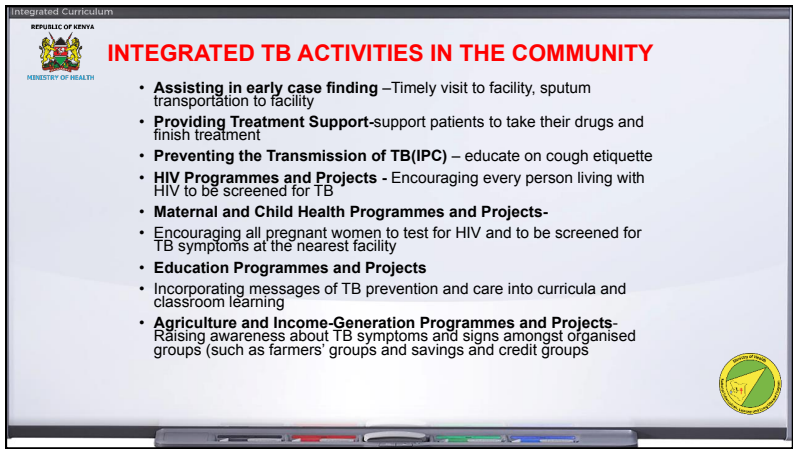
Summary A&C
TB Prevention
•Proper health education will increase knowledge on TB prevention and early detection of disease
•Increase knowledge on cough etiquette and opening of windows for proper air circulation
•Improved knowledge for parents to take newborn children for BCG vaccinations
Case Detection
•Improve quality of laboratory monitoring.
•Increase public knowledge of TB symptoms and where to seek care.
•Provide high-quality TB diagnosis and DOTS referral through public/private partnership.
Treatment Completion
•Reduce treatment defaults by 20%.
•Expand community DOTS programs to all regions.
•Increase political commitment and funding for TB.
•Reduce Stigma and hence good adherence to treatment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INTEGRATED TB ACTIVITIES IN THE COMMUNITY
• Assisting in early case finding –Timely visit to facility, sputum transportation to facility
• Providing Treatment Support-support patients to take their drugs and finish treatment
• Preventing the Transmission of TB(IPC) – educate on cough etiquette
• HIV Programmes and Projects - Encouraging every person living with HIV to be screened for TB
• Maternal and Child Health Programmes and Projects-
• Encouraging all pregnant women to test for HIV and to be screened for TB symptoms at the nearest facility
• Education Programmes and Projects
• Incorporating messages of TB prevention and care into curricula and classroom learning
• Agriculture and Income-Generation Programmes and Projects- Raising awareness about TB symptoms and signs amongst organised groups (such as farmers' groups and savings and credit groups

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Principles of ENGAGE-TB

- Mutual understanding and respect.
- Consideration for local contexts and values.
- A single national system for monitoring with standardised indicators.

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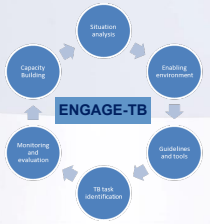
The ENGAGE-TB Approach

- The ENGAGE-TB approach seeks to shift the global perspective of TB from a medical illness to a more comprehensive socio-economic and community problem.
- ENGAGE-TB is a brand that suggests six components to facilitate the engagement of Non State Actors in TB and TB/HIV interventions.



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Monitoring Community Engagement

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Monitoring of community activities

CHV Tools

- *Community referral*
- *Community screening tool*
- *CHV reporting form*
- *Contact tracing form*
- *Treatment interruption tracing form*

CHEW Tools

- *CHW Summary tool*
- *Chalk board*

MODULE 10: MONITORING AND EVALUATION

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Community TB indicators

Minimum:

1. # Presumptive TB cases referred from community
2. # of patients with successful treatment outcomes
3. # of patients provided DOTs by CHVs

Other:

- # and % of treatment defaulters traced by CHVs
- # and % of contacts traced and referred by CHVs to facilities for TB screening

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Kenya Lung health Training Course

Monitoring and Evaluation

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OUTLINE

- Objectives.
- Module 1: Introduction to Monitoring and Evaluation
- Module 2 : Overview of M&E Processes in TB, Leprosy and Lung Disease
- Module 3.: Data Management in TB, Leprosy and Lung Disease
- Module 4: Data Quality Assurance
- Module 5: Data Demand and Information Use (DDIU)
- Module 6: Research and Dissemination

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Objectives

- At the end of the session participants should be able to:
  - Understand National TB surveillance system
  - Understand importance of a functional M&E system in Management of TB, Leprosy and Lung Disease
  - Understand how to fill the various tools used in Management of TB, Leprosy and Lung Disease
  - Understand the process and importance of Data Quality Assurance (DQA)
  - Understand importance of data use and procedures in research and dissemination

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Module 1

Introduction to Monitoring and Evaluation

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Question

- What is monitoring is your own words?

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Monitoring Click to edit Master title style

- Monitoring is
  - Is defined as a regular/ continuous collection, analysis, and dissemination of information
  - It is tracking the progress of project implementation, with reference to the project plan
  - It is the tracking and reporting of priority information for a program or project in terms of its inputs and intended outputs and outcomes
- Types of monitoring
  - Input/output monitoring focuses on collecting data describing individuals served, services provided and the resources used to deliver services
  - Outcome monitoring focuses on tracking the expected outcome or result of a program

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Levels of Monitoring

- Monitoring is organized at different levels;
  - Facility health care workers assist with information collection on an ongoing basis;
  - County and Sub county coordinators perform quarterly analyses of information collected and make appropriate decision;
  - Managers from national level analyze data, conduct field visits at specific times and provide necessary feedback. They also provide obligated reports to international bodies such as WHO and Global Fund.

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Purpose of Monitoring

- To check that activities are implemented, measure progress towards objectives, identify problems as they come up, identify strengths that can be built on, and adapt to changing circumstances.
- The overall purpose is to identify strengths and weaknesses in a program, and provide the people responsible for program-planning and decision making with sufficient information *to make the right decisions* at the right time to improve its quality.
- Informs day to day management of interventions

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Domains of Monitoring

Domain	Definition
Input	Resources going into conducting and carrying out the program activities.
Process	Set of activities in which program resources (human and financial) are used to achieve the results expected from the program
Outputs	Immediate results obtained by the program through the execution of activities e.g. number of TB patients started on treatment
Outcome	An intermediate change obtained by the program through the execution of activities e.g. improved treatment success rate
Impact	Long-term and lasting significant changes following an intervention e.g. reduced TB burden in Kenya

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Exercise 1

Example	Classification
Change in case notification rate after 5 years of program implementation	
Proportion of TB/HIV coinfected patients put on ART	
National curriculum used to train health care workers	
Number of TA missions held nationally in a given year	
Proportion of counties participating in biannual performance review meetings	
Mortality rate among TB/HIV coinfected patients	
Printing and distribution quality of Monitoring and Evaluation tools	

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Evaluation Click to edit Master title style

Evaluation is
- Is a systematic episodic event
- periodic assessment of the relevance, effectiveness, and efficiency of a project or program .
- Measures impact (both expected and unexpected) in relation to stated objectives

Evaluation is used to
- Assess the changes in the target group;
- Assess the extent to which objectives have been met, in other words, the process of determining the effectiveness of a program or a project; and
- Track the outcomes and impacts of programs or projects at the larger population level, as opposed to the program or project level

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Types of Evaluations

- Baseline or formative evaluation;
- Mid-term evaluation;
- Summative or end-of-term evaluation.

