**FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA**

**MINISTRY OF HEALTH**

****

NATIONAL COMPREHENSIVE TUBERCULOSIS, LEPROSY AND TB/HIV TRAINING MANUAL for HEALTH CARE WORKERS.

PARTICIPANTS’ MANUAL

March 2016

ADDIS ABABA

**COMPREHENSIVE TRAINING MANUAL FOR CLINICAL AND PROGRAMMATIC MANAGEMENT OF TBL AND TB/HIV**

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**March 2016**

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# ACRONYMS

|  |  |
| --- | --- |
| ACSM | Advocacy Communication and Social Mobilization |
| ACH | Air change per hour |
| AFB | Acid Fast bacillus/bacilli |
| AIDS | Acquired Immuno-Deficiency Syndrome |
| ART | Antiretroviral therapy |
| BCG | Bacilli Calmette Guerin |
| CBTC | Community Based TB care |
| CPT | Cotrimoxazole Preventive Therapy |
| DOT | Directly Observed Treatment |
| DOTS | Directly Observed Treatment Short course |
| DR-TB | Drug Resistance TB |
| DST | Drug Susceptibility Testing |
| EPTB | extrapulmonary tuberculosis |
| EQA | External Quality Assurance |
| FDC | fixed-dose combination |
| FMoH | Federal Ministry of Health |
| HAART | Highly Active Anti-Retroviral Treatment |
| HCW | Health Care Worker |
| HEWs | Health Extension Workers |
| HFs | Health Facilities |
| HIV | Human Immuno-Deficiency Virus |
| IPT | Isoniazid Preventive Therapy |
| IRIS | Immune Reconstitution Inflammatory syndrome |
| LPA | Line Probe Assay |
| MDR-TB | Multi-Drug Resistant TB |
| NGOs | non-governmental orgainizations |
| NNRTI | Non-Nucloside Reverse Transcriptase Inhibitor |
| NRTI | Nucloside Reverse Transcriptase Inhibitor |
| OIs | Opportunistic infections |
| PFSA | Pharmaceuticals Fund and Supply Agency |
| PLHIV | People living with HIV |
| PMTCT | Prevention of Mother-to-child transmission of HIV |
| PPM | Public-private mix |
| PTB | Pulmonary Tuberculosis |
| RHB | Regional Health Bureau |
| SOPs | Standard operating procedures |
| TB | Tuberculosis |
| TB/HIV | Tuberculosis and HIV Co-infection |
| TBL | Tuberculosis & Leprosy |
| TTS | TB treatment supporter |
| UVGI | Ultra-Violet Germicidal Irradiation |
| WHO | World Health Organization |
| XDR-TB | Extensively Drug Resistance TB |

# I. Introduction

## i.i Background to the training curriculum

### Scope of this training manual

This document is developed based the sixth edition of the national TB, leprosy and TB/HIV guideline and to be used by the training participants in the delivery of the six-day in-service training course on “ National comprehensive TBL and TB/HIV training for health workers.”

### Target audiences

Target groups for this course include:

* + - The TBL & TB/HIV program managers assigned at national, regional, zonal and woreda level health offices and developmental partners;
    - Clinicians (Physicians, Health officers and BSc/Diploma Nurses)

Besides, recruitment of trainees should focus on health care workers working in public, private (including workplaces) and nongovernmental health institution providing diagnostic and treatment services to patients with TB and/or leprosy in order to maintain optimal delivery of quality and patient centered service for their clients.

The training is designed for small groups of participants, with classroom size of 25-30 persons, are led and assisted by “facilitators” as they work through the module.

### Training methods and materials

This national curriculum on comprehensive clinical and programmatic management of TB, Leprosy and TB/HIV applies the modular type of training methodology with adult learning principles whereby facilitators use varieties of teaching methods based on the facilitators guide.

The facilitator guide clearly presents instructions on the method of delivery, material needed for each section and answers to review exercises & case studies. In addition, the guide provides elaborates and justification for key areas identified for discussions between the participants and the facilitators. Hence, facilitators of this course must read the guide ahead of time to get acquainted with the training and meet the objective of the course at end.

Each participant will receive the following materials:

* The national TBL & TB/HIV training module
* The national TBL and TB/HIV guideline
* The national PMDT guidelines (optional)

### Duration of the course

The TBL and TB/HIV basic course is designed to be delivered in six days with 24 sessions of 90 minutes each.

At the end of each training day, participants are expected to spend 30 minutes to respond to exercises designed to review the topics covered over the day; and responding to the exercises and follow-up discussion should be part of Recap session on the beginning of the next training day. Answers with explanation for the questions are provided on the facilitator guide.

## i.ii Training objectives

**General Objective**: is to equip participants with the necessary knowledge, attitude and skills to practice quality and patient-centered care for patients with Tuberculosis and Leprosy, as well as on programmatic aspect of TB, Leprosy and TB/HIV.

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

* Apply the national TB control strategies for the prevention and control of tuberculosis
* Apply international standards of TB care (ISTC) of case management of TB
* Demonstrate skills needed to provide patient-centered quality TB care
* Implement nationally recommended TB-HIV collaborative activities
* Discuss on National leprosy control strategies
* Provide quality case management for patient with leprosy
* Implement TB infection control in their health facility
* Demonstrate skills for keeping quality recoding and reporting in TB and TB/HIV
* Discuss aspects of TB and TB-HIV drug supplies management

## i.iii Epidemiology of TB, DR-TB and TB/HIV

TB is a major public health problem throughout the world. About a third of the world’s population is estimated to be infected with tubercle bacilli and hence at risk of developing active disease.

According to the WHO Global TB Report 2015, 9.6 million people are estimated to have fallen ill with TB in 2014 while an estimated 1.5 million people died of TB. In addition, an estimated 3.3% of these new TB cases and 20% of the previously treated cases have believed to harbour MDR-TB whereas, an estimated 190 000 people died of MDR-TB.

Ethiopia is among the 30 High TB, HIV and MDR-TB Burden Countries, that accounted for 80% of all estimated TB cases worldwide, with annual estimated TB incidence of 207/100,000 populations and death rate of 33 per 100,000 populations for 2014. Among the notified TB cases in 2014, 1300(1.6%) of new TB cases and 11.8% of previously treated TB cases were estimated to harbour MDR TB.

National DR-TB sentinel report in 2013 shows the MDR-TB prevalence of 2.3% among new TB cases and 17.8% among previously treated TB cases, which indicates increasing trends in TB drugs resistance burden compared to the first DRS survey conducted in 2003-2005.

TB and HIV co-infection is an additional problem in the control of TB in the country whereby 10-15% of annually notified TB patients were found to have HIV co-infection.

## i.iv TB Control Strategies

Ethiopia has achieved the millennium development goals for TB in 2015 and now adopted new post-2015 Global TB Strategy called “END TB strategy”.

This strategy aims to end the global TB epidemic, with targets to reduce TB deaths by 95% and to cut new cases by 90% between 2015 and 2035, and to ensure that no family is burdened with catastrophic expenses due to TB.

**Pillar 1 - Integrated, patient-centered care and prevention:** this pillar builds on the Stop TB Strategy and focuses on early detection, treatment and prevention for all TB patients including children, and aims to ensure that all TB patients not only have equal, unhindered access to affordable services, but also engage in their care.

Key components of this pillar include;

* 1. Early diagnosis of tuberculosis including universal DST, and systematic screening of contacts and High-risk groups
  2. Treatment of all people with TB including drug-resistant TB, and patient support
  3. Collaborative TB/HIV activities, and management of co-morbidities
  4. Preventive treatment of persons at high risk, and vaccination against TB

**Pillar 2 - Bold policies and supportive systems:** Effective implementation of the End TB Strategy requires government stewardship, high-level political commitment and enhanced resources and this pillar intends to ensure strong participation across government, communities and private stakeholders. Key components:

1. Political commitment with adequate resources for TB care and prevention
2. Engagement of communities, civil sociality organizations, and public and private providers
3. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and ration use of medicines, and infection control
4. Social protection, poverty alleviation and actions on other determinants of tuberculosis

**Pillar 3 - Intensified research and innovation:** this pillar aims to intensify research from the development of new tools to their adoption and effective roll-out in countries to break the trajectory of the epidemic and reach the global targets. Key components:

1. Discovery, development and rapid uptake of new tools, interventions and strategies
2. Research to optimize implementation and impact, and promote innovations

|  |
| --- |
| Discuss on the new initiatives incorporated in END TB strategy as compared to the previous initiatives in the “STOP TB strategies”? |
| -  -  -  - |

# 1. BASIC concept in TUBERCULOSIS

**TIME ALLOTED:**

**LEARNING OBJECTIVES**

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

* Discuss on the causes of Tuberculosis
* Explain mode and determinants of transmission of TB
* Discuss on the clinical manifestations TB disease

## 1.1 Transmission and pathogenesis of TB

**Tuberculosis (TB)** is a disease caused by an organism called *Mycobacterium tuberculosis*, a rod-shaped bacillus. Occasionally the disease can also be caused by *Mycobacterium bovis and Mycobacterium africanum*. M tuberculosis is usually affecting the lungs in which case it is called *pulmonary TB*.

Tuberculosis is mainly transmitted person-to-person by inhalation of infected ***droplet nuclei***, which are expelled into the air when an untreated infectious pulmonary TB patient coughs or sneezes.

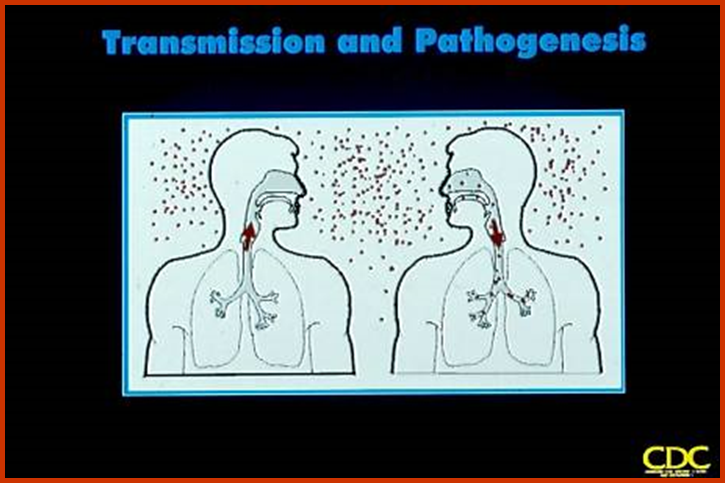


Figure 1. Illustration of the release of droplets during coughing (left) and how transmitted to another person during inhalation of droplets (Right).

Risk of infection depends on the extent of an individual’s exposure to droplet nuclei and on susceptibility to infection. Two factors determine an individual’s risk of exposure:

1. The concentration of droplet nuclei in contaminated air and
2. The length of time spent breathing that air.

The extent of an individual’s exposure to droplet nuclei is determined by the ***proximity*** and ***duration of contact*** with an infectious source case.

*The risk of infection of a susceptible individual is therefore high with* ***close, prolonged, indoor exposure to a person with sputum smear-positive pulmonary TB.***

**Who is at higher risk of developing active tuberculosis?**

Persons living in the same household and those having frequent and close contact with an infectious TB patient have the greatest exposure the bacilli and hence, to develop infection.

TB affects individuals of all ages and both sexes. There are, however, groups, which are more vulnerable to develop the disease: **Poverty, malnutrition and over-crowded living conditions** have been known for decades to increase the risk of developing the disease. **HIV infection** has been identified as a major risk factor for developing tuberculosis. The age group mainly affected is between 15 and 54 years.

## 1.2 Natural history of TB

In the great majority (90-95%) of persons infected with *M. Tuberculosis,* the immunological defence either kills the inhaled or ingested bacilli or keeps them suppressed (silent focus) causing ‘**latent *M. Tuberculosis* infection’**. Latent TB infection can be detected by tuberculin skin test.

Only 5-10% of such infected persons (primary infection) develop active disease. Following primary infection, rapid progression to disease is more common in children less than 5 years of age. Patients with weakened immune systems, such as those with HIV infection, are at greater risk of developing TB disease. HIV positive people with latent TB infection have a 10% annual and 50% lifetime risk of developing active TB disease.

**Active TB disease** is the result of direct progression of the primary lesion as a continuous process within a year or so after infection, or from the reactivation of latent TB, which remained dormant since the initial infection, or a result of re-infection from recent transmission. It usually affects the lungs (more than 85%) but can involve any part of the body.

Table 1.LatentTB Infection versus Active TB Disease:

|  |  |  |
| --- | --- | --- |
| ***Characteristics:*** | **Latent TB Infection** | ***Active TB Disease*** |
| **M. tuberculosis in the body** | Yes | Yes |
| **Tuberculin skin test reaction** | Positive | Positive |
| **Symptoms** | No | Yes |
| **Chest x-ray** | Normal | Abnormal if pulmonary |
| **Sputum smears and cultures** | Negative | \*Positive |
| **Infectiousness** | Not | Pulmonary TB is infectious |
| **A case of TB** | No | Yes |

*\* May not be true in immunocompromised individuals.*

## 1.3 Clinical Presentation of Tuberculosis

The clinical presentation of Tuberculosis is most commonly the result of involvement of the lungs (more than 80% of cases); however, organ specific presentations may be seen upon involvement of extra-pulmonary organs, most commonly lymph nodes, pleura, spine, joints, genito-urinary tract, nervous system or abdomen:

**Pulmonary Tuberculosis:** A persistent and progressive cough, often accompanied by non-specific systemic symptoms such as fever, night sweats or loss of weight, is the commonest presentation of pulmonary tuberculosis.

However, cough might not be the predominant presentation for certain population group, particularly in people living with HIV, young children, and severely malnourished. Hence, high index of suspicion is required to diagnose TB. A history of household/close contact with a person with infectious TB, and presence of documented recent weight loss may indicate the presence of TB in such patients to warrant investigation.

Some patients may present with chest pains (due to pleurisy, muscle strain), breathlessness (due to extensive lung disease or concomitant pleural effusion), localised wheeze due to local Tuberculous bronchitis, or because of external pressure on the bronchus by an enlarged lymph node.

**Extra-pulmonary TB**: patients may present with non-specific symptoms such as unintentional weight loss, night sweats and fever for more than 2 weeks. Other symptoms depend on the site or organ affected. The most common types of extra-pulmonary tuberculosis are:

**Tuberculous lymphadenitis**: caused by lymphatic spread of the organism, is one of the commonest forms of extra-pulmonary TB. Involvement of the lymph nodes is commoner in children and in person in the later stages of HIV infection. Slowly developing painless Cervical Lymph node enlargement (regardless of HIV infection) is the commonest sites of involvement, though axillary and intra-abdominal lymph nodes may be affected.

**Clinical presentations**: Initially cervical lymph nodes are firm and discrete, but later they become matted together and become fluctuant. The overlying skin may breakdown with the formation of abscesses and chronic discharging sinuses, which heal with scarring. In HIV infected patients, lymphadenopathies can be acute and resemble acute pyogenic lymphadenitis.

***Tuberculous pleural effusion:*** Tuberculous is the commonest cause of a unilateral pleural effusion. It is also the commonest form of HIV-related extra-pulmonary disease. Management of tuberculous pleural effusion should aim at starting TB treatment promptly and determining the HIV-status of the patient.

Clinical features:

* Presentation is most often acute with a non-productive cough, chest pain, shortness of breath and high temperature.
* Findings on clinical examination may include:
* Tracheal and mediastinal shift away from the side of the effusion
* Decreased chest movement
* Stony dullness on percussion on the side of the effusion.

***TB of bones:*** TB can affect any bone but most commonly affects the vertebral column. It is seen both in children and adults and can be severe, with neurological sequelae. Involvement of the intervertebral disc occurs by spread of a lesion from the vertebral body. In many cases more than one intervertebral disc is involved. It is characterized by loss of bone density and slow bone erosion, with the disc space being maintained for a long time (differentiating it from pyogenic infections). Involvement of the thoracic vertebrae causes localized back pain, deformity of the spine, and in extreme cases an angulated kyphosis (gibbus). Spread may occur into the soft paravertebral tissue to form a so-called “cold abscess”.

**Miliary Tuberculosis**: presents with constitutional features rather than respiratory symptoms. Early symptoms are vague and lack specificity. Lassitude, anorexia, failure to thrive and prolonged unexplained fever are common. Therefore, a high index of suspicion is necessary. TB meningitis is the commonest cause of death if miliary TB is untreated.

**CNS TB( including TB meningitis)** : The patient may present with constitutional features and chronic meningitis and there is gradual onset and progression of headache and decreased consciousness. It is most common in children between 6 month and 4 years of age. More commonly, the signs and symptoms progress slowly over several weeks; hence, high index of suspicion is important for early identification of these patient and to prevent complications and death.

Differential diagnosis of Pulmonary Tuberculosis

|  |  |
| --- | --- |
| Diseases | Clinical features |
| Bacterial pneumonia |  |
| Lung abscess |  |
| bronchiectasis |  |
| Lung cancer |  |

# 2: Diangosis of TUBERCULOSIS

**Time Allotted:**

**Learning Objectives:**

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

* Explain laboratory methods for TB diagnosis
* Discuss the sputum collection protocol for examination
* Discuss the TB case finding strategies
* Explain on Patient evaluation processes for Tuberculosis
* Interpret and use the TB diagnostic algorithms

## 2.1 Tuberculosis diagnostic Methods

The diagnosis of TB disease may be reached either by:

* Bacteriologic confirmation using:
  + **ZN/FM microscopic examination**
  + **molecular techniques** like Xpert MTB/RIF assay and Line probe Assay
  + **culture media**
* Clinical decision of expert clinician by analyzing the supportive evidences from:
  + Medical imaging of the affected organs eg. X-ray, ultrasound, etc.
  + Histo-pathologic studies of sample obtained from body tissue or fluid
  + Biochemical analysis of body fluids: glucose, cell counts, protein…
  + Heamatology tests: Complete blood cell count, ESR

1. **Bacteriological Methods:**

**Smear Microscopy:** is a bacteriologic confirmatory technique used to diagnose infectious TB cases and monitor treatment response .It is cheap, simple, produces rapid & reliable results.

The following two staining methods can be used to identify acid-fast bacilli:

**ZN microscopy**: has low sensitivity (40-60%) and requires 5,000-10,000 bacilli per ml of sputum to get positive results.

**Fluorescence auramine staining (LED FM):** requiresless time for slide reading and has additional 10% sensitivity over ZN microscopy to identify bacillus.

**Reporting and Interpreting AFB Microscopy results**: Since the number of TB bacilli seen in a smear reflects the degree of infectiousness of the patient, the TB laboratory should issue AFB results indicating the bacillary load.

**Table 1. Showing proper recording of the results of ZN and FM Smear Microscopy.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ZN Staining** | | **Auramine Staining** | | |
| **Number of bacilli seen on smear(100X)** | **Results reported** | **Number of bacilli seen on smear (200X)** | **Number of bacilli seen on smear (400X)** | **Results reported** |
| No AFB per 100 oil immersion fields | No AFB Seen | No AFB in one length | No AFB in one length | No AFB observed |
| 1-9 AFB per 100 field | Scanty | 1-4 AFB in one length | 1-2 AFB in one length | \*Need confirmation |
| 10-99 AFB per 100 field | + | 5-49 AFB in one length | 3-24 AFB in one length | Scanty |
| 1-10 AFB per field | ++ | 3-24 AFB per field | 1-6 AFB per field | + |
| >10 AFB per field | +++ | 25-250 AFB per field | 7-60 AFB per field | ++ |
| >250 AFB per field | > 60 AFB per field | +++ |

**Culture:** is a bacteriologic confirmatory test for MTB. It is highly sensitive technique that can detect 10 to 100 viable bacilli per ml of sputum. It allows species identification and drug susceptibility testing and assists to monitor treatment response for drug resistance TB patient.

On the other hand, it is more expensive, requires higher biosafety level setup, well trained laboratory personnel and results takes longer turnaround time.

* ***Solid culture media****:* (Löwenstien-Jensen) is culture media which has several advantages including ease of preparation, low cost and low contamination rate compared to liquid media. However, the long turnaround time for result limits its use in peripheral labs.
* ***Liquid culture media* :**( MGIT 960 system) is a specially enriched culture media developed to shorten the time required for bacillary growth to 5-15 days. It has additional 10 % sensitivity over LJ solid media. However, the method is prone to higher contamination rate and the cost for culture media is expensive.

**Drug susceptibility testing (DST):** is required to make a definitive diagnosis of drug resistant TB. It can be done either by phenotypic or genotypic techniques.

***Phenotypic DST methods:*** can be determined either by observation of growth or inhibition of the bacilli in a medium containing anti-TB drugs. It is the gold standard technique to test susceptibility to various TB drugs. However, the technique can only be performed on MTB isolates grown on culture media and result takes longer time.

***Genotypic (Molecular) DST techniques:*** refer toDNA PCR technologies that are specifically designed to detect genetic mutations associated with resistance to Ant-TB drugs. Their role is limited to diagnostic/screening purpose and cannot be used to monitor treatment response as they detect the genetic material of MTB from both live and dead bacilli. These technologies provide rapid results. At present, Xpert MTB/RIF assays and LPA are the two genotypic techniques recommended for wider use in Ethiopia:

* **Xpert MTB/RIF Assay**: is an automated genotypic technique used todetect MTB and screen for Rifampicin resistance directly from the sputum and is highly sensitive to detect MTB even in smear negative cases. It produces results in two hours.
* Its biosafety precaution is similar to direct smear microscopy making the technology feasible for peripheral laboratory.
* The test might be unsuccessful due to power interruption, or errors/invalid results. In these instances a second specimen must be collected for a repeat Xpert test. Moreover, it does not inform susceptibility to INH.
* The service is under rapid expansion in Ethiopia and at the moment available in most referral and zonal hospitals.

***Line Probe Assay (LPA):*** is a rapid genotypic DST test used to detect resistant strains for both Isoniazid and Rifampicin. It can be performed directly from smear positive samples. However, if the sputum is smear negative, growth of bacilli should first be demonstrated on culture (preferably on liquid medium) to perform DST for isoniazid and rifampicin using LPA. In addition, LPA can also be performed to screen resistance for certain second line anti-TB drugs though the result needs careful interpretation.

LPA service in Ethiopia is available at national and in most regional reference laboratories and few referral MDR-TB hospitals.

|  |  |  |  |
| --- | --- | --- | --- |
| **Method** | | **Advantage** | **Limitation** |
| Smear microscopy | ZN and FM | Cheap, simple, rapid & reliable results  Diagnosed infectious TB cases  FM add at least 10% sensitivity than ZN | Low sensitivity |
| Culture | Solid (e.g LJ) & Liquid  (e.g MGIT) | Highly sensitive (can detect 10- 100 viable bacilli per ml specimen)  Allows species identification and drug susceptibility testing  Recommended for monitoring of treatment response for DR-TB patient  MGIT has additional 10 % sensitivity over LJ | Long turnaround time  MGIT is prone to higher contamination rate  Costly for installation and maintenance  High bio-safety level requirement  Needs well trained personnel |
| DST | **Phenotypic** | Enable to have definitive diagnosis of M(X)DR-TB | Long turnaround time  Costly, require sophisticated biosafety setup and need well trained personnel |
| **Genotypic**   * Xpert MTB/RIF assay * LPA | Provide rapid results | cannot be used to monitor treatment response |
| Diagnosis MTB and Rifampicin resistance directly from the sputum  More sensitive to detect MTB even in smear negative cases  Does not require sophisticated bio-safety precautions | Requires continuous electrical supply |
| Detectresistant for both Isoniazid and Rifampicin Screen resistance for certain second line TB drugs  Capacity to perform large volumes of test per day | Only performed either from smear positive or culture positive isolates Requires three rooms for different steps  Require sophisticated biosafety setup and need well trained personnel |

1. **Histo-Pathological Examination**

Pathology plays a complementary role in confirming the diagnosis of TB. Multiplication of tubercle bacilli in any site of the human body causes a specific type of inflammation, with formation of characteristic granuloma that can be found on histo- pathological examination.

Samples for pathologic examination can be collected using:

* *Fine needle aspiration* from accessible mass like peripheral enlarged lymph nodes
* *Aspiration of effusions* from serous membranes; serous fluid analysis however, is much less useful for diagnosis than histology and culture of a serous membrane biopsy specimen.
* *Tissue biopsy* from any body tissues such as serous membranes, skin, endometrium as well as bronchial, pleural, gastric or liver tissue.

1. **Radiological Examination**

Chest X-ray is a rapid and convenient method to evaluate patients who cannot produce sputum or who have negative results from bacteriologic tests, and to diagnose extra pulmonary TB (such as pleural effusions and pericardial TB).

Although parenchymal infiltrates, lymph node enlargements or cavities are suggestive of TB; x-ray findings must be interpreted in the light of the patient’s history and clinical findings.

Indication for use of chest x-rays:

* To evaluate patients who cannot produce sputum or have negative bacteriologic results,or to diagnose extra pulmonary TB (such as pleural and pericardial TB)
* To assist in the diagnosis of suspected complications of TB disease; eg. fibrosis
* To help in diagnosing other concomitant lung diseases such as bronchiectasis, lung abscess ...

Besides, all individuals with chest x-ray findings suggestive of PTB should also undergo examination with bacteriologic confirmatory test to assess for infectious Pulmonary TB.

*Analysis of lateral CXR may be indicated when intra-thoracic lymphadenopathy is suspected to cause TB related manifestation mainly in young children (under Five years of age).*

**Vertebral X-ray**: X-ray of the spines also helps to evaluate patients with suspected involvement of the vertebrae, and finding suggestive of TB. Vertebral X-ray may be normal in early disease, as 50% of the bone mass must be lost in order for changes to be visible on X-ray. Plain X-ray (PA and Lateral view) of the affected vertebra can show *vertebral destruction and narrowed disc space.*

1. **Ultrasonography studies**

The ultrasound can be used as a supplementary investigation in the diagnosis of Extrapulmonary TB particularly abdominal and pericardial TB. Abdominal U/s shows matted lymph nodes and loops of intestine, full of debris, and multiple foci of splenic abscess while the pericardial U/S may show septate pericardial effusion with full of debris in the pericardial cavity.

## 2.2 Specimen collection

Obtaining an adequate quantity of good quality sputum is critical to ensuring accurate test results:

### 2.2.1 Number of specimens required for examination

**A. Specimen for presumptive pulmonary TB cases:**

How many specimens are required to make the diagnosis of TB from sputum samples?

* *Two consecutive sputum specimens collected on spot-spot schedule for AFB smear microscopic examination*
* *A single sputum specimen collected at spot for Xpert MTB/RIF*
* *A third sputum specimen may be collected on spot for Xpert MTB/RIF Assay as follow-on test to AFB microscopy for patients with two negative sputum smear result and in whom clinical suspicion for TB remains high after administration of Broad spectrum Antibiotic.*

**Recommended Sputum collection schedule and frequency for AFB microscopic**: Though the existing recommendation for sample collection on “Spot-morning-spot” schedule may find very little additional number of patients, The NTP has made changes considering the evidences that show the majority of smear positive patients can be detected with two specimens collected on spot-spot schedule in quality assured laboratories. In addition, “Spot-morning-spot” schedule has the following disadvantages:

* Patient are required to make two days visits to the clinic increasing patients missing out
* Diagnostic delays as sample processing would not be done unless the third specimen is collected
* high risk of missing a TB case, if only the first specimens were received

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| **Why the change from three to two consecutive sputum specimens (spot-spot) schedule?** |
| **Answer:** Based on evidences, good quality microscopy of two consecutive sputum specimens (spot-spot) identifies 95–98% of smear-positive TB patients in quality Assured laboratories. |
| Advantages:   * + Greatly reduces the workload of laboratories   + Has the potential for offering same-day diagnosis   + Is better for patients because it reduces the number of visits while largely maintaining sensitivity. |
| Disadvantages:   * + Very minor loss in the number of cases detected. |

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| *Revised National recommendations on the use of smear microscopy for the diagnosis of Tuberculosis:* |
| * *The recommended number of sputum specimen required for evaluation using microscopy is changed from three samples (spot-morning-spot) to two samples (spot-spot).* * *One sputum smear positive result confirms the diagnosis of bacteriologically confirmed Tuberculosis.* * *Considering the increased sensitivity of Xpert MTB/RIF Assay over Sputum smear microscopy to diagnose TB; Xpert MTB/RIF Assay is preferred initial test for patients who are children and/or people living with HIV (PLHIV).* * *For patients whose sputum smears microscopy result is twice negative and in whom clinical suspicion for TB remains high after administration of Broad spectrum Antibiotic, Xpert MTB/RIF Assay is advised as follow on test.* |
| **The Recommended Sputum collection schedule and frequency for microscopic and XpertMTB/RIF tests** **as follows:** |
| ***Collect two "on-the-spot" sputum samples for smear microscopy:***  Instruct to produce the sample on same day, give one labelled container to produce the first sample immediately, and give the second container when the patient brings the first sample and instruct to produce the second sample after 30 minutes to 1 hour. |
| ***Collect one "on-the-spot" sputum samples for Xpert MTB/RIF Assay:***  Instruct the patient on the techniques of quality sample production, and Give one labelled falcon tube to Collect the sample. |

**B. Specimen for presumptive extra-pulmonary TB cases:**  patients suspected of having extra-pulmonary TB, analysis of the body fluid or tissue from the suspected site must be conducted preferably, using bacteriologic confirmatory tests. The specimen collection should be handled by trained HCWs.

***Note that one positive result confirms the diagnosis of TB from any specimen collected either from pulmonary or extrapulmonary site.***

### 2.2.2 Collection of Good quality sputum

Patients need to be instructed and supported to collect good quality sputum for examination.

**Patient education and instructions for Sputum collection:**

|  |
| --- |
| **Educate your patient on:** |
| * Requirements of good quality specimen:   + Should come from the lungs.   + Should not be Saliva or nasal secretions.   + Should not contain food or other particles * the volume of specimen required to be collected:   + 2-5ml of sputum using sputum cup for smear microscopy   + 1-4 ml of sputum using Falcon tube for Xpert MTB/RIF Assay * need for the patient to use a labelled container for collection * How to securely close the lid by pressing down on the centre of the lid * The benefit of coughing up in a well-ventilated designated area |
| **Instruct your patient:** |
| * The direction of the “designated coughing area” in the clinic for spot collection * To rinse the mouth with clean water to remove food and other particles * To take deep in and out breathes 2–3 times * To cough deeply from your chest to produce sputum * To expectorate into the open container close to your mouth and try not to spoil the outside of the container * To wash your hands after collecting the sample * To bring back the sample to the laboratory |

## 2.3 Transportation of specimen

Once the specimen is collected by the patient, it may need to be transported to laboratories located outside of the facility for culture, DST and/or pathologic examination. All the standard precautions must be applied to reduce contamination of samples and enhance the recovery of mycobacteria.

During transportation of specimens:

* Use “triple box container” to store and transport the samples keeping the cold chain (*See Annex for National Sample collection and referral SOP)*.
* Record patients’ information correctly on the laboratory request form including the telephone numbers of the patients and the facility
* Use “sample transportation log sheet” to send and receive the samples from the courier
* The laboratory personnel at the sending HF and testing laboratory should sign on the “sample transportation log sheet” upon issuing and receiving samples from the courier.
* The testing laboratory should return the patients’ lab reports promptly based on the agreed turn-around time.

## 2.4 Recommended TB case finding approaches in ethiopia

The identification of a TB case is a stepwise approach whereby individuals with presumptive TB are identified using recommended case finding strategies, and investigated using appropriate diagnostic algorithms and techniques.

The objectives of early identification of a TB case are:

1. To start the treatment as early as possible, and
2. To interrupt the chain of transmission

**Recommended TB case finding approaches to identify individuals with presumptive TB:**

* **Passive TB case finding**: Screening of TB among individuals who are self-presented to health facility.
* **Systematic screening for active TB:** is the systematic identification of people with suspected active TB in a predetermined target group, using sensitive TB symptom-based algorithms. Among those screened positive, the diagnosis needs to be established by rapid and sensitive confirmatory diagnostic tests and additional clinical assessments, which together have high accuracy.

In Ethiopia, the following three TB High risk groups should be systematically screening for active TB:

* Systematic TB screening among TB contacts
* Systematic TB screening among high risk groups ( intensified TB case finding)
* Systematic TB screening of individuals living in congregated settings

(Details will be presented in section three)

## 2.5 Identification of Individuals with Presumptive TB

Identification of individuals with presumptive TB should routinely be practiced at community and health facility levels:

**Identification at community level**: Health extension workers at health post implementing the community based TB care package should screen all individuals presenting to the health post and during their regular home visits for TB-symptoms particularly among contacts of an infectious pulmonary TB cases. The identified presumptive TB cases should be referred to the catchment health centers for clinical evaluation and investigation.