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Definition of Terms used in Evaluation

Term	Definition
Efficiency	A measure of how economically resources/inputs (funds, expertise, time etc.) are used to achieve results in a project or program.
Effectiveness	The extent to which an intervention has attains its major relevant objectives in a project or program..
Relevance	the extent to which the objectives, outputs, or outcomes of an intervention are consistent with beneficiaries' requirements, Program policies, country needs, and/or global priorities.
Sustainability	The degree to which services or processes continue once inputs (funding, materials, training, etc.) provided by the original source(s) decreases or discontinues.

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Monitoring vs Evaluation

- Monitoring
  - Ensures implementation is going according to plan
  - Improves the quality of routine work
  - Provides baseline for evaluations
  - Feeds into program planning and development
- Evaluation
  - Demonstrates value of undertaking to both internal and external clients
  - Able to compare different approaches to achieving a particular objective
  - Useful for policy and advocacy

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Monitoring vs. Evaluation

- Monitoring
  - Aims at improving efficiency and effectiveness of a program
  - Keeps work on track; allows one to correct anything that may go wrong during implementation
- Evaluation
  - Compares actual impacts achieved to those agreed upon in strategic plans or project proposals (compares set targets to actual targets achieved)

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Monitoring vs. Evaluation

- Monitoring
  - Allows for determination of sufficiency of resources and prudent use of these resources
- Evaluation
  - Determines whether or not resources were used efficiently
  - Looks at opportunity costs
  - Assesses sustainability

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Monitoring vs. Evaluation

- Monitoring
  - Determines sufficiency and appropriateness of current capacity to do the job on hand
  - Informs day-to-day management
  - Formative
- Evaluation
  - Assesses implications for the stakeholders
  - Assesses technical soundness and appropriateness of strategy
  - Can be formative or summative

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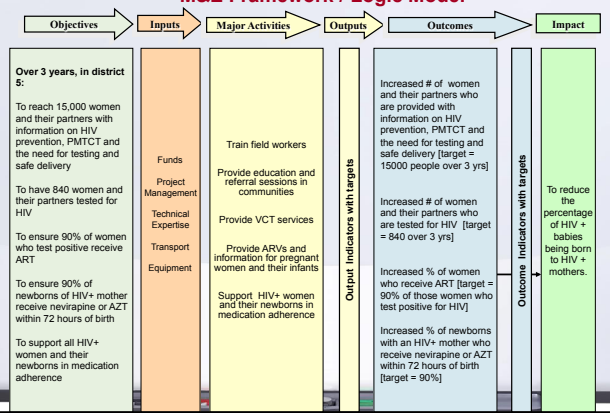
M&E Framework / Logic Model



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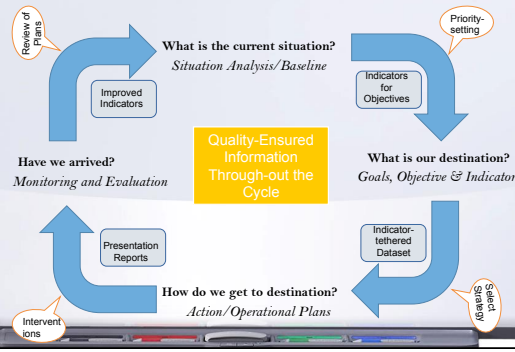
M&E and Management Planning Cycle [MPC]



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Exercise 2.

- Develop an M&E framework for the TB control under Objective 3 ;To intensify efforts to find the “missing” cases of TB, Leprosy and Lung disease.

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Module 2

M&E Processes in TB, Leprosy and Lung Disease

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TB Burden and Trends

- TB is a leading cause of death in Kenya – 5th after HIV, Cancer, Stroke and Diabetes
- Kenya is one of the 22 high TB burden countries in the world that account for 80% of annual global TB burden
- In the last decade Kenya notified > 85,000 TB cases of all forms, 6 to 13% being paediatric cases.
- Case detection rate is at 75% while treatment success rate is at 88%

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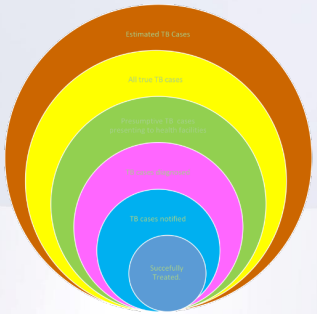
TB Case Finding Cascade



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Importance of M&E in TB Management

- Helps in assessing progress towards achieving the set objectives and goals
- Provides evidence for timely decision making
- It allows learning from experience and improves planning and management of program
- For accountability to stakeholders

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Components of a functional M&E System

- Should have a well defined M&E plan.
- Have clear data sources
- Human and financial resources
- Clearly defined roles and responsibilities at all levels
- DQA and technical assistance mechanisms should be in place
- Working partnerships for planning, coordination and management e.g. TB/HIV collaboration
- Data demand and use
- Surveys and Surveillance

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Overview of Types of Tools Used in TB, Leprosy and Lung Disease Recording and Reporting

- Facility/community based and patient tools
- Individual records and case listing
  - Cross sectional- eg AFB/GeneXpert register
  - Longitudinal – TB register
- Request forms- e.g. AFB/GeneXpert
- Referral tools – intra and inter facility
- Transfer out forms
- Supervision/TA tools
- Reporting tools
- Progress tracking tools – e.g. wall charts

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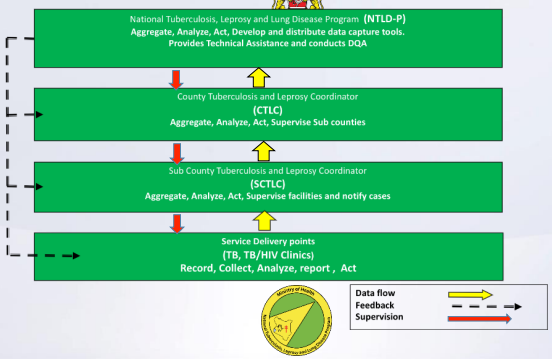
Flow of TB Data



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Failure of TB health information system is mostly premised on

- Management functions
  - Data management perceived as an added duty to the health care worker .
  - Poor infrastructure
  - Low working morale
- Little involvement of lower levels at the design stage [design-reality gap]
  - Data collection not perceived as a function of a health care provider.
  - Sub optimal utilization of data at service delivery point– no traces of data use for decision making.

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Module 3

Data Management in TB, Leprosy and Lung Disease Program

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Exercise: Group Work

- Discuss in groups (10 Minutes):
  - Define the terms recording, reporting and indicator. (5mins)
  - What's the importance of recording and reporting in management of TB, Leprosy and Lung Disease (give five points)? 5 minutes.
- Report in plenary (10mins)

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Definitions

Recording: The practice of capturing data n writing for the purpose of preserving evidence. The data captured in NTLD-P include patient management indicators, commodities' consumption, lab indicators etc over time. Information is written directly on paper forms and registers

Reporting : Involves Compiling and submitting information in required format from one level to another

Indicator: A variable or measurement used to assess progress towards stated goals

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Importance of Recording and Reporting

- Helps in monitoring and evaluation by health workers and managers at different levels
- Monitor patient's response to treatment
- Assess program performance
- To aid in effective program planning
- Aid staff to provide adequate services to the individual patient
- Ensure patient quality of care, continuum of care, sharing of information with patient and transfer of information between health facilities
- Accountability
- Continuous improvement of processes.

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Module 4

Routine Indicators used to Track progress in Management of TB, Leprosy and Lung Disease

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Exercise: Individual work

- Come up with 3 indicators for TB, Leprosy and Lung health and write them on post-it (5 min)
- Post your answers on the wall for participants to review
- Discussion and summary (25 min)

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Core TB

Indicator definition	Description (include Numerator and denominators)	Source of data	Frequency	Level
Treatment Success Rate (bacteriologically confirmed.)	**Numerator:** number of bacteriologically confirmed cured and treatment completed among those started on treatment. **Denominator:** Total numberof bacteriologically confirmed cases notified.	Facility TB treatment register and Patient records cards TIBU Cohort report.	Quarterly.	Facility Sub,county County and National.
Treatment Success Rate (all forms)	**Numerator** Number of TB cases (all forms) who successfully completed treatment **Denominator**. Total number of TB cases (all forms) who were notified.	Facility TB treatment register and Patient records cards TIBU Cohort report	Quarterly.	Facility Sub,county County and National.
Number of TB cases (all forms) notified to the national program	Number of TB cases (all forms) notified to the national program	TB register TIBU	Quarterly	Facility Sub county County and National
Number of Bacteriologically confirmed TB cases	Number of Bacteriologically confirmed TB cases that were notified.	TB register TIBU	Quarterly	Facility Sub county County National

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TB/HIV

Indicator definition	Description (include Numerator and denominators)	Source of data	Frequency	Level
Number and Percentage of TB patient tested for HIV with known results	**Numerator:** Number of TB patient tested for HIV with known results **Denominator:** Total Number of TB patients all forms notified.	TB register TIBU	Quarterly	Facility Sub county County National
TB/ HIV Co-infection rate	**Numerator**: Number of TB patient with HIV positive results. **Denominator**: Total number of TB all forms tested for HIV.	TB register TIBU	Quarterly	Facility Sub county County And National
Percentage of TB patient who tested HIV positive and initiated on ART.	**Numerator:** Number of TB patient who tested HIV positive and have been put on ART **Denominator:** Number of TB patient who tested HIV positive	TB register TIBU	Quarterly	Facility Sub county County National
Proportion of children under 5 who are contacts of TB patients put on IPT	**Numerator:** Number of children under 5 exposed to smear positive TB patients put on IPT **Denominators:**	Contact and IPT registers	Quarterly	Facility Sub county County

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DR TB

Indicator definition	Description (include Numerator and denominators)	Source of data	Frequency	Level
Number of laboratory confirmed DR-TB patients enrolled in second line anti-TB treatment	Number of DR TB cases notified	DR TB registers TIBU	Quarterly	Facility Sub county County National
Percentage of eligible TB patients receiving Drug Susceptibility Testing (Molecular and conventional) for DR TB among the people eligible for Drug Susceptibility Testing according to national policy.	**Numerator**: Number of cases done DST. **Denominator**: Number of Cases eligible for DST.	TB Registers Lab Records LIMS	Quarterly	Facility Sub county County National
Treatment Success Rate (TSR) among DR-TB cases	**Numerator**: Number of DR TB cases who got cured or completed treatment.	DR TB registers	Quarterly	Facility Sub county

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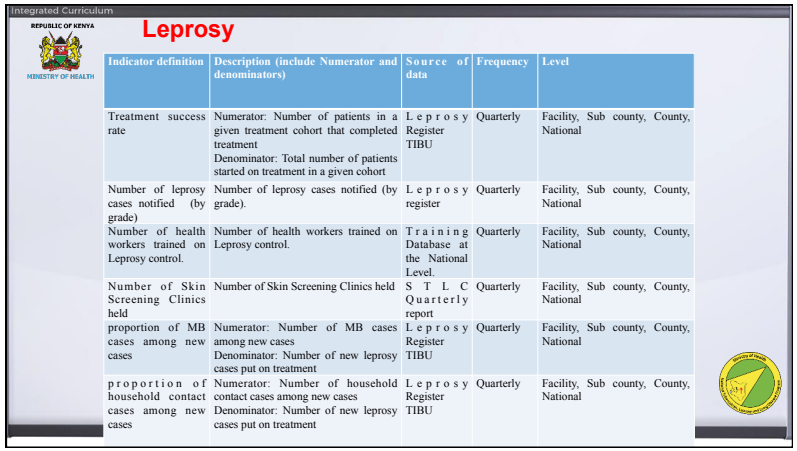
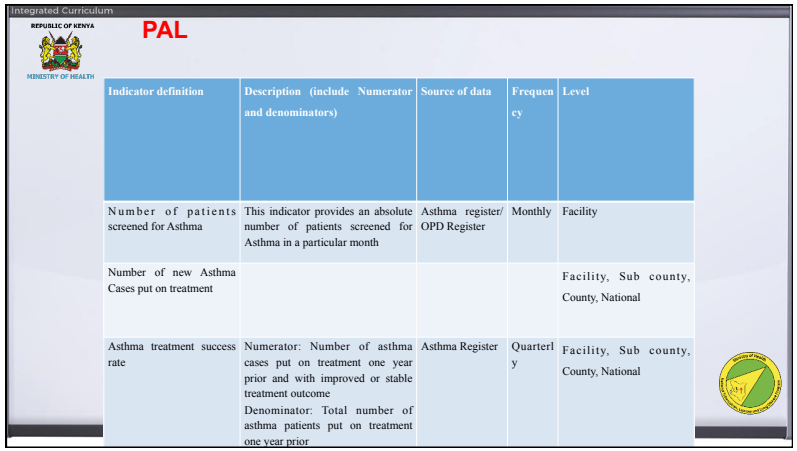
Nutrition

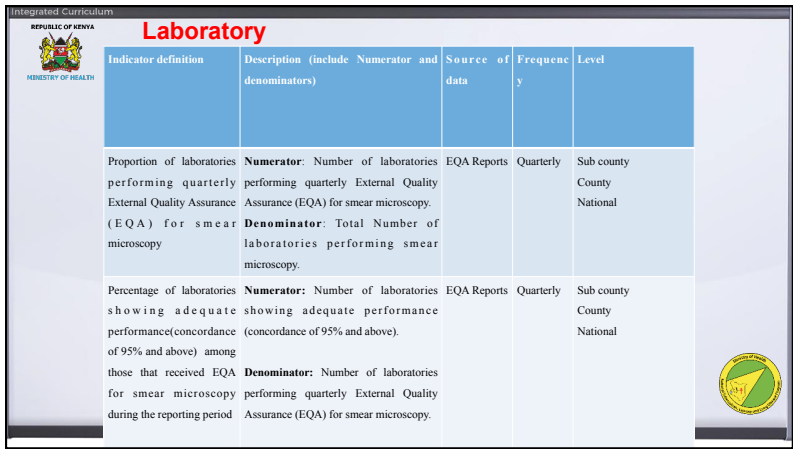
Indicator definition	Description (include Numerator and denominators)	Source of data	Frequency	Level
Percentage of patients on treatment with BMI recorded in the treatment register	**Numerator**: Number of patients on treatment with recorded BMI in the treatment register. **Denominator**: Number of patients (all forms) on treatment.	TIBU TB registers	Quarterly	Facility Sub county County National
Percentage of patients with BMI under 18.5 on nutrition support	**Numerator:** Number of patients with BMI under 18.5 on nutrition support. **Denominator:** Total Number of patients with BMI under 18.5.	TIBU TB registers	Quarterly	Facility Sub county County National