**Identification at Health facility level:** health care workers should screen their clients, contacts of TB cases and high risk group patients for TB-symptoms, initiate proper clinical evaluation and diagnostic work up using nationally standardized algorithms. At health facility level, TB screening services should be integrated in services outlets likes OPDs, In-patients wards, under-five clinic, PMTCT to identify all clients visiting the health facilities.

|  |
| --- |
| How to identify a presumptive TB case at the community or health facility level?   * By integrating TB screenings questions and identify those with presumptive TB. |
| Who is a presumptive TB case?  :An individual with clinical manifestations consistent with TB: i.e |
| * + Persistent cough of 2 weeks or more (or any duration if HIV positive)   + Fever for more than 2 weeks   + Drenching night sweats   + Unexplained weight loss (more than 1.5 kg in a month) |
| Any individual with one or more of the above manifestations should be identified as Presumptive TB cases and appropriate clinical evaluation should be initiated. |

## 2.6 Patient evaluation and diagnostic approaches for Tuberculosis

Anyone with symptoms of TB should be evaluated for TB disease. Evaluation for TB includes a medical history, a physical examination, appropriate bacteriologic examination, chest radiograph, and histological examinations.

**The medical history:** ask whether the patient has:

* 1. Symptoms of TB
  2. Close contact with a known TB or chronically coughing patient
  3. Risk factors for developing TB disease
  4. History of TB treatment in the past
  5. Socio-demographic profile
  6. Working in high TB transmission area

1. **Symptoms of TB disease:** Ask patients about their symptoms. An important part of the medical history is checking for symptoms of TB disease and identification of household contacts. Most patients with TB disease will have one or more symptoms that may lead them to seek medical care.

*The general symptoms of TB disease (pulmonary or extra-pulmonary) include:*

* + *Weight loss*
  + *Fatigue*
  + *Malaise*
  + *Fever*
  + *Night sweats*
  + *Loss of appetite*

*Symptoms of pulmonary TB disease include:*

* + Coughing, Coughing up sputum or blood
  + Pain in the chest when breathing or coughing
  + Dyspnea (shortness of breaths)

*Symptoms of extra-pulmonary TB disease:*

The clinical presentations depend on the body part affected by the disease.

1. **Close contact history with chronically coughing patient:** Ask for history of household or close contact with TB patient or chronic cougher.
2. **Risk factors for developing TB disease:** The health worker should check for risk factor/s in a patient for developing TB disease. The following conditions appear to increase the risk that TB infection will progress to disease:
   1. Age Under 5 years
   2. Infection with HIV
   3. Recent TB infection (<1year)
   4. Co-morbid conditions like Diabetes mellitus, Malnutrition….
   5. Immunosuppressive therapy (prolonged therapy with corticosteroids)
3. **Previous TB disease:** Ask patients whether they have ever been diagnosed with or treated for TB disease. The risk of acquired drug resistance is higher in previously treated patients.
4. **Socio-demographic profile:** people living in over-crowded area, people coming from high TB prevalent settings including congregated settings like prisons, homeless shelters, orphanages, refugees…etc. the risk of acquiring drug resistant TB is higher in individuals coming from congregated settings.
5. **Working in high TB transmission areas:** People working in health care settings or people working in congregated settings… are at high risk of acquiring not only TB but also drug resistant forms of TB.

**Physical examination:**

Physical examination is an essential part of the clinical evaluation of a patient. It cannot confirm or rule out TB disease, but it can provide valuable information about patients’ overall condition. Hence, do examination of the patient with particular focus to chest and other suspected organs.

## 2.7 Diagnostic Algorithm for evaluation of patients with presumptive Pulmonary TB

The Revised national algorithm for TB diagnosis, drug susceptibility testing and management of the patients is based on the results of recommended tests.

* All individuals who present with symptoms of pulmonary TB should have a bacteriological confirmation examination either with Xpert MTB/RIF assay or sputum microscopy.
* Use of rapid screening tests, such as Xpert or LPA, is recommended for screening of drug resistant TB from nationally prioritized patients groups. Culture and phenotypic DST are used to perform resistance testing to second line drugs.
* Besides, supportive evidences from X-ray abnormalities or histopathological examinations may be used to investigate patients for whom the clinician have high index of suspicion despite the negative results from confirmatory tests.

The choice of microscopy and Xpert MTB/RIF assay as primary test depends on the age, HIV status, the risk of harboring drug resistant TB and the anatomic site of presumptive TB disease.

|  |
| --- |
| *If the Xpert machine is not available at the site, send sample for Xpert testing site while proceeding with other investigations including AFB and manage the patient as per the clinician decision.* |

Note that offering HIV test is recommended in evaluation of individuals with presumptive Tuberculosis.

|  |  |  |
| --- | --- | --- |
| The national TB program recommendation on use of bacteriologic tests for TB diagnosis: | | |
| Preferred test | **Patient group** | **Remark** |
| ZN/FM smear microscopy | HIV negative/unknown status adult patients with low risk for drug resistance |  |
| Xpert MTB/RIF Assay | HIV positives with presumptive TB  Children with presumptive TB  Presumptive DR-TB cases  Presumptive TB involving the meninges | if Xpert MTB/RIF assay not available; refer sample for Xpert, and do ZN/FM smear microscopy to minimize time required for Dx. |

Figure 1. Showing National TB Diagnostic algorithm.



*1 Presumptive TB is defined as cough of two or more week s (any duration for HIV positives).*

*2 Presumptive DR-TB is defined based on National PMDT Guideline.*

*3 EPTB diagnoses: CSF, LN aspirate, Pus, Pleural biopsy or fluid samples are recommended for Xpert test.*

*4 Do sputum AFB microscopy on two spot samples collected at least in 30min to 1hr apart.*

*5 Investigate for Smear AFB Negative results (antibiotic treatment followed by Xpert as follow on test).*

*6 RR-TB result in patient with low risk for DR-TB needs to re-confirmed with Xpert test on fresh specimen, and:*

*- if result shows RR TB for second time, treat with Second line drugs, or*

*- if result shows MTB but No RR TB, treat with first line drugs, and do Culture and conventional DST.*

**I**

**Interpretation of sputum results**

1. **Results of Xpert MTB/RIF Assay:**
2. When Xpert MTB/RIF does not detect MTB:

* conduct clinical evaluation and if the clinicians still have a strong suspicion of TB, especially in PLHIV and children, that warrants further investigation such as CXR, culture, repeat Xpert test or a trial of antibiotics.

1. When Xpert MTB/RIF detects MTB without RIF resistance:

* start or continue patient on first line Anti-TB regimen

1. When Xpert MTB/RIF detects MTB with Rifampicin resistance:

* Patients with high or moderate risk for DR-TB : Patient should registered as RR TB and started on Nationally recommended regimen for MDR TB
* Patients with low risk for DR-TB: Immediately Repeat Xpert MTB/RIF test on fresh specimen,
  + - if result shows RR TB again treat with Second line drug;
    - If result shows MTB but without RR treat with first line drugs and do Culture and conventional DST.

1. **Results of Sputum AFB microscopy:**
2. When Sputum AFB microscopy shows one or two positive results:

* Register the patient as bacteriologic confirmed TB cases and
* Initiate first line Anti-TB regimen

1. When Sputum AFB microscopy report says two negative results:

* See section 2.8 below

## 2.8 Diagnostic Approach for patients with negative sputum Smear Results

If the presumptive TB patient that are not detected by Smear microscopy may need to be re-evaluated for Active TB and if the clinical suspicion remains high, the health care workers may consider using a more sensitive diagnostic tests and even use of supportive diagnostic tests like radiography, Ultrasonography, blood test, to aid the health worker to investigate the patient for TB.

Use of Xpert MTB/RIF assay as add on test is advised for patients with two negative sputum smear results and after antibiotic treatment, if the clinical suspicion of TB diseases remains high with persistent symptoms and findings consistent with tuberculosis. If Xpert MTB/RIF test is not available, diagnosis of TB may need to be reached using evidences from supportive techniques such as chest X-ray *and with the help of an experienced clinician.*

|  |
| --- |
| Xpert MTB/RIF Assay as Add-on test is recommended:  A patient with presumptive TB and for whom:   * Negative sputum smear results from two sputum specimens), and * A trial of treatment with broad-spectrum antimicrobial agent fails1, and * Clinical evidence of persistent symptoms and findings consistent with tuberculosis. |
| *1fluoroquinolones should be avoided as they are active against M. tuberculosis complex* |

*1 clinical re-evaluation includes focused history, contact history, persistence/ worsening of symptom & sign consistent with TB.*

*2 if Xpert service is not accessible, repeat two AFB on spot and send sample to Xpert, Do CXR and interpret the findings along with the clinical and laboratory evidences with the help of an experienced clinician.*

*3 Negative Xpert result cannot rule out presence of Active pulmonary TB.*

*4 RR-TB result in patients with low risk for DR-TB needs to be re-confirmed with Xpert test on fresh specimen, and*

*- if result shows RR TB again treat with Second line drug;*

*- if result shows MTB but No RR TB, treat with first line drugs and do Culture and conventional DST.*

**Negative sputum Smear AFB result in presumptive pulmonary TB patient**

**IMPROVEMENT**

**NO IMPROVEMENT, *and clinical re-evaluation1 suggests Tuberculosis***

**Xpert MTB/RIF assay2**

**Treat with Broad spectrum Antimicrobials**

**(**Excluding Anti-TB drugs and fluoroquinolones)

**MTB Detected,**

**RIF Resistant detected**

**NEGATIVE Xpert MTB/RIF TEST3**

**TREAT DR-TB4**

**If clinical suspicion of TB persists**

***Re-evaluate/refer to hospital for further investigation: CXR, Consider culture; supportive tests like ESR, Histopathology….Use opinion of TB expert clinicians .***

**MTB Detected, RIF resistance not detected**

**TREAT TB**

**Unsuccessful Xpert MTB/RIF TEST**

**Repeat Xpert with fresh sample**

Fig 2. Diagnostic algorithm for Presumptive pulmonary TB patients with Negative sputum results for AFB microscopy

|  |
| --- |
| Review Exercise on Day I: |

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_are at increased risk of progression to Active TB, if infected? | True | False |
| 1. malnourished |  |  |
| 1. HIV infected |  |  |
| 1. Diabetics |  |  |
| 1. A four year old child |  |  |
| 1. 40 years old adult |  |  |

|  |  |  |
| --- | --- | --- |
| statement about Latent TB in children | True | False |
| 1. They may transmit infection to susceptible host |  |  |
| 1. They may have clinical manifestation of TB |  |  |
| 1. Sputum culture may be positive |  |  |
| 1. If treated, may reduce risk of developing active TB |  |  |
| 1. Can be diagnosed by Xpert MTB/RIF Assay |  |  |

|  |  |  |
| --- | --- | --- |
| About manifestation of TB in immunocompetent adult person: | True | False |
| 1. Constitutional systemic symptoms |  |  |
| 1. On-and-off type of Cough |  |  |
| 1. Pus discharge on the side of the neck |  |  |
| 1. Chronic and persistent cough |  |  |



|  |  |  |
| --- | --- | --- |
| Select bacteriologic confirmatory diagnostic methods for MTB | True | False |
| 1. LED FM microscopy |  |  |
| 1. Liquid culture |  |  |
| 1. Radiology |  |  |
| 1. Histopathology |  |  |
| 1. Xpert MTB/RIF |  |  |



|  |  |  |
| --- | --- | --- |
| Spot-Spot schedule for sputum sample collection: | True | False |
| * 1. Does not benefits the patient |  |  |
| * 1. Can identify the majority of smear positive patients in Quality Assured labs |  |  |
| * 1. AFB can be done twice from single sample collected on spot |  |  |
| * 1. No need for designated are sputum collection area |  |  |
| * 1. No convenient for the patient |  |  |

|  |  |
| --- | --- |
| Management of patient when Xpert MTB/RIF test detects: | Management decision |
| 1. MTB detected, rifampicin resistance detected |  |
| 1. No MTB |  |
| 1. Error |  |
| 1. MTB detected, rifampicin resistance not detected |  |

|  |  |
| --- | --- |
| Treat a patient with sputum AFB results of: | Management |
| * 1. One positive and one Negative results |  |
| * 1. Two negative results |  |
| * 1. Two positive results |  |



|  |  |  |
| --- | --- | --- |
| Xpert MTB/RIF assay is recommended for: | True | False |
| * 1. Screening of rifampicin resistance |  |  |
| * 1. Diagnosis of MTB after two negative smear results and after antibiotic trial |  |  |
| * 1. Screening for Isoniazid resistance |  |  |
| * 1. Diagnosis of TB in children |  |  |
| * 1. Diagnosis of TB in HIV patients |  |  |

## 2.9 Recommended approach for Patients with Presumptive Extrapulmonary TB

Extra-pulmonary TB contributes to 20-30% of all TB cases. Lymphatic system and pleural membrane involvement constitute around 60% of all EPTB cases. EPTB involvement is more commonly seen in HIV patients with advanced immune-suppression and young children.

Extrapulmonary TB cases are either under-diagnosed or over-diagnosed as isolation of *M.tuberculosis* from Extrapulmonary specimens rarely feasible and there is no standard protocol to diagnose TB in organs other than the lung.

General approach to Patient with presumptive Extrapulmonary TB:

* Try to confirm the diagnosis of Tuberculosis using available techniques
* Evaluate your patient for concomitant Pulmonary TB that may not be apparent
* Offer HIV testing as patient may have HIV
* Collect and examine using FNAc for all accessible sites(ex: Lymph ones)
* Analyse specimens from EPTB sites using Xpert MTB/RIF, smear, and culture
* Analyse fluid aspirates (: from pleural, peritoneal, CSF) for smear microscopy, Xpert MTB/RIF assay and culture in addition to biochemical analysis
* Remember “Negative results” may not rule out possibility of TB
* Arrange early referral for patients with serious form of ETB to higher level (hospital)

Table 2. Summary of clinical findings and practical Diagnostic investigations for EPTB

|  |  |  |
| --- | --- | --- |
| **common clinical presentations** | **Site of TB disease** | **Investigation** |
| Symptoms: A painless enlarged mass, usually at the sides of the neck, may present discharge, Not responding to a course of Antibiotics.  Signs: Asymmetrical, painless, non-tender lymph node enlargement for more than one month +/- discharging sinus. Commonly seen on the sides of the neck. | **TB adenitis ( commonly cervical)** | Fine needle aspiration when possible for culture and histology  GeneXpert( see Annex I) |
| Symptoms: Chronic cough and shortness of breath  Signs: Dullness on percussion and reduced breath sounds +/-chest pain | **Pleural TB, pericardial TB** | CXR  Pleural tap for Xpert and biochemical studies |
| Symptoms: Reduced playfulness, Headache, irritability/abnormal behaviour, vomiting (without diarrhoea), weight loss, reduced level of consciousness, +/- convulsions.  Signs: neck stiffness, lethargic, bulging fontanelle, cranial nerve palsies, +/- unconsciousness.  Meningitis of acute or sub-acute onset, not responding to antibiotic. | **TB** **meningitis** | Lumbar puncture obtain CSF# CXR |
| Non-specific, lethargic, presentation of Acute pneumonia with high fever, shortness of breath, respiratory distress | **Miliary TB** | CXR, Lumbar puncture obtain CSF to rule out TB meningitis |
| Deformity of spine ( especially of an acute onset) over thoraco-lumbar area, +/- lower limb weakness/paralysis | **Spinal TB** | X-ray of the vertebra,  CXR to check for pulmonary sites |
| Symptoms and signs of heart failure, Distant heart sounds, difficulty to palpate Apical beat | **Pericardial TB** | CXR  Echocardiography,  Pericardial tap |
| Unilateral Swelling of the end of long bones with limited movement, usually at knee or hip | **TB bone and** **joint** | X-ray bone and joint  Joint tap |

# 3. SYSTEMATIC SCREENING for active TB and patient management

**Time Allotted:1 hour**

**Session Objectives:**

* Systematic screening for active TB
* Discuss on contact tracing and management
* Manage latent TB infection
* Discuss on systematic TB screening for High risk groups
* Explain TB control in congregated settings.

## 3.1 Systematic screening for active TB

It refers to the systematic identification of people with suspected active TB in a predetermined target group, using sensitive TB symptom-based algorithms. Among those screened positive, the diagnosis needs to be established by rapid and sensitive confirmatory diagnostic tests and additional clinical assessments, which together have high accuracy.

What are the benefits of implementing systematic active screening for targeted population groups where TB prevalence is known to be higher than the general population?

|  |  |
| --- | --- |
|  | Benefits |
| *Individual*: | Reduce the risk of poor treatment outcomes  Reduce health sequel  Avoids the adverse social and economic consequences of TB  reduces catastrophic economic burden by the patient and family |
| *Community*: | Reduce TB transmission and  Improves productivity and social stability |
| *Program*: | early case detection and treatment  addresses health inequity and indiscrimination |

In Ethiopia, systematic screening for active TB is recommended for the following High TB risk groups:

* **Household contacts and other close contacts**
* Population with **increased risk of progression** to active TB if infected: include PLHIV, under-five children, Diabetics, malnourished and those with immunosuppressive conditions
* Population with **increased risk of exposure** to MTB: individuals living/working in congregated settings: prisons, orphanages, homeless shelters, urban poor slums, refugee, and migrants

## 3.2 Systematic screening and management of contacts

**Contact**: Any person who has been exposed to an index case.

**Close contact**: A person who is not in the household but who shared an enclosed space, such as a social gathering place, workplace, or facility, with the index case for extended daytime periods during the 3 months before the start of the current treatment episode.

**Household contact**: A person who shared the same enclosed living space as the index case for one or more nights or for frequent or extended daytime periods during the 3 months before the start of the current treatment episode.

**Contact investigation**: refers to the systematic evaluation of individuals who have been in close contact with potentially infectious TB cases within three months of the commencement of TB treatment.

The main purposes of conducting contact screening and management are:

* to identify contacts of all ages with undiagnosed TB disease among the contacts of an index case, and
* To provide preventive therapy for contacts without TB disease who have increased susceptibility to develop Active TB disease following recent infection.

### 3.2.1 Identification of contacts of an Index TB case

Contact tracing and investigation should be conducted for household or other close contacts of the index TB case. Priority should be given when the index TB cases either:

* + has infectious pulmonary TB,
  + has presumptive or confirmed drug-resistant TB,
  + is a child under 5 years of age or
  + Is a PLHIV.

The TB focal should initiate contact tracing upon registering the index case to receive TB treatment.

Hence, up on registering a case of pulmonary TB for treatment, the TB focal should:

* Interview the index case to assess the need for contact tracing
* Educate the patient on the need for initiating contact tracing and investigation
* If household/close contact are identified, communicate the responsible HEW
* The HEW will identify the households of the index case and conduct initial screening using “symptom based TB screening questions” to identify those who require appropriate evaluation for TB at health facility
* HEW should refer these contacts to the health facility:
  + Symptomatic contact of the index patient
  + Contacts who are living with HIV
  + Contacts who are under-five children
  + Contact of an index case with presumed/confirmed DR-TB
* The TB focal person should arrange for evaluation of referred cases.

### 3.2.2 Appropriate clinical Evaluation and Management of TB exposed contacts

All referred contacts should receive appropriate evaluation as the patient management depends on various factors and patient conditions*.*

During evaluation, gather the following necessary information to determine on the next action:

* Age of the person
* HIV status of the contact
* Risk for harbouring drug resistant TB in the source
* Presence of Active Tuberculosis

***Scenario I: If the source case is presumptive/confirmed Drug resistant TB:*** Contacts who are exposed to a source case with presumptive or confirmed DR-TB should be managed as:

If the contact is clinically well and no Active TB at time of evaluation:

* Do not give any chemoprophylaxis to prevent TB;
* Educate the client to have quarterly clinical evaluation for at least two years.

If the contact is sick and presumptive TB is diagnosed:

* Do detailed clinical and laboratory evaluation to diagnose DR-TB and screening for drug resistant TB at least for Rifampicin
* If decided to treat for TB, DONOT treat such patient on first line Anti-TB treatment, Refer to MDRTB treatment center if facing difficulty of deciding on next action.

If the contact gets sick on follow up evaluation,

* Conduct full clinical evaluation and work up for DR-TB as per the recommendation on latest version of the national PMDT guideline.

***Scenario II: If the source case has susceptible TB or low-risk for DR-TB***: Such contacts can safely be evaluated using TB screening question and decided on next action as follows:

If the contact is clinically well and no Active TB at time of evaluation:

* Treat for latent TB infection if contact is under five children or PLHIV.
* Educate the client to seek early medical attention if gets sick in 1 to 2 years’ time.

If the contact is sick and presumptive TB is diagnosed:

* Do detailed patient evaluation and investigation for Tuberculosis as per the guideline (see section on evaluation of patient with presumptive TB).
* If TB is diagnosed, register the patient on the current open cohort and treat for TB.

**Identification of an index pulmonary TB case**

Trace for child who is household/ close contact of the index case

When the index TB case has Drug susceptible TB case

When the index TB case has a risk factor or confirmed Drug resistant TB case

Child < 5 Years

Child > 5 Years

Well Child

Symptom consistent with active TB

Well Child

Symptom consistent with active TB

Quarterly clinical monitoring for possible development of active TB disease for two years 2

Evaluate for DR TB 3

Evaluate for TB

IPT 1

*1 IPT is provided for period of six months with 10mg/kg.*

*2 No chemoprophylaxis is recommended for Asymptomatic contacts of DR-TB index cases.*

*3 Evaluation for DR-TB must include Rapid DST as part of initial evaluation as patient management requires Drug susceptibility pattern.*

**Flow chart for contact tracing and management of a contact of TB cases**

### 3.2.3 Treatment of latent TB infection

Latent tuberculosis infection (LTBI) is defined as a state of persistent immune response to stimulation by *Mycobacterium tuberculosis* antigens without evidence of clinically manifested active TB. One-third of the world’s population is estimated to be infected with *M. tuberculosis*.

The lifetime risk of reactivation TB for a person with documented LTBI is estimated to be 5–10%, with the majority developing TB disease within the first five years after initial infection. Why do we treat latent TB infection?

1. Because the risk of developing active TB disease in higher among high-risk population.
2. Preventive treatment can avert the reactivation to active TB, with an efficacy ranging from 60% to 90%.

For whom treatment of latent TB infection is recommended in Ethiopia?

* Under-five children who are exposed to TB in the past one year, &
* People living with HIV regardless of their age

Which treatment regimen is recommended in Ethiopia?

***Isoniazid Preventive Therapy (IPT) for six month period***: isoniazid is given to individuals with latent infection with *Mycobacterium tuberculosis* in order to sterilize the infection and hence, prevent progression to active disease. Screening for exclusion of active TB in HIV infected persons is the single most important step that should precede the decision to initiate IPT.

Studies have shown that providing IPT to treat latent TB infection does not increase the risk of developing INH-resistant TB as long as active TB is rule out. Therefore, concerns regarding the development of INH resistance should not be a barrier for IPT provision.

***IPT for HIV infected population***: should be provided to all HIV-infected individuals at enrolment to HIV care after symptom based screening for presence of active TB regardless of their CD4 count, ART status, and pregnancy status.

|  |
| --- |
| **National policy on use of IPT for HIV infected patients:** |
| * *IPT should be administered at enrolment to HIV care after ruling out active TB* * *IPT is to be administered once and should not be repeated unless there is strong indication on its benefits which is to be decided by senior physician* * *IPT should be administered only for six months* * *IPT should not be administered right after completing full course of TB treatment* * *IPT can be administered for patients who had history of TB treatment before two years* |

***IPT for HIV negative TB exposed under-five children***: should be administered for under-five asymptomatic children who are exposed to TB within the past one year.

**Dosing of INH for IPT:**

The dose of INH is 300mg/day for adults and 10mg/kg for children daily administered for six months. It is also advised to co-administered vitamin B-6 (25mg/day) with Isoniazid to prevent INH-induced peripheral neuropathy.

Table 4: showing weight based dosing of INH preventive therapy for children

|  |  |  |
| --- | --- | --- |
| **Weight Ranges(kg)** | **Dose Given (mg)** | **INH 100mg tab** |
| < 5 | 50 | ½ tablet |
| 5.1-9.9 | 100 | 1 tablet |
| 10-13.9 | 150 | 1 ½ tablet (or ½ adult tablet) |
| 14 -19.9 | 200 | 2 tablets |
| 20 -24.9 | 250 | 2 ½ tablets |
| >25 | 300 | 1 adult tablet |

**Contraindications to IPT**

Individuals with any one or more of the following conditions should *not* receive IPT.

* Symptoms compatible with tuberculosis even if the diagnosis isn’t yet confirmed.
* Active hepatitis (chronic or acute)
* Regular and heavy alcohol consumptions
* Prior allergy or intolerance to isoniazid
* Symptoms of peripheral neuropathy

Note that past history of TB and current pregnancy should not be contraindications for administering IPT.

*NB: Administer IPT for TB exposed asymptomatic under five children when the index cases has pulmonary TB ( both Bacteriologically and clinically diagnosed).*

**Placement of IPT Clients**

IPT should be part of a comprehensive care for HIV positive individuals; therefore, these patients should be initiated and monitored at ART clinic and the information should be documented in the Pre-ART/ART register.

IPT for HIV negative under-five children should be administered and followed up at the TB clinic and information should be recorded on unit-TB register.

**Monitoring of Patients on IPT**

Patients should be given one-month supply of Isoniazid for six months. At each follow-up visit, the health care worker should:

* Educate patient about, adherence side effects, and importance of coming to health facility if develops symptoms suggestive of TB.
* Evaluate and counsel patients on importance of adherence to treatment
* Evaluate for drug toxicity including signs/symptoms of hepatitis, peripheral neuropathy, and rash).
* Evaluate for signs and symptoms of active tuberculosis or other OIs.
* Stop IPT, if active TB is diagnosed and start full course of anti-TB treatment.

**Adherence monitoring on IPT:** patients should be supported at home level either by HEWs or family supporter to ensure daily administration Isoniazid. Monthly scheduled follow up needs to be integrated with other treatment services for which the client is appointed for.

**Treatment interruption management**: IPT is said to be completed if a patient completed the full course of therapy within nine months period (i.e. the six months doses should be finished in nine months’ time).

If the client discontinues treatment for a period of less than three months:

* Resume the same course by adding for the missed doses at the end

If the client discontinues treatment for a period of more than three months:

* Re-initiate new course of IPT for six months

## 3.3 Systematic TB screening for active TB among High-risk group

Integrating intensified case finding (ICF) in the care of high-risk groups is so far limited to the HIV care services as HIV infection carries the strongest risk of progression to Active TB disease. However, growing evidences are showing significantly increased relative risk for progression to TB among individuals with conditions that compromises the immune status of the patient.

**Recommended high-risk Population groups:**

* Patients attending chronic care services for HIV,
* Patients attending chronic care services for Diabetes mellitus
* Children attending under-five clinics
* Malnutrition therapy unit, and
* Chronic care clinics where patient with major organ failure attend service

**Recommended Actions:**

* **Integrate Symptom-based TB screening service** up on scheduled visits for chronic care by clients and in IMNCI/ICCM clinic for under-five children

**Appropriate evaluation and investigation for TB:**

* Individuals who are identified as having “positive TB screen” for Symptom based screening question should undergo detailed and appropriate clinical evaluation and investigation for TB as per the national guideline.
* Use of sensitive tests like Xpert may be used to confirm the diagnosis of TB, if resource allows, and
* The recommendation to treat latent TB infection in Ethiopia is limited to PLHIV and TB exposed under-five children. *See section on treatment of latent TB infection*.

## 3.4 Systematic screening and management of Active TB in congregated settings

**Congregate setting** is defined as an environment where a number of people meet or gather and share the same space for a period of time.

What are the reasons for high risk of TB transmission in congregated settings?

|  |  |
| --- | --- |
| **Factors pertaining to the setting:** | **Factors pertaining to the inhabitants:** |
| * Unchecked mixing of undiagnosed infectious TB individuals with susceptible inhabitants * Poor access to TB diagnostic and treatment services * Poor TB infection control settings * Overcrowding | * Economically dis-advantageous and culturally marginalized * Poor adherence history to treatment * High rate of HIV infection and malnutrition * Substance misuse and abuse * Poor treatment support |

**Commonly identified TB high-risk congregated settings:**

* Individuals living/working in prisons, orphanages, homeless shelters, urban poor slums, refugee, and migrants …

**Recommended TB screening strategy:**

* **Integrate Symptom-based TB screening** up on entry, periodically and at exist from these institutions:

***Screening on entry*:** aims to detect undiagnosed TB upon entry and initiate appropriate evaluation before mixing up with potentially susceptible in habitants. And also helps to identify those who were receiving treatment prior to admission.

***Periodic Mass Screening of inhabitants and staff***: Mass screening means to check the whole population of inhabitants (or other segment of population) to identify presumptive TB cases and evaluate with appropriate sensitive tools to diagnoses TB. This helps to diagnose TB among previously undetected cases. This could be resource intensive.

***Exit Screening of inhabitants***: it gives an opportunity to detect TB among inhabitants prior to the release to their family and community. ,

* **Appropriate evaluation and investigation for TB:** Individuals with “positive TB screen” result should undergo appropriate clinical evaluation and investigation for TB as per the national guideline. Use of sensitive tests like Xpert is advised to diagnose TB and screen for drug resistance, if resource allows.
* **Arrange referral before release:** before releasing inhabitants on treatment, arrange for transfer out to nearby facility to endure completion of treatment.

# 4. DeFinition of TERMS AND patient Registration

**Time Alloted: 30 minutes**

**Session Objectives:**

* To familiarize with the standard terms and definitions used in TB program
* To classify TB patients as per the national recoding and reporting system
* To assign TB patient into the appropriate registration group

## 4.1 Rationale for classifications and registration of TB Case

Assigning TB patients in to predefined categories facilitates patient registration, standardization of treatment regimen, monitoring of response and to define treatment outcome. It is also vital for recording and reporting system of the program and to analyze performance.

## 4.2 TB case definitions

The programmatic definitions Tuberculosis are based on the level of certainty of the diagnosis and on whether or not laboratory confirmation is available.

***Presumptive Tuberculosis****:* Refers to a patient who presents with symptoms or signs suggestive of TB, in particular cough of two weeks or more duration.

***Bacteriologically confirmed TB case***: Refers to a patient from who has at least one positive result either by smear microscopy, culture or Xpert MTB/RIF assay.

***Clinically diagnosed TB case***: Refers to a patient who does not fulfill the criteria for bacteriological confirmation but has been diagnosed with active TB by a clinician and decided to treat with a full course of TB treatment.

This definition includes cases diagnosed on the basis of X-ray abnormalities or suggestive histopathology and Extrapulmonary TB cases diagnosed without laboratory identification of the mycobacterium.

*NB: Clinically diagnosed cases should be re-classified as bacteriologically confirmed case if evidence of bacteriologically positive result obtained before the reporting period..*

## 4.3 TB case classification

Bacteriologically confirmed or clinically diagnosed cases of TB cases are also classified according to:

* anatomical site of disease
* history of previous treatment
* drug resistance
* HIV status

### 4.3.1 TB case classification by anatomical site

**Pulmonary tuberculosis (PTB)** refers to any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree.

* Miliary TB is classified as PTB because there are lesions in the lungs.
* Tuberculous intra-thoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, constitutes a case of Extrapulmonary TB.
* A patient with both pulmonary and Extrapulmonary TB should be classified as a case of PTB.

**Extrapulmonary tuberculosis (EPTB)** refers to any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges.

* The case definition of an EPTB case with several sites affected depends on the site representing the most severe form of disease.

### 4.3.2Classifications based on history of previous TB treatment

**New TB cases:** refers to patients have never been treated for TB or have taken anti-TB drugs for less than 1 month.

**Previously treated TB case:** refers to patients that have received 1 month or more of anti-TB drugs in the past.

* Due to the increasing burden of drug resistant TB, Classifications based on history of previous TB treatment are the main criteria used to decide on treatment regimen.
* Note that Selection of TB treatment regimen does not consider information from bacteriological confirmation, site of disease and HIV status of the patient.

### 4.3.3 Classifications based on drug resistance

1. **Mono-drug resistance**: resistance to one first-line anti-TB drug only.
2. **Poly-drug resistance**: resistance to more than one first-line anti-TB drug (other than both Isoniazid and Rifampicin).
3. **Multidrug resistance (MDR-TB)**: resistance to at least both Isoniazid and Rifampicin.
4. **Extensive 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 (- Isoniazid and Rifampicin).
5. **Rifampicin resistance (RR-TB)**: 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 mono-drug resistance, multi-drug resistance, poly-drug resistance or extensive drug resistance.

|  |
| --- |
| *Note that, for reporting purpose, enumerate DR-TB diagnosed patients based on the most advanced resistance level. For instance, patients diagnosed with Xpert will be counted only on RR-TB while patients with LPA diagnosis of resistance to R and INH will be counted as MDRTB not as RR-TB cases to avoid double counting on DR-TB case finding report.* |

### 4.3.4 Classifications based on HIV status

**HIV-positive TB patient** refers to any bacteriologically confirmed or clinically diagnosed TB case who has a positive result from HIV testing conducted at the time of TB diagnosis or other documented evidence of enrolment in chronic HIV care( in the pre-ART or ART care).