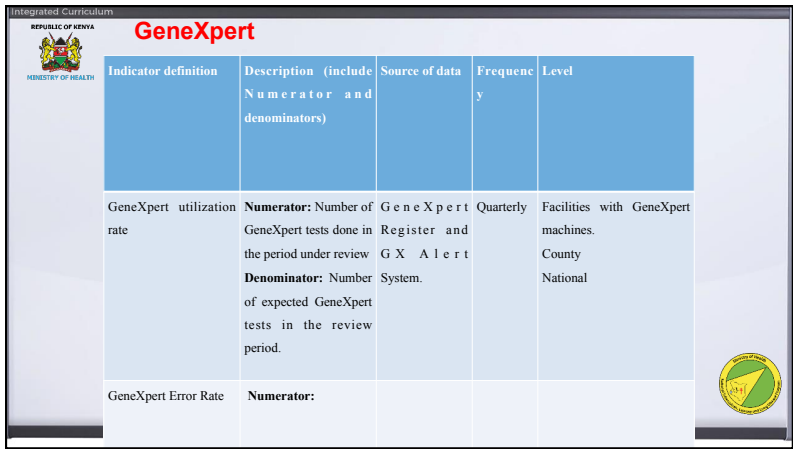
Indicator definition	Description (include Numerator and denominators)	Source of data	Frequency	Level
Treatment success rate	Numerator: Number of patients in a given treatment cohort that completed treatment Denominator: Total number of patients started on treatment in a given cohort	Leprosy Register TIBU	Quarterly	Facility, Sub county, County, National
Number of leprosy cases notified (by grade)	Number of leprosy cases notified (by grade).	Leprosy register	Quarterly	Facility, Sub county, County, National
Number of health workers trained on Leprosy control.	Number of health workers trained on Leprosy control.	Training Database at the National Level.	Quarterly	Facility, Sub county, County, National
Number of Skin Screening Clinics held	Number of Skin Screening Clinics held	STLC Quarterly report	Quarterly	Facility, Sub county, County, National
proportion of MB cases among new cases	Numerator: Number of MB cases among new cases Denominator: Number of new leprosy cases put on treatment	Leprosy Register TIBU	Quarterly	Facility, Sub county, County, National
proportion of household contact cases among new cases	Numerator: Number of household contact cases among new cases Denominator: Number of new leprosy cases put on treatment	Leprosy Register TIBU	Quarterly	Facility, Sub county, County, National



Indicator definition	Description (include Numerator and denominators)	Source of data	Frequency	Level
Number of patients screened for Asthma	This indicator provides an absolute number of patients screened for Asthma in a particular month	Asthma register/ OPD Register	Monthly	Facility
Number of new Asthma Cases put on treatment				Facility, Sub county, County, National
Asthma treatment success rate	Numerator: Number of asthma cases put on treatment one year prior and with improved or stable treatment outcome Denominator: Total number of asthma patients put on treatment one year prior	Asthma Register	Quarterly	Facility, Sub county, County, National



Indicator definition	Description (include Numerator and denominators)	Source of data	Frequency	Level
Proportion of laboratories performing quarterly External Quality Assurance (EQA) for smear microscopy	**Numerator**: Number of laboratories performing quarterly External Quality Assurance (EQA) for smear microscopy. **Denominator**: Total Number of laboratories performing smear microscopy.	EQA Reports	Quarterly	Sub county County National
Percentage of laboratories showing adequate performance(concordance of 95% and above) among those that received EQA for smear microscopy during the reporting period	**Numerator:** Number of laboratories showing adequate performance (concordance of 95% and above). **Denominator:** Number of laboratories performing quarterly External Quality Assurance (EQA) for smear microscopy.	EQA Reports	Quarterly	Sub county County National



Indicator definition	Description (include Numerator and denominators)	Source of data	Frequency	Level
GeneXpert utilization rate	**Numerator:** Number of GeneXpert tests done in the period under review **Denominator:** Number of expected GeneXpert tests in the review period.	GeneXpert Register and GX Alert System.	Quarterly	Facilities with GeneXpert machines. County National
GeneXpert Error Rate	**Numerator:**			

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IPC

Indicator definition	Description (include Numerator and denominators)	Source of data	Frequency	Level
Number of health workers trained as TOT on TB Infection Prevention Control(IPC)	Number of health workers trained as TOT on TB Infection Prevention Control(IPC)	Training Database at the National Level	Quarterly	Facility Sub county County National
Number of TB IPC team members trained on IPC	Number of TB IPC team members trained on IPC	Training Database at the National Level	Quarterly	Facility Sub county County National
Number of Health Care Workers (HCWs) sensitized on facility	Number of Health Care Workers (HCWs) sensitized on facility	Facility Based Reports	Bi - Annually during TA	Facility Sub county County National

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Community

Indicator definition	Description (include Numerator and denominators)	Source of data	Frequency	Level
Number and Percentage of patients referred by CHVs	**Numerator**: Number of patients(all forms) referred by CHVs **Denominator**: Number of patients (all forms) put on treatment.	TB Register TIBU	Quarterly	Facility Sub county County National
Number and percentage of Patients on DOTs by CHV	**Numerator**: Number of patients(all forms) on DOTS by CHVs **Denominator**: Number of patients (all forms) put on treatment.	TB Register TIBU	Quarterly	Facility Sub county County National

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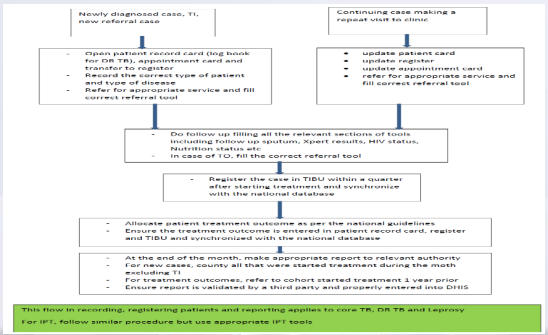
Data Recording and Reporting Cycle in Management of TB, Leprosy and Lung Disease



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Core TB Tools

No	Name of Tool	Purpose	Location	Filled By
1	Patient Record Card	The card is filled by health worker and acts patient clinical record card.	TB Clinic	Clinicians
2	Patient Appointment **Card(ITB,IPT, DRTB, Leprosy and Asthma)**	The card is used for scheduling TB appointment and acts as a reminder to patient	Patient	Clinicians
3	Facility TB Register	It is a TB Case listing which summarizes key variables for tracking TB patient progress and outcomes	TB Clinic	Clinicians
4	Sputum/GeneXpert	Used by clinicians to request for sputum / GeneXpert tests	TB Clinic	Clinicians to request and lab personnel to fill results
5	AFB Register	It is a case listing for all AFB microscopy tests done in the lab.	Lab	Lab personnel
6	Patient referral form from TB clinic.	Used for referring patients for management of other conditions than TB	TB clinic.	Clinicians.
7	Patient referral form to TB clinic	Used for referring presumptive TB cases from HIV clinic and other service delivery points to TB clinic	Other service delivery points outside TB clinic	Clinicians

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IPT & DRTB Tools

No	Name of Tool	Purpose	Location	Filled By
IPT				
8	Intensive Case Finding /IPT Card – Adults -	This form is used both for screening of adult HIV patients for TB and recording IPT information for eligible patients	TB and HIV clinics.	Clinicians
9	Intensive Case Finding/IPT – Peds	This form is used both for screening of children for TB and recording IPT information for eligible children	TB and HIV clinic	Clinicians
10	IPT Register	It is a Case listing which summarizes key variables for tracking IPT patient progress and outcomes	TB and HIV clinic	Clinicians
DR TB				
12	Culture/DST Log Book	To capture patients whose samples have been sent for culture and DST and results	TB clinic	Clinicians
13	Culture request form	Used to request for culture/DST for DR TB surveillance	TB Clinic	Clinicians
14	DR TB Patient Log Book	Individual patient management booklet that records all information regarding the patient.	TB clinic	Clinicians
15	DR TB Register	DRTB Case listing which summarizes key variables for tracking patient progress and outcomes	TB clinic	Clinicians
16	DR TB Patient Appointment Card	The card is used for scheduling IPT appointment and acts as a reminder to patient	Patient	Clinicians
17	DR TB baseline and follow up test request form	Baseline and follow-up request form for DR TB patient.	TB clinic	Clinicians

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Commodities and Community TB Tools

No	Name of Tool	Purpose	Location	Filled By
COMMODITY TOOLS				
18	Facility Daily Activity Drug Register	To monitor the use of the TB and DR-TB drugs on a daily basis	TB clinic/ Pharmacy	Clinician/ Pharmacist
19	FCDRR	It's a reporting tool for consumption of TB, and DR TB drugs	TB clinic/ Pharmacy	Pharmacist/ clinician
20	Bin Card	This card is used to monitor stock of commodities in facility store or pharmacy	Pharmacy/Store	Pharmacist
21	S11	This form is in triplicate and is used to issue out commodities to various service delivery points within the facility	Pharmacy/Store	Pharmacist
22	PV Reporting Tools	To record and report all Adverse Drug Reactions experienced by patients on anti TB drugs	TB Clinic	Clinicians
Community TB				
23	Community Monthly Reporting Tool	Reporting tool for community TB	Facility	CHV
24	Community Treatment Interrupters tracing form	used to track patient who have defaulted TB treatment.	Community	CHV
25	Community TB Screening Form	It is an ICF cards Used for screening TB in the community	Community	CHV.
26	Community Referral Form	Used to refer presumptive TB cases,contact tracing and treatment interrupters from community to the facility for diagnosis and treatment	Community	CHV.

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Commodities and Community TB Tools

No	Name of Tool	Purpose	Location	Filled By
LEPROSY				
28	Leprosy appointment card	The card is used for scheduling leprosy appointment and acts as a reminder to patient	Patient	Clinician
29	Leprosy record card	The card is filled by health worker and acts as patient clinical record card	TB Clinic	Clinician
30	Leprosy register	It is a leprosy case listing which summarizes key variables for tracking TB patient progress and outcomes	TB Clinic	Clinician
PAL				
31	Asthma Register	It is Asthma Case listing register which summarizes key variables for tracking Asthma patient progress	Outpatient/Chest Clinic	Clinician
32	Asthma Record Card	The card is filled by health worker and acts as patient clinical record card used for clinical notes during treatment	Outpatient	Clinician
JOB AIDS/ SOPs				
33	Monthly Data Chart	It's a monthly summary chart that shows facility performance in various indicators	TB Clinic	clinician
34	Data/Information flow chart	This is a chart that provides clinicians with information on how information flows from facility	TB Clinic	

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Practical Session

- By the end of this session participants will be able to:
  - Accurately complete different tools

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Exercise 1: Accurately completing recording and reporting tools

- Participants work within the existing working groups for 15 mins
- You are working in Mkombozi health center
  - ✓What TB recording and reporting tools need to be completed using this information?
  - ✓Complete the tools using the information
  - ✓Comment on the adequacy of the information provided to complete the tools
  - ✓As a TB control manager, suggest one way to improve on the quality of data / information in the various data capture tools (consider AFB register and TB treatment register
- Each group will report in plenary (After one group presents, others will add what is missed) (15 mins)

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Module 5

Data Quality Assurance (DQA)

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DQA Terms

- Data Quality
- Data Quality Assessment (DQA) or RDQA.
- Quality Assurance (QA)
- Quality Improvement (QI)

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Definitions of Terms (1)

- Data Quality - the degree of excellence exhibited by the data in relation to the representation of the actual scenario. The state of completeness, validity, consistency, timeliness, and accuracy that makes data appropriate for a specific use
- Data Quality Assessment (DQA)- a process of verifying the quality of data, assessing the system that produces that data, and developing actions to improve both the process and the system

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Definitions of Terms (2)

- Routine Data Quality Assessment (RDQA) - A continuous/regular process of verifying the quality of data, assessing the system that produces that data and developing action plans for improvement
- Quality Assurance (QA) - A process that focuses mainly on measuring compliance with established standards
- Quality Improvement (QI) - A systematic process to improve the quality of health care by monitoring quality, finding out what is not working, and fixing the problems of health care delivery

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Definition of Terms (3)

- Quality:
  - ✓A state of being free from defects or deficiencies
  - ✓The extent to which something has features which are good or bad.
- Quality in Health
  - ✓The most desirable outcome of a health intervention in terms of:
    - Maximum well-being for the client, considering:
      - Risks and benefits
      - Gains and loses
    - ✓ Provider satisfaction
    - ✓ Efficiency
    - ✓ Individual and social balance

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Dimensions of Data Quality

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Exercise 1 (cont)

Dimension of data quality	Definition
1. Completeness	a. Data has sufficient detail, eg on age, sex etc.
2. Accuracy	b. Data appropriately inclusive as per the information system
3. Integrity	c. Data consistent, regardless of who is collecting or using.
4. Reliability	d. Data up to date (current) and information available in time

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Exercise 1 (cont)

Dimension of data quality	Definition
5. Confidentiality	e. System used to generate data protected from deliberate bias or manipulation for political or personal reasons.
6.Precision	f. Data correct, with minimal errors i.e no bias
7. Timeliness	g. Clients are assured that their data will be maintained according to national and/or international standards for data.

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Dimensions of data quality

Definitions

- Accuracy Data correct, with minimal errors i.e no bias
- Validity.Ensuring the same fields are used consistenly for the same information captured.
- Completeness: Data appropriately inclusive as per the information system
- Timeliness: Data up to date (current) and information available in time

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Dimensions of data quality (cont)

- Reliability: Data consistent, regardless of who is collecting or using.
- Precision: Data has sufficient detail, eg on age, sex etc
- Integrity: System used to generate data protected from deliberate bias or manipulation for political or personal reasons.

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Factors that Influence Data Quality


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Factors that Influence Data Quality
There are three general factors:
1. Technical determinants
2. Systemic and environmental determinants
3. Behavioral determinants


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Determinants
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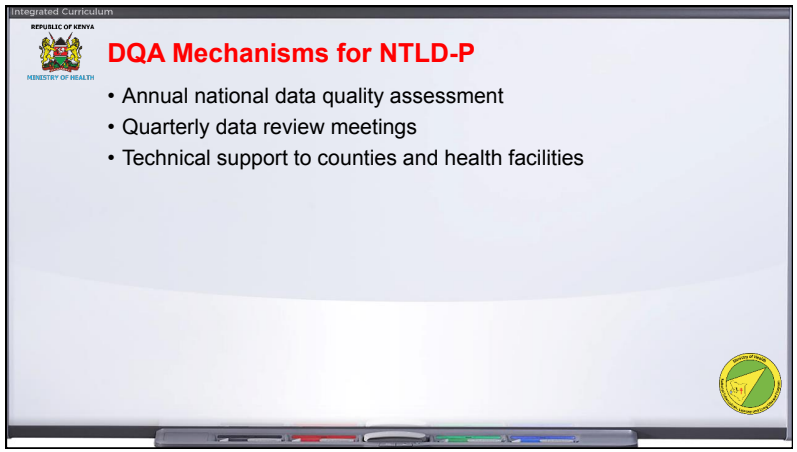
Technical determinants
• Standard indicators
• Data collection forms
• Information technology
• Data presentation
• Personnel training
Systemic and environmental determinants
• Resources
• Roles and responsibilities
• Organizational culture
Behavioral determinants
• Motivation
• Attitudes and values
• Confidence
• Sense of responsibility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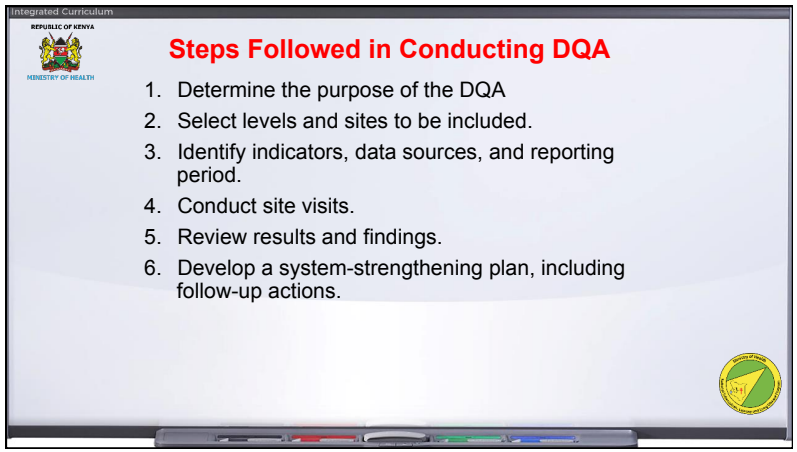
DQA Mechanisms for NTLD-P
• Annual national data quality assessment
• Quarterly data review meetings
• Technical support to counties and health facilities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Steps Followed in Conducting DQA
1. Determine the purpose of the DQA
2. Select levels and sites to be included.
3. Identify indicators, data sources, and reporting period.
4. Conduct site visits.
5. Review results and findings.
6. Develop a system-strengthening plan, including follow-up actions.