**HIV-negative TB patient** refers to any bacteriologically confirmed or clinically diagnosed TB case 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** refers to any bacteriologically confirmed or clinically diagnosed case of TB who has no result of HIV testing and no other documented evidence of enrolment in chronic HIV care. If the patient’s HIV status is subsequently determined, he or she should be reclassified accordingly.

## 4.4 Patient registration groups for drug susceptible TB

**New patients:** patients that have never been treated for TB or have taken anti-TB drugs for less than 1 month.

**Relapse patients:** patients that have previously been treated for TB were declared *cured* or *treatment completed* at the end of their most recent course of treatment, and is now diagnosed with a recurrent episode of TB (either a true relapse or a reinfection).

**Treatment after failure:** patients are those who have previously been treated for TB and whose *treatment failed (: smear positive results after fifth month during treatment)* at the end of their most recent course of treatment.

**Treatment after loss to follow-up:** patients have previously been treated for TB and were declared *lost to follow-up* at the end of their most recent course of treatment and is now diagnosed with TB.

**Others:** patients who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented, or patients that do not fit into any of the categories listed above.

**Transfer in:** A patient who is transferred in to continue treatment in a given reporting unit after starting treatment in another reporting unit. *(the final outcome of TI patients are to be reported back to the sender (transferring out) health facility but not to the program)*

# 5. TREATMENT OF TUBERCULOSIS

**TIME Allotted:**

**LEARNING OBJECTIVES**

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

* Define the objectives of TB treatment
* Identify TB drugs formulations used in Ethiopia
* Select the appropriate treatment regimen
* Initiate TB treatment
* Monitor progress of patient during treatment
* Define treatment outcome

## 5.1 Treatment of drug susceptible Tuberculosis

The aims of treatment of Tuberculosis are:

* To cure the patient from TB
* To prevent death from TB disease and its late effects
* To prevent relapse of TB
* To prevent the development of acquired drug resistance, and
* To decrease TB transmission

In order to achieve these aims, it is vital for the anti-Tuberculosis medications to have bactericidal activity, sterilizing activity and ability to prevent development of drug resistance.

The essential anti-Tuberculosis drugs possess these vital activities to different extents. Isoniazid and Rifampicin are the most powerful bactericidal drugs, active against all population of TB bacilli. Rifampicin is the most potent sterilizing drug available. Pyrazinamide and streptomycin are also bactericidal against certain populations of TB bacilli. Pyrazinamide is only active in acidic environment while Streptomycin is bactericidal against rapidly multiplying TB bacilli. Ethambutol is used in association with more powerful drugs to prevent the emergence of resistant bacilli.

Hence, Anti-TB treatment is said to be adequate when it is administered:

* in appropriate combination of drugs
* in the correct dosage
* regularly taken by the patient, and
* For a sufficient period of time.

## 5.2 Standardized TB treatment

Standardized treatment refers to the administration of one treatment regimen for a defined patient group with similar characteristics.

Standardization of treatment regimen facilitates the proper administration of treatment by the patient and the drug supply management system for the program.

### 5.2.1 Standard First Line regimens

Regimen designing for susceptible TB treatment considers the patients’ prior TB treatment history with Anti-TB drugs as the main risk factor for developing acquired drug resistance.

As a result, there are two standardized Frist line TB treatment regimens developed for New and previously treated patient.

Table 7. Showing the Standard TB treatment regimen in Ethiopia

|  |  |  |  |
| --- | --- | --- | --- |
| **TB Patient type** | **Standard Regimen** | | **Patient registration groups receiving the regimen** |
| **Intensive phase** | **Continuation phase** |
| New TB case | 2(RHZE) | 4(RH) | * New TB patients |
| 2(RHZE)S | 10 (RH) | * New patients with CNS TB( meningitis, tuberculoma) |
| 2(RHZE) | 10 (RH) | * New TB patients involving vertebra and Osteoarticular space |
| Previously treated TB case | 2(RHZE)S, (RHZE) | 5(RHE) | * Relapse * Treatment after LTFU * Treatment after failure of New regimen * Others |
| RR-/M/XDR-TB cases | Second line drugs | | Confirmed cases of RR-/M/XDR-TB cases |

### 

### 5.2.2 Phases of chemotherapy

TB treatment is administered in two phases:

***Intensive (initial) phase***

* It renders the patient non-infectious by rapidly reducing the load of bacilli in the sputum, usually within two weeks in majority of drug susceptible TB cases
* The regimen in this phase consists of:
  + Combination of four drugs for the first eight weeks for new cases, or
  + Combination of five drugs for the first eight weeks followed by four drugs for the next four weeks for previously treated cases.

***Continuation phase***

* This phase aims to sterilize the remaining semi-dormant bacilli and is important to ensure cure/ completion of treatment and prevent relapse after completion of treatment.
* The regimen in this phase consists of:
  + Combination of two drugs to be taken for 4 months for new cases, or
  + Combination of three drugs to be administered for 5months for previously treated cases.

### 5.2.3 Adult first line Anti-TB formulations in Ethiopia

Most Anti-TB Drugs used in first line TB treatment are procured as fixed dose combination (FDC) as follows:

Table 6. Showing First line Anti-TB Drug formulationsfor Adult & those weighing >25kg

|  |  |  |  |
| --- | --- | --- | --- |
| **DRUGS** | **FORMULATION** | **STRENGTH(mg)** | **Preparation, route** |
| HRZE | Tablet | 75/150/400/275 | FDC, oral |
| HR | Tablet | 75/150 | FDC, oral |
| HRE | Table | 75/150/275 | FDC, oral |
| E | Tablet | 400 | Loose, oral |
| STM | Powder for injection | 1000 | Loose, Parental |

### 5.2.4 Anti-TB Drug dosages

Anti-TB Drugs dosing are age & weight dependent. Children weighing less than 25kg should use pediatric dosing chart while those patients weighing greater than or equal to 25kg and adults are treated following dosage recommendations for adults developed based on patients’ weight band.

Table 8. Showing weight band TB treatment dosage for TB cases

**Dosage of new regimen for New adult TB cases: 2(RHZE)/ 4(RH)**

|  |  |  |
| --- | --- | --- |
| **Patients weight band**  **(Kg)** | **Treatment regimen and Dose** | |
| **Intensive phase:**  **2(RHZE)** | **Continuation Phase:**  **4(RH)** |
| **20-29** | **1 ½** | **1 ½** |
| **30-39** | **2** | **2** |
| **40-54** | **3** | **3** |
| **≥55** | **4** | **4** |

**Dosage of retreatment regimen for adult TB cases: 2S (RHZE),1(RHZE) / 5(RH)E**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Patients Weight band**  **(Kg)** | **Treatment regimen and dose** | | | |
| **Intensive phase :**  **2S(RHZE),(RHZE)** | | **Continuation phase:**  **5(RH)E** | |
| **(RHZE)** | **S** | **(RH)** | **E** |
| **20-29** | **1 ½** | **500mg** | **1 ½** | **1 ½** |
| **30-39** | **2** | **500mg** | **2** | **1 ½** |
| **40-54** | **3** | **750mg** | **3** | **2** |
| **> 55** | **4** | **1000mg** | **4** | **3** |

*NB: See paediatrics section for dosing & treatment regimen for paediatric TB*

The national program has started the implementation TB patient kit system for treatment of TB in adults (details of TB kit are presented in DSM section).

### 5.2.4 How to read the drug code for TB treatment regimens

In the standard code for TB treatment regimens, the duration of each phase is stated in months. The number of doses for a standardized daily regimen is as follows:

**2S(RHZE),1(RHZE) / 5(RH)E**

The number before the letter is the duration of the phase in months. This initial phase is 2 months with S and 1 month without S to make the total of 3 month of initial phase.

The slash mark separates the intensive phase from the continuation phase of the regimen,

This continuation phase is of 5 months’ duration.

If there is no subscript number after a letter, frequency of treatment with that drug is daily.

When 2 or more drugs (letters) appear in parentheses, this indicates the drugs are available as Fixed dose combination, FDC.

## 

## 5.3 Pre-treatment Evaluation and TB Treatment initiation

### 5.3.1 Before you initiate your patients on TB treatment:

* Gather baseline information on:
  + How diagnosis of TB has been made
  + Check for confirmatory Bacteriologic information
  + Determine the site of involvement
  + Offer HIV test
  + Assess risk for drug resistance
  + Calculate BMI and classify the patients’ nutritional status
  + Asses for Co-morbid conditions like pregnancy, renal or liver disease ...
* Classify the TB type
* Assign the registration group for the patient
* Identify appropriate Treatment supporter
* Initiate contact screening and investigation
* Provide Adherence counseling training both for the patient and Supporter

### 5.3.2 Provide Adherence support

Provision of adherence support to all TB is one of the components of standard of care for TB patients. Adherence support should start from preparing the patient for treatment and continues throughout the course of treatment to till the completion.

Adherence support and monitoring should be done during all the scheduled visits of the patient. The principles of 5 A’s should be applied to timely identify potential adherence barrier on the patient and solve the difficulties with the patient to improve adherence.

**Preparation of TB patient and their family for treatment using 5 A’s:**

**ASSESS:** Questions asked initially about:

* The patient’s understanding of the disease and properties of TB therapy
* Ability to keep appointments and adhere to other medications
* Psychosocial and behavioral barriers of adherence (mental illness, substance abuse)

**ADVISE:** Provide necessary information to the patients and treatment supporter using **non-**

**Judgmental and culturally accepted** language

* Educate on basic information about the disease and the treatment
* TB treatment need to be administered at the nearest possible health facility
* TB treatment is free in all DOTS implementing sites
* Explain the need for achieving high level of adherence and role treatment supporter
* Advice what to do if encountered with adherence problem
* Advice on life style modification to avoid barriers to adherence – e.g. substance use
* Discuss on treatment plan and assist to adapt into the living style of the patient
* Educate the treatment supporter about TB and how to observe the patient.

**AGREE:** Reach to consensus with the patient and the treatment supporter on:

* Duration of the treatment and monitoring arrangements
* Arrangement for daily DOT and administration of injection, if any
* Suitability of the identified TB treatment supporter
* Strategies that the patient prefers to improve his/her adherence

**ASSIST:** Assist your patient to manage difficulties by:

* Providing educational material on TB
* Predicting possible adherence barriers
* Integrating time and venue for DOT into work and home routines
* Linking to available psychosocial support

**ARRANGE:** The health worker and the patient has to:

* Arrange how TB treatment is administered and supervised
* Arrange time and venue for daily DOT
* Arrange follow-up appointments
* Regularly update treatment card and Unit TB register
* Link to support groups
* Next date of visit

If your patient is ready to initiate TB treatment, continue with regimen selection as follow:

### 5.3.3 Steps to initiate TB treatment

* Assess whether the patient has taken anti-TB drugs for at least one month in the past and determine if your patient is a:
  + New TB patient,
  + Previously treated TB patient, or
* Assess the patient for the risk of harboring drug resistant TB with the following question and decide on the need for DST:
  + Prior TB treatment history,
  + contact history with drug resistant TB case especially in the past 1 to 2 years period, and
  + history of living or working in high DR-TB prevalent area such as congregated settings, health facilities
* Select the regimen based on the three standard treatment regimens: New patient regimen, Retreatment regimen or regimen for DR-TB.
* Consider modification, if the patient has additional situation or co-morbid condition ( See 4.4 & 4.5 below)
* If your patient is diagnosed with serious form of Extrapulmonary TB, decide on the need for adjuvant treatment with steroids (See section 5.3.5 below).
* Weigh the patient and determine the appropriate weight band
* Select the appropriate TB treatment regimens are given in the following table 7
* Register the patients information on UNIT TB register and Initiate treatment

**Table 7.Showing how to select a TB Treatment Regimen**

| **TB patient type** | | **Recommended TB Treatment regimen** | **Additional Action(s)** |
| --- | --- | --- | --- |
| **New** | Low to medium risk to DR-TB | *Treatment as new:* 2(RHZE)/4RH | *Do rapid DST if the cases from high TB risk settings* |
| *known contact of known MDR-TB case* | *Do rapid DST before making decision on the appropriate regimen* | *If patient is too sick or DST result delays, refer the patient to MDRTB treatment center for evaluation and need for empirical treatment with SLD* |
| **Previously treated** | Relapse after one course of treatment, Treatment after Loss to follow up  Other previously treated | *Treat as retreatment:*  2S (RHZE) ,1(RHZE)/5(RH)E | *Do rapid DST for all cases in this group as they carry medium (10-20%) risk to acquired drug resistance.*  *If DST confirms* ***RR-/M-/XDR-TB, STOP Retreatment regimen and refer/link to DR-TB center for SLDs treatment*** |
| Treatment after failure of New regimen | *Do rapid DST to decide on the appropriate regimen.* | *If DST result fails to return in one week time, restart with re-treatment regimen and wait the DST for next action.* |
| * Treatment after failure of Retreatment regimen,   or   * Relapse after second or subsequent courses of treatment | *Do rapid DST before making decision on the appropriate regimen* | *If patient is too sick or DST result delays, refer the patient to MDRTB treatment center for evaluation and need for empirical treatment with SLD* |
| **RR-/M-/XDR-TB cases** | Patient with confirmed DST result showing at least Rifampicin resistant, OR  TB patient for whom panel team decided to start **empiric** full course SLD treatment | *Treat with full course of Second-line treatment* | *Refer patient to DR-TB register and unit* |
| **Transfer in** | | Continue same treatment regimen | *Assess the treatment response to decide on the need for DST* |

## 5.4 TB TREATMENT in special conditions and situations

If TB patient is identified as having additional especial conditions or co-morbid conditions, consider the following accordingly:

|  |  |
| --- | --- |
| Patient status | Recommendations |
| Pregnancy | * Most anti-TB drugs, except streptomycin are safe. * Avoid streptomycin to prevent permanent deafness in the baby. * Add supplementary Pyridoxine. |
| Oral contraception | * Rifampicin interacts with oestrogen containing oral contraceptive pills with a risk of decreased protection against pregnancy. * Advice a female TB patient in reproductive age group to use either progesterone containing pills like Depo-Provera or to use other methods like IUCD, or condoms. |
| Breastfeeding | * A breastfeeding woman can be treated with standard treatment regimen. * Add supplementary Pyridoxine. * If the mother has infectious TB, consider evaluation of the new born for TB and consider preventive treatment if asymptomatic. |
| Patients with TB & Leprosy | * Patients suffering from both diseases require appropriate anti-TB chemotherapy in addition to the standard MDT. * As Rifampicin is common in both regimens, avoid administering Rifampicin from MDT for the period of TB treatment. |
| Patient with renal failure | * Managing TB in patients with renal failure should be in consultation with specialist physician at hospital level * Avoid Streptomycin & Ethambutol as they are excreted mainly through kidney * Isoniazid, Rifampicin and Pyrazinamide are safe as they are eliminated or metabolized through the biliary system. * Treat with 2RHZ/4(RH) with standard dose. * Add supplementary Pyridoxine. |
| Patients with chronic liver disease ( cirrhosis) | * Do not give Pyrazinamide because this is the most hepatotoxic * Treat with Isoniazid & Rifampicin plus one or two non-hepatotoxic drugs such as Streptomycin and Ethambutol for eight months. * If the patient has severe liver damage, use alternative regimen with Streptomycin plus Isoniazid plus Ethambutol in the initial phase followed by Isoniazid & Ethambutol in the continuation phase with a total duration of 12 months. * Hence, for TB patients with liver disease, recommended regimens are: 2SERH/6(RH) or 9(RH)E or 2SEH/10(EH) |

## 5.5Treatment of Serious Forms of Extrapulmonary TB

The basic principles that underlay the treatment of pulmonary TB also apply to treatment of TB in Extrapulmonary organs. However, patients with serious form of ETB (involving pericardium or meninges) should be managed at hospital level with the help of specialist as they are usually associated with fatal outcome.

Recommended additional actions for patients with Extrapulmonary TB include:

* Extension of the continuation phase of treatment to 10 months for TB involving Vertebra, Osteoarticular space, or CNS
* For patients with CNS TB(:meningitis or tuberculoma), streptomycin is known to have good penetration of blood brain barrier and should be added in the regimen, i.e. 2S(RHZE)/10RH
* Administration of adjuvant treatment with corticosteroids for severe form of TB including:
  + CNS TB
  + Pericardial TB
  + Adrenal TB
  + Miliary TB with respiratory distress especially in children
  + Vertebral TB with signs of weakness in the extremities.

Administration of steroid as adjuvant treatment:

* Administer prednisolone 1mg/kg (Max 60mg/day) for total period of six to eight weeks
* Start with 60 mg of prednisone for 4 weeks, followed by 30 mg for 4 weeks, 15 mg for 2 weeks, and finally 5 mg for the 11th and final week.

Or,

* Administer dexamethasone for a total of 6-8 weeks.
* Start with initial dose of 8 mg per day for children < 25 kg and 12 mg per day for children > 25 kg and adults for 3 weeks and then taper the dose during the following 3 weeks.

## 5.6 Adherence support and monitoring during treatment

### 5.6.1 Directly Observed Treatment (DOT)

To ensure optimal administration of all doses of the TB treatment, patients are advised to be supported by trained person selected by the patient. This is called **directly observed treatment- DOT**.

National control program recommends observation of the administration of each and every dose of TB treatment by either a health worker, Health extension worker or a community TB treatment supporter.

Do the following to ensure DOT practice:

* Identify and train TB treatment supporter with the patient before initiation of treatment
* Get informed consent of the supporter to assist the patient
* Arrange convenient place for supervision of treatment administration to take place
* Orient the treatment supporter to mark on the “treatment supporter card” upon observing each administered dose by the patient
* Convince the supporter to report any difficulty observed by the patient

Note that the information captured daily on “supporter card” should be transferred regularly to the “unit TB register” on treatment monitoring chart column whenever the patient visits the clinic for drug refill.

### 5.6.2 Assigning TB Treatment Supporters

TB Treatment Supporter (TTS) is trained person identified primarily by the patient to support administration TB treatment at home/community.

The roles of TB treatment supporters:

* Daily supervise treatment for patients who are not able to follow their DOT at either health facility or health post level
* Educate and support TB patients and family
* Mark on the TB treatment card upon supervising the patient taking each dose
* Report any adherence problems encountered by the patient
* Assist in tracing patients who interrupted treatment

**Select TB Treatment Supporter who fulfil the below Criteria:**

* Acceptance by the patient
* Close residence with the patient, preferably patient’s family member
* Willingness to support the daily treatment of TB patients
* Ability to read and write
* Sympathetic and considerate
* Willing to keep confidentiality

**Who can be a treatment supporter?**

* Health extension worker
* Family member
* Neighbour
* Community figures

### 5.6.3 Patient monitoring during TB treatment

Appropriate monitoring of individual TB patient for response to treatment is important to ensure that all patients are responding to the prescribed treatment and achieve favorable treatment outcome.

The recommended schedule for evaluation by the TB focal is at end of intensive phase, five months in to treatment, and at end of treatment to assess patients for:

1. Clinical monitoring for persistence or reappearance of clinical feature of TB, including weight monitoring
2. Adjust treatment doses based on current weight
3. Bacteriologic monitoring for treatment response using AFB microscopy
4. Treatment adherence by reviewing the “treatment supporter card”
5. risk for developing acquired drug resistance, and need for screening with DST
6. occurrence of Adverse drug reaction, and
7. Development of TB complications.
8. **Clinical Monitoring of TB patients:**

All TB Patients registered to receive TB treatment including those with bacteriologically confirmatory results and clinically diagnosed TB cases should be monitored clinically for:

* Improvement or persistence of clinical manifestations of TB (as compared to the compliant at time of diagnosis)
* Occurrence of symptoms indicating side of TB drugs
* Changes in body weight during the course of treatment

Weight is a useful indicator of clinical improvement and should be monitored monthly and documented on UNIT TB register at end of intensive phase and five month into treatment. Treatment dosage should be adjusted accordingly.

Whenever there is unsatisfactory response to treatment, alternative diagnoses and the possibility of drug resistance must be considered.

1. **Bacteriologic monitoring of Bacteriologically confirmed pulmonary TB patients:**

TB patients initially diagnosed with bacteriological confirmation of pulmonary tuberculosis (: with a positive result from smear microscopy, culture or Xpert MTB/RIF assay) must be additionally assessed bacteriologically using AFB microscopy to ensure their response to treatment.

For bacteriologically confirmed New pulmonary TB patients, Do sputum smear microscopy at end of 2nd, 5th and 6th month of therapy (See the flow chart for follow up of new smear positive PTB patients below).

For bacteriologically confirmed previously treated pulmonary TB patients, Do sputum smear microscopy at end of 3rd, 5th and 8th month of therapy (See the flow chart for follow up of previously treated smear positive PTB patients below).

Note that:

* Bacteriologically confirmed extrapulmonary TB cases are to be monitored clinically only as obtaining sample for follow up examination might not be possible
* Do not use Molecular technique like Xpert MTB/RIF assay for monitoring of response during TB treatment as the technique may give false positive result due to identification of dead bacilli.

Fig 3. Flow Chart for Sputum AFB Follow-up for bacteriologically confirmed New PTB Patients

***Bacteriologically confirmed New TB Patients 1***

**Neg**

**Pos**

**Neg**.

***Declare Cure/complete***

**AFB Smear at end of 2nd month**

If DST result shows susceptibility at least for Rifampicin;

Continue with 4 RH

Send Sputum sample for DST2;

Start continuation phase

If DST result shows resistance at least for Rifampicin3

Start continuation phase

Do AFB Smear at end of 5th mth

Neg

Smear at end of 6th month

**Declare Failure**

**Pos**

* Stop First line TB Rx;
* Assign “Moved to MDR” as outcome, and
* Refer/Link patient to MDRTB center

**Pos**.

*1BActeriolgically confirmed TB patients include those diagnosed by positive result on AFB microscopy, Xpert MTB/RIF Assay or culture;*

*2DST may be performed from one sputum sample using Xpert MTB/RIF, LPA or conventional DST based on availability. Information on rifampicin may be enough to decide on Next Action.*

*3 if DST result shows resistance to INH but susceptible to Rifampicin; treat with RHZE for 9 months.*

**Interpretation of follow up AFB microscopy results:**

For patients receiving **New TB regimen**:

* If AFB results at the end of intensive phase:
  + Is negative, start continuation phase of treatment
  + remains positive; initiate continuation phase and Do rapid DST and decide on next action based on the result
  + If DST shows resistance at least to Rifampicin, stop treatment assign “moved to MDRTB” as final outcome and link patient to MDR-TB center
* If AFB results at the end of fifth month (or later on treatment):
  + Is Negative, continue with the same treatment.
  + Is Positive, Declare “treatment failure” as final outcome and re-evaluate the patient to identify for causes of non-response (check adherence, Do rapid DST…)
* If AFB results at the end of Sixth month of treatment:
  + Is Negative, declare final outcome as “cured” or if does not meet criteria for cure but completed standard treatment with no sign of treatment failure, assign outcome as “completed”.
  + Is Positive, Declare “treatment failure” as final outcome and re-evaluate the patient as previously treated case and Do rapid DST.

|  |  |
| --- | --- |
| Fig 4. Flow Chart for Sputum AFB Follow-up for bacteriologically confirmed previously treated PTB Patients  ***Bacteriologically confirmed previously treated TB Patients1***  **Pos.**  **Pos.**  **Neg.**  **Declare Cure/ complete**  Smear for AFB at the end of 3rd mth  Send Sputum for FL DST1 and start continuation phase  **Send sputum for FL DST at least for Rifampicin2;**  **Initiate regimen for previously treated**  Start continuation phase  Smear at end of 5th mth  **Neg.**  Smear at end of 8th mth  **Declare Treatment failure**  **Pos**.  If DST result shows susceptibility at least for Rifampicin;  **Continue same treatment**  If DST result shows **resistance** at least for Rifampicin; STOP FL TB treatment; and Assign “Moved to MDR” as outcome, and Refer to MDRTB center  **Neg.**  If DST result shows **susceptibility** at least for Rifampicin;  **Continue same Rx**  *1refer a patient who has failed second course of TB treatment to MDR-TB center for further evaluation.*  *2DST may be performed from one sputum sample using Xpert MTB/RIF, LPA or conventional DST based on availability. Information on rifampicin may be enough to decide on Next Action* |  |

**Interpretation of follow up AFB microscopy results:**

For patients receiving **previously treated TB regimen:**

* If AFB sputum smear results at the end of 3rd month of therapy:
  + Is negative, continue with the continuation phase
  + Is Positive, Do rapid DST and decide on next action based on the result
  + If DST shows resistance at least to Rifampicin, stop treatment assign “moved to MDRTB” as final outcome and link patient to MDR-TB center
* If AFB results at the end of fifth month:
  + Is Negative, continue with the same treatment.
  + Is Positive, Declare “treatment failure” as final outcome, STOP the re-treatment regimen and consider referral to MDR-TB centers for further evaluation and consideration for treatment with SLDs
* If AFB results at the end of Eighth month of treatment:
  + Is Negative, declare final outcome as “cured” or if does not meet criteria for cure but completed standard treatment with no sign of treatment failure, assign outcome as “completed”.
  + Is Positive, Declare “treatment failure” as final outcome, STOP the re-treatment regimen and consider referral to MDR-TB centers for further evaluation and consideration for treatment with SLDs

## 5.7 Assigning final treatment Outcome for your patient

Upon an individual TB patient finished receiving full course of treatment or reached to the point of evaluation, the TB focal should analyse patient information and assign one final outcome and register on unit TB register as treatment result.

There are seven possible outcomes to be assigned and one patient could only have one possible result as follows:

Assign **“cure”** only for pulmonary confirmed TB patients with follow up AFB negative result at month six and at either of the second or fifth month.

*Make sure the AFB follow up results are properly updated and recorded on UNIT TB register before decision on outcome.*

Assign **“complete”** for:

* for pulmonary confirmed TB patients whose follow up AFB does not fulfill criteria for cure
* for clinically diagnosed TB patients (pulmonary Negative and Extrapulmonary TB patients) who completed full course of TB treatment
* Note that bacteriologically confirmed Extrapulmonary TB patients are not suitable for monitoring with AFB and will have “completed” as an outcome.

Assign **“Treatment failure”** for pulmonary confirmed TB patients whose follow up smear results remain positive at or beyond fifth month into treatment.

Assign **“Died”** for TB patient who is reported dead while receiving TB treatment, cause of death may not be related to TB.

Assign **“Lost to follow up (LTFU)”** for TB patient on treatment for at least four weeksand who has discontinued TB treatment for eight or more consecutive week.

Assign **“Not Evaluated”**, for patient whose final treatment outcome is not known at time of evaluation.

*Note that information on final treatment outcome patient who are transferred to other reporting facility should be collected from the receiving facility and outcome assigned accordingly.*

*If information on final outcome of transferred out patients cannot be retrieved, assign as “Not Evaluated”*

Assign **“Moved to MDR-TB”** for TB patient who arefound to harbor drug resistant strain at least for Rifampicin, with documentation of lab result, before fifth month of TB treatment. Such patients are believed to be miss-classified as drug susceptible while having resistant strains from the start of treatment.

## 5.8 Management of TB patients adverse reaction to Anti-TB drugs

Generally first lines anti TB drugs have fewer side effects. However, the health workers should regularly monitor for occurrence of side effects to the Anti-TB drugs administered to the patient.

**Anti TB drugs adverse effects are grossly classified as:**

1. *Minor side effect:* this may occur more frequent and managed symptomatically without interruption of anti-TB drugs. If the patient continues to be concerned about a minor side effect even after following the advice, refer/consult the patient to an experienced clinician.
2. *Major side effect:* Not common and it needs to stop the responsible drug or all anti-TB drugs and refer the patients to a higher level.

Table 12. Symptom-based approach to management of anti-TB drug side effects

|  |  |  |  |
| --- | --- | --- | --- |
| **Side-effects** | | **Responsible drugs** | **Management** |
| **a. Minor**  **[Continue anti TB drugs]** | Anorexia, nausea, abdominal pain | Rifampicin; Pyrazinamide | Give tablets with small meals or before bed time |
| Joint pains | Pyrazinamide | Aspirin |
| Burning sensation in feet | Isoniazid | Pyridoxine 100mg daily |
| Orange/red urine | Rifampicin | Reassurance |
| **b. Major**  **[Stop drug(s)**  **responsible]** | Itching, skin reaction | Streptomycin;  Rifampicin or Isoniazid | Stop, then reintroduce with desensitization1 |
| Deafness | Streptomycin | Stop streptomycin |
| Dizziness (vertigo, imbalance and nystagmus) | Streptomycin | Stop streptomycin |
| Jaundice; hepatitis\* | Most anti-TB drugs | Stop all anti-TB drugs and refer |
| Vomiting and confusion | Most anti-TB drugs | Stop all anti-TB drugs and refer |
| Visual impairment | Ethambutol | Stop Ethambutol and refer |
| Shock, purpura and acute renal failure | Rifampicin | Stop Rifampicin and refer |

## 5.9 Approach to Management of patients who interrupts Treatment

If your patient doesn’t attend two scheduled appointment to collect the drugs and/or receive their treatment, The TB focal person must start communication with the treatment supporter and Health extension worker to retrieve the patient and resume treatment the soonest possible. The steps include:

* Assessing the reasons why the patient has interrupted treatment
* Jointly developing an action plan to address the problems
* Re-assess the patient and investigate
* resume treatment as appropriate

**Treatment interrupters** are patients who received treatment for at least 4weeks and discontinued treatment for less than eight consecutive weeks.

**Lost to follow up** are patients who received treatment for at least 4 weeks and discontinued treatment for more than consecutive eight weeks.

Such patients should be managed as follows:

* Manage clinically diagnosed TB cases in consultation with trained clinician and add the missed doses at the end of each phases of treatment.
* The management of Bacteriologically confirmed New pulmonary TB patients who have interrupted treatment is complex and takes into consideration of multiple variables including their immune status, degree of remission of the disease with the previous treatment and drug susceptibility. A simplified decision tree is suggested in the table below.

Table 11 Management of New Pulmonary TB Treatment Interrupters

|  |  |  |  |
| --- | --- | --- | --- |
| Duration of interruption | Recommended Action | Result, if any | Recommended intervention |
| Patient interrupted treatment for a period of less than four weeks# | 1) Trace the patient  2) Establish the cause for interruption of treatment  3) Address the problem or concerns/ counsel patient | No lab investigation required | - Continue treatment and add the missed doses at the end of the treatment phase  - If the interruption occurred **during the intensive phase**, the duration of this phase must be extended by the number of missed days.  - If the interruption occurred **during the continuation phase**, the duration of this phase must be extended by the number of missed days |
| Patient interrupted treatment for a period of four to eight weeks# | 1) Address causes for interruption with the patient  2) Collect sputum for Rapid DST , preferably Xpert  3) Continue same treatment from where it stopped, and wait for DST results for any further action | Xpert MTB positive and Rif  sensitive | Continue treatment and add the missed  doses at the end of the treatment phase |
| If Xpert MTB positive and Rif  resistant | * Stop treatment * Register patient as “RR-TB” * Refer to the MDR-TB treatment initiating site for further management |
| Xpert detects No MTB/ not done/not available | * Continue same regimen * Arrange sputum sample referral for DST * Decide on next action based on DST result |
| interrupted treatment for a period of more than eight weeks (LTFU) | 1) Address causes for interruption with patient  2) Collect sputum for Rapid DST, preferably Xpert  5) Re-start treatment with regimen for previously treated, and wait for DST results for any further action | If Xpert positive and Rif sensitive | * Register as “Treatment after LTFU” * Restart Regimen for previously treated |
| If Xpert positive and Rif Resistant | * Stop treatment * Register patient as “RR-TB” * Refer to the MDR-TB treatment initiating site for further management |
| *Source. National Tuberculosis Management Guidelines. South Africa. 2014*  *# interrupter applies if the patient has taken treatment for period of four or more weeks* | | | |

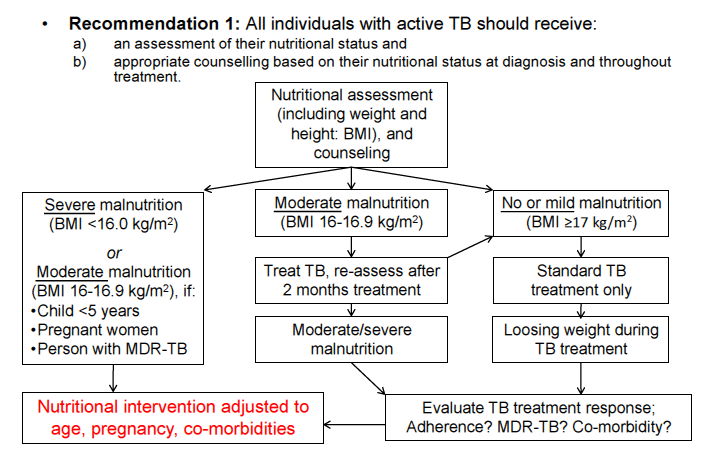
## 5.10 Assess, classify and support Nutritional status of your TB patients

Nutrition assessment, counseling, and support (NACS) is an approach that aims to improve the nutritional status of individuals with Active TB by integrating simple assessment of nutritional status and providing appropriate nutritional counseling and support based on their nutritional status.