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Common Data Errors Observed in the Field

- Missing data
- Duplicate data
- Capture in the wrong data variable/field.
- Unlikely values for a variable
- Contradictions between variables
- Calculation errors
- Transcription error
- Late reporting

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Ways of Identifying Errors

- Look
  - Across each line
  - Top to bottom
- Look for
  - Missing data values
  - Obvious fluctuations
  - Inconsistencies between data elements
  - Mathematical errors when calculating indicator performance

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Ways of Identifying Errors

1. Review documentation
2. Trace and verify numbers
3. Perform “cross-checks” of the verified totals with other data sources
4. Perform “spot-checks” to verify the actual delivery of services
5. Look for seasonal variations over time, variations outside of the set ranges, and facility comparisons

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Exercise 2: Dimensions of data quality

- Quality of data is described using the following terms: Completeness, accuracy, timeliness, reliability, precision, integrity and confidentiality.
- Participants will work individually and match the definitions of quality with the correct definitions

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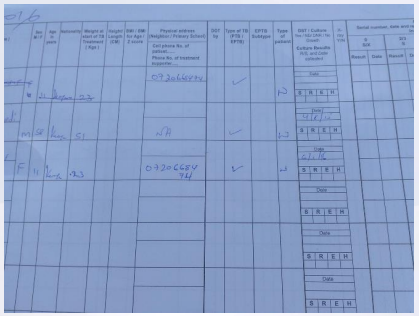
Data Quality Assessment.

Exercise 3

- Participants will work in existing groups
- Assess the quality of data in the registers provided (identify a section of the register for this exercise)
- Prepare a one page (flip chart) presentation and present to plenary



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Kenya Lung health Training Course

Monitoring and Evaluation

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Module 6

Reports: Compilation, analysis, data quality

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Preparation of programmatic reports

Exercise 1:

Participants will work in the existing groups and prepare the following reports

- Case finding
- Cohort
- AFB work load

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Exercise 1 (cont)

- Analyses:

Case finding

-Proportion smear positive patients below 15 years

-Proportion of total patients tested for HIV

-Proportion of total patients who are smear positive

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Exercise 1 (cont)

- Treatment outcomes
  - Number evaluated
  - Cure rate
  - Treatment success rate
  - Dead (%)
  - Lost to follow up (%)
  - Transfer out (%)
  - Treatment Failed (%)

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Exercise 1 (cont)

- AFB workload report
  - New presumptive (total)
  - New presumptive (positive) and %
  - Follow ups (total)
  - Follow ups (positive) and proportion
  - Total smears done in the month
  - Total positive smears and proportion

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Monitoring and Evaluation

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Module 7

E-recording and reporting

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Why E-recording and reporting.

- Computerized implementations of TB recording and reporting registers and quarterly reports
- Recommendations for revised forms to increase analyses and reporting requirements
- Under-utilization of existing data to improve TB control and epidemiological research
- Requirement for closer integration with other diseases such as HIV/AIDS and integrated epidemiological analyses
- Requirements to improve efficiency and control through better utilization modern information and communication

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Advantages of e-Recording and Reporting

- Improves the accuracy of reporting as it brings compilation closer to the source of the data and removes a level of transcription.
- Improves patient and treatment management through better record keeping and reporting at the facility
- Supports electronic data interchange for patient transferring in or out of facilities
- Computers generally useful for other tasks and improve skills development at facilities

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Research

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What is research

- Research can be defined as:
  - Search for knowledge
  - Systematic investigation
  - The need to establish novel fact or ideas
  - Solve new or existing problems
  - Prove new ideas or develop new theories

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What is Operations Research?

- Any research designed to produce practically usable knowledge that can improve program implementation
- Typically, OR uses systematic research techniques to:
  - assist program decision making
  - achieve a specific outcome
- OR aims to study the processes by which programs are implemented and interventions are delivered and the impact of those processes and interventions

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Operation Research cont'

- OR describes the disciplines that is focused on the application of information technology for informed decision-making
- OR relies to a large extent, on tools from the basic disciplines of mathematics, statistics and computer science
- Different from General Scientific Research
  - NOT intended to generate general knowledge about a subject
  - Does NOT engineer study population or control the study environment

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The purpose of operation research is:

- To identify problems during the implementation of program activities
- Determine workable solutions
- Test solutions in the field
- Plan for scale up
- OR Provides the proof for Evidence-Based Programs

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OR Provides the Evidence for Evidence-Based Programs

Compares

(arrives at best practices by comparison)

Evaluates

(provides evidence of effect, supports decisions with empirical evidence)

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Execution of TB Operations Research

- Identify the program problem or deficiency
- Determine the specific research question
- Determine source data (and possibly revise research question)
- Ensure they have an approved protocol/concept paper from the necessary authority

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Execution of TB Operations Research cont'

- Review resources and limitations
  - Ensure all ethical considerations are adhered to when collecting/abstracting patient level data
  - Analyze data
- Follow the laid down procedures in dissemination of results
  - Ensure all ethical considerations are adhered to when collecting/abstracting patient level data
  - Analyze data
- Follow the laid down procedures in dissemination of results

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Characteristics of a Good Research Question

- A good research question is:
  - Specific
  - Concise
  - Relevant to the program
  - One which can be answered using data

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Characteristics of a Good Research Question

- PECO
  - Patient / population: who are the relevant patients / population?
  - Exposure: What are the exposures (or the strategies) we want to compare?
  - Comparison: Is there a group without the exposure or strategy to compare to?
  - Outcome: What are the consequences that we wish to study?

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:

- Literature documenting a Medical Ethics goes back thousands of years
  - Historically pertain to the relationship between a clinician and a patient (example: Hippocratic Oath)
- Strict ethical principles governing human subjects research were developed in the modern era

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Ethics

- Ethics is:
  - The science of morals and constitutes a certain number of rules of good conduct
- Medical ethics refers to:
  - Rules that health professionals are subject to in their daily practice.
  - It involves ethical rules that apply to everyone, the scientific ethical rules, and morals, which are unique for each individual.
  - Must allow access to care for all, under optimal conditions for medical care, without any discrimination

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Six Principles of Medical Ethics

- Autonomy: patients have a right to refuse
- Beneficence: practitioners always act in best interest of patient
- Non-maleficence: "First, do no harm"
- Justice: fairness and equality (distribution of resources)
- Dignity: patients treated like people, with all rights accorded to them
- Truthfulness: patients have a right to full disclosure

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Types of Data Sources

- Primary source
  - Data is original i.e. collected afresh for survey
    - The researcher determines what to collect
  - Example: obtained by filling out questionnaire, examining sputum or taking weight of respondent
- Secondary source
  - Data already exists i.e. was collected by someone else for a different (other than survey) purpose
    - The researcher can only access what is there
  - Example: Medical record, TB registers or TB Reports

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Advantages

Primary source	Secondary source
• Measures variables specific to research objectives or hypothesis	• Inexpensive
• Data collection is standardized	• Fast and efficient
• Semi-structured interview allows more fluid data collection	• Not necessary to contact patients/participants

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Disadvantages

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Primary source	Secondary source
• Costly	• Data source may not be standardized
• Time-consuming	• Purpose for data collection not specific to research objectives
• Interviewer biases	• Missing data
• Interviewer selection & training	• Reliability & validity of data
• Response rates	

MODULE 11: SOCIAL PROTECTION, POVERTY ALLEVIATION AND ACTIONS ON OTHER DETERMINANTS OF TUBERCULOSIS

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Social protection

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Definition Click to edit Master title style

- The ILO describes social protection as “nationally defined sets of basic social security guarantees which secure protection aimed at preventing or alleviating poverty, vulnerability and social exclusion”.