TB focal person should assess their TB patient for Nutritional status assessment:

* At initial assessment and preparation of TB treatment
* At end of intensive phase of TB treatment, and
* Upon documenting unintentional weight loss during TB treatment.

Use this algorithm below to summary how to assess and classify your TB patients’ nutritional status:



**Nutritional Support:** Nutritional care plan and management of malnourished patients with TB has three care plans depending on the degree of malnutrition and the age of the Patient:

|  |  |  |
| --- | --- | --- |
| CARE PLAN | Degree of Malnutrition | Intervention |
| A | Severe acute malnutrition (SAM) | Ready to Use Therapeutic Foods (RUTF) or Plumpy nut\* |
| B | Moderate acute malnutrition (MAM) | Ready to Use Supplementary Foods (RUSF) or Plumpy sup# |
| C | Mild or no acute malnutrition | Nutritional counseling on essential elements |
| *\*Plumpy nut is an energy dense fortified therapeutic food designed for the treatment of SAM.*  *#Plumy sup is an energy dense fortified supplementary food designed for treatment of MAM.* | | |
| *Duration of Intervention:*  *If a TB patient has SAM, RUTF is given for 3 months (or less if patient comes out of SAM before completion of 3 months). Treatment is then continued with RUSF for 3 months.*  *If a TB/HIV co-infected or MDR-TB patient has MAM at initial time of assessment, RUSF is given for 3 months.* | | |

\*Supplementary foods are generally recommended for MDR TB patients to accelerate recovery and weight gain knowing the fact that majority had previous unsuccessful treatment history and higher prevalence of malnutrition.

Provide nutritional counseling support for all TB patients with Active TB as part of routine adherence support to TB:

|  |
| --- |
| Essential elements for Nutritional counselling of all patients with Active TB: |
| 1. Have nutritional status checked (especially weight) upon scheduled visits to clinic 2. Eat more and a variety of food stuffs 3. Maintain a high level of hygiene and sanitation 4. Drink plenty of clean and safe (boiled or treated) water 5. Maintain a healthy lifestyle and practice infection control at home 6. Get tested for HIV 7. Take your medicines properly and on time under DOT 8. Seek early treatment for adverse drug reactions 9. Follow instructions for taking your TB medicine in relation to food and other drugs |

|  |
| --- |
| Review Exercise on Day II: |

1. Manage the child:

|  |  |
| --- | --- |
| How do you manage “a 3 year old of child identified as contact of Pulmonary TB case”? | Management decision |
| 1. if sick & the source has HIV co-infection and susceptible TB |  |
| 1. if clinically well and the source has MDR-TB |  |
| 1. if sick and the source has MDR-TB |  |
| 1. if clinically well and the source has susceptible TB |  |
| 1. if sick and the source has susceptible TB |  |



|  |  |  |
| --- | --- | --- |
| Tracing for HH contacts is high priority if the index TB patient is/has: | True | False |
| 1. Under-five child |  |  |
| 1. Smear positive adults TB case |  |  |
| 1. Dx of MDR-TB |  |  |
| 1. TB of the vertebra |  |  |
| 1. HIV co-infection |  |  |

1. Matching on the information to assign the patient into proper registration group/outcome

|  |  |  |
| --- | --- | --- |
| **Answer** | **Definition** | **Type of patients** |
|  | A 20 yr old patient, who had been released as “cured” three years back, has returned back with TB symptoms & Xpert MTB/RIF test detected MTB but not RR from sputum samples. | A. Return after LTFU |
|  | A female patient who returns back with diagnosis of TB following interrupting TB treatment for ten weeks after receiving treatment for 5 weeks | B. Relapse |
|  | A 33 years old TB patient whose sputum smear remains positive at the end of third month of TB treatment | C. Treatment after Failure |
|  | A 19 yrs old TB patient whose follow up sputum smear is positive at month sixth during treatment and to be re-initiated with regimen for previously treated after Xpert MTB/RIF results showed susceptibility to Rifampicin. | D. No Answer provided |
|  | A 4 yrs old patient who has never had history of prior TB treatment | E. New |
|  | A 28 yrs old TB patient whose sputum is positive for MTB by Xpert MTB/RIF at month sixth during treatment | F. Failure |

**4.** Biruck is 19 years old and has been coughing with chest pain for 2 weeks. He completed TB treatment a year ago. His sputum results for Xpert detect MTB but not RR.

a) TB Type: bacteriologic diagnosed clinically diagnosed TB

b) His registration group is: New Transfer in Treatment after default

Relapse Treatment after failure Other

c) What treatment regimen is needed?

**5. A**ndargachew is an 18-year-old high school graduate who has been on anti-TB for 2 months after being diagnosed as new smear positive pulmonary TB. Now, he is transferred to your health facility to continue his medication:

a) What type of patient is he? New Transfer in Treatment after default

Relapse Treatment after failure Other

b) What addition follow up care you will give Andargachew?

**6.** Desalegn was referred to the clinician for assessment because his sputum was positive for AFB. He reported that he interrupted taking the drugs three months ago after taking anti-TB drugs for six weeks:

a) Patient registration group: New Transfer in Return after LTFU

Relapse Treatment after failure Other

b) Additional investigation you would request for Dessalegn? Why?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# 6. CHILDHOOD TUBERCULOSIS

Time allowed:

**Learning objectives**

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

* Describe the epidemiology of TB in children
* Explain the pathogenesis of TB in children
* Identify the symptoms and signs of TB disease in children.
* Describe the diagnostic approaches in childhood TB and TB-HIV
* Explain the treatment of TB in children

## 6.1 Basic concepts of TB in children

Tuberculosis (TB) is a major public health problem throughout the world. Almost 1.3 million cases and 450,000 deaths occur in children each year. The burden of TB in Ethiopia is one of the highest in the world. Childhood TB reflects recent transmission within a community. Cases of TB in children usually represents between 5-15% of all TB cases.

**Peculiarities of childhood TB:**

* The commonest age of presentation of childhood TB disease is between 1 and 4 years.
* Young age is a risk factor for infection, for progression from infection to disease, and for spread of disease to other parts of the body, i.e. dissemination.
* Risk of progression to disease is increased when primary infection occurs in the very young (0–4 years) – and in immuno-compromised children.
* Children under one year of age are more liable to develop Miliary and TB meningitis
* Most children with TB are not infectious to others.
* The commonest type of TB in children is smear-negative PTB.
* In adolescents, PTB is generally like adult PTB

**Children at greater risk of developing TB include:**

* Children who are in close contact with a newly diagnosed smear-positive TB case
* Children less than 5 years of age
* HIV-infected children
* Severely malnourished children

**Age influence on the Disease progression:** Young children carry higher risk of disease progression to Active TB disease right after recent exposure to infectious cases. The risk peaks among under-five children as the immune system that prevent disease progression usually matures around the age of 6 to 7 years of age. The graph below shows Age specific risk for disease after recent primary infection.

As shown in the graph, the risk of disease progression increases as the age of child gets younger indicating the need to give priority for implementing Active contact tracing and screening for all under five children whenever an index cases is diagnosed (*see section 5.4 contact screening and management on the management*).

### 6.1.2 Clinical manifestations of TB in children

Clinical Manifestations: In children TB disease presents in various clinical forms: Primary or post-primary pulmonary tuberculosis; Acute disseminated tuberculosis (meningitis & Miliary tuberculosis); and Extra pulmonary tuberculosis.

**Signs and symptoms of childhood TB:**

The clinical features of childhood TB are constitutional symptoms and local signs and symptoms which depend on the part of the body affected.

**Pulmonary Tuberculosis:** The most common clinical presentation is persistent respiratory symptoms and poor weight gain. A child may have non-productive cough and /or mild wheezes.

In infants or HIV-infected, pulmonary TB can also present as acute pneumonia.

More than 50% of infants and children with radiographically moderate to severe pulmonary tuberculosis have no physical findings and are discovered only by contact tracing.

Non-productive cough and mild dyspnea are the most common symptoms.

Systemic complaints such as fever, night sweats, anorexia, and decreased activity occur less often.

Some infants and young children with bronchial obstruction have localized wheezing or decreased breath sounds that may be accompanied by tachypnea or, rarely, respiratory distress.

**Extra-pulmonary tuberculosis in children:** Extra-pulmonary TB (EPTB) can occur at any age. Young children are particularly susceptible. Children of less than 2 years of age are at risk of disseminated disease causing Miliary TB or TB meningitis. If a patient has extra-pulmonary TB, look for pulmonary TB.

## 6.2 TB case finding in children

In addition to the case finding approaches used for adults, integrating TB screening services in to child health services(: IMNCI/ICCM and at especial service clinics) are important intensify TB case finding in children:

**Systematic TB screening at IMNCI/ICCM clinic:** At IMNCI/ICCM clinic, Health workers should consider possibility of TB in a sick child at initial visit and/or during follow up visit:

1. **Consider TB in a sick child at first visit:**

* Presumptive TB should be considered and evaluation for TB should be initiated, if the child has either one or more of clinical manifestations consistent with TB in children.
* Besides, for under-five child with contact history with infectious TB patients, appropriate evaluation for TB should be made and if Active TB is excluded, treatment for latent TB should be administered.

1. **Consider TB in a child during follow up visit**:

If a sick child who initially presented with cough is not responding to either to first line antibiotic treatment for pneumonia or to one-month of standard nutritional therapy for malnutrition, or has recurring pneumonia and has confirmed HIV infection.

At the community level, health extension workers additionally shouldidentify and refer a sick or TB exposed child during regular household visit and upon identification of an index TB case for appropriate evaluation.

## 6.3 Diagnosis of TB in children

Health care workers should try to diagnose TB in children at outpatient settings based on careful clinical assessment. Contact history is a very important part of assessment for children suspected of having TB. As young children rarely produce sputum, bacteriologic confirmation TB in children relies on clinical evidences. However, the health care worker should attempt to do gastric aspiration to get adequate material for smear examination. For older children capable of expectorating, sputum sample is to be collected as for adults.

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| **The diagnosis of TB can be made with confidence in the majority of children using careful clinical assessment.** |

There are two key factors in suspecting tuberculosis in children:

(1) Identification of an infectious adult close to the child, especially in the family, and;

(2) Loss of weight or failure to thrive.

### 6.3.1 Approach to Diagnosis of TB in Children

TB in children could easy be over- or under-diagnosed as obtaining appropriate specimen for bacteriological confirmation of TB is usually not feasible. A trial of treatment with anti-TB medications is not recommended as a method to diagnose TB in children. The decision to treat a child should be carefully considered and once such a decision is made, the child should be treated with a full course of therapy.

**Who should be evaluated for possible TB disease?**

* A child with symptoms suggestive of TB, with history of exposure to an infectious pulmonary TB patient;
* A child with pneumonia, pleural effusion, or a cavitary or mass lesion in the lung that does not improve with standard antibiotic therapy;
* *Patients with fever of unknown origin, failure to thrive, significant weight loss*; severe malnutrition and/or other immunosuppressive conditions( such as measles in the previous 3 months, whooping cough, HIV, being on medication like steroids), or unexplained lymphadenopathy.

***Any child with symptoms suggestive of TB, with history of exposure to an adult or adolescent pulmonary TB patient should be investigated for TB.***

### 6.3.2 Recommended approaches for evaluation of a child for Tuberculosis

Reaching a bacteriological confirmation of Tuberculosis in children is not possible in most instances. Hence, health care workers need to have high index of suspicion of TB in a sick child especially in those who are not improving to standard first line therapy and need to carefully assess the child to support the diagnosis of Tuberculosis based on clinical grounds.

**The following approaches are recommended to be followed:**

|  |
| --- |
| 1. **Careful history** (including history of TB contact and symptoms consistent with TB)  2**. Clinical assessment** (including serial weight)  3. **Diagnostic tests**   * Bacteriologic confirmatory tests( ZN/FM microscopy, Xpert MTB/RIF assay & culture) * Chest X-ray * HIV testing * Histopathology |

**a. Careful medical history**

The clinician must not only focus on identifying the key clinical symptoms reported by the child’s caregiver but also further characterize the symptoms to differentiate from similar manifestations of other diseases that could mimic TB in the child.

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| Important symptoms suggestive of tuberculosis that should be obtained from the medical history include:   * Contact history * Cough, especially persistent and non-improving * Weight loss or failure to gain weight * Fever and/or night sweats * Fatigue, reduced playfulness, inactivity |

**Further characterize the symptom to assist for Symptom-based identification of TB:**

**Cough*:*** *Persistent, non-remitting cough for >2 weeks not responding to conventional antibiotics (amoxicillin or co-trimoxazole) and/or bronchodilators;*

**Fever:** *Persistent documented fever (>38ºC/100ºF) >2 weeks after common cases such as malaria or pneumonia have been excluded*

**Weight loss:** *Documented weight loss or not gaining weight during the past 3 months (especially if not responding to de-worming together with food and/or micronutrient supplementation), or failure to respond to standard treatment of severe malnutrition.*

**Fatigue and reduced playfulness:** *if the family/care-giver reports that the child’s exhibits reduced daily physical mobility and lack of interest to play or interact with the surrounding.*

**Beware of Atypical clinical presentations of Tuberculosis in children:**

* *Acute severe pneumonia*
* Presents with fast breathing and chest in-drawing
* Occurs especially in infants and HIV-infected children
* Suspect PTB if poor response to antibiotic therapy – if 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, not responsive to bronchodilator therapy and associated with other typical features of TB.

**b. Document History of TB Contact**

Young children living in close contact with a source case are at particular risk of acquiring TB infection and further progression to Active disease usually within the first year of exposure/infection. The risk of infection is greatest if the contact is at household level, and if the source case has infectious Pulmonary TB. Infants and young children are especially likely to have contracted TB at home.

|  |
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| ***History of close contact with a patient (adult or adolescent or child) with pulmonary TB within the last year is a strong indication of possible TB disease in the “symptomatic” child.*** |

If no source case is readily identified at home, always ask for a person in close neighborhood or school with chronic cough and request to have clinical assessment for TB.

*Ask/Assess the child’s caregiver for the following information about the identified contacts:*

* Possible contact history with DR-TB patients
* The regimen of the TB treatment
* Adherence and response to TB treatment
* The outcome of TB treatment

*Note: If a source is not responding to standardized TB treatment, consider the possibility of drug-resistant TB. This should be taken into consideration when treating the child.*

**c. Do clinical Assessment ( including Growth Assessment)**

Conducting thorough physical examination is part and parcel of diagnosing childhood tuberculosis. Most children present with pulmonary tuberculosis and the clinical findings may be limited to respiratory system. However, physical examination should always be complete looking for possible clinical sign of Tuberculosis.

**GROWTH ASSESSMENT:** Documented weight loss or failure to gain weight, especially after being treated in a nutritional rehabilitation program, is a good indicator of chronic disease in children, including TB.

In children less than five years old, serial weights plotted on the WHO 2005 weight-for-age charts helps to decide if the child is either underweight (weight-for-age Z-score<-2.00) or failing to thrive.

In children 6-19 years, the WHO 2007 BMI-for-age charts should be used to decide if the child is either thin (BMI-for-age-Z score <-2.00) or failing to thrive.

**d. Relevant** **Investigations**

**Bacteriological Confirmation:** Although bacteriological confirmation of TB is not always feasible, it should be sought whenever possible by either Xpert MTB/RIF assay, AFB microscopy or culture.

**Xpert MTB/RIF Assay:**  is the preferred investigative modality for children with presumptive tuberculosis. It can be performed on either pulmonary samples or samples collected from suspected Extrapulmonary sites.

**Zeil Nelson/ Fluorescent LED microscopy**: can be used in areas where Xpert is not readily available or when the result of an Xpert test is still pending to minimize delay to reach diagnosis and commence treatment.it is also used for treatment response monitoring for bacteriologically diagnosed cases.

**Solid/Liquid Culture**: Hence, its use is reserved for difficult cases and to cases where information on culture and DST is required to reach the definitive diagnosis. This service can be accessed through MDRTB treatment hospitals.

**Obtaining appropriate specimen:** under five Children usually do not expectorate sputum requiring health worker to try various procedures to collect the appropriate specimen.

***Gastric aspirate or induced sputum:*** *usually performed in children unable to provide sputum by coughing and are particularly useful in cases of diagnostic uncertainty or screening for drug resistance.*

1. **Radiologic examination**

**Chest X-ray:** remains an important tool for diagnosis of PTB in children for whom bacteriologic confirmation of TB was not possible. The following abnormalities on CXR are suggestive of TB:

* Enlarged hilar lymph nodes and opacification in the lung tissue
* Miliary mottling in lung tissue
* Cavitation (tends to occur in older children)
* Pleural or pericardial effusions are forms of Extrapulmonary TB that tend to occur in older children
* The finding of marked abnormality on CXR in a child with no signs of respiratory distress (no fast breathing or chest in-drawing) is supportive of TB

*Analysis of lateral CXR may be indicated when intra-thoracic lymphadenopathy is suspected to cause TB related manifestation mainly in young children (under Five years of age).*

*Interpretations of abnormal findings on CXR should be made in light of the clinical presentation of the child and with help of experienced clinician.*

**Vertebral X-ray**: Spinal X-ray may be normal in early disease, as 50% of the bone mass must be lost for changes to be visible on X-ray. Plain X-ray (PA and Lateral view) of the affected vertebra can show vertebral destruction and narrowed disc space.

1. **Tissue examination:** Histological examination to look for caseation and granulomatous inflammation should be performed from specimen collected by FNA or tissue biopsy. Trained HCW should collect sample from accessible affected site (in particular from cervical lymph node enlargement) to support the diagnosis of TB from Extrapulmonary sites.
2. **HIV testing:** Rapid HIV test should routinely be offered as part of evaluation to all children with presumptive /diagnosed TB as the interpretations of clinical findings and other diagnostic evidences for HIV infected is different from HIV not infected child.
3. **TST and IGRA:** TST and IGRA tests are Antigen-Antibody detection test used for confirmation of TB infection, however, due to limitations associated with the test and the local TB epidemiology, the national program does not recommend the routine use of these tests for screening and diagnosis of TB in children.

### 6.3.3 Approach to a child with presumptive Extrapulmonary Tuberculosis

TB in children could involve different part of their body. Though there is no standard approach to evaluate and investigate a child with presumptive Extrapulmonary Tuberculosis. *See section 2.7 evaluation patients for of EPTB for some practical approach.*

## 6.4 Establishing Diagnosis of Tuberculosis in HIV negative Children

***A) Diagnosis of TB based on bacteriologic confirmation***

Bacteriologic confirmation of TB is reach when the TB bacilli are detected on either of the bacteriologic techniques (Xpert MTB/RIF, AFB microscopy or culture) from the biologic specimen.

***B) clinical diagnosis of TB based Algorithmic Approach***

The diagnosis of TB can be reached safely by using structured algorithm by combining the evidences from clinical history, contact information, physical findings including weight and supportive evidences from investigations.

Fig 5. Algorithm for screening Tuberculosis in HIV uninfected children

**Bacteriologic**

**Clinical Dx**

Negative or not done

Smear / GeneXpert Positive

* Positive contact history
* Physical signs suggestive of PTB
* CXR suggestive of PTB\*

Treat for TB

If only one or none of the features are present

Make a diagnosis of TB if two or more of these features are present

If child is very sick, admit to hospital for further investigation and management

If child not very sick give 7days antibiotics then review after 2-4 weeks

TB suspected on the basis of typical and persistent symptoms

If child improves complete treatment and discharge to routine follow up

If no improvement re-evaluate for TB

**C) Diagnosis of TB can also be made if the child has either:**

* + Radiological picture of Miliary pattern;
  + Histopathological findings compatible with TB; or
  + Presence of clinical features suggestive of TB, documented contact history and decision by experienced clinician to treat TB.

## 6.5 TB Treatment in Children

The standard case definitions, classification, patient registration and assigning outcome of treatment for TB in children are similar to that of adults.

The principles and management and monitoring of patient during treatment is also similar to Adult (see also treatment section for adult)

**TB treatment regimen in children**

|  |  |  |  |
| --- | --- | --- | --- |
| TB Type | TB type | Regimen | |
| **Intensive phase** | **Continuation phase** |
| New | * New smear positive, negative & extra-pulmonary TB | 2(RHZE) | 4(RH) |
| * TB meningitis * Bone TB (Osteoarticular) | 2(RHZE) | 10 (RH) |
| Previously treated\* | Previously treated smear-positive pulmonary TB:   * + Relapse   + Treatment after LTFU   + Treatment failure | 2(RHZE) | 4(RH) |
| MDR-TB | * Confirmed cases of MDR-TB | Second line anti-TB drugs | |

*\* previously treated children must receive regimen for the New as the risk of developing acquired drug resistance in children is very uncommon due to paucibacillary nature of TB*

*Additional notes of treatment of TB in children:*

1. Administer Anti-TB drugs daily
2. Adult dosage can be used if the child’s body weight is 25 kg or more
3. Children receiving TB treatment must be weighed at least on monthly basis
4. Treatment doses should be adjusted as the child crosses weight bands
5. Check tablet strengths regularly to avoid toxicity
6. Pyridoxine is recommended for children with severe malnutrition, or taking ART
7. Streptomycin shouldn’t be used as part of the first line treatment regimen for children
8. Ethambutol is safe in children at a dose of 20 mg/kg (range 15– 25 mg/kg) daily.
9. Adverse events are less common in children than in adults.

**Anti-TB drugs dosage for children:** determining theoptimal dosage of Anti-TB drugs for children has been a challenge due to limited information on pharmacokinetics of the drugs in children. The revised recommended dosage is presented in Table 13.

**Table 13: Recommended doses of first-line anti-TB drugs for children**

|  |  |  |
| --- | --- | --- |
| **Drug** | **Recommended Dose** | |
| **Daily Dose and range (mg/kg body weight)** | **Maximum (mg)** |
| **Isoniazid** | 10 (7-15) | 300 |
| **Rifampicin** | 15 (10-20) | 600 |
| **Pyrazinamide** | 35 (30-40) | - |
| **Ethambutol** | 20 (15–25) | - |
| Children weighing 25kg and more can be treated using recommendation for adults | | |

**Pediatrics anti-TB formulations in Ethiopia:** the pediatric FDCs formulations available so far are revised globally to constitute the most approximate doses in the FDCs as per the current recommended dosage of anti-TB drugs for children. The national program will introduce the new FDC formulations using (RHZ 75/50/150) as soon as possible to replace the current FDCs using (RHZ 60/30/150) to administer optimized formulation to treat TB in children (see table A and B below for dosage per weight band for children):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PATIENT TYPE** | **DRUGS** | **STRENGTH(MG)** | **FORMULATION** | **PREPARATION, ROUTE** |
| **Pediatric**  ( body weight less than 25kg) | RHZ | 60/30/ 150 | dispersible tab | FDC, oral |
| RHZ\* | 75/50/150 | dispersible tab | FDC, oral |
| RH | 60/30 | dispersible tab | FDC, oral |
| RH\* | 75/50 | dispersible tab | FDC, oral |
| E | 100 | dispersible tab | Loose, oral |
| H | 100 | dispersible tab | Loose, oral |

*\*shows the new FDC preparation for Rifampicin and Isoniazid*

Table 14 : Pediatric FDC dosing regimens

|  |  |  |  |
| --- | --- | --- | --- |
| **A. Pediatric FDC dosing for children using RHZ (60/30/150)** | | | |
| **Weight band  (kg)** | **Intensive phase (**2 months) | | **Continuation phase** (4 months) |
| **RHZ 60,30,150 tab** | **E 100 tablet** | **RH 60,30 table** |
| 4 to 6 | 1 | 1 | 1 |
| 7 to 10 | 2 | 2 | 2 |
| 11 to 14 | 3 | 2 | 3 |
| 15 to 19 | 4 | 3 | 4 |
| 20 to 24 | 5 | 4 | 5 |
| 25+kg | Adult dosages recommended | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **B.**  **Pediatric FDC dosing for children using RHZ (75/50/150)** | | | |
| **Weight bands** | **Intensive phase** (2 months) | | **continuation phase** (4 months) |
| **RHZ 75/50/150 tablet** | **E 100mg tablet** | **RH 75/50 table** |
| 4-7kg | 1 | 1 | 1 |
| 8-11kg | 2 | 2 | 2 |
| 12-15kg | 3 | 3 | 3 |
| 16-24kg | 4 | 4 | 4 |
| 25+kg | Adult dosages recommended | | |

**Corticosteroids:** Corticosteroids may be used for the management of some complicated forms of TB, e.g. TB meningitis, airway obstruction by TB lymph glands, and pericardial TB (for dosing see treatment of severe forms of TB in adults).

**Action to be done for children coming for second time of TB treatment:**

Children who received full course TB treatment are unlikely to relapse or to develop acquired drug resistance as they have paucibacillary TB and are treated aggressively. Hence, They should be treated with regimen for the new even if it is their second time.

Before putting such children on TB treatment for second time:

* Evaluate the treatment adherence of the child on previous course
* Check the administration of adequate dosage
* Evaluate for presence of contact history with Drug resistant TB case

**Treatment failure in children**:

Children should not fail treatment as long as the diagnosis of TB is correct and proper treatment is administered. Hence, re-evaluate your children to confirm the diagnosis of TB and rule out other diagnosis.

## 6.6 Tuberculosis in newborns

Once a pregnant woman has been on anti-TB treatment for at least 2–3 weeks, she is generally no longer infectious. If a pregnant woman with TB has been on treatment for TB for several weeks before delivery, it is less likely that the baby will become infected. The risk is highest if a mother is diagnosed at the time of delivery or shortly thereafter.

If a pregnant woman is found to have pulmonary TB shortly before delivery, then the baby, and if possible, the placenta, should be investigated for evidence of congenital TB infection. If the result is positive, the baby should be treated with full course of standard TB treatment.

If the newborn is asymptomatic, he/she should receive IPT for months, followed by BCG immunization. Breastfeeding can be safely continued during this period.

# **7. Mangement OF DRUG RESISTANT TUBERCULOSIS**

**TOTAL TIME FOR THIS UNIT: -**

**LEARNING OBJECTIVES**

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

* Discuss the basics of Drug-Resistant TB
* Describe the DR-TB case finding strategy
* Discuss DR-TB treatment in Ethiopia

## 7.1 Introduction and Clinical manifestations of DR-TB

Resistance to a drug is said to occur when a strain of Mycobacterium tuberculosis failed to be killed by administration of one or more anti-TB drugs. The laboratory technique used to perform resistance testing is called drug susceptibility test (DST).

***Clinical manifestations of DR-TB***: There are no differences in the clinical manifestations of Drug resistant TB from the susceptible ones. Cough of two or more weeks is the main symptom with or without fever, chest and/or back pains, hemoptysis, and significant weight loss.

Patients with Drug resistant form of clinical TB can never be differentiated from those with the drug susceptible TB using clinical evaluation, conventional smear AFB tests or Chest X-ray.

## 7.2 Diagnosis in DR-TB

Systematic targeted screening for drug resistance among high risk patient groups is the recommended case finding strategy at the moment.

Assess all presumed or diagnosed TB cases for:

* History of prior TB treatment for more than one month;
* History of close contact with presumptive or confirmed DR-TB cases;
* Living or working in high risk settings for DR-TB like health institutions, prisons, homeless shelters and other congregated settings; or
* Unsatisfactory response to standard TB treatment as presented by failure of smear conversion to negative after end of intensive phase

Table shows presumptive DR-TB cases categorized by the level of risk for development of DR-TB as high risk or moderate risk.

|  |  |  |
| --- | --- | --- |
| **Risk for TB Drug resistance** | **Risk group by TB type** | **Action to be taken** |
| High  (40-80%) | - Failure of re-treatment for TB  - Symptomatic close contacts of confirmed/presumed DR-TB cases | - Perform Rapid DST  - If not clinically stable, consider SLD treatment by the MDR-TB panel team decision |
| - Failure of New TB regimen | - Perform Rapid DST  - As around 60% of such patients in Ethiopia remains to be susceptible to at least to Rifampicin, start re-treat­ment regimen awaiting DST result for further decision |
| Medium  (10-20%) | - Relapse of TB disease  - Return after loss to follow up  - New TB patient who remain sputum smear positive at 2nd month of treatment  - presumptive/confirmed TB in patients from congregated settings (prison, homeless shelters, refugee camps, high DR-TB prevalent area)  - presumptive or confirmed TB in Health care workers  - Other previously treated case | - Perform Rapid DST  - Treat with First-Line anti- TB regimen till DST result is available |

**Suspect Identification and Referral Procedures for DR-TB case finding:**

* Identify TB patients meeting the criteria for Presumptive DR-TB.
* Educate the patient on basics of DR-TB and need for contact investigation.
* Inform the patient for the need for performing DST to confirm the diagnosis.
* Arrange sputum sample transport to the designated laboratory.
* Treat patient as per the national TBL guideline until result is ready and counsel on improving infection control measures at household level.
* Collect the DST result and decide on the subsequent management.
* Facilitate early referral of confirmed DR-TB cases to the designated DR-TB TIC.

**Arranging referral of confirmed cases**: DR-TB patients may be diagnosed at regular outpatient clinics, inpatient department, and/or under-five clinic. The linkage of all RR/MDR-TB diagnosed cases within the health facility must be arranged and facilitated by the TB focal at TB clinic.

Steps on arranging referral for confirmed RR/MDRTB to TIC:

* All diagnosed RR/MDRTB cases from OPDs and inpatient departments should be clinic linked to TB clinic;
* The TB focal record all RR/MDRTB cases on “*UNIT TB register*” using red colour to differentiate them from drug susceptible patients; Note that, these patient should be counted only on case finding report of the facility either as RR-TB and MDR-TB case and do not count them on drug susceptible TB reporting.
* Then, the TB focal counsel the patient on the management of the DR-TB and assist the patient to select the nearest/convenient TIC to continue with MDRTB treatment
* See Recording and recording section to demonstrate on how to record and report such care.

## 7.3 MDR-TB Treatment Regimens in Ethiopia

Any Second line Anti-TB regimen for DR-TB treatment should be constructed based on the principles of regimen construction as provided in the national PMDT guideline.

In Ethiopian context, the standardized DR-TB regimen for a newly diagnosed MDR-TB patient is:

***Intensive phase: 8 Z-Cm6-Lfx–Pto-Cs***

***Continuation phase: 12 Z-Lfx–Pto-Cs***

If the MDRTB patient has any one of the following condition, the regimen may need either drug or dose modification:

* Patient with History of previous exposure to second-line anti-TB drugs
* Patient who is household contact of a patient with DR-TB
* Children
* Pregnant
* Patient with Co-morbid diseases (Chronic renal dysfunction, HIV, Liver disease)

**Phases and duration of treatment MDR TB**

**Intensive phase**: refers to the initial period of treatment when maximal bacillary load reduction is aimed. This period is noted by the presence of an injectable drug.

**Continuation phase**: refers to the period where the injectable drug is discontinued and patient continues to take oral drugs. The duration of treatment is guided by culture conversion.

***Determining the duration of the injectable phase of treatment:***

The injectable should be continued for at least eight months or at least four months after the patient becomes culture-negative—whichever is longer.

In cases where culture results is not available, Clinicians must present the case to the panel team meeting to decide on the length of administration of injectable by reviewing the general condition of the patients, results from follow up AFB smears, and X-rays. *The decision of the panel to end the intensive phase must be recorded on treatment card of the patient.*

***Determining the total duration of MDR-TB treatment:***

Second line Treatment should continue for a minimum of 20 months or at least 18 months after the patient has converted culture-negative—whichever is longer.

Some patients with extensive pulmonary disease may require prolonged treatment up to 24 months or even longer based on the expert clinician decision.

If patients do not have follow up culture results to guide on the total duration of treatment, the panel team must review the case at end of 20 months of treatment and decide on completion of treatment. *The decision of the panel to end the intensive phase must be recorded on treatment card of the patient.*

## 7.4 Monitoring of response during treatment with SLDs

Patients receiving SLDs treatment should be monitored daily for adherence and adverse drug reactions at TFC level. In addition, they need to have scheduled clinical evaluation for response by an experienced clinician and laboratory monitoring tests at TICs level.