This definition covers protection against:

- General poverty and social exclusion,
- Lack of affordable access to health care,
- Lack of labor market protections,
- As well as a lack of work-related income.

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Why is social protection important in TB Click to edit Master title style

- The World Health Assembly(WHA) in May 2014 adopted a new “End TB Strategy” setting required interventions to end the global TB epidemic by 2035

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Background

End TB Strategy

- The new “End TB Strategy” was adopted in May 2014 by the World Health Assembly and sets the required interventions to end the global TB epidemic by 2035.
- This strategy places a greater emphasis on preventing TB through addressing social determinants of TB, including poverty alleviation policies and social protection programs.

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Post 2015 Strategy

A WORLD FREE OF TB
ZERO deaths, disease, and suffering due to TB

END THE GLOBAL TB EPIDEMIC

- *Provides a unified response to ending TB deaths, disease, and suffering.*
- *Builds on three strategic pillars underpinned by four key principles.*

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Strategy

VISION	A world free of tuberculosis – zero deaths, disease and suffering due to tuberculosis			
GOAL	End the global tuberculosis epidemic			
INDICATORS	MILESTONES		TARGETS	
	2020	2025	SDG 2030	END TB 2035
Reduction in number of TB deaths compared with 2015 (%)	35%	75%	90%	95%
Reduction in TB incidence rate compared with 2015 (%)	20% (<85/100 000)	50% (<55/100 000)	80% (<20/100 000)	90% (<10/100 000)
TB-affected families facing catastrophic costs due to TB (%)	Zero	Zero	Zero	Zero
PRINCIPLES				
1. *Government stewardship and accountability, with monitoring and evaluation* 2. *Strong coalition with civil society organizations and communities* 3. *Protection and promotion of human rights, ethics and equity* 4. *Adaptation of the strategy and targets at country level, with global collaboration*				

- *Provides a unified response to ending TB deaths, disease, and suffering.*
- *Builds on three strategic pillars underpinned by four key principles.*

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Components

PILLARS AND COMPONENTS

1. **INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION**
   - A. Early diagnosis of tuberculosis including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups
   - B. Treatment of all people with tuberculosis including drug-resistant tuberculosis, and patient support
   - C. Collaborative tuberculosis/HIV activities, and management of co-morbidities
   - D. Preventive treatment of persons at high risk, and vaccination against tuberculosis
2. **BOLD POLICIES AND SUPPORTIVE SYSTEMS**
   - A. Political commitment with adequate resources for tuberculosis care and prevention
   - B. Engagement of communities, civil society organizations, and public and private care providers
   - C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control
   - D. Social protection, poverty alleviation and actions on other determinants of tuberculosis
3. **INTENSIFIED RESEARCH AND INNOVATION**
   - A. Discovery, development and rapid uptake of new tools, interventions and strategies
   - B. Research to optimize implementation and impact, and promote innovations

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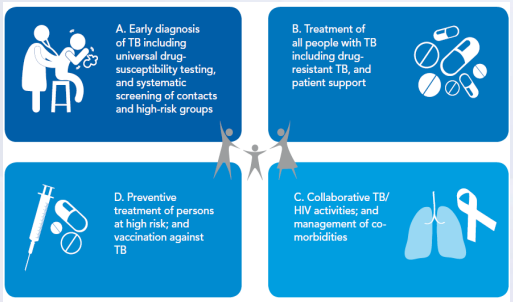
Pillar 1: Integrated patient centred care and prevention



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Pillar 2: Bold policies and supportive systems

A. Political commitment with adequate resources for TB care and prevention

B. Engagement of communities, civil society organizations, and all public and private care providers

D. Social protection, poverty alleviation and actions on other determinants of TB

C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control

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Pillar 3: Intensified Research and Innovation

A. Discovery, development and rapid uptake of new tools, interventions and strategies

B. Research to optimize implementation and impact; and promote innovations

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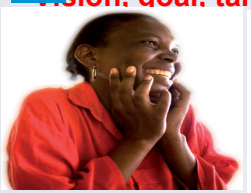
END TB

Vision, goal, targets, milestones



	MILESTONES		TARGETS	
	2020	2025	SDG* 2030	END TB 2035
Reduction in number of TB deaths (compared with 2015 (%))	35%	75%	90%	95%
Reduction in TB incidence rate (compared with 2015 (%))	20%	50%	80%	90%
TB-affected families facing catastrophic costs due to TB (%)	0%	0%	0%	0%

Vision:
A world free of TB
Zero TB deaths,
Zero TB disease, and Zero TB suffering
Goal:
End the global TB epidemic

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The global strategy and targets for tuberculosis prevention, care and control after 2015, were endorsed by all member states at the 2014 world health assembly

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Social Protection Programs

Examples of social protection programs are but not limited to;

1. Noncontributory transfer programs targeted to the poor ; cash transfers, food stamps, in-kind transfers, school feeding programs, etc
2. Schemes that deliver benefits based on contributions of their own members; National Health Insurance Fund(NHIF),National Social Security Fund-pensions(NSSF), un unemployment insurance.
3. Regulatory aspects of labor; active labor market policies e.g Maternity protection, income support for the unemployed

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Why social protection in TB

- The strategy aims to end the global TB epidemic, with targets to reduce TB deaths , new diagnosis and to ensure that no family is burdened with catastrophic expenses due to TB.
- The strategy places a greater emphasis on preventing TB through addressing social determinants of TB, including poverty alleviation policies and social protection programs.

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Indicator	Recommended Target
TB treatment coverage ≥ 90%	TB treatment coverage ≥ 90%
TB treatment success rate ≥ 90%	TB treatment success rate ≥ 90%
% TB-affected households that experience catastrophic costs due to TB 0%	% TB-affected households that experience catastrophic costs due to TB 0%
% Newly notified TB patients diagnosed with WHO-recommended rapid tests ≥ 90%	% Newly notified TB patients diagnosed with WHO-recommended rapid tests ≥ 90%
LTBI treatment coverage ≥ 90%	LTBI treatment coverage ≥ 90%
Contact investigation coverage ≥ 90%	Contact investigation coverage ≥ 90%
DST coverage of TB patients ≥ 100%	DST coverage of TB patients ≥ 100%
Documentation of HIV status among TB patients ≥ 90%	Documentation of HIV status among TB patients ≥ 90%
Case fatality ratio ≤ 5%	Case fatality ratio ≤ 5%

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TB

- People living in poor communities tend to have limited knowledge and are faced with various unlimited barriers to: diagnosis, treatment and care.
- This is further influenced by age ,gender ,social economic status, cultural and geographical areas that intertwine with poor ineffective health care systems .
- All these and more lead patients to experience catastrophic costs and effects.