**Monitoring at TIC level:**

Once the patient is stabilized for two to four weeks period at TIC level, he/she can be linked to the identified TFC to continue treatment.

The TIC will continue to be responsible for:

* For conducting scheduled monitoring of treatment response: *Patients need to see their physician on monthly basis during the injectable phase and every one to three months during the continuation phase of treatment depending on the feasibility of arranging follow up visits.*
* To receive any referral from TFC for consultation and inpatient admissions
* To make any major decisions like discontinuing or change of a second line drug or regimen
* Defining period of injectable and final outcome of treatment
* Performance reporting on DR-TB using HMIS reporting tool.

During scheduled evaluation, Clinicians are expected to evaluate their patients for:

* Persistence or reappearance of symptoms of TB including weight monitoring
* Treatment adherence by reviewing the “treatment supporter card”
* Risk for developing acquired drug resistance, and need for second line DST
* Occurrence of Adverse drug reaction, and
* Development of TB complications.

**Table: Schedule for clinical and laboratory monitoring**

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Baseline** | **Intensive phase** | **Continuation phase** |
| Clinical assessment | √ | Monthly | Monthly |
| Audiometry | √ | 4th month | If clinically indicated |
| Simple hearing test | √ | Monthly | If clinically indicated |
| Sputum smear | √ | Monthly | Monthly |
| Sputum culture | √ | Monthly | Every 1-3 months |
| Second line DST | √ | If culture remain positive at end of fourth month | Evidence of DR-TB treatment failure |
| Liver function tests | √ | If clinically indicated | If clinically indicated |
| Serum Creatinine | √ | Monthly | If clinically indicated |
| Serum potassium | √ | Monthly | If clinically indicated |
| Thyroid stimulating hormone (TSH) | √ | 3rd and 6th month | Every 6 months |
| HIV testing | √ | If clinically indicated | If clinically indicated |
| Pregnancy test (15-49 yrs) | √ | If clinically indicated | If clinically indicated |
| CBC | If HIV or Anemia | If clinically indicated | If clinically indicated |
| Chest X-ray | √ | End of Intensive phase | End of treatment |

**Monitoring at TFC level:**

Criteria for linking patient to TFC are:

* DR-TB patient with stable clinical condition, and
* demonstrating satisfactory adherence to treatment

Steps to link a patient to TFC:

The panel team at TIC level must identify the preferred TFC with the patient during pre-treatment evaluation and start the necessary arrangement as follows:

* Identify the TFC and communicate with the zonal/woreda TB focal person about the patient conditions and plan to continue treatment at the local TB clinic
* Assess the Patients if he/she fulfils the discharge criteria from TIC
* Prepare a copy of patient’s treatment card and treatment supporter card
* Orient the patient and the supporter on next steps when they are linked to TFCs
* Develop care plan for the patient by TIC when the patient continues treatment at the TFC level (including drug dispensing to the TFC, mentoring support and catchment area meeting…)
* Link the patient with the TB focal at TFC, and discuss on the individual case scenario and develop care-plan together.

At TFC level, the TB focal and other clinical staffs are responsible:

* To administer daily injection( If in intensive phase) and observe the morning treatment dose
* Dispense the evening dose, and ensure the proper administration of the medicines under supervision of the “treatment supporter” at home and check the treatment supporter card.
* Screen for common adverse effects of the Second line drugs regularly:

Ask for following symptoms at least weekly:

* Muscle cramp and unusual weakness and fatigue
* Slow mood, difficulty of falling asleep, loss of appetite..
* Recent change in behaviour and mood
* Pain and/or recent swelling over joints
* Refer patients suspected of developing serious adverse events like hypokalaemia, hypothyroidism, psychosis..
* Arrange/Assist patient to conduct scheduled visits to TIC
* Conduct contact tracing, evaluation and quarterly follow up of all household and close contacts of the patients within three months’ time before time of diagnosis. See Annex 3 for checklist for clinical monitoring of MDRTB patients at TFC.

In addition, the TB focal at TFC, must keep the “DR-TB follow up register” updated and produce report regularly and submit a copy to woreda health office and TIC on patient status on treatment. *Note that the reporting unit for MDRTB treatment using HMIS reporting forms is the TIC not the TFC.*

## 7.5 Management of Mono- and Poly-Drug Resistant TB cases

In Ethiopia, access to full first line DST may not be obtained routinely to inform about the full drug resistant pattern limiting the diagnosis mono- and poly DR-TB cases.

**INH Resistant TB**: the commonest scenario will be information about INH resistance from LPA at reference lab. Hence, there will be incomplete data to suggest specific regimens for INH resistance as it may be combined with either or all of S, E & Z.

**Registration and Management**: Patients with INH resistance follow case definitions and classification system as susceptible TB case and are registered on the Unit TB Register (Drug susceptible TB register) with red color pen and additional reminder on “Remark column”. Such patients should receive RHZE for 9 months without any change in regimen during continuation phase.

**Patient Monitoring and outcome**: These patients are advised to be monitored similarly as Drug susceptible TB.

* Do Xpert MTB/RIF test at the baseline, second, third and fifth month of treatment to check for possible amplification of resistance to rifampicin.
* If the DST shows resistance to rifampicin, STOP first line anti-TB treatment and switch over to SLD treatment.
* If the DST shows susceptibility to rifampicin at specified time, continue first line anti-TB treatment and continue monitoring treatment response with AFB smear at second, fifth and end of treatment.

**Post treatment follow up**: As INH resistant cases may amplify resistance for rifampicin and present back as an early relapse case with MDR-TB after completion of the nine month regimen, post treatment follow up should be arranged at month three and six after release from treatment. During post treatment follow up, the health care worker should assess the patient using clinical symptom-based screening for TB, and Do bacteriologic evaluation Xpert MTB/RIF assay if they become symptomatic.

# 8. TB/HIV COLLABORATIVE ACTIVITIES

**TIME ALLOTTED:**

**LEARNING OBJECTIVES**

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

* Impacts of HIV/AIDS on TB control
* Impacts of TB on HIV/AIDS
* Rationale for TB/HIV Collaboration
* Clinical management of patients with TB/HIV co infection
* Principles of TB prevention among HIV positive people

|  |  |
| --- | --- |
| *Kato stilll thin and reading dissemented TB* | Hailu is a 27 years old man, who is HIV positive and diagnosed with pulmonary tuberculosis. His CD4 count is 600cells/mm3  What additional information would you like to know?  How would you manage him?  *Discuss on your response later after completion of the section* |

## 8.1 Introduction

HIV infection leads to progressive immunodeficiency and increased susceptibility to infections, including TB. As HIV infection progresses, CD4 lymphocytes decline in number and function. The immune system is less able to prevent the growth and local spread of Mycobacterium tuberculosis, leading to the progression of recent or latent TB infection to active TB disease. The life time risk of HIV positive individuals to develop TB is 50% and the annual risk 10%. In Ethiopia, among TB patients tested for HIV, in 2012, 15% were HIV positives.

HIV not only increases the number of TB cases but also alters the clinical course of TB disease. Although tuberculosis can occur at any point in the course of progression of HIV infection, the clinical pattern of disease changes. As HIV related immune suppression increases, there are increasing numbers of smear negative pulmonary TB, extra-pulmonary TB and disseminated TB cases. TB is also more difficult to diagnose as immunosuppression progresses. Co-infected patients have an increased mortality due to rapid disease progression, late diagnosis and other opportunistic infections.

Appropriate TB case management including the provision of comprehensive HIV care to the co-infected patient will l prolong the lives of people living with HIV and AIDS, minimize the negative effects of TB on the course of HIV and interrupt the transmission of M. tuberculosis.

### 8.1.1 Impacts of HIV on TB

The consequences of HIV on TB include the following:

* Over-diagnosis of sputum smear-negative PTB (due to difficulties in diagnosis)
* Under-diagnosis of sputum smear-positive PTB (due to excess laboratory workload)
* inadequate supervision of anti-TB chemotherapy
* High morbidity and mortality during treatment, due to other OIs
* high default rates because of adverse drug reactions
* high rates of TB recurrence and relapse
* Poor adherence due to pill burden, drug-drug interaction, adverse effects, stigma and discrimination

### 8.1.2 Impact of TB on HIV

In an individual infected with HIV, the occurrence of active TB may affect the patient in many ways:

* TB increases HIV replication, which leads to increased viral load. This results in more rapid progression of HIV disease & the occurrence of other OIs.
* The management of TB and HIV co-infected individual is challenging because of: poor adherence due to pill burden, increase adverse effect, drug-drug interaction and IRIS.
* TB is a leading cause of morbidity & mortality among people living with HIV.

## 8.2 Nationally Recommended TB/HIV Collaborative Activities

TB/HIV collaborative activities are the frame work for integrating the programmatic and clinical management of HIV and TB co-infection with aim to reduce the diseases burden, maximize the resource required and provide integrated patient care at facility level. The collaborative activities are categorized into three:

* + 1. **Strengthen the Mechanisms for integrated TB and HIV services delivery**
* Strengthen the coordination mechanism for integrated TB/HIV services at all levels;
* Conduct surveillance to determine HIV burden among TB patients and TB burden among HIV patients;
* Carry out joint TB/HIV planning for integrated TB and HIV services delivery;
* Conduct monitoring and evaluation of collaborative TB/HIV activities.
  + 1. **Decrease the burden of TB among HIV patients** with three I’s
* Intensify TB case finding and ensure quality TB treatment
* Initiate TB prevention
  + Earlier initiation of ART and
  + Isoniazid preventive therapy
* Ensure Tuberculosis infection control in healthcare and congregate settings

**C. Decrease the burden of HIV among TB patients**

* Provide HIV testing and counselling to presumptive and confirmed TB patients
* Provide HIV prevention services for presumptive and confirmed TB patients
* Provide co-trimoxazole preventive therapy for HIV positive TB patients
* Ensure HIV/AIDS prevention, treatment and care for HIV positive TB patients
* Provide antiretroviral therapy for HIV positive TB patients timely.

## 8.3 management OF TB/HIV co infections in Adults

### 8.3.1 Intensified TB case finding and provision of quality TB treatment

Intensified Tuberculosis case finding using symptom-based TB screening questions should be instituted at HIV care and treatment clinics for all HIV positive clients. Any HIV positive patient with TB screen positive result should undergo appropriate evaluation and investigation for TB (see Annex 2 for Diagnostic Algorithm).

Diagnosis of TB is challenging in HIV positive individuals, especially when the stage of the disease is advanced. Standard TB diagnostic approaches and clinical algorithms should be followed to guide the diagnosis of TB in PLHIV. Note that Antibiotic trials are not recommended in the diagnosis of TB in HIV positive individuals.

*Clinical assessment:* Thorough clinical evaluation of the patient, including exclusion of other OIs, should be done. In patients with unsatisfactory treatment response to standard treatment for Acute bacterial pneumonia or PCP, re-evaluate for possible tuberculosis, particularly if respiratory symptoms persist after treatment.

**Xpert MTB/RIF***:* Xpert MTB/RIF is preferred primary diagnostic test for presumptive TB in people living with HIV due to its higher sensitivity to detect MTB.

**AFB microscopy**: AFB Microscopy is indicated in the diagnosis of TB in HIV infected presumptive TB cases if access to Xpert MTB/RIF test is limited. It should also be used to monitor treatment response.

**Sputum culture**: sputum culture is the gold standard for the diagnosis of tuberculosis. In patients with negative Xpert MTB/RIF and sputum smears, sputum culture should be encouraged as part of the diagnostic procedure for people living with HIV.

**Chest radiography**: Chest X-ray plays a significant role in avoiding diagnostic delays of TB in PLHIV. It can also be an important entry point to diagnose non-tubercular chest diseases, which are common among HIV positives.

**Diagnosis of extra-pulmonary tuberculosis in HIV positive:** Extra-pulmonary tuberculosis is more common among PLHIV compared with HIV-uninfected individuals. The accurate diagnosis of extra-pulmonary tuberculosis is complex and difficult, particularly in peripheral health facilities with limited diagnostic capacity. Therefore, it is important for healthcare workers to have high-index of suspicion and evaluate patients carefully (*See section 2.8).*

### 8.3.2 Treatment of patients with TB/HIV co infections

Patients diagnosed with TB/HIV co-infections require prompt initiation of treatment for both Tuberculosis and HIV, including any other OIs diagnosed.

**Management of a TB patient who is already on ART**

* Evaluate for ART treatment failure and/or Immune reconstitution syndrome.
* Start anti-TB
* If necessary, modify ART regimen to avoid drug-drug interaction

**Management of a TB patient who is not on ART**

* Start anti TB first
* Initiate co-trimoxazole preventive therapy
* Initiate recommended ART regimen after anti-TB drugs are tolerated after 2-8 weeks
* Monitor closely for toxicities

In addition, the following consideration needs to be addressed:

* Which disease to treat first
* What treatment regimens to use
* The timing of initiation of ART during TB treatment
  + 1. **Which disease to treat first:** in line with the principle of treating all OIs before starting ART. Treatment priority is given to Tuberculosis and HAART should be initiated later.
    2. **Which treatment regimen to use:**
* **Anti-tuberculosis treatment:** All HIV positive clients with active TB should be treated with standard anti-TB treatment regimen.
* **Antiretroviral treatment:** the following principles apply in ART regimen selection for the treatment of HIV infection with concomitant anti-TB treatment.
* ART should be started in all TB patients, including those with drug-resistant TB, irrespective of the CD4 count.
* For first line ART: a regimen of two NRTIs with one NNRTI preferably Efavirenz is used. The previous recommendation of increasing the dose of Efavirenz to 800mg /day is no longer apply.
* For second line ART: a regimen of two NRTI with one PI (boosted Lopinavir). Note that the dose of the ritonavir should be doubled to counter the effect of Rifampicin on the Protease inhibitors.

The following table summarizes the recommendations based on the preferred first line and second line ART regimens in Ethiopian national ART guideline

|  |  |  |
| --- | --- | --- |
| Population | Preferred first Line regimens | Alternative First Line regimens |
| Adults (including pregnant and breastfeeding women and adults  with TB co-infection)) | TDF + 3TC + EFV | AZT + 3TC + EFV  AZT + 3TC + NVP  TDF + 3TC + NVP |
| Adolescents (10 to 19 years)  ≥35kg(including those  with TB co-infection)) | TDF + 3TC + EFV | AZT + 3TC + EFV  AZT + 3TC + NVP  TDF + 3TC + NVP  ABC + 3TC + EFV |

**If patient is on second line regimen, management should be as follows:**

If patient is diagnosed to have HAART treatment failure while TB diagnosis is made; same NRTI backbones as recommended for adults and adolescents plus double-dose LPV/r (that is, LPV/r 800 mg/200 mg twice daily) or standard LPV dose with an adjusted dose of RTV (that is, LPV/r 400 mg/400 mg twice daily).

If the patient is already on second line ARV when TB is diagnosed, Do one of the followings:

* If the patient was on ATV/r the PI should be switched to LPV/r.
* If patient was on LPV/r –maintain it with adjustments as described above.

NB: If you suspect second line ARV failure consult experts in HIV care and treatment clinics.

* + 1. **Timing of ART initiation during the course of TB treatment**

The following table summarizes the recommendations for timing of ART initiation when TB and HIV are diagnosed at the same time.

|  |  |
| --- | --- |
| **Patients with Tuberculosis found to be HIV positive** | **HIV positive patients taking ART diagnosed with TB** |
| Anti-tuberculosis treatment should be initiated first, followed by ART as soon as possible within the first 8 weeks of treatment. | Start anti-TB  Modify ART regimen to avoid drug-drug interaction  Evaluate for treatment failure |

## 8.4 Management of TB/HIV Co-Infection in Children

In HIV infected children tuberculosis is often severe, progressive and likely to involve extra-pulmonary sites. The mortality rate for TB/HIV co-infected children is high, particularly if there is evidence of advanced immune suppression. HIV counseling and testing should be offered to all children with diagnosis of tuberculosis; on the other hand, all HIV-exposed and infected children should be screened regularly for TB using symptom based TB screening questions and appropriate evaluation should be conducted for cases who fulfill the screen positive criteria.

### 8.4.1 TB Screening in Infants and Children

**Symptom screening:** Children living with HIV who have any one of the following symptoms –poor weight gain[[1]](#footnote-1), fever, current cough or contact history with a TB case – may have TB and should be evaluated for TB and other conditions. If the evaluation shows no TB, administer IPT regardless of their age.

### 8.4.2 Diagnosis of TB in HIV-infected children

The approach to diagnosing TB in children living with HIV is essentially the same as for  
diagnosis in HIV-negative children. However, reaching to TB diagnosis may be more challenging for the following reasons:

* Clinical features consistent with pulmonary TB in children may be present due to other diseases.
* Children living with HIV have a very high incidence of acute and chronic lung  
  diseases other than TB.
* Children living with HIV may have lung disease of more than one cause (co-infection), which can mask response to therapy.
* There is an overlap of radiographic findings in TB and other HIV-related lung disease.

The recommended approach for evaluation of a child for TB should apply also for HIV infected children with presumptive TB.

The diagnostic algorithm below is simplified approach recommended to evaluate HIV infected children who fulfill symptom screen criteria to reach to the diagnosis of TB.

Fig 6. Algorithm for the diagnosis of TB in HIV infected children

Sputum smear or Gene-Xpert Negative or not done

Smear / GeneXpert Positive

Consider TB contact history

Treat for TB

Contact smear-negative or not known

Contact smear positive

Physical signs and CXR suggest other diagnosis# **Not TB=> Treat other conditions with Follow up**

Physical signs or CXR suggestive of PTB

TB suspected on the basis of typical and current symptoms

Cough, fever, weight lose, decreased playfulness)

### 8.4.3 Principles of TB /HIV co-infection Management in children

Management principles and considerations for children with HIV and TB co-infection is similar to Adult with co-infection. Summary of regimen selection is indicated in table below:

|  |  |  |  |
| --- | --- | --- | --- |
| Recommended regimens for children and adolescents initiating ART while on TB treatment | | | |
| Younger than 3 years | | | Two NRTIs + NVP, ensuring that dose is 200 mg/m2, or  Triple NRTI (AZT + 3TC + ABC) c |
| 3 years and older | | | Two NRTIs + EFV, or  Triple NRTI (AZT + 3TC + ABC) c |
| Recommended regimen for children and infants initiating TB treatment while receiving ART | | | |
| Child on standard  NNRTI-based  regimen  (two NRTIs + EFV  or NVP) | Younger than  3 years | Continue NVP, ensuring that dose is 200 mg/m2  Or Triple NRTI (AZT + 3TC + ABC)c | |
| 3 years  and older | If the child is receiving EFV, continue the same regimen  If the child is receiving NVP, substitute with EFV, or  Triple NRTI (AZT + 3TC + ABC)c | |
| Child on  standard PI based  regimen  (two NRTIs +  LPV/r) | Younger than  3 years | Triple NRTI (AZT + 3TC + ABC) c  or  Substitute NVP for LPV/r, ensuring that dose is 200 mg/m2 | |
| 3 years  and older | If the child has no history of failure of an NNRTI-based regimen:  Substitute with EFVe ,or  Triple NRTI (AZT + 3TC + ABC)c ,or  Continue LPV/r; consider adding RTV to achieve the fulld therapeutic dosed  If the child has a history of failure of an NNRTI-based regimen:  Triple NRTI (AZT + 3TC + ABC)c  Consider consultation with experts for constructing a second line regimen | |

### 8.4.4 BCG Vaccination for HIV-exposed infants

BCG vaccination is contraindicated in symptomatic HIV-infected infants. The implementation of selective BCG vaccination strategies may not be feasible in most of the TB high endemic settings including Ethiopia. Hence, it is advisable to give BCG at birth for all HIV positive and exposed infants as per the national EPI protocol. Evidence also shows that HIV positive infants are not symptomatic at birth.

|  |
| --- |
| Now discuss on the case that was presented on the start of the section. |

# 9. Airborne infection control in context of TB and DR-TB

LEARNING OBJECTIVES

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

* Explain basic concepts underlying TB and DR-TB transmission
* Justify the need for implementing airborne infection measures for TB
* Mention the standard sets of packages of TB IC measures
* Prioritize & implement basic TB IC activities at health facility level
* Demonstrate Donning and use of respirators

## 9.1 Basic facts on TB Infection Control in Ethiopia

* In Ethiopia, transmission risk of tuberculosis in health facilities, household and congregated settings are a major concern due to the weak implementation of Infection Control measures in the face of high TB, MDR TB and HIV prevalence.
* Emergence of drug resistant form of TB has become a growing threat as they have limited treatment options favouring the higher risk for transmission.
* Undiagnosed patients are main source of M. tuberculosis transmission.
* Lack of performance indicator to measure the quality of control measures

Tuberculosis infection control (TB IC) relies heavily on:

* **Early diagnosis** (active case finding through cough surveillance at all service points and use of rapid diagnostics like Xpert MTB/RIF test), and
* Prompt administration of **effective treatment**.
* Quality of implementation of control measures at high risk areas

## 9.2 Set of TB Infection Control Measures for Health facilities

TB infection control is a combination of measures aimed at minimizing the risk of TB transmission within populations (from an infectious case to other patients, visitors or family members and health care workers in health facility, congregate and community settings).

***High-risk areas for TB transmission include****:*

* + - * TB and medical wards
      * Outpatient departments, radiology department, laboratories and waiting areas where potentially infectious TB patients visits to receive
      * Spaces reserved for aerosol generating procedures (e.g. sputum collection areas*,* bronchoscopy rooms)

There are four **components of TB infection control**: Managerial, Administrative, Environmental control measures and Personal Respiratory Protective measures.

1. **Managerial control measures**

Managerial control measures provide the managerial framework for the implementation of TB infection control in health-care facilities, congregate settings and households.

1. **Administrative controls**

Administrative control measures aims at preventing the **generation of and exposure to infectious droplet nuclei** by implementing measures whereby people with TB symptoms be promptly identified, separated and treated.

This strategy includes the following:

* Prompt identification of potentially infectious cases (**triage**);
* **Separate** infectious cases and fast track their service;
* Control the **spread of** pathogens (cough etiquette and respiratory hygiene) and
* Minimize **time spent** in health-care facilities.

An administrative control also includes a package of interventions for Health care workers on TB and HIV prevention.

1. **Environmental controls**

The second level in TB Infection control is the use of environmental or engineering controls. The environmental measures aim in **reducing the concentration** of infectious droplets by increasing the **air exchange of the room/space**. Air exchange per hour of 6-12 ACH are the recommended level for TB infection control.

1. **Personal Respiratory protection**

Personal respiratory protection is considered the third line of defence for TB control and useful only when the risk of TB cannot be adequately reduced by other meaures.

## 9.3 Minimum Package of TB infection control interventions for TB treatment facilities

**Which TB IC measure for Health-care facilities?**

* Implementation of controls as a combination of measures reduces transmission of TB in health-care facilities.
* Administrative controls should be implemented as the first priority because they have been shown to reduce transmission of TB in health-care facilities.
* Administrative controls are needed to ensure that people with TB symptoms can be rapidly identified and, if infectious, can be separated into an appropriate environment and treated promptly.

Minimum Package of TB IC Interventions at Health facility level

|  |
| --- |
| 1. ***Managerial Measures for facility-level TB infection control:*** 2. **Identify and/or strengthen TB Infection control/IP Committees**  * Develop TOR and establish or strengthen IP/TB IC Committee * Assign TB IC focal person with clear Job description * Do facility TB IC risk assessment * Develop annual plan (plan should include What to do, when, who will do and how)  1. **Rethink** the use of available spaces and consider **renovation** of existing facilities or **construction** of new ones to optimize implementation of controls. 2. Conduct on-site **surveillance of TB** disease among health workers and assess the facility. 3. **Address advocacy, communication and social mobilization (ACSM)** for health workers, patients and visitors. Use both audiovisual, Verbal and written communication materials. 4. **Monitor and evaluate** the set of TB infection control measures: Implementation should be followed daily, IP/TB IC committee should meet at least quarterly and the whole TB IC plan should be evaluated at least annually. |
| 1. ***Administrative controls:*** 2. Promptly identify people with TB symptoms (triage). 3. Separate infectious patients (fast track services for outpatients and keep them separate from others in inpatient), 4. Minimize time spent in health-care facilities.    * Rapid diagnosis of TB and DR TB using available diagnostic tests (Smear Microscopy or if available Xpert MTB/RIF test).    * Put patients on Effective treatment based on DST status. 5. Control the spread of pathogens (cough etiquette and respiratory hygiene) and 6. Provide a package of prevention and care interventions on TB and HIV for health workers |
| 1. ***Environmental******controls:***   **Maximal utilization of natural ventilation systems**   * + Opening doors and windows to attain at least **12** Air Change per Hour   + Utilization of additional mechanical ventilations in places where natural ventilation is inadequate   + Proper client-HCW sitting arrangement   + Encouraging DR-TB patients to stay out-door, as much as possible. |
| 1. ***Personal protective equipment:* Use particulate respirators.**  * Availing N-95 respirator for health care workers who are involved in care of DR-TB patients   + Use Quality assured N-95/FFP2 respirator (NIOSH/CDC/CEN approved).   + Ensure correct use by doing facial seal check every time Respirators are used.   + A respirator can be worn for for a week period as long it is intact and properly handled(See Annex 4). * **Surgical masks for DR-TB patients until culture conversion.** Other materials like piece of cloth or tissue paper can be used when surgical mask is not available. |

**Which set ups should implement the minimum TB IC measures?**

All health-care facilities, public and private, caring for TB patients or persons suspected of having TB should implement the measures described in this policy.

**Getting started with TB IC Implementation**

1. Establish or strengthen a TB IC/IP committee
2. Assign a TB IC focal person
3. Do TB IC risk assessment annually
4. Develop a do-able TB IC plan (See Annex 4)
5. Monitor progress regularly

Develop TB IC plans in phases & implement the components based on realities at each facility level.

Scale up TB IC activities from easier to implement activities to more complex components step by step where staffs follow their progress before adding on more components.

## 9.4 Demonstrate Donning and use of respirators

Respirator is a device that helps to protect the inhalation of infectious droplet nuclei.

* It should fit closely to the face to prevent leakage around the edges.

**DOs AND DON’Ts OF RESPIRATORS**

* Always wear N-95 respirator before entering MDR-TB ward/isolation room
* Visual inspection to N-95 Filtering face-piece Respirator prior to each use for its integrity, deformity, deterioration or loose part
* Replace damaged/soiled N-95 Respirator
* Keep the respirator in a clean, dry place.
* Never clean or decontaminate your N95 Respirator
* Do not share respirators with other person
* Post warning signs on entrance of ward or OPD or Laboratory where persons entering should wear a respirator to remind them.
* Remember patients should wear surgical masks to prevent transmission to others but attendants should wear N95 respirators.

Use Annex 4 to demonstrate how to Donning and proper use respirators in your facility.

|  |
| --- |
| Review Exercise on Day III: |

1. TB in children may manifest as:

|  |  |  |
| --- | --- | --- |
|  | True | False |
| 1. Severe pneumonia in very young children 2. Recent onset of deformity(gibbus) over the back 3. Painless swelling over the lateral aspect of the neck 4. No apparent/subtle symptoms especially in malnourished and HIV infected child |  |  |

1. \_\_\_\_\_\_\_\_\_\_\_\_ is important for diagnosis of TB in young children

|  |  |  |
| --- | --- | --- |
|  | True | False |
| 1. chronic and persistent cough lasting more than two weeks 2. history of contact with infectious TB case 3. document weight loss or failure to thrive 4. Not responding to standard treatment for common childhood illnesses |  |  |

3. Confirmatory diagnosis of TB in children can be obtained from\_\_\_\_\_\_\_\_\_\_\_\_\_:

|  |  |  |
| --- | --- | --- |
|  | True | False |
| 1. Chest x-ray 2. Mycobacteriologic examination of biologic specimen 3. Tuberculin skin test(TST) 4. Clinical history and history of document contact history with TB case |  |  |

1. About the evaluation of a child with presumptive TB:

|  |  |  |
| --- | --- | --- |
|  | True | False |
| 1. A thorough and accurate contact history is a very important diagnostic information 2. Sputum should be examined in all suspected cases whenever available 3. Chest X-ray is an important tool for the assessment of suspected intra-thoracic TB 4. HIV testing is not important in the assessment of young children with TB 5. Documenting changes in weight is important tool in diagnosis |  |  |

|  |  |
| --- | --- |
| **Part II: Write T for correct statement and F for wrong statement for question 5 to 10.** | |
| \_\_\_\_\_\_ | 5. Diagnosis of TB in children can be made using clinical criteria |
| \_\_\_\_\_\_ | 6. Treatment trail with Anti-TB medicines is useful to confirm diagnosis of TB in children |
| \_\_\_\_\_\_ | 7. Nutritional assessment & counselling should be provided for a child receiving Anti-TB |
| \_\_\_\_\_\_ | 8. Asymptomatic Children who are contacts of a MDR-TB patient should receive IPT |
| \_\_\_\_\_\_ | 9. Integrating TB screening question in IMNCI clinic would improve TB case finding in children |
| \_\_\_\_\_\_ | 10. Household contact tracing is not recommended, if the index case is a child. |

**Q11. Jembere Mulatu** (JM), A 34 year old male patient, who took only 4 months of New patient regimen last year has returned to the health facility. The follow up sputum smear was negative on the 2nd month. Thereafter, he stopped treatment since he was already feeling better. Now the patient complains of worsening cough for the last 4 weeks with back pain, hemoptysis and weight loss. His sputum examination result was smear-positive.

|  |  |
| --- | --- |
| **Questions 1** | **Answers 1** |
| Is he Presumptive DR-TB case? Yes/No |  |
| Risk group (High, moderate)? |  |
| Patient investigation and management |  |

**Results of LPA** : Rifampicin and INH resistance

On 27/10/2000, the MDR TB panel team of the TIC decided to start the patient on DR-TB treatment as per the current national protocol. The patient weighed 52kg and tested HIV negative on 20/10/2000 and CXR showed Right upper lobe infiltrates. He brought his wife, Tilaye Kebede, as treatment supporter who lives in the same address

|  |  |
| --- | --- |
| **Questions** | **Answers** |
| Outcome of treatment on UNIT TB register |  |
| Patient management |  |

Q12. ME, 51 years old lady, came to your health facility with referral paper from one of the district hospitals to continue TB treatment( regimen for the new) at your clinic due to change of patient address. Up on evaluation you have realized she is on the fifth month of TB treatment, she told you that dry cough re-appeared. She is also known to have type 2 diabetes mellitus and she is taking glibenclamide 5 to 10mg po per day for the past 10 years. You have also recognized that she has a four year old child at home who is in good health condition. The patient also told you her mother is as well a type 2 diabetic. The fifth month sputum smear of the patient turned out to be positive, her Weight: 59 kg. Her Height is 165cm.

|  |  |
| --- | --- |
| **Questions 1** | **Answers 1** |
| Is she Presumptive DR-TB case? Yes/No |  |
| Risk group (High, moderate)? |  |
| Patient investigation and management |  |

Part II: DST results FLD at 5th month

A result of Xpert MTB RIF test on 10/12/2001 shows rifampicin resistance.

|  |  |
| --- | --- |
| **Questions** | **Answers** |
| Outcome of treatment on UNIT TB register |  |
| Patient management |  |

Q13. Lidetu Yibeltal, A 55 year old male has been complaining of cough, night sweats and fatigue for three weeks. When interviewed, he says that he has not been sick for a long time but his 25 year old son who lived in the same house with him died of confirmed MDR-TB last year. The patient has no previous history of TB. He is also known to have HIV and is on ART (TDF, Lamivudine and EFV) for past 2 years. His Weight now is 54 kg. His Height is 170cm. His sputum smear is Negative. He has a few bilateral nodular infiltrates on chest X-ray.CD4 count 5 months ago was 360

|  |  |
| --- | --- |
| **Questions** | **Answers** |
| Presumptive DR TB(Y/N) |  |
| Risk Group?(High, Moderate) |  |
| Approaches to patient investigation and management? |  |

DST: results FLD 01/10/2000.

Results of Gene Xpert test showed:

MTB Detected, Rifampicin Resistant

Panel team decided to initiate DR-Tb treatment on 7/10/00.

|  |  |
| --- | --- |
| **Questions** | **Answers** |
| Outcome of treatment on UNIT TB register |  |
| Patient management |  |

Q14. ON TB/HIV CO-MANAGEMNT

|  |  |
| --- | --- |
| **Patient information** | **Management decisions** |
| I. A patient diagnosed with PTB tested HIV positive upon registering to TB treatment. Her CD4 count is 75. |  |
| II. A patient is in HIV Care and on TDF/3TC/NVP since 3 years, is in T- stage 2 and has a CD4 count of 450. He is diagnosed with Bacteriologic confirmed TB by Xpert today. The patient has no other stage 3 or 4 clinical conditions. |  |
| III. A patient is in HIV Care for one year, not on ART, has a CD4 count of 600 and is in clinical stage 3. No other stage 3 or 4 condition. Currently diagnosed with clinical PTB. |  |
| IV. A patient is diagnosed with lymph node TB and currently on New TB patient regimen since 6 weeks. He developed oral thrush and tested HIV positive and His CD4 count is 300. |  |

**Exercise on implementation of TB Infection control**

1. Matching: Match interventions in column one with appropriate actions or practices from column two (more than one answer may apply).

|  |  |
| --- | --- |
| Column one  \_\_\_\_\_\_\_\_\_\_Managerial Measures to decrease TB transmission  \_\_\_\_\_\_\_\_\_Administrative measures to reduce risk of TB transmission  \_\_\_\_\_\_\_\_ Mechanical ventilation  \_\_\_\_\_\_\_\_ Natural ventilation | Column two   1. Open window 2. Open door 3. Advocacy ,Communication & social mobilization about TB Infection control 4. Window fans 5. Move people suspected of having TB to front of line 6. Speed up diagnosis of TB 7. Training Health care providers on TB infection control 8. Build Waiting room outside without walls 9. Provide tissue paper for coughing patients 10. Renovating rooms |

1. Mark each statement as ‘True’ or ‘False’ and explain why
2. \_\_\_\_Coughing patients should be sent to the toilet to produce sputum samples
3. \_\_\_ A face mask (surgical type) worn by a coughing patient with TB can help Prevent TB transmission.
4. \_\_\_ A face mask (surgical type) worn by a health worker is a good way to protect him from TB infection.
5. \_\_\_Coughing patients should be sent outdoor to produce sputum sample.
6. \_\_\_ The risk of TB transmission is only in adult medical and TB clinics.

# 10. Recording and Reporting in TB & TB/HIV Activities

**TIME ALLOTTED:**

***Learning objectives***

At the end of this session participants will be able to:

* Introduce TB and TB/HIV forms
* Compile data to generate TB and TB/HIV reports
* Analyze and interpret key TBL and TB/HIV performance indicators for decision making

## 10.1 Introduction to Monitoring & Evaluation

**Monitoring** of a program or intervention involves the collection of routine data that measure progress toward achieving program objectives.

**Evaluation** is a systematic process limited in time of collecting, analyzing, and using information to assess the effectiveness, relevance, and impact of achieving your program’s goals. It provides feedback that helps to determine the consequences, outcomes, and results.

When you read that the TB case detection rate (CDR) of your region is 72%, have you ever wondered how this calculation was derived? Or when you hear that the TB mortality of Ethiopia declined from 64% to 18%? Do you wonder how this data is known?

These types of statistics and other similar information are obtained by installing proper monitoring and evaluation system.

Generally, M&E is the process by which data collection is designed, collected, analyzed, and presented in order to provide information to policy makers and others for use in program planning and resource management. In order to get these crucial information, the program needs to gather the necessary data using standardized recording and reporting tools.

## 10.2. Recording and reporting of TBL & TB/HIV control activities

TBL and TB/HIV prevention and control program has standardized registers to record patients’ information and to systematically monitor and evaluate progress of patients’ treatment response and their treatment outcome. In addition, standardized reporting tools are developed to collate the data and analyze key performance indicators and interpret the findings for decision making.

The registers and reporting formats of TB and TB/HIV collaborative activities are integrated within the National Health Management Information System (HMIS) of the FMOH.

The forms includes:-

|  |  |
| --- | --- |
| Formats | Units |
| TB Unit Register | Health facility |
| HMIS reporting format | Health facility |
| TB Treatment supporter card | Health facility/ Health post |
| Presumptive TB card | Health Post |

**Unit TB Register (left)**

Write work place of TB patient as” HF” for patient who is working in both public and private the health facility (Clinic, Health center or Hospitals) at the time of TB diagnosis including health care workers and supporting staffs.

Write “NHF” for TB patient working in other sectors including those working in RHB, Zonal and Woreda health offices.

Write the patient’s category as:

BC/PTB: for bacteriologically confirmed pulmonary TB cases

CD/PTB: for clinically diagnosed pulmonary TB cases

EP: for all Extrapulmonary TB cases

Write the name of month for each month of intensive treatment as follow: If treatment begins in Tikmt, write “Tik” on the first line of column 14. When the month is completed, and if the patient continues treatment, write the name of the next Month Hidar as “Hid” on the second line of column 14, etc, for as long as intensive phase treatment continues.

Write ‘HEWs’ if the patient was initially referred by HEWs.

Write ‘Self’ if the patient was initially visited health facility by him/herself.

Write ‘Other HF’ if the patient was initially referred for TB diagnosis/treatment from other health facilities

Tick (✓) each day when the patient receives DOTS treatment and Mark (X) for days not receiving DOTS treatment.

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| **MRN** | **Unit TB No.** | **Name of the patient** | **Sex (M/F)** | **Workplace (Health Facility; Non health Facility)** | **Name of contact person** | **Source of Initial referral ( HEWs, Self, other HF)** | **Xpert MTB/ RIF result** | **Smear result** | **Category N.R.F.L.T.O** | **Intensive phase** | | **Treatment started (DD/MM/YY)** | **Write the month** | **Intensive phase treatment monitoring chart** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|
| **Address of the patient  (Woreda, Kebele, Hno,Phone No.)** | **Age** | **Address contact person (Woreda, Kebele, Hno,Phone No. )** | **Lab. no.** | **Lab. no.** | **P/Pos, P/Neg or EP** | **Drug** | **Dose** | **Days:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Weight** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **10** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** | **25** | **26** | **27** | **28** | **29** | **30** |
| **(1)** | **(2)** | **(3)** | **(4)** | **(5)** | **(6)** | **(7)** | **(8)** | **(8)** | **(10)** | **(11)** | **(12)** | **(13)** | **(14)** | **(15)** | **(16)** | **(17)** | **(18)** | **(19)** | **(20)** | **(21)** | **(22)** | **(23)** | **(24)** | **(25)** | **(26)** | **(27)** | **(28)** | **(29)** | **(30)** | **(31)** | **(32)** | **(33)** | **(34)** | **(35)** | **(36)** | **(37)** | **(38)** | **(39)** | **(40)** | **(41)** | **(42)** | **(43)** | **(44)** |
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**Unit TB Register (Right)**

Upper space- Write the name of the health facility that the DR TB patient referred for treatment.

Middle space - Enter treatment started date using Ethiopian Calendar (DD/MM/YY)

Lower Space-Write a new unique patient identification number assigned by MDR TB treatment initiating center. The MDRTB unique number is assigned as:

**Region/Type of facility/facility code/five digit serial number with DR prefix.**

**For instance**, If a patient is started on SLD treatment at St peter hospital and is the 22nd patient to be put on SLD at the center.

His/her unique MDR number will be: 14/08/020/DR00022

Please write only the five digit number with DR prefix on the space provided as the facility type and code are already written at the top of each page

Upper space: Write total number of under 5 children who are Household and/ or close contacts (Number)

Middle space: Enter number of under 5 children Household and/ or close contacts screened for TB at HF at least once (Number)

Lower space: Enter number of under 5 children free from TB and put on IPT

Upper space: Write total number of Household and/ or close contacts (Number)

Middle space: Enter number of Household and/ or close contacts screened for TB at HF at least once (Number)

Lower space: Enter number of TB cases diagnosed among contact of index TB cases(Number)

Upper space

Enter Y=”**Yes**” if the patient is presumptive MDR-TB (suspect)

as per the national guideline

Enter N=”**No**” if the patient is NOT presumptive MDR-TB (suspect) as per the national guideline.

Lower space**: DST result**

Enter ’RR-TB’ if patient DST result is resistance to Rifampicin resistance only

Enter “MDR-TB’= if patient DST result of the patient is resistance to both Rifampicin and INH

Enter No RR/No MDR- if the DST result of the patient shows no resistance to INH and Rifampicin

Enter XDR= if the DST result of the patient show resistance to any fluoroquinolone and to at least one of three second-line injectable drugs (capreomycin, kanamycin and amikacin), in addition to multidrug resistance.

Mark(✓) under Health Post if individual patient received support for treatment adherence(all efforts and services provided including treatment observation, adherence counseling, pill counting and other activities to monitor both the quantity and timing of the medication taken by a patient) at health post by HEWs at least during continuation phase of the treatment.

Mark(✓) under Health facility If the treatment adherence support provided by the health care worker at health facility throughout the course of the treatment

Enter the days in the rows for the monthly column when the patient attended for monitoring

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| HIV test offered (√) | HIV test performed (√) | HIV test result (R *or* NR *or* I) | CPT started (DD/MM/YY) | Enrolled in HIV care (DD/MM/YY) | ART started (DD/MM/YY) | Presumptive MDR (Y/N) | If DR-TB Confirmed, linked to (Name of HF) | Total HH and/or Close Contacts (Number) | Total under 5 HH and/or Close Contacts | Sputum results, | | | Continuation phase | | Continuation phase treatment monitoring chart weekly attendance | | | | | | | | | | | | | | Write the date (DD/MM/YY) that treatment was stopped in appropriate column: | | | | | | | Treatment Adherence support provided at | | Remarks |
| Cured | Treatment Completed | Treatment Failure | Died | Lost to Follow Up | Not Evaluated | Moved to MDR-TB Register |
| lab.name, serial nr.& weight of the patient. | | |
|  |
| Unique ART No. | DST Result (RR/MDR, No RR/No MDR/XDR) | Date MDR TB started (DD/MM/YY) | Total contacts Screened for TB (Number) | Total under 5 contacts and/or Close contact Screened for TB | Months | | | Drug | Dose | Week of the Month | Month: | | | | | | | | | | | | | Health Facility | Health Post |
| Unique MDR TB ID | TB Diagnosed among Contacts (Number) | Total under 5 HH and/or Close contact free from TB and put on IPT | 2nd /3rd | 5th | 6th/ 8th |  |  | Ham | Neh | Pag | Mes | Tik | Hid | Tah | Tir | Yek | Meg | Mia | Gin | Sen |
| (45) | (46) | (47) | (48) | (49) | (50) | (51) | (52) | (53) | (54) | (55) | (56) | (57) | (59) | (60) | (60) | (61) | (62) | (63) | (64) | (65) | (66) | (67) | (68) | (69) | (70) | (71) | (72) | (73) | (74) | (75) | (76) | (77) | (78) | (79) | (80) | (81) | (82) | (83) |
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| **Exercises 1.** **Read the following exercise and fill out on the appropriate register** |

**I ‐ Patient’s Identification:**

**Name**: Girmay Yihun MRN – 2636

**Sex**: M **Age**: 27

**Occupation**: Farmer **Marital Status**: Married

**Weight**: 52 **Address**: Gelan, Gende Kore Kebele **House No.** New

**Tele**. 0909219800

Treatment Supporter – Adanech Gebru Tel 0909219801

**II- Medical History:**

He came with referral slip from Gelan health Post on Tir 4, 2007; he has cough for three weeks with associated symptom of fever, night sweating, loss of appetite, weight loss, and right side chest pain. He has been successfully treated for Extra pul TB two years before in Akaki health center. He lives with his wife( Adanech Gebru) and two children of two and six years old.

Since Girma was previously treated patient; GeneXpert was ordered to screen for Rifampicin resistance TB. Based on the lab report ( Sr No. 124) he was diagnosed as susceptible MTB in Tirunesh Beijing hospital; put on standard retreatment regimen on Tir 6, 2007 at Akaki health center. He was also offered HIV test and the result was negative.

TB focal person communicated the HEW to trace and conduct TB screening for the family members. After screening the HEWs referred the two children as the wife doesn’t have symptom of TB. The TB focal person evaluated the children and initiated IPT for two year old child.

After completing the intensive phase , follow up AFB test was done and turned negative, he gained 4 Kgm. Then after completing fourth month of treatment, Girma want to follow his treatment at newly opened HC called “Gelan” which is very near to his house.

The TB focal person of Akaki Health center wrote a transfer letter and He continued his treatment at Gelan health Center starting from Miazia 30, 2007.

Gelan HC wrote a feedback to Akaki HC about Girma’s treatment and the information says that Girma has finished treatment and follow up sputum at end of 8th months was negative.

Fill the above patient information on TB unit register.

(Divide the classroom in two groups and group one will fill for Akaki and group two for Gelan Health center.)

## 10.3 Reporting of TB & TB/HIV control and activities

TB and TB/HIV service data is collected both from public and private health facilities on quarterly basis using the standard HMIS reporting tools of the country. In addition, all TB reporting facilities are responsible to report in the same reporting period cases identified DR-TB case through their facility.

Note that all report on DR TB enrollment, six month interim result and final outcome should only be reported from DRTB treatment initiating hospitals (TICs). But Health centers serving as Treatment follow up centers (TFC) may generate patient status report to be submitted to their TIC using program reporting tool.

**Basic concepts while compiling service data and generate quarterly reports:**

**Cohort:** is a group of TB cases registered on unit TB register to receive treatment in specific reporting period.

**Reporting periods in TBL and TB/HIV**: one quarter of the reporting year has three months; it follows HMIS reporting calendar as presented below.

**Reporting timeline:** Within one week of the end of the reporting period from Health facility.

**Data Source:** Unit TB Register

**Preparation for compiling service data for quarterly TB and TB/HIV reports:**

* Identify and mark the beginning and end date of the Quarter to count cohort of patients to be reported in the reporting period
* Check for the completeness and gross errors on individual patients’ information
  + Check for completeness of follow up smear results for bacteriologic confirmed pulmonary TB cases
  + Assign final treatment outcome of TB cases registered in the same reporting period of pervious year
  + Communicate and collect patient information and outcome for transferred out patients from the receiving health facility and update accordingly
  + Draw table based on HMIS reporting form and tally
  + Count the tally and record on standard HMIS reporting form
  + Submit to the HMIS unit of Health facility
  + Archive the copy of the quarter report in TB clinic
  + Analyze and Display plan and performance of the service data in TB clinic
* For compiling case notification report, use cohort cases registered during this reporting period.
* For compiling final treatment out, use cohort cases registered during the same quarter of the previous year.

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| **Exercises 2.** **Read the following exercises and compile TB and TB/HIV reports** |

Use the filled UNIT TB Register to answer the following questions below:

* + - 1. List at least five recording errors?
  1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
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  4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
     + 1. Define final treatment outcome for each patient registered to receive treatment (use the filled register)
       2. In quarter II of the year:
  6. . How many new all forms of TB cases are registered \_\_\_\_\_\_\_
  7. . How many New Bacteriologically confirmed TB cases\_\_\_\_\_\_\_\_\_\_
  8. . How many New clinically diagnosed TB cases\_\_\_\_\_\_\_\_\_\_
  9. . How many retreatment TB cases \_\_\_\_\_\_\_
  10. . How many HIV Co infected TB cases\_\_\_\_\_\_\_\_\_\_
  11. . How many DR –TB cases (RR or MDR)\_\_\_\_\_\_
  12. How many TB cases were initially referred by HEWs\_\_\_\_\_\_\_
      + 1. Generate final treatment outcome report of the patients in second quarter using the registered case (insert the table #)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Total TB patients in the cohort | # cured | # Completed | # Died | # Lost to  follow up | Treatment failure | Not evaluated | Moved to MDR TB register |
|  |  |  |  |  |  |  |  |

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## 10.4 Analyze Indicators and Utilize the Information for Decision Making

**An indicator** is a specific measure of program performance that is tracked over time by the monitoring system. TBL and TB/HIV indicators should be compiled and analyzed at all levels to evaluate the program performance (*see Annex for the detail description of the TBL and TB/HIV indicators*).

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| **Exercises 3.** **Read the following exercises and Analyze and interpret indicators** |

1. Look at data shown in the table for Woreda xx and answer the question?

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Type of TB | Total number of patients registered during the quarter | Treatment outcomes | | | | | | Remark |
| Cured | Treatment completed | Died | Rx Failure | LTFU | Transfer out |
| Bacteriologically confirmed pul. Cases | 10 | 8 | 1 | 1 | 0 | 0 | 0 |  |
| Clinically diagnosed pul TB cases | 50 | 0 | 41 | 1 | 1 | 3 | 4 |  |
| EPTB | 40 | 0 | 35 | 1 | 1 | 2 | 1 |  |

1. Calculate cure rate for the woreda and interpret the performance: \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Calculate treatment success rate of bacteriologically confirmed pul. Cases for the woreda and interpret the performance: \_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Calculate treatment success rate of Clinically diagnosed TB cases for the woreda and interpret the performance: : \_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Calculate the lost to follow up rate and interpret the performance: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. During the previous quarter, of 50 TB cases who began treatment at Adama health Centre, 20 were tested for HIV before or during TB treatment. seven of the TB patients were HIV-positive and initiated ART. However, two of them have not started CPT.

Calculate the following indicators:

* Proportion of TB patients that were tested for HIV: \_\_\_\_\_\_\_\_\_
* Proportion of HIV-tested TB patients that are HIV-positive:\_\_\_\_\_\_\_\_\_\_\_
* Proportion of HIV-positive TB patients on CPT: \_\_\_\_\_\_\_\_\_\_\_\_

Interpret the performance of the clinic on TB/HIV: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# 11 LEPROSY

***Time Alloted:***

***Learning objectives***

At the end of this session participants will be able to:

* Discuss on the burden and National Leprosy control strategy
* identify and evaluate patient to diagnose leprosy
* Discuss Multidrug therapy for leprosy
* Manage patient with complication of leprosy
* Explain the principles of Prevention of disability

## 11.1 Epidemiology of Leprosy in Ethiopia

Globally, 213,899 new cases of leprosy were detected during 2014 and the registered prevalence at the beginning of 2015 was 175,554. Thirteen countries globally (five in Africa including Ethiopia) accounted for 94% of all new cases detected during 2014. The proportion of cases with MB leprosy among new cases in the Africa region ranges from 47.2% to 94.7%. The proportion of children among new cases of leprosy in the African region ranges from 1.4% to 34.5%. Similarly the proportion of disability grade 2 ranged from 0% to 28%. In the region the proportion of females among newly detected cases of leprosy was in the range of 16.2% to 62% during 2014.

In Ethiopia, a total of 3758 (74% MB) new leprosy cases were registered in 2015 with 10.2% Grade II disability rate at time of diagnosis. The proportion of children among new cases was 12.8%. During the same period, the treatment completion rate was 94% for Pauci-bacillary and 93% for Multi-bacillary leprosy.

## 11.2 National Leprosy Control Strategy

The main principle of leprosy control is based on timely detection of new cases and provision of effective chemotherapy with multi drug therapy. The emphasis will remain on providing patient care that is equitably distributed, affordable and easily accessible.

The Global Leprosy control strategy for 2020 aims to meet:

* Zero grade II disability in children due to leprosy
* Reduce new leprosy cases with grade II disability to less than one case per million population.

The main elements of the strategy are:

* Ensure political commitment and adequate resources for leprosy control
* Contribute to Universal health coverage with a special focus on underserved populations, women and children
* Promote early case detection with focus on contact management and active case finding in high endemic areas
* Strengthen patient and community awareness on leprosy
* Sustain leprosy knowledge among the health workforce
* Promote societal inclusion through addressing all forms of discrimination and stigma
* Develop tools and procedures that are home/community-based, integrated and locally appropriate for the prevention of disabilities/impairments and for the provision of rehabilitation services
* Promote coalition building among persons affected by leprosy
* Strengthen surveillance & information systems for program monitoring and evaluation
* Conduct basic and operational research and its use for evidence based policy making
* Promote partnerships with non-state actors including private sector for further reduction of leprosy burden at national, regional, district and community levels.

## 11.3 Basics of Leprosy

Leprosy is a chronic infectious disease caused by *Mycobacterium leprae*, an acid-fast bacillus. The disease mainly affects skin, peripheral nerves, mucosa of the upper respiratory tract and the eyes. It affects persons in all age groups and both sexes. The age group mainly affected is between 15 and 45 years. Factors related to poverty increase the risk of developing the disease.

**Mode of Transmission:** Leprosy is transmitted through air‑borne spread of droplets from the nasal mucosa and mouth, containing the bacilli expelled by untreated leprosy patients and inhaled by healthy persons. Persons living in the same household and in close contact with an infectious person have the greatest risk to get infected and develop the disease.

**Natural Evolution:** Under normal circumstances, only a very small proportion (less than 5%) of all individuals who are **infected** by the leprosy bacilli will develop the **disease** during their lifetime. In the majority of people, the immunological defence kills the bacilli. The disease slowly progressed with an average incubation period of 3 to 5 years, but it may vary from 6 months to more than 20 years. If not treated, leprosy can cause severe disability, mainly as a result of peripheral nerve damage.

## 11.4 Leprosy Case Finding Strategies

The main objectives of Leprosy case finding are:

* To identify infectious leprosy cases
* To initiate early treatment and to interrupt the chain of transmission.
* To prevent the occurrence of irreversible nerve damage and disability

Two types of case finding strategies are recommended based on the burden of leprosy:

**Voluntary Self-reporting of leprosy**: is recommended for low leprosy burden woreda, as identified by leprosy mapping conducted in 2015. It aims detect active leprosy cases from patients who voluntarily visit health facilities. Healthcare personnel should identify persons with cardinal symptoms of leprosy.

**Active case finding:** is recommended for high leprosy burden woreda, as identified by leprosy mapping conducted in 2015. It aims to intensify early leprosy case detection with the help of health extension workers and health professionals, and to strengthen contact investigation and management for household contacts.

**Contact Investigation and management for leprosy**: Household contacts and other close contacts are at an increased risk of acquiring Leprosy infection and progression to disease. Hence, promotion of contact tracing may contribute to early identification of leprosy cases, thus decreasing its severity and reducing transmission to others.

Trace for leprosy contact and investigate for Active Leprosy diseases:

* Upon diagnosing a new Leprosy case, initiate contact tracing for household members and close contacts
* Arrange with health extension workers to examine all household and close contacts
* Evaluate all leprosy contacts for symptoms and signs of leprosy
* Identify those with signs and symptoms compatible with leprosy
* Diagnose leprosy in contacts with the cardinal sign of leprosy and initiate MDT.
* Educate asymptomatic contacts about the purpose of a contact screening, early signs of the disease, risk of transmission and importance of conducting early medical evaluation and treatment.
* Advice contacts to return if they notice suspected skin lesions, motor or sensory changes
* Record the details of the contacts (full name, age, sex, address…) on a register
* Repeat leprosy screening for contacts at least every year for five consecutive years.

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| ***NB: Contact evaluation for leprosy should be conducted at time of diagnosis, before release from treatment and annually for subsequent five years.*** |

Role of health extension workers and health development army at the Community level:

* HEWs and health development army (HDA) should create awareness about cardinal signs and symptoms of leprosy and its consequences if untreated at early stage
* Identify suspected leprosy cases during household visits and at health post level
* Arrangement of referral to the catchment health center for appropriate evaluation
* Facilitate contact tracing for household contacts at least at time of diagnosis of a leprosy case and before release from treatment
* Provide patient support while receiving MDT
* Retrieve patients who happens to disappear without the knowledge of the managing health worker

## 11.5 Identification and evaluation of patient to diagnose Leprosy

### 11.5. 1 Identification of a Leprosy Suspect

Leprosy should be considered in an individual who presents with:

* Pale or reddish patches (skin patch with discoloration) on the skin
* Painless swelling or lumps in the face and earlobes
* Loss of or decreased sensation on the skin
* Numbness or tingling of the hands and/or the feet
* Weakness of eyelids, hands or feet
* Painful and/or tender nerves
* Burning sensation in the skin, or
* Painless wounds or burns on the hands or feet.

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| Pale or reddish discoloration of the skin is the most common & early symptom of Leprosy. |

11.5.2 Patient evaluation to diagnose Leprosy

Over 95% of leprosy cases can be diagnosed on clinical grounds. Laboratory investigation is indicated only in doubtful cases for confirmation and for patient classification.

Evaluate your patient for leprosy as follows:

* 1. ***Take detail Clinical History***

Ask:

* **General information**: socio-demographic information of the patient.
* **Characterize the presentations**:
* History of onset, duration of symptoms,
* Presence of painless wounds/burns
* Ask for burning sensation; any noticed weakness upon picking or holding objects or closing eyelids; unusual sensation in hands and feet (numbness, tingling)
* presence of itching sensation
* History of previous leprosy treatment.
* History of prolonged household or other close contact history with leprosy patient
  1. ***Conduct Physical E*xamination**

Examine the patient thoroughly with focus to the skin, nerves and eyes as follow:

**Examination of the Skin:** Examination for skin lesion must always be carried out with adequate light (preferably natural light):

* Inform client about purpose of the examination
* Request the client to remove all garments
* Examine systematically from head to toes, including the front and back sides.
* Check for presence of skin patches or nodules
* If a skin lesion is identified, Check for sensation over the lesions

**Checking Skin sensation:** Any skin lesions should be checked for sensory loss using a “wisp of cotton wool” as follows:

* **Explain** the patient on the purpose of the test and what is expected from him.
* **Prepare** a wisp of cotton wool by rolling its end into a fine point.
* **Demonstrate patient** how to respond to the examination and practice the test first while the patient’s eyes opened by pressing the cotton wisp gently on the skin till it bends
* **Check for definite loss of sensation over the skin lesion** by repeating the same procedure with the patient’s eyes closed, check first on the normal skin and then on the skin patch
* **Document the finding** the patient response.

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| *Definite loss of sensation in the skin patch is indicative of leprosy.* |

**Examination of the Nerves:** Leprosy may affect most peripheral nerves including greater auricular, ulnar, median, radial cutaneous, peroneal and posterior tibial nerve (See below in the diagram). The ulnar and peroneal nerves are the ones that are most commonly enlarged and can be felt quite easily.

|  |  |
| --- | --- |
| **DO Nerve Palpation:**  Palpation of the nerves aims to check for cord enlargement and/or tenderness:   * Palpate the nerves starting from the head and going down to the feet. Compare the right and left sides. * When palpating a nerve, always use the pulp of two or three fingers to roll over the affected nerves. |  |

|  |
| --- |
| *A Definite Enlargement Of one Or more Peripheral Nerves is indicative of Leprosy.* |

C) Examination of Skin Smears

Bacteriological examination of skin smears:

* Is recommended only for doubtful cases to confirm the diagnosis and/ or classification of leprosy
* Collect two samples from different spots over one skin lesion, and fix the specimen on one slide to do AFB test
* One positive-smear result is confirms the diagnosis of leprosy
* Note that negative smear AFB result doesn’t rule out leprosy

If diagnosis of Leprosy remains doubtful, decide on next actions:

* Consider other skin disease and treat accordingly
* Consult an experienced health workers or a dermatologist, or
* Re-evaluate the patient after three- months.

### 11.5.3 Establishing diagnosis of Leprosy

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| --- |
| *The cardinal signs of leprosy are:*  *1. Definite loss of sensation in a pale (hypo-pigmented) or reddish skin lesion.*  *2. Thickened or enlarged peripheral nerve with or without tenderness.*  *3. The presence of acid-fast bacilli in a slit skin smear.* |
| *Criteria: Presence of one or more of the three cardinal signs is confirmatory to the diagnosis of Leprosy.* |

## 11.6 Case definition, classification and patient registration

The purpose defining terms, classify and patient registration groups is to:

* facilitate the patient registration, reporting and cohort outcome analysis
* Guide on the appropriate treatment regimen
* Predict the risk of developing complication

### 11.6.1 Case definition

***A case of leprosy*** is a person with one of the cardinal signs of leprosy requiring MDT.

### 11.6.2 Leprosy classification

Upon confirming the diagnosis of leprosy:

* Count the number of skin lesions, and
* check for presence of nerve involvement

Classify as:

|  |  |
| --- | --- |
| **Criteria** | **Leprosy classification** |
| * One to five leprosy skin lesions, or * Only one nerve trunk enlarged | **Paucibacillary (PB) Leprosy** |
| * Six or more skin lesions, or * Less than six skin lesions, which have a positive slit skin smear result, or * Enlargement of more than one nerve | **Multibacillary (MB) Leprosy** |

**Note:**

* Leprosy cases that are doubtful to be classified should be taken as a Multi-bacillary case of leprosy
* Patients with pure neural leprosy should also be classified and treated as a MB case.
* See Annex V for algorithm

### 11.6.1 Patient registration group

Leprosy patients who need treatment with MDT Should be registered as follows:

**New Cases**: A patient with MB or PB leprosy who have never received treatment before.

**Other Cases**: all other patients including a case with relapse, Return after default, Transfer-

in and other unclassified cases.

|  |  |  |
| --- | --- | --- |
| **Patient registration** | **Definition** | **Management** |
| **New** | A patient with MB or PB leprosy who has never had treatment for leprosy before | Treat according to the clinical assessment (and/or laboratory diagnosis). |
| **Relapse** | A patient declared “treatment completed” after a course of MDT, but who reports back to the HF and found to have active leprosy. | Treat according to the new clinical assessment (and/or laboratory diagnosis) independent of the previous category of treatment. |
| **Return after LTFU** | An MB or PB who returns for treatment after having missed more than 3 months’ doses of MDT (both cumulative and consecutive). | **Treat MB** according to the **new** clinical assessment (and/or laboratory diagnosis) independently from the previous treatment category. |
| **Transfer in** | A patient received from another HF to continue treatment. | Treat according to the **previous** classification assessed in the original health facility. |
| **Other** | Any leprosy patient requiring chemotherapy and who does not fit any of the above mentioned categories, including patients who relapse after treatment with dapsone mono-therapy in the past. | Treat according to the clinical assessment (and/or laboratory diagnosis). |

## 11.7 Examination of nerves, Eyes and Hands & feet

After diagnosis of leprosy is made, the health workers need to examine the peripheral nerves, eyes, hands and feet for loss function and disability.

### 11.7.1 Conducting Nerve Function Testing

The following nerve functions tests must be carried out:

* Voluntary Muscle Testing (VMT)
* Sensory Testing (ST)
* Autonomic nerve function test for dryness of palms and soles

**i) Voluntary Muscle Testing (VMT):** VMT is done to check Muscle strength of eye, hands and feet. The strength should be graded as Strong (**S**), Weak (**W**) or Paralyzed (**P**).

The muscle strength of eyes, hands and feet is tested as follows:

***Voluntary muscle testing (VMT) of the eyes: eye closure***

* Ask the patient to close his eyes lightly as in sleep.
* Observe whether or not the closure on both eyes is complete. Inability to fully close the eye is called lagophthalmos (paralysis “labeled as P” of the eyelid muscles).
* If there is lagophthalmos, measure lid gap in mm as shown in the diagram below

|  |  |
| --- | --- |
|  | **Lid Gap Measuring Procedures**   1. Explain the procedure to the patient. 2. Ask the patient to close his/her eyes lightly, as in sleep. 3. Measure and record any gap in mm as illustrated on the right side. 4. If closure is normal, record: “0 mm.” |

* If the patient is able to fully close his/her eyes, then **ask** the patient to close his eyes firmly, gently try to open the eyelids using the pulp of your thumbs to check for strength.
* Grade the eye muscle strength as weak (W) if the eyelids open easily; or strong (S) if it is difficult to open the lids.

***Voluntary Muscle testing (VMT) of the hands and feet:***

Check for range of movement on the fifth finger:

* ASK patient to abduct 5th finger (move finger away from the rest). If patient cannot move the finger, record as paralysis (P), an indication of ULNAR nerve damage
* If movement is normal, test for resistance by pressing gently over the proximal phalanx of the 5th finger using your index finger as shown in the diagram below, holding the other 3 fingers steady and ask the patient to maintain the position and RESIST the pressure of the examiner’s index finger as strongly as possible.
* Press gradually more firmly and judge whether resistance is strong (S) or weak (W).

COMPARE the right hand with the left hand always.

Check for range of movement of both thumbs:

* ASK the patient to first flex the thumb over the palm (touch the root of 5th finger) and later point the thumb to his/her nose while you hold the remaining 4 fingers. If patient cannot move the thumb, record as paralysis (P), an indication of MEDIAN nerve damage.
* If movement is normal, test for resistance by PRESSSING gently over the proximal phalanx of the thumb using your (examiner’) index finger as shown in the diagram below, holding the other 4 fingers steady and the ask the patient to maintain the position and RESIST the pressure of the examiner’s index finger as strongly as possible.
* Press gradually more firmly and judge whether resistance is strong (S) or weak (W).

COMPARE the right hand with the left hand always.

Check for the range of movement of the wrist:

* ASK the patient to extend the wrist. If patient cannot extend the wrist, record as paralysis (P), an indication of RADIAL nerve damage called WRIST DROP.
* If movement is normal, test for resistance by PRESSING gently over the dorsum of the hand as shown in the diagram below, whilst you (examiner) hold the wrist with your other hand. And ask the patient to maintain the position and resist the pressure as strongly as possible.
* Gradually, press more firmly and judge whether resistance is strong (S) or weak(W).