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The cycle of TB and poverty 1/2

- TB is a disease of poverty, an estimated 95% of new TB cases and 98% of all TB deaths are in the developing world, with more than half of all deaths occurring in Asia.
- The risk of becoming infected with TB is associated with malnutrition, crowding, poor air circulation, and poor sanitation

all factors associated with poverty.

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"TB is the child of poverty – and also its parent and provider." – Archbishop Desmond Tutu

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The cycle of TB and poverty 2/2

- Even when TB services are free of charge, the disease is costly to the poor.
- The average TB patient loses three to four months of work time and up to 30% of their yearly household earnings.
- Families may be forced to sell what little livestock or land they have to access diagnosis
- The poverty cycle worsens as children are forced to quit school as there is no money for uniforms or fees, or because they have to work to support the family.
- In this manner, poverty is passed on from generation to generation.

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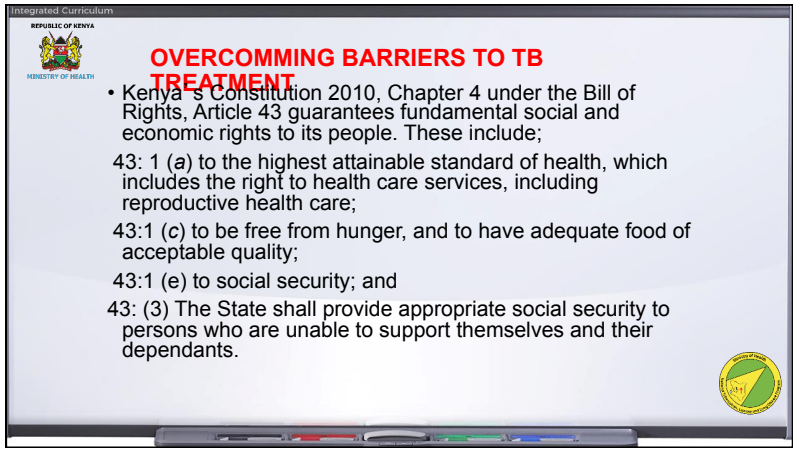
CHALLENGES AND BARRIERS THAT HINDER PATIENTS ACCESS TO TB TREATMENT

- **Economic barriers – there is a complex pathway to care for poor people**
- **Geographical barriers – distance from services providing TB diagnosis and treatment**
- **Socio-cultural barriers – stigma and lack of knowledge of TB and available TB services**
- **Health system barriers – lack of health system responsiveness**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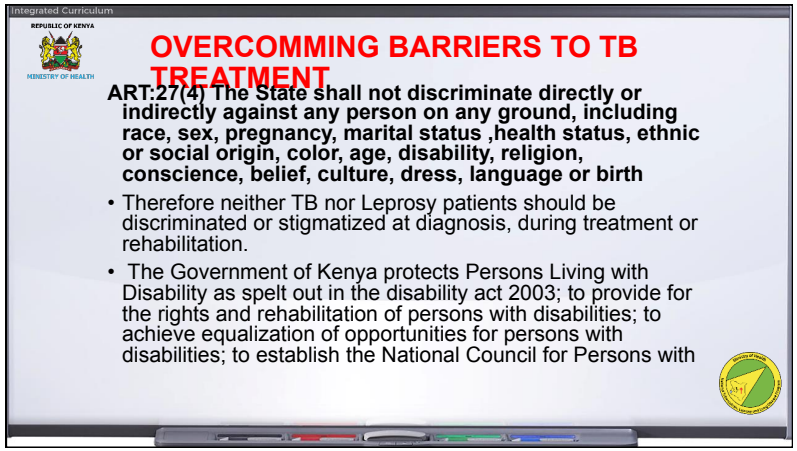
OVERCOMMING BARRIERS TO TB TREATMENT
• Kenya 's Constitution 2010, Chapter 4 under the Bill of Rights, Article 43 guarantees fundamental social and economic rights to its people. These include;
43: 1 (a) to the highest attainable standard of health, which includes the right to health care services, including reproductive health care;
43:1 (c) to be free from hunger, and to have adequate food of acceptable quality;
43:1 (e) to social security; and
43: (3) The State shall provide appropriate social security to persons who are unable to support themselves and their dependants.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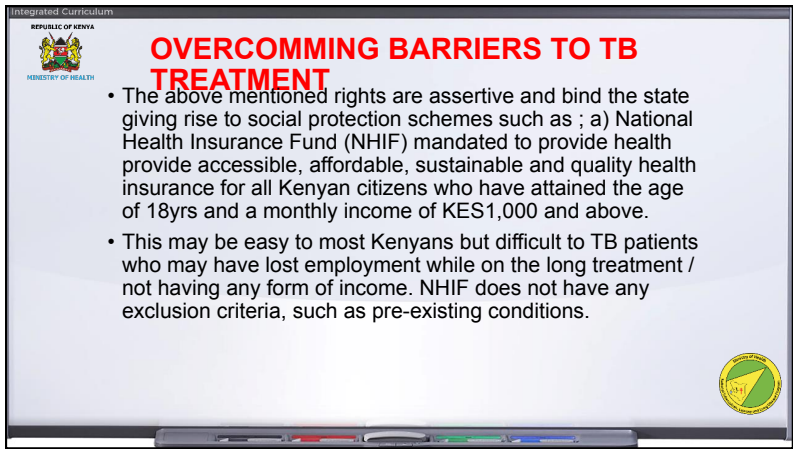
OVERCOMMING BARRIERS TO TB TREATMENT
ART:27(4) The State shall not discriminate directly or indirectly against any person on any ground, including race, sex, pregnancy, marital status ,health status, ethnic or social origin, color, age, disability, religion, conscience, belief, culture, dress, language or birth
• Therefore neither TB nor Leprosy patients should be discriminated or stigmatized at diagnosis, during treatment or rehabilitation.
• The Government of Kenya protects Persons Living with Disability as spelt out in the disability act 2003; to provide for the rights and rehabilitation of persons with disabilities; to achieve equalization of opportunities for persons with disabilities; to establish the National Council for Persons with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OVERCOMMING BARRIERS TO TB TREATMENT
• The above mentioned rights are assertive and bind the state giving rise to social protection schemes such as ; a) National Health Insurance Fund (NHIF) mandated to provide health provide accessible, affordable, sustainable and quality health insurance for all Kenyan citizens who have attained the age of 18yrs and a monthly income of KES1,000 and above.
• This may be easy to most Kenyans but difficult to TB patients who may have lost employment while on the long treatment / not having any form of income. NHIF does not have any exclusion criteria, such as pre-existing conditions.


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Proposed strategies

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Policy directions by the state

- Standardized treatment regimens offered only by the State and subsidized in private hospitals
- Decentralization of TB treatment diagnostic services
- Isolation policy
- Job protection policy

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2.Inter sectoral articulation

- Prioritizing most vulnerable populations, through joint actions with other related public sectors
  - Chronic illness HIV – PLWAS,cancers and diabetis
  - people living with disabilities
  - Declare TB patients temporarily impaired till after treatment

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3. Articulation with civil society

- Social movement (NGOs), Parliamentary Caucus, Subcommittee on chronic Diseases Related to Poverty in both Senate and parliament and the County parliaments.
- Stop TB partnership
- Strengthen the engage TB strategy

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4.Pursue a TB specific benefit

Pursue a TB specific benefit through the inclusion of TB and leprosy in the existing social protection programs

- Offer patient support (enablers and incentives) : addressing food security -Nutritional support could include nutritional counseling, cash transfers and subsidizing food costs and/or food vouchers
- Baseline and follow up investigations fee waived and transport support to all TB and Leprosy patients living below one dollar/day
- Upon diagnosis needy patients should be assisted to join the national health insurance scheme(NHIF)