COMPARE the right hand with the left hand always.

Check the movement of the feet

* ASK patient to dorsi-flex his foot (move up his foot at the ankle). If patient cannot dorsi-flex the foot, record as paralysis (P), an indication of PERONEAL nerve damage called FOOT DROP.
* If movement is normal, test for resistance by PRESSING gently over the dorsum of the foot as shown in the diagram below, whilst you (examiner) hold the leg with your other hand. And ask the patient to maintain the position and resist the pressure as strongly as possible.
* Gradually, press more firmly and judge whether resistance is strong (S) or weak (W).

COMPARE the right foot with the left foot always.

|  |  |
| --- | --- |
| **a. Is movement full?** | **b. Is resistance full?** |
| **Little finger in**: test of ulnar nerve function  *Hold these 3*  *fingers straight* | *Patient tries to hold a card between ring- and little fingers. Assessor pulls card gently.* |
| **Straight Thumb up:** test of median nerve function    Patient moves thumb base fully *out and across* | Assessor resists at side of thumb  *(not at front or back)* |
| **Wrist up:** test of radial nerve function |  |
| **Foot up**: test of peroneal nerve function |  |

**ii) Sensory Testing (ST):** Sensory testing is done to check the presence of sensation in the eyes, hands and feet. The sensation of eyes, hands and feet is tested as follows:

***Sensation of the eyes (cornea):***

* ASK patient to blink his/her eyes.
* Observe the patient's spontaneous blinking while talking to him/her. If there is a blink, corneal sensation is normal. If there is no blink, the eye is at risk.

***Sensation of palms and soles:***

Sensation test on palms and soles should be done with a ball‑point pen. The tests are done on ten standard points.

**Hand and Foot Mapping, Including Sensation Test (ST)**

|  |  |
| --- | --- |
| 1. Explain the test to the patient. Rehearse it with the patient. Then test. The eyes of the patient should be covered. | 1. Compare sensation of the little finger with that of the thumb and sensation of one hand with the other to see if there is difference. Compare findings with those shown on any earlier records. |
| 1. Support the patient’s hand or foot so that fingers/toes are well supported to prevent joint movement during the test. | 1. Record:   ( **√ )** If the patient feels,  If not, (­ **X** ) |
|  | 1. Mark any wounds ( ), open crack ( ) clawing of digits (c) and bone loss or absorption (­ **X** ) on the Patient Record Card or VMT/ST Form. |
| 1. Dent the patient’s skin by 1-2 mm at dot sites using a ball-point pen -- asking the patient to point to the exact site whenever he/she feels. The stimuli should be irregular in timing and placing. |  |
| 1. Look for any CHANGE. Make sure that the change is real and not due to inaccuracies in testing. |  |

### 11.7.2 Examination of the Eye

***Check for Visual Acuity:***

Vision of both eyes of the patient should be tested according to the demonstration below and should be recorded on the Patient Record Card.

|  |  |
| --- | --- |
| * Test vision with good light falling on the assessor. * Ask the patient to cover one eye, then count the number of fingers that the assessor holds up. * Test at 6 meters. If the patient cannot see at 6 meters, re-test at 3 meters. * Record the findings |  |

***Look for other eye problems/complications****:*

Look for injury of cornea and loss of vision due to incomplete blink and/or eye closure.

### 11.7.3 Examination of Hands and Feet

Examine the hands and feet with focus to the following evidences of complications as a result of peripheral nerve damage:

Look for:

* + Skin cracks on palms and soles with sensation loss
  + Wounds on palms and soles with sensation loss
  + Clawed fingers and toes
  + Foot drop
  + Wrist drop
  + Shortening and scarring in fingers and toes with sensation loss

## 11.8 Disability Grading in Leprosy

**Disability** is a broad term covering any impairment, activity limitation or participation restriction affecting a person.

Every new case of leprosy must be assigned a “Disability Grade”, which depicts the condition of the patient at diagnosis. The grade is on a scale of 0, 1 or 2. Each eye, each hand and each foot is given its own grade, so the patient actually has six grades, but the highest grade given is used as the Disability Grade for that patient.

|  |  |
| --- | --- |
| **Disabilities grading criteria for Leprosy** | |
| **Eyes** | **Description** |
| **Grade 0** | No disability found. This means there is no eye problem due to leprosy and no loss of vision. |
| **Grade 1** | The eyes are not given a grade of 1. |
| **Grade 2** | Visible damage or disability is noted. This includes the inability to close the eye fully (lagophthalmos) or obvious redness of the eye (typically caused by a corneal ulcer or uveitis). Visual impairment or blindness (vision less than 6/60 or inability to count fingers at 6 meters) due to leprosy should be graded as grade 2. |
| **Hands and Feet** | **Description** |
| **Grade 0** | No disability found. This means there is no loss of sensation or visible deformity or damage. |
| **Grade 1** | There is loss of sensation in the palm of the hand or sole of the foot, but no visible deformity or damage. |
| **Grade 2** | There is visible damage or disability due to leprosy. This includes weakness or paralysis of muscles on the hands and feet, wounds and ulcers as well as visible deformities such as a foot drop or a claw hand or absorption of fingers. |
| ***Interpretation:***  *The highest grade in one of the six sites (eyes, hands or feet) is the overall disability grade for that patient.* | |

**Table showing Differential diagnosis of Leprosy:**

|  |  |
| --- | --- |
| **Disease** | **Clinical Features** |
| **Tinea versicolor** | The lesions are hypo-pigmented, but without loss of sensation. They often itch. When an anti‑fungal ointment is applied they usually clear up within 6 weeks. |
| **Ringworm (Tinea corporis)** | The lesions are well-defined areas of hypo-pigmentation with white scales and without loss of sensation. They usually clear up within 6 weeks when an anti‑fungal ointment is applied. |
| **Vitiligo** | There are usually completely white areas of skin. The skin texture is normal and there is no loss of sensation |
| **Birthmarks** | Lightly or deeply pigmented areas of different sizes, which are present since birth or shortly afterwards without undergoing any change. |
| **Psoriasis** | Raised areas with white fatty scales, which itch and bleed easily on scratching (pin point bleeding). There is no loss of sensation |
| **Molluscum contagiosum** | Nodular lesions with a depression in the centre. Firm squeezing results in the appearance of a creamy substance. |
| **Onchocerciasis** | Hypopigmented macules are often one of the manifestations. There is itching and no loss of sensation. In a later stage there are mottled lesions, in particular on the loins and shins. |
| **Cutaneous leishmaniasis** | Small erythematous papules appearing after bite of sand fly and later changing to dry crusted lesions. |
| **Post kala‑azar cutaneous leishmaniasis** | Nodular, papular lesions and diffuse infiltrates, usually located on the face. These may occur one or more years after treatment of visceral leishmaniasis. Skin smears are negative for AFB. |
| **Syphilis** | Secondary syphilis presents with a considerable variety of lesions, e.g. papular and nodular lesions. Skin smears are negative for AFB. Positive serology for treponematosis. |
| **Pityriasis alba** | The lesions are often restricted to the face making differentiation from leprosy difficult since loss of sensation in the face is not easy to demonstrate. The lesions subside spontaneously, leaving hypopigmented macules. Besides, new lesions may appear at other sites. |
| **Nutritional deficiencies** | Usually over the cheek, single or multiple, ill‑defined, hypopigmented patches with other features of vitamin deficiencies such as glossitis and stomatitis. The patches will clear after the administration of vitamins. |

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| Review Exercise on Day IV: |

1. One is not diagnostic of leprosy.
2. skin lesion with definite loss of sensation
3. Thickened or enlarged peripheral nerve.
4. Skin nodule over the trunk
5. The presence of acid-fast bacilli in a slit skin smear.
6. Choose the examinations needed to determine the disability grading of a leprosy patient.
7. Visual acuity
8. Strength testing of eye closure, little finger out, thumb up, wrist up and foot up
9. Sensory testing of palms and soles
10. Mapping of wounds and secondary impairments in the hands and feet
11. All

3. A 14 year old girl was brought to a hospital because her parents noticed discoloration of the skin on her back of unknown duration. The skin lesions are not itchy. She has history of close contact with a known leprosy patient. When the health worker examined her, he found 6 hypo pigmented skin lesions which are flat. On sensory examination, there is definite loss of sensation on the patches. There is no abnormality detected on examination of the peripheral nerves.

1. What is your diagnosis and why?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. How do you treat this patient( the regimen and duration of treatment? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. An 18 year old boy came to a health facility complaining of numbness, tingling and burning sensation on his hands of 4 weeks duration. The health worker examined him and found enlarged ulnar and peroneal nerves. He has loss of sensation on the right palm.

1. What is your diagnosis and why?

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1. How do you treat this patient?

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1. What do you do on monthly follow visit of this patient?

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1. Classify your patient as MB and PB and assign registration group:

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| --- | --- | --- |
| **Case** | **Classification**  ( PB or MB) | **Case definition** |
| Mohammed comes to your health centre with a single anaesthetic skin patch. There is no nerve involvement. He reports the skin patch has been present for one year and that he was treated in another health centre with an ointment and some tablets. He cannot remember the name of the drugs he took. |  |  |
| Having completed treatment for PB leprosy, Almaz comes back with new complaints and nodules. A skin smear shows acid-fast bacilli. |  |  |
| Bekele was diagnosed and began treatment for MB leprosy in March. Three months later (in June), because his skin was becoming darker, he stopped taking treatment. Now he has returned to your facility in November complaining of numbness in his feet. He still has more than 10 patches on his trunk and legs. |  |  |

1. Incorrect about timing to perform nerve function test (VMT and ST) for a leprosy patient?
2. At time of diagnosis of leprosy
3. At any time if the patient complains loss of sensation and/or change in muscle strength
4. Routinely every month while the patient is on MDT.
5. Just before release from treatment.
6. Not important for MB patient
7. Grade your leprosy patient for Disability:

|  |  |
| --- | --- |
| **Description** | **Grade** |
| Patient has no any eye problem due to leprosy and no loss of vision. |  |
| Patient has loss of sensation over the sole of the foot with visible foot drop |  |
| The patient fails to close the eye fully (lagophthalmos) |  |
| Patient has failed to count fingers at 6 meters |  |
| Patient has loss of sensation in the palm of the hand, but no visible deformity. |  |
| Patient with evidence of absorption of fingers. |  |

## 11.9 Treatment of Leprosy

The objective of the treatment is to:

* Cure leprosy by rapidly eliminating the bacilli;
* Prevent the emergence of drug resistance;
* Prevent relapse; and
* Prevent disability.

**Multi-drug Therapy (MDT)** is a combination of drugs that is very safe and effective in treating leprosy and preventing the emergence of drug resistance.

* Patients are considered no longer infectious after taking the first dose of MDT.
* Virtually no relapses or recurrences of leprosy should occur after completion of MDT
* MDT is provided free of charge
* Never treat a case of leprosy with a single drug
* All drugs are all taken by mouth.
* The MDT are supplied in special blister packs for both MB and PB cases(see below)
* Each blister pack contains supplies for 4 weeks (28 days).
* Pauci-bacillary (PB) MDT blister pack contains Rifampicin and Dapsone
* Multi-bacillary (MB) blister pack contains Rifampicin, Clofazimine and Dapsone.

|  |  |
| --- | --- |
| **Drugs Used in MDT:** | **Formulations** |
| Rifampicin(R): | supplied as 150mg and 300mg tables to be administered once in a month. |
| Clofazimine(C): | supplied as 50mg and 100mg tablets to be administered orally. |
| Dapsone( DDS): | supplied as 50mg and 100mg tables to be administered daily. |

**MDT Regimen**

There are two types of MDT regimens. The Paucibacillary (PB)-MDT and Multibacillary (MB)-MDT:

***PB-MDT Regimen:*** This regimen consists of Rifampicin and Dapsone for a total duration of 6 months. It is to be prescribed to all cases classified as **Paucibacillary** (PB) Leprosy.

|  |  |  |  |
| --- | --- | --- | --- |
| Drugs | 0-5 yrs old | 6-14 yrs old | ≥ 15 yrs old |
| Rifampicin (4-weekly supervised) | 300 mg | 450 mg | 600 mg |
| Dapsone (daily, unsupervised) | 25 mg | 50 mg | 100 mg |

***MB-MDT regimen:*** This regimen consists of Rifampicin, Dapsone and Clofazimine to be taken for 12 months. It is to be prescribed to all cases classified **as** Multibacillary (MB) Leprosy.

|  |  |  |  |
| --- | --- | --- | --- |
| Drugs | 0-5 yrs old | 6-14 yrs old | ≥ 15 yrs old |
| Rifampicin  (4-weekly supervised) | 300 mg | 450 mg | 600 mg |
| Clofazimine  (4-weekly supervised) | 100 mg | 150 mg | 300 mg |
| Clofazimine  (unsupervised) | 50 mg twice a week | 50 mg every other day | 50 mg daily |
| Dapsone  (daily, unsupervised) | 25 mg | 50 mg | 100 mg |

**MDT drugs are provided in blister calendar packs, each containing drugs a four weeks (one month) supply** except for children below 10 years. The appropriate dose for children under 10 years of age can be decided on the basis of body weight. [Rifampicin: 10 mg per kilogram body weight (mg/kg); Clofazimine: 1 mg/kg daily and 6 mg/kg monthly; Dapsone: 2 mg/kg daily. The standard child blister pack may be broken up so that the appropriate dose is given to children under ten years of age. Clofazimine administration can be spaced out as required.

|  |  |
| --- | --- |
| **MDT blister packs for adults** | **MDT Blister Packs for Children** |
|  |  |

**Duration of MDT**

**PB:** is treated for6 months and the full course of treatment must be completed within 9 months after initiation of treatment.

**MB:** is treated for 12 months and the full course of treatment must be completed within 15 months after initiation of treatment.

**Administration of MDT:**

**PB:**

* The **monthly supervised dose** is Rifampicin & Dapsone (R & DDS) and is taken under DOT at the start of treatment (day 1) and every 28th day of the month for 6 consecutive months.
* The **daily self-administered dose** is Dapsone and is taken every day for 6 months. The full course of treatment must be completed within 9 months after initiation of treatment.

**MB:**

* The **monthly supervised dose** is with Rifampicin, Clofazimine & Dapsone (R, C & DDS) and is taken under DOT at the start of treatment (day 1) and then every 28th day of the month for 12 consecutive months.
* The **daily self-administered dose** is with Clofazimine and Dapsone and is taken every day for 12 months. The full course of treatment must be completed within 15 months.

At time of Pre-treatment preparation, the health worker should:

* Instruct the patient and make understand which drugs to be taken on daily basis and which drugs to be taken once a month.
* Arrange for scheduled visit to the health facility on every 28th days to directly administer the once-a-monthly observed dose.
* Inform the patient that leprosy drugs are to be taken orally and on an empty stomach or two hours after a meal.

## 11.10 Treatment in Special Conditions

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| --- | --- |
| **Pregnancy and Breast-feeding** | The standard MDT regimens are safe, both for the mother, the foetus and the neonate. It therefore can be administered during pregnancy and breast-feeding. |
| **Patients Co-infected with HIV** | Patients infected with HIV usually respond equally well to leprosy treatment as those without HIV infection. |
| **Patients Co-infected with TB** | Skip the monthly dose of the Rifampicin in the leprosy MDT regimen as Rifampicin is used over the course of TB treatment.  Once the TB treatment is completed, the patients should continue their MDT. |

## 11.11 Monitoring of patient during Treatment and post treatment Follow-up

During the monthly scheduled visit, the Health workers should do the followings:

* Administer the once-monthly supervised dose
* Provide regular adherence counselling and support
* Conduct nerve function tests (VMT and ST of the eyes, hands and feet) to detect nerve function damage early and to prevent the occurrence of disability.
* Advice on need for immediate reporting to health facility if they notice any problem/complication

This should be done regularly every month as long as the patient is on MDT and just before Release from Treatment (RFT)

REMEMBER to examine the eyes, hands and feet (including VMT-ST) at any time if the patient complains loss of sensation and/or change in muscle strength or problem with vision.

*Nerve function assessment at the end of treatment should be compared with that of the start of treatment. This includes comparing disability grades and VMT-ST status at the start and completion of treatment. The assessment should be scored as improved (I), same (S) or deteriorated (D) and be recorded in the patient record card and unit leprosy register.*

## 11.12 Referral of Leprosy Patients for Special Care

The patient conditions that require referral to an experienced physician or hospital include:

|  |  |
| --- | --- |
| * Severe reaction with no response to steroid treatment (: two weeks for PB patients and four weeks for MB patients, respectively) * Recurrent/chronic reaction * Red and/or painful eye * Diabetes mellitus | * Not improved with current treatment * Developed a reaction for the second time * Deep ulcer(s); and * Permanent paralysis that is fitting for reconstructive surgery. |

When a patient is referred, attach the copies of the sensation maps and strength records showing recent changes with the patient’s referral form.

## 11.13 Assigning final Treatment Outcome

**Multibacillary (MB) cases** should complete a total of 12 month doses of MDT within a maximum period of 15 months.

* After completion of the 12 month doses of MDT, the patient should be released from treatment (RFT) and recorded as ***treatment completed.***
* If a patient misses some treatment, the number of doses missed should be added on at the end to compensate for the missed doses. If the patient fails to complete their treatment within 15 months after initiation in total, should be recorded as ***“Lost to follow up”*** ( :previously called default).
* If a MB patient who is reported as LTFU (: previously called “defaulter”) reports back to the clinic, the patient should be registered in current open cohort as “*return after LTFU*” with a new registration number and MDT should be restarted. The previous number should be recorded in the column ‘remarks’ to indicate such patients have been included in two different cohorts.
* If a patient fails to complete the second course of MDT, she/he should not be given a third chance. Such patients must be recorded as LTFU immediately after they have missed the 4th month doses of MDT. They should be advised to report immediately if they notice recurring signs of active disease.
* Assign “dead”, If the patient dies for any cause during the course of MDT
* Assign “***not evaluated***” (: previously called “Transfer out”), if no information can be obtained for transferred out or any other patients for whom outcome information cannot be obtained.

**Pauci-bacillary (PB) cases** should complete 6 month doses of MDT within a maximum of 9 months period.

* After completion of the 6 month doses of MDT, the patient should be recorded as ***treatment completed*** and released from treatment (RFT)**.**
* Patients who have missed more than 3 month doses of MDT in total should be recorded as ***Lost to follow-up*** (:previously called defaulter).DONOT start MDT treatmentunless they have signs of active leprosy disease.
* Assign “dead”, If the patient dies for any cause during the course of MDT
* Assign “***not evaluated***” (: previously called “Transfer out”), if no information can be obtained for transferred out or any other patients for whom outcome information cannot be obtained.

## 11.14 Follow-up and Care after Release from Treatment (RFT)

Upon release from treatment, Advice the patient and their supporter on key messages:

* After completing MDT treatment, the risk of recurring is very unlikely
* The skin patches from leprosy will not disappear immediately.
* Loss of sensation, muscle weakness and other nerve damage may also persist.
* Leprosy reaction can still develop after RFT, hence advice to report immediately if the patient experience any unusual symptoms.
* Return to the health facility annually for 2 years after release from treatment to identify any late reaction or nerve function damage.
* Visit or report to the nearby health facility whenever they have complaints.
* If some disability is already present, teach the patient on how to practice self-care at home and Arrange for any follow-up or referral that may be necessary.

Care to leprosy patients after release from treatment include:

* Management of neuritis
* Provision of protective foot wears
* Provision of Vaseline ointment
* Basic medications such as analgesics, antibiotics, eye ointments have to be provided.

All these care activities should be recorded in the RFT register and some of them (like neuritis treatment and provision of protective foot wears) should be reported quarterly.

## 11.15 Leprosy Reactions, Complications and Their Management

Complications of leprosy may occur or may have already occurred at the time of treatment. These include:

* adverse drug reaction
* leprosy reaction
* complications of advanced disease, and
* Psychosocial problems.

### Management of Adverse Effects of drugs used in MDT

Drugs used in MDT are generally well tolerated with very minimal occurrence of serious adverse effects.

Educate the patient on common side effects:

* To anticipate some minor side effects that are of no harm and temporary
* To report to the HCW if they notice any unusal feelings or sickness

Management approach to adverse drug reaction:

* If the patient develops minor adverse effect => Conservative management
* If the patient develops major adverse effect => Refer to higher center for appropriate management

Table 18: Adverse effects of MDT drugs

|  |  |  |  |
| --- | --- | --- | --- |
| **Side Effects** | | **Responsible Drug (s)** | **Action** |
| **Minor** | Itching and skin rash | Rifampicin | Reassurance |
| Loss of appetite, nausea and abdominal pain | Rifampicin | Give drugs with food |
| Orange/red urine, faeces, saliva and sputum | Rifampicin | Reassurance (harmless and will disappear after cessation of MDT) |
| Brown discoloration of skin lesions and pigmentation of the conjunctiva | Clofazimine | Reassurance (harmless and will disappear after cessation of MDT) |
| Dryness of the skin and ichthiosis (thick, rough and scaly skin) | Clofazimine | Apply Vaseline ointment |
| Insomnia (sleeping difficulties and disturbances) | Dapsone | Give the drug in the morning |
| Anaemia | Dapsone | Give iron and folic acid |
| **Major** | Jaundice (Yellowish discoloration of the sclera, skin and mucous membranes) | Rifampicin  Dapsone | Stop treatment and refer |
| Skin rashes, severe itching and urticaria (pale red, raised itchy bumps) | Dapsone & Rifampicin | Stop treatment and refer |

### Leprosy Reactions

Leprosy reaction is an immunological response to the bacilli, presenting as acute inflammatory episodes.

* It is the sudden appearance of symptoms and signs of inflammation on the skin, eyes and peripheral nerves.
* Clinically manifest with acute onset of redness, swelling and sometimes tenderness of the existing skin lesions or with appearance of even new skin lesions. There may be swelling, pain and tenderness of nerves, often accompanied by loss of function.
* It can occur before, during and after release of the patient from treatment.
* It often results in the long-term problems related to leprosy (deformity and disability) by damaging the nerve damage.
* Therefore, early detection and adequate management of reactions is very important.

**Types and recommended management of leprosy reactions:**

1. Type 1 reaction: also called Reversal Reaction
2. Type 2 reaction: also called Erythema Nodosum Leprosum (ENL)

**i. Type I Reaction**

Reversal reaction occurs both in PB & MB patients. Consider Type I reaction in patients with any of the following manifestations:

* Pain over the lesion
* The lesion becomes more red, warm, swollen and tender
* Oedema of the face, hands and feet
* Deterioration in the nerve function

**Reversal reaction could be a mild or severe form of reaction:**

**Mild reaction** is one that appears only on the skin (as long as it does not occur over a major nerve or in the face). It may manifest with mild fever and slight swelling (oedema) of the limbs. Patient management requires rest and analgesics.

**Severe reactions** affect the nerves or eyes and require corticosteroids treatment.

**Management of Mild Reversal Reaction:**

**Diagnosis:** when a leprosy patient hasswelling and redness of the skin lesions appearing areas other than the face and overlying nerve trunk. There should not be any evidence of nerve involvement.

***TREAT***: patient should be treated with analgesics acetyl-salicylic acid (Aspirin 600 mg up to 6 times a day [adult dosage].

***Examine*** the patient after one week. If the signs persist, continue the same treatment for another week after ruling out any new nerve damage. If nerve damage observed, manage the patient as severe reaction.

**Management of Severe Reversal Reaction:**

**Diagnosis:** when a leprosy patient develops one or more of the following signs:

* Pain or tenderness on palpation in one or more nerves, with or without loss of nerve function.
* Change in voluntary muscle testing (including eye closure) of less than six months duration. The change can be from strong to weak, weak to paralysis, or strong to paralysis.
* Change in Sensory test of less than six months duration. A change is considered to be significant when any hand or foot has increased loss of sensation at two or more points.
* A raised, red swollen patch overlying a nerve trunk or around an eye.
* Red, raised and ulcerating skin lesions.
* Edema of hands or feet.
* A mild reaction persisting for a period longer than 6 weeks.

***TREAT:***

* **Assess if the patient requires** referral to hospital.
* **Rest the affected limb** if there is evidence of nerve involvement
* **Administer prednisolone** as seen the guide for recommended dosing.

Follow patients on prednisolone treatment (for reaction) every 2 weeks.

* Assess the patient condition and do VMT and ST at each visit.
* Refer any patient in whom nerve function deteriorates during the standard course or those not showing adequate improvement after 4 weeks of prednisolone.
* Refer a patient who has responded positively to a previous full course of prednisolone, but the reaction re-occurs or the nerve function deteriorates.

ii. Management of Type II Reaction (also called Erythema Nodosum Leprosum: ENL)

ENL is a type II severe form reaction. It occurs in MB patients only. It usually appears quickly and may disappear within 1-2 weeks. Erythematous (red) and tender (painful) sub-cutaneous nodules are more commonly seen on the face and/or the external surface of the limbs.

Diagnosis: Suspect/confirm Type II reaction if a patient has one or more of the following:

* Appearance of Erythematous sub-cutaneous nodular lesions with ulceration
* Tenderness on palpation or spontaneous pain in (a) nerve trunk(s)
* Loss of muscle strength and/or loss of sensation in eyes, hands or feet for < 6 months
* Painful eyes, with redness around the limbus cornea, increased lacrimation, fixed narrowing (constriction) of the pupil and diminishing vision (irido‑cyclitis)
* Painful testicular swelling (orchitis)
* Painful swollen fingers (dactylitis)
* General condition: fever and malaise

**Management**: patients with ENL must be managed at higher level preferably at leprosy specialized hospital with the help of senior expert physician. Hence immediate referral has to arranged if diagnosed at peripheral health facility.

|  |  |
| --- | --- |
| **Criteria for referral to a hospital during reaction:** | |
| * ENL reaction * Deep ulcer(s) * Red and/or painful eye * Pregnancy * Younger than 12 years of age * Severe peptic ulcer disease | * Diabetes * General illness with fever * Patient who improved during previous courses, but develops a reaction for 3rd time * Severe depression or psychosis * Suspected relapse |

For the Management of Severe Reactions in Hospitals**:** *see the national TBL and TB/HIV guideline*

**Relapse in Leprosy:** Relapse is defined as the re-occurrence of the disease at any time after the completion of a full course of treatment with MDT.

* If a full course of treatment has been administered properly, relapse is generally rare.
* Most relapses occur long after the treatment was given, sometimes more than 10 years later.
* Relapse cases can be treated effectively with the same MDT regimen as there is minimal risk of acquired drug resistance in leprosy.

Table 20: Table showing differentiation between relapse and reactions

|  |  |  |
| --- | --- | --- |
| Criteria | Relapse | Reaction |
| Development of signs | Slow | Sudden |
| Duration after treatment completion | > 3 years | < 3 years |
| Site | New patches | Over old patches |
| Tenderness/ pain | No (unless also in reaction) | Nerves usually, skin sometimes |
| Damage | No (unless also in reaction) | Sudden and rapid |
| General condition | Not affected (unless also in reaction) | Often fever, joint pain etc. |
| “therapeutic trial” using steroids | No clinical improvement | Rapid clinical improvement |

**MB relapses** should be investigated by using skin smears, histopathology and, where possible, for drug sensitivity using recently standardized molecular tests. Hence, such cases should be referred to higher level immediately.

**Management approach to patient with relapse:**

**At peripheral level:** Suspected relapses should be referred for further investigation and management decision to a referral center.

**At Referral level:** Suspected PB relapse: PB relapse is diagnosed by the appearance of a definite new skin lesion and/or a positive skin smear. However, the diagnosis of a PB relapse can never be absolutely certain. A skin smear should be carried out, if at all possible, to ensure that an MB case is not being misclassified as PB. The evidence for either a relapse or a reaction must be weighed and a decision made. A case PB relapse is treated with six-month course of PB-MDT.

MB relapse is diagnosed by the appearance of definite new skin lesions and/or an increase in the bacterial index (BI) of two or more units at any single site compared to BI taken from the same site at the previous examination. Care should be taken not miss patients suffering from leprosy reactions. MB relapses are generally treated with 12 months’ of MB-MDT.

* DO careful examination of the skin and asses the nerve function in order to identify any signs of a recent reaction.
* Arrange for a skin smear test to be done; an MB relapse is associated with an increase in the bacillary load. Obviously, if no previous smear has been done, it is impossible to identify an increase. In this case, the presence of solid staining bacilli in the smear provides support to the diagnosis of a relapse.
* If the diagnosis id uncertain after these investigations:
* A trial of steroids may be considered and if it is a reaction, clinical signs would begin to settle in 10-14 days while remain unchanged in cases of relapse.

### 

### Complications in Leprosy

Advanced disease of leprosy may results in eye problems leading to blindness because of damage to the cornea, or due to damage to the internal structures of the eye. The health worker must refer to an eye specialist any patient who reports decreased vision or has a red or painful eye.

Patients may already have sunken nose, loss of eyebrows and the so-called ‘leonine’ face, which used to be characteristics of untreated MB leprosy; these are cosmetic problems and visible disfigurements that lead to severe stigma and discrimination. Plastic surgery is needed to correct these lesions.

Patients with suspected complication should be referred to the nearest hospital for appropriate management.

## 11.16 Prevention of Disability (POD) in Leprosy

Most disability and deformity result directly or indirectly from loss of function of peripheral nerves supplying the eyes, hands and/or feet.

Disability and deformity can be prevented by timely detection and prompt treatment of neuritis. Poor treatment of leprosy can cause permanent disability and deformity, which aggravates hopelessness, and stigma and fear against those affected.

The following procedures best prevent disability:

* Early diagnosis of leprosy and prompt treatment.
* Recognise nerve function impairment at the time of diagnosis and start treatment with steroids for recent development (less than 6 months).
* Recognise and promptly treat new signs and symptoms of leprosy reactions with nerve involvement during treatment.
* Educate patients to recognise early signs of nerve function impairment and report this immediately.
* Train patients on self-care for patients at risk of developing disabilities.

**Interventions for Preventing Disability**

Patients as well as health workers should learn how to manage specific leprosy-related problems and disabilities. There are three categories under which useful interventions can be practiced to prevent (further) disability in leprosy. These are:

1. Home-based self-care
2. Simple interventions organized at the local clinic
3. Referral for complex interventions that require specialty care
4. **Home-based Self-care to Prevent Disability:**

Health workers should educate leprosy patients about self-care while they are on treatment and upon release from treatment to help them prevent disability.

The most effective self-care training is:

* Specific to the patient (targets disabilities they have/are at risk of)
* Practical (the patients actually do the self-care with the health worker)
* Achievable by the patient (promotes simple and affordable methods)
* Repeated (what has been taught is reviewed each time the patient visits to make sure that they have understood and are practicing it).
* Empowering(the patient believes “I can do it” in terms of self-care and prevention of further impairments)

**Self-care for the Eyes**

|  |  |  |
| --- | --- | --- |
| **If there is:** | **Motor weakness: can’t close eyes fully**  **(lagophthalmos)** | **Sensory impairment**  **(corneal anaesthesia)** |
| **The patient must be advised to:** | * **Exercise** (close the eyes strongly) if the muscles are weak, or * Do ‘passive blink’ often if eyelid muscles are completely paralyzed * **Cover** the eyes with a clean cloth when sleeping; | Do “Think-blink” **exercises** (consciously blink eyes frequently) |
| * **Protect** eyes during the day, e.g., use spectacles, hat, scarf; * **Inspect** the eyes daily using mirror and check for foreign bodies or redness; * **Clean** eyes daily with clean water; and * Apply lubricating eye drops or one drop of caster oil in the morning and evening. | |

**Self-care for the Hands**

When patients have problems on the hands, advise them to do the following at home:

* Inspect the hands daily for signs of injury.
* Soak the insensitive hand in water for about 30 minutes every day to maintain skin elasticity and prevent dryness of the skin.
* smoothen the callus, and then apply oil or petroleum jelly when the skin is still wet to prevent it from drying out.
* Use a clean cloth to cover any open wound.
* Avoid handling hot materials with bare hand.
* If there is weakness of the muscle in the hand, passive stretching and active exercises should be done to prevent muscle tightening and ensure some strengthening.

**Self-care for the Feet**

When the patient has problems on the feet, advise for the following to be done at home:

* Inspect the feet daily for signs of injury.
* Soak and then apply oil to the feet. As for the hands, rub away the callus.
* Walk as little as possible slowly. Rest frequently.
* If ulcers are present, rest is essential.
* Use a clean cloth to cover open wounds.
* If there is a foot-drop, do passive stretching to prevent a contracture of the Achilles tendon.

1. **Simple Interventions Organized at the Local Clinic:**

When the patient has eye problems:

* Provide to the patient saline drops for use at home if the eyes are very dry.
* Treat conjunctivitis with antibiotics and an eye pad.
* Refer more serious eye problems to an eye clinic or ophthalmologist.

When the patient has problems on the hand:

* Provide available cooking gloves if the patient has insensitive hands.
* Refer more serious hand problems to the referral centers for physical rehabilitation

Interventions on the Feet**:** Provision of Protective Footwear

Any kind of footwear will protect the feet as long as it has:

* Hard sole (so thorns, glass and the like on the road can’t penetrate);
* Soft insole (to spread force and prevent blisters);
* Back-strap or heel cup (so footwear can’t fall off); and
* Flexible, adjustable, good fit (e.g. made of leather or cloth, with laces, buckles, or Velcro).

If no deformity is present, provide proper protective footwear (canvas shoes, embedded with MCR) or market shoes. Patients can collect canvas shoes, embedded with micro cellular rubber (MCR), and other orthopedic appliances from MDT providing health facilities and nearby orthopedic workshops respectively. If significant foot deformity is present, use special orthopedic appliances made in orthopedic workshops.

Refer more serious problems to the referral centers for physical rehabilitation.

Closed plastic shoes are not suitable as they exacerbate sweating, blisters, and infection of the skin as well as underlying tissues.

1. **Arrange early referral for speciality care at leprosy referral hospital for:**

* Any acute eye problem
* lagophthalmos
* Thick callus and chronic ulcers
* weakness or a contracture/claw-hand
* invasive infection (the hand is hot, red and swollen)
* Foot-drop

## 11.17 Prevention of Leprosy

**Chemo prophylaxis:** Unlike TB, there is no indication for chemoprophylaxis for leprosy.

**BCG:** BCG vaccination has a documented and substantial effect in preventing leprosy and is therefore considered as an important tool for leprosy prevention.

|  |
| --- |
| Review Exercise on Day V: |

1. A 50 year old man on treatment for MB leprosy came to a health facility complaining of painful nodules on his arms and legs of 2 weeks duration. On examination, there are multiple sub-cutaneous nodules which are tender and erythematous. There is loss of sensation on his right foot.
2. What is your diagnosis and why?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. How do you treat this patient?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. A 34 year old woman on treatment for MB leprosy came to a health facility complaining of reddish discoloration of the skin patches on her arms of one week duration. On examination, the skin lesions are erythematous and hot. There is loss of sensation on her left palm.
2. What is your diagnosis and why?
3. How do you treat this patient?
4. How do you follow this patient?
5. Select the common minor side effects of MDT:
   * Brownish discoloration of the skin
   * Orange discoloration of the urine
   * Occasional Itching of the skin
   * Skin lesions with exfoliation
6. Select the correct statement about key messages that should be informed to a leprosy patient when released from treatment?

\_\_\_\_\_\_\_\_\_\_\_\_\_skin patches caused by the leprosy will not disappear immediately

\_\_\_\_\_\_\_\_\_\_\_\_\_Leprosy reaction can still develop after MDT

\_\_\_\_\_\_\_\_\_\_\_\_\_Relapse of leprosy is common

\_\_\_\_\_\_\_\_\_\_\_\_\_Practice self-care at home regularly

\_\_\_\_\_\_\_\_\_\_\_\_Once successfully completed MDT, No need to have post treatment follow up

1. Write true or false for the following statements?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Reactions in leprosy are always painful

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Reactions are the result of some immunological changes

\_\_\_\_\_\_\_\_\_\_\_\_\_\_We can predict which leprosy patients will definitely go into reaction

\_\_\_\_\_\_\_\_\_\_\_\_\_\_Reactions always lead to permanent disability

\_\_\_\_\_\_\_\_\_\_\_\_\_\_Eyes can be affected directly due to reactions

# 12. COMMUNITY TB CARE and PUBLIC-PRIVATE MIX in TB care

**TIME Allotted:**

**Learning objectives**

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

* Introduce the principles of community based TB care
* Explain Public private mix model in Ethiopia

## 12.1COMMUNITY BASED TB CARE

**Community Based TB care (CTBC):** It is a working partnership between the **health sector** and the **community** in the prevention and care activities of TB.

Objectives of CTBC

* To increase community awareness on TB transmission, prevention and treatment
* To identify and prompt referral of TB suspects for early diagnosis and initiation of treatment
* To improve access to DOT service
* To ensure retrieval of absentees/interrupters

Components of CTBC

* Community awareness creation and social mobilization on TBL and TB/HIV prevention and control activities.
* Promotion of TB Infection control at community and household level
* Identification and referral of TB suspects
* TB contacts tracing and referral
* Community based DOT and treatment adherence
* Retrieving TB treatment interrupters/absentees and defaulters

In Ethiopia, the presence of health extension workers (HEW) in the community simplifies the implementation of uniform and standardized TB prevention and control activities across the country.

## 12.2 Public Private Mix –DOTS (PPM DOTS)

Engaging all relevant health care providers in TB care and control through public-private mix approaches is an essential component of the END TB Strategy under Pillar II.

Public-Private Mix (PPM) approach in TB represents a comprehensive approach for systematic involvement of all relevant health care providers in TB control to achieve national and global TB control targets.

PPM encompasses diverse collaborative strategies such as public-private (between public and the private-for-profit and private for-non-profit sector), public-public (between public and other public sector care providers such as general hospitals, prison or military health services and social security organizations), and private-private (between an NGO or a private hospital and the neighbourhood private providers) collaboration.

### 12.2.1 Rationale for collaboration of private sectors in TB control activities in Ethiopia

* Strong governmental Political commitment
* Growing interest of the private sectors in health sector investments
* Increased access to TB diagnosis, care and treatment services
* Engaging the privates would improve standardized TB case management and rational use of anti-TB drugs
* The increasing community participations and ownership in producing and maintaining its own health

### 12.2.2 Objectives and Benefits PPM-DOTS

* To optimize the use of available resources in public and private for TB diagnosis, care and treatment
* To improve equity and access to effective and affordable TB control and prevention services
* To increase patient satisfaction
* To reduce financial burden on public health system
* To strengthen referral linkage and communication among health care providers both in public and private

### 12.2.3 Service Areas for Engaging Private Sectors in PPM DOTS

Private sectors and other relevant providers are encouraged to engage on the delivery of one or more of the following TB and TB/HIV services:

* Advocacy, communication and social mobilization
* Identification and referral of TB suspects to nationally accredited diagnostic centers
* Participation in diagnostics and Quality assurance services
* Treatment delivery services
* Community TB care services
* Mentoring, Supportive supervisions and monitoring of performance
* Delivering TB/HIV interventions
* Sputum sample collection and transportation services to the designated diagnostic centers
* Delivering MDR-TB diagnostic and/or treatment services
* Participate in operational researches

Up on agreement to deliver TB services, the PPM provider should sign memorandum of understanding (MOU) with the responsible governmental body.

### 12.2.4 Potential Private Care providers for engaging in PPM DOTS

The Potential Private Care providers for engaging in PPM DOTS program in Ethiopia include:

* Private-for-profit:
  + Private hospitals, Clinics, centers, diagnostic labs, drug outlets
* Private-for-non-profit
  + FBO clinics, NGO clinics, workplace clinics
* Other governmental organizations
  + Uniformed service clinics, prison, factory
* Civic Society Associations and community structures
  + anti-TB clubs, formal association, local NGOs

### 12.2.5 Steps to Engage PRIVATE HEALTH Facilities in PPM DOTS Service

**1. Consensus and Sensitization**

**2. Site Selection**

**3. Rapid Needs Assessment**

**4. Memorandum of Understanding**

**5. Capacity Building (training)**

**6. Logistics management**

**7. Community Mobilization**

**8. Supportive Supervision**

**9. Referral network**

**10. Monitoring and Evaluation**

### 12.2.6 Role and responsibility of various stakeholders in PPM DOTS

Role and responsibility of various stakeholders for successful implementation of PPM DOTS in Ethiopia is defined as follows:

***Key responsibilities of the Regional Health Bureau:***

* Periodically assess and identify accredited facilities for PPM-DOTS
* Supply anti-TB drugs free of charge with adequate shelf life
* Establish a reliable system for re-supply
* Ensure affordability and quality of TB diagnosis
* Assure quality by involving private clinics in regional EQA scheme
* Provide training to providers to PPM-DOTs
* Provide guidelines, recording and reporting formats
* Link PPM-DOTS with MDR-TB diagnosis and treatment centres

**Key responsibilities of the Woreda/Town Health Office:**

* Provide all programmatic support and monitoring of performance
* Support PPM-DOTs facilities in defaulter tracing and linkage to community TB
* Provide periodical supportive supervision
* Provide recording and reporting supplies and guidelines and jobs aids
* Ensure in uninterrupted supply of TB medicines and commodities

***Key commitments of private providers:***

* Follow the standards and recommended protocols as per the national guidelines
* Standard facility level inventory control for TB medicines and other supplies
* Report on program activities following HMIS reporting format and system
* Communicate promptly to Woreda offices regarding lost to follow up patient
* Sign Memorandum of Understanding with RHB

Reporting from the registered reporting PPM DOTS sites should be based on the guidance and tools from the national HMIS system, and reports should be submitted to the Town Health offices.

Besides, TB Patients that are diagnosed and linked to TB clinic of the public facility should be marked on the “column # 7” on source of the patients as “private” and reported accordingly.

# 13. Introduction to Tuberculosis commodity SUPPLY MANAGEMENT System

**TIME Alloted:**

**LEARNING OBJECTIVES**

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

* Dispense TB treatment using TB patient kit
* Understand the key aspects of the different components of TBL pharmaceuticals supply management cycle
* Be familiarized with standard IPLS formats used in TB
* Build the essential skills to manage TB commodities at Health facility level

## 13.1 TB PATIENT KITS

The national TB control program has implemented the use of “TB patient kits” for the treatment of Adult TB patients as it has the following benefits:

* + contributing to efficient procurement,
  + simplifying drug quantification,
  + promoting rational drug use,
  + promoting the DOTS strategy, and
  + facilitating drug management.

### 13.1.1 Introduction to TB patient kit

**What is TB patient kit?**

A TB patient kit contains the full course of treatment for a single patient and thus assures the TB patient that his or her medicines will be available throughout treatment.

The kit provides health workers with a container that has all required medicines in the necessary strengths and quantities.

This helps limit confusion and wastage, and makes it easier to monitor the regularity of treatment; avoiding stock-outs.

|  |  |
| --- | --- |
|  | TB kits come with a booklet/ insert containing:   * Introduction explaining the purpose of the TB kit. * Instructions on: * how to prepare the kit for a patient according to the different weight bands; * how to administer the correct amount of drugs during Intensive and Continuation Phases; and * how to prepare the injections of streptomycin and how to dispose of the syringes and needles (previously treated only). * Product information on the medicines. |

### 13.1.2 TB patient kit formulations

TB patient kit is available in two preparations for treatment of New TB and previously treated TB patients. It contains all the drugs needed to treat one adult patient of the middle weight band (from 40 kg to 54 kg).

1. **TB patient kit for New TB patients**

Treatment consists of Intensive Phase of 56 daily doses (2 months) and Continuation Phase of 112 daily doses (4 months).

A kit for New TB patients contains two separate boxes:

* *One for the Intensive Phase*: 4 drug fixed-dose combination tablets (FDC-4) (RHZE 150/75/400/275 mg).
* *One for the Continuation Phase*: 2 drug fixed-dose combination tablets (FDC-2) (RH 150/75 mg)

NB on blister pack contains 28 tables packed in blister sheets of 4 rows of 7 tablets.

1. **TB patient kit for Previously treated patients**

Treatment consists of Intensive Phase of 84 daily doses (3 months) and Continuation Phase of 140 daily doses (5 months). The kit contains all the drugs needed to treat 1 patient of the middle weight band (from 40 to 54 kg).

A kit for previously treated Tb patients contains three separate boxes:

* for the Intensive Phase:
  + - * + 4 drug fixed-dose combination tablets (FDC-4) (RHZE 150/75/400/275 mg).
        + Streptomycin, water syringes and needles (S 1 g).
* for the Continuation Phase:
* 3 drug fixed-dose combination tablets (FDC-3) (RHE 150/75/275 mg).

### 13.1.3 Dose Adjustment for using patient kits

Dosage according to the patient's weight is essential in tuberculosis control. Patients kits contain all the drugs needed for the most common weight band of patients 40-54 kg. Kits are easily adjustable by health workers at the start of the treatment by removing or adding blister sheets to accommodate other standard weight bands. One blister pack contains 28 tables of FDC.

* + - 1. Pre-packed TB kit for NEW TB Patient contains:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Drugs Name | Daily FDC tablets per day  (A) | Duration of treatment in Months  (B) | Total tabs required per phase  (C=A x B ) | Number of tablets in one Blister pack (D) | Total of Blister packs required for a kit  (=C/D) |
| RHZE 150/75/400/275mg | 3 | 2 | 168 | 28 | 6 |
| RH 150/75 mg | 3 | 4 | 336 | 28 | 12 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Patient weight | RHZE FDC blisters needed in Intensive Phase | Adjustment  (from the pre-packed) | RH blisters needed for continuation phase | Adjustment (from the pre-packed) |
| 20-29 | 3 | Remove 3 blister | 6 | Remove 6 blister |
| 30-39 | 4 | Remove 2 blister | 8 | Remove 4 blister |
| 40-54 | 6 | None | 12 | None |
| ≥55 | 8 | Add 2 blister | 16 | Add 4 blister |

* Adjustment to be made to the kit based of patient weight band for NEW TB Patient:
  + - 1. Pre-packed TB kit for previously treated TB contains:

|  |  |  |  |
| --- | --- | --- | --- |
| **Drugs Name** | **Total number of tablets for one PK (A)** | **Number of tablets in one blister (B)** | **Total number of blisters for one patient (=A/B)** |
| **RHZE 150+75+400+275mg** | 252 | 28 | 9 |
| **Streptomycin 1gm inj.** | 56 | 1 | 56 |
| **Water for Inj. 5ml** | 56 | 1 | 56 |
| **Disposable syringe 5ml** | 56 | 1 | 56 |
| **RH 150 +75mg** | 420 | 28 | 15 |
| **Ethambutol 400mg tab** | 280 | 28 | 10 |

* Adjustment to be made to the kit based of patient weight band for Previously Treated TB:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Patient weight | RHZE Blister needed for intensive phase | Adjustment  *(from the pre-packed)* | RH Blister needed for continuation phase | Adjustment  *(from the pre-packed)* | Ethambutol blister needed for continuation phase | Adjustment  *(from the pre-packed)* |
| 20 – 29kg | 41/2 | Remove 41/2 blister | 71/2 | Remove 71/2 | 71/2 | Remove 21/2 blister |
| 30-39 kg | 6 | Remove 3 blister | 10 | Remove 5 | 71/2 | Remove 21/2 blister |
| 40- 54 kg | 9 | None | 15 | 0 | 10 | None |
| ≥55 kg | 12 | Add 3 blister | 20 | Add 5 | 15 | Add 5 blister |

Note that Streptomycin needs NO ADJUSTMENT for all weight bands as one vial is to be used for one day making the total required 56 doses.

EX: To compute Treatment dose requirement for NEW TB:

**Note that:**

* *TB patient kit is only for adults and adolescents*
* *A kit is pre-prepared only for weight band range of 40-54kg*
* *Patients weighing either below 40kg or exceeding 54kg kit needs to be adjusted before initiation of treatment*
* *If patient interrupt treatment before completion of full course, readjust the kit to be used by another patient.*
* *Note that one blister pack contains FDC 28 tabs*
* *Always level the patients details on the outer cover of the patient kit*

### 13.1.4 Using TB kits at health post level

As DOT is recommended to be supervised at the community level in the health post by health extension workers, the TB kits should be stored at the health post level. Up on linking the patient to the health post, kit should be transferred to the health post by the extension worker. If the storage capacity at the health post is limited, the continuation phase of the kit may be delayed till the patient finishes the intensive phase and can be transferred later.

### 13.1.5 Using TB kits for patients known to be referred out before completing treatment

Big referral hospitals and some PPM sites may transfer-out significant number of their patients leaving the opened kit behind unused. To minimize drug wastage, it is advised not to open a new kit for patient known to be transferred out and use from the supply box if there is any RHZE. If the facility has excess opened kits, better to return to PFSA for re-distribution.

## 13.2 Essential TB commodity supply management in IPLS/LMIS

The IPLS is the primary mechanism through which all public health facilities get re-supply of essential medicines and vital health commodities. As per the national IPLS, Anti-TB commodities are stored at central warehouse, PFSA hubs and health facilities providing TB treatment services.

The respective PFSA hubs re-supply hospitals and health centers every two months, while Health posts are re-supplied by the catchment health center monthly, based on their consumption report generated by the pharmacy unit of the center using logistics management information system (LMIS).

TB clinics (- including PPM Sites) with no access to PFSA service are re-supplied by the respective woreda/Town Health office.

### 13.2.2 Essential data items for LMIS

The LMIS uses the following three variables on each pharmaceutical:

1. ***Stock on hand***: The quantities of usable stock available at a particular point in time.
2. ***Consumption Data***: The quantity of pharmaceuticals used during the reporting period.
3. ***Losses/Adjustments***: **Losses** are the quantities of products removed from stock for any reason other than provision of services to patients or issuing to another facility (e.g. expiry, lost, theft, or damage) and are recorded as negative numbers.

**Adjustments** are quantities of a product received from any source other than PFSA mechanism, or issued to or received from other health facilities. An adjustment may also be a correction due to an error in mathematics. An adjustment could be a negative or positive number. *Note that reasons for losses/adjustments are registered under the Remark column.*

### 13.2.3 LMIS in IPLS

In the management of Essential TB commodities, the following standard LMIS recording and reporting forms are used:

***Bin Card:*** is an individual stock keeping card that keeps information about a single lot of a product. The bin card should note quantities received or issued by the store, stock on hand of the specific product, as well as any losses and adjustments, etc. (See Annex 6)

*Note that all dispensing units, including TB clinics, are required to have regularly updated bin cards. Bin card is to be displayed at the bins (or shelf) where the lot is stored.*

***Internal Facility Reporting & Requesting Forms (IFRR):*** This form is used to re-supply the service outlets using the pharmaceuticals within the facility. Hence, the TB focal must fill the IRRF on agreed intervals to be re-supplied with the essential TB commodities from the institutional store. (see Annex 7)

*Note that All TB commodities supplied from PFSA must be stored at the institutional store before supplies to TB clinic to dispense for clients.*

***Facility Combined Report And Requisition Form (RRF):*** this form is used byHospitals and Health Centers to combine all supplies to be reported and ordered from PFSA hubs to get re-supply.This form is expected to be filled every 2 months by the health facilities and be sent to PFSA hubs and woreda Health office.

***Consumption Records:*** is used to record the quantity of each item dispensed to a patient. Consumption records are completed by health personnel at the TB clinics whenever supplies are dispensed to patients.

|  |
| --- |
| Note that, TB units:   * Are considered as one dispensing unit and use standard forms i.e. bin care, consumption report and IRRF * TB drugs at the “TB unit” must be store in lockable cabinet * Get re-supply from the health facility pharmacy store every two weeks upon submission of filled IRRF * Must use IRRF for re-supplying the health posts under their catchment * All IRRF should be filed and be checked periodically by Woreda/Town health office during supportive supervision |

*Note: Health Post data is already included in the Health Centre information and it is not added up in the aggregation again for it would be double counting of the Health Post data.*

### 13.2.4 Anti-TB commodities inventory management at facility level

The purpose of an inventory control system is to inform personnel when and how much of a commodity to order and to maintain an appropriate stock level to meet the needs of patients to prevents shortages, oversupply, and expiry of commodities.

* At health centers/ hospital level, maximum of four months’ stock, and minimum of two months’ stock of Anti-TB medicines are recommended while two weeks are order points to request emergency re-supply.
* At health post level, maximum two months of stock and minimum one month of stock are recommended while one week of time is set to be order point to request emergency re-supply from catchment Health center.

The pharmacy unit at health center/hospitals re-supplies Anti-TB commodities to the “TB clinic” on every two weeks interval using IRRF. Note that the “TB unit” of the facility must add up the consumption at the clinic and catchment health posts to calculate IRRF and get re-supply from the pharmacy store.

|  |
| --- |
| Review Exercise on Day VI: |

**Exercise** 1. Tesfaye is a 33year old TB patient is just diagnosed with extrapulmonary TB. He gave no history of prior TB treatment and weighed 38kg:

a. prepare TB kit for the patient:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

After receiving TB treatment using TB kit for six weeks, Tesfaye did not report for 10 consecutive weeks and the TB focal decided to use the leftover drugs from Tesfaye’s kit for Ketema who is newly diagnosed with extrapulmonary TB and weighing 55kg:

b. reconstitute Tesfaye’s kit for Ketema: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Matching column “A” with “B”

|  |  |  |  |
| --- | --- | --- | --- |
| “A” | | “B” | |
|  | Stock on hand | A | the quantity of each item dispensed to a patient |
|  | Consumption Data | B | the quantities of usable commodity available at a particular point in time. |
|  | Internal Facility Report, Issue and Receipt voucher | C | to maintain a record of the products that are issued and received at dispensing unit |
|  | consumption record | D | The quantity of drugs used during the reporting period |
|  | Bin card | E | to report on quantity of drugs used, lost or transferred, and the stock at hand |

2. Health facility X reported a beginning balance of 20 boxes of RHZE of 672 tabs with expiry date of 30/10/17 for 8boxes & expiry date of 30/8/17 for 12 boxes and 40 boxes of RH of 672 tablets. During the reporting period facility X received 60 boxes and 120 boxes of 672 tabs of RHZE with expiry date of 30/10/17 and RH respectively. Assuming the number of active TB patients in this facility to be 200 and there is no loses & adjustment for this reporting period:

1. Update Bin card for RHZE( use Bin card on Annex 6)
2. Calculate Average monthly consumption for this reporting period.
3. Calculate Quantity of drugs to be requested for the next reporting period (use IRRF on Annex 7).

END OF COURSE

**TB Laboratory Requesting and reporting Form**

1. **PATIENT IDENTIFICATION:**

Patient Full Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Age (Yrs): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Sex (M/F): \_\_\_\_\_\_\_\_\_\_\_\_\_

Region: \_\_\_\_\_\_\_\_\_\_\_\_\_Zone/Subciity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_Woreda:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Kebele:\_\_\_\_\_\_\_\_\_House No: \_\_\_\_\_\_\_ Tel.: \_\_\_\_\_\_\_\_\_

Referring Health Facility: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Co-infection: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **TB DISEASE TYPE & TREATMENT HISTORY:**

**Site**: 🞏 Pulmonary 🞏 Extra pulmonary (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Registration Group**: 🞏 New 🞏 Relapse 🞏 After default 🞏 after failure of first treatment 🞏 After failure of re treatment 🞏 other **Previous TB drug use**: 🞏 New 🞏 First line 🞏 second line 🞏 MDR TB contact

1. **REQUEST FOR TESTING AT TB LABORATORY:**

**Reason**: 🞏 Diagnosis: If diagnosis, presumptive TB / RR-TB/ MDR-TB? 🞏 Yes 🞏 No

🞏 Follow up: If Follow up, at \_\_\_ months during treatment 🞏 Follow up at \_\_\_ months after treatment

**Specimen**: 🞏 Sputum 🞏 Other (Specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date specimen collected: \_\_\_\_/\_\_\_\_/\_\_\_\_ (Ethiopian Calendar)

**Requested tests**: 🞏 Microscopy 🞏 Xpert MTB/RIF test 🞏 Culture 🞏 Drug Susceptibility Testing (DST)🞏 Line probe assay

Person requesting examination: Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **LABORATORY RESULT:**

Sample Number: \_\_\_\_\_\_\_\_ Date specimen received: \_\_\_\_/\_\_\_/\_\_\_ (Ethiopian Calendar) Date of result: \_\_\_\_/\_\_\_/\_\_

Examined by (name and signature): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Microscopic examination result**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Negative** | **Positive**  🞏 Ziehl-Neelsen (ZN) 🞏 Fluorescence  🞏 Direct Smear 🞏 Concentrated Smear | | | |
| **1-9(Scanty)** | **1+** | **2+** | **3+** |
|  |  |  |  |  |

**Xpert MTB/RIF test result** (*to be completed in the laboratory)*

Date sample collected: \_\_\_\_/\_\_\_/\_\_\_ Date of result: \_\_\_\_/\_\_\_/\_\_\_ Examined by (name and signature): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***M. tuberculosis:***🞏Detected 🞏 Not detected 🞏 Invalid / No result / Error

***Rifampicin resistance:*** 🞏 Detected 🞏 Not detected 🞏 Indeterminate result

**TB Culture result:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date Sample collected | Media used  (liquid or  solid) | Lab.  serial  number(s) | Result (Tick One) | | | | | | |
| Negative  (0 colonies) | 1-9  (<10  colonies) | +  (10-100  colonies) | ++  (>100  colonies) | +++  (Innumerable/confluent  growth) | NTM 1 | Contaminated |
|  |  |  |  |  |  |  |  |  |  |

**Drug susceptibility test (DST) and line probe assay (LPA) results**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date Sample Collected | Method a | Laboratory  Serial number(s) | Resultsb (mark for each drug) | | | | | | | | | |
|  |  |  | H | R | E | S | Amk | Km | Cm | FQ | Other( ) | Other( ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

a  Method, Specify: solid media DST; liquid media DST; direct LPA; indirect LPA

b Results codes: R = Resistant; S = Susceptible; C = Contaminated ; ND = Not done

Date reported: \_\_\_\_/\_\_\_\_/\_\_\_\_ (Ethiopian Calendar) Name/ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_Reviewed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1 Non-tuberculous mycobacteria

# Annexes

## Annex 1: Approach to patient with Enlarged Lymph Nodes

Approach to patient with Enlarged Lymph Nodes

ENLARGED LYMPH NODES

REFER PATIENT FOR BIOPSY

LYMPH NODES are firm to soft, and/or matted but not fixed with underlying structure

LYMPH NODES are hard and appear fixed with underlying structure

EXTRA- INGUINAL SITES

INGUINAL SITE

Work up for other disease first

Check for symptoms of pulmonary TB

NO TB

TB

YES

NO

Evaluate for TB

Do FNA cytology & Xpert

Re-evaluate after 4-8 weeks

Work up for other disease, and consider Antibiotic

INITIATE ANTI-TB TREATMENT

if not improving,

REFER PATIENT

## Annex 2: Algorithm for TB screening among adults and adolescents living with HIV



## Annex 3: checklist for clinical patient monitoring at TFC level

|  |  |
| --- | --- |
| **Patient clinical monitoring tool** | |
| **ASK:** | **LOOK:** |
| **At first Visit:**   * *history of current and previous TB treatment* * *Medications profile* * *Social profile and living conditions* * *Contact screening* * *Symptoms of Adverse reaction* * *History of Any comorbid conditions*   **At every visit:**   * *How have you been?* * *Have your TB symptoms improved?* * *Cough? Sputum? Difficult breathing?* * *Fever/night sweats? Appetite?* * *What problems have you had taking your medicines?* * *Have you missed any doses?* * *Adherence problem* * *Have you had any problems with your treatment supporter?* * *Have you had any symptoms of ADRs:*   Nausea/vomiting?  Fatigue?  muscle ache?  Skin rash?  Tingling in hands or feet?  Decreased hearing?  Ringing of ears?  Headache?  Seizures? Loss of consciousness?  Feeling anxious? Feeling sad or unhappy? Mood change? Feeling cold?   * *Ask for screening all contacts* * *Last menstrual period (LMP) if women?* * *Socioeconomic and any other concerns?* | **For All patients:**   * *Signs of TB* * *Signs of co-morbid diseases* * *Signs of ADRs* * *Signs of complication or failure* |
| **CHECK:** |
| **At every visit:**   * *Weight, Height, BMI and MUAC* * *Measure temperature* * *Count respiratory rate* * *Signs of co-morbid diseases* * *Look for pallor. If pallor, check hemoglobin.* * *Look at whites of the eye—yellow?* * *Signs of ADRs* * *If any new symptoms: Do further assessment of symptoms and consult/Refer.*   **For pt with special conditions:**   * *Do Blood glucose test, if DM* * *Creatinine, if chronic renal disease* * *CBC, LFT &CD4, if HIV/AIDS positive* * *TSH, if hypothyroidism documented* * *Serum electrolyte, if hypokalemia documented and still on injectable*   **For children:**   * *Anthropometry with Wt, Ht and MUAC* * *Developmental milestone if under five* * *Commitment of care giver’s* |
| **ADMINISTER:** | **DECIDE:** |
| * Daily supervised treatment * Daily Injection during intensive phase * Treatment for Minor ADRs * Link patient support group * Link for patient support services * Update the recording forms | * Time for sputum, culture and other lab monitoring test and arrange with the patient * To refer pts for regular scheduled visit to TIC * To refer cases with severe ADR +/- complication |

## Annex 4:Respirator Fitting (Donning) and Removal (Doffing) Instructions

1. Cup the respirator in your hand, with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand.



1. Position the respirator under your chin with the nosepiece up. Pull the top strap over your head resting it high at the top back of your head. Pull the bottom strap over your head and position it around the neck below the ears.



1. Place your fingertips from both hands at the top of the metal nosepiece. Using two hands, mold the metallic strip around the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece.

*! Pinching the nosepiece using one hand may result in improper fit and less effective respirator performance. Use two hands.*



1. Do user seal check as described above and shown in the picture below



1. Removal Instructions: cup respirator in hand to maintain position on face. Pull bottom strap over the head. Still holding respirator in position, pull top strap over your head and remove respirator.

## Annex 5: Simplified TB IC Plan for Health care facility

Name of Health Facility\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **TB IC activity** | **Responsible** | **Frequency** | **Indicators** | **Remark** |
| **Managerial** | IP/PS & TB IC committee establishment and functionality | Facility manager: \_\_\_\_\_\_\_\_\_\_\_ | Monthly meeting | Documented minutes |  |
| Assign TB IC Focal person | Facility manager: \_\_\_\_\_\_\_\_\_\_ | Annually | Assigned and working |  |
| TB IC Risk assessment | IP/PS & TB IC committee: \_\_\_\_\_\_\_\_\_\_\_ | Annually | Documented assessment |  |
| Develop TB IC plan | IP/PS & TB IC committee: \_\_\_\_\_\_\_\_\_\_\_ | Annually | Documented plan |  |
| TB and TBIC awareness creation , training and education for staffs and visitors | Focal person/ IP/PS & TB IC committee: \_\_\_\_\_\_\_\_\_\_ | Daily | List and dates of topics provided |  |
| Ensure provision and posting of Client education material on TB in every service outlets | Focal person/Unit heads: \_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_ | Monthly | Posted materials |  |
| Monitoring of IP/PS & TB IC activities | Focal person/ IP/PS & TB IC committee: \_\_\_\_\_\_\_\_\_\_ | Monthly | Evaluation document |  |
| **Administrative** | Triaging: Identify those have cough lasting for ≥ 2 weeks or Confirmed TB and MDR TB patients | Triage /card room officer/ Facility Manger: \_\_\_\_\_\_\_\_\_\_ | Daily | Documented suspects in logbook |  |
| Separating coughing patients from others and Fast tracking services | Assigned provider/ TB IC focal : \_\_\_\_\_\_\_\_\_\_\_ | Daily | Observed practices |  |
| Cough Etiquette and respiratory hygiene | Focal person/ unit heads/ HCW: \_\_\_\_\_\_\_\_\_\_ | Daily | Observed practices |  |
| Monitor sputum AFB result turnaround time. | Laboratory head/ TB IC focal person: \_\_\_\_\_\_\_\_\_\_ | Daily | Result provision within 36 hr |  |
| Monitor inpatient stay of presumptive and confirmed TB or MDR TB Patients. | focal person/ TB IC focal person: \_\_\_\_\_\_\_\_\_\_\_ | Daily | Admitted for clear indications and stay < 7 days |  |
| **Environmental** | Opening clinic windows and doors  (all Service outlets) | Service outlet heads: \_\_\_\_\_\_\_\_\_\_ | Daily | Observed practices |  |
| **Personal PE** | -Ensure N95 respirator used according to guidelines  -Avail piece of cloth or handkerchief or tissue paper for M/XDR TB Patients | MDR TB focal person: \_\_\_\_\_\_\_\_\_\_ | Daily | Observed practices |  |

## Annex 6: Flow Chart for Diagnosis and Classification of Leprosy

**Major nerve trunks**

**Skin patch**

**Test the skin patches for sensation**

**(use cotton wool)**

**Palpate the nerves**

**Thickened/tender nerve(s)**

**with or without**

**sensory/motor deficit**

**Definite**

**sensory loss**

**Doubtful**

**sensory loss**

**No**

**sensory loss**

**Review after**

**6 months**

**1 to 5 skin patches or 1 thickened/tender nerve trunk**

**Classifying Leprosy (Clinically)**

**6 or more skin patches or more than 1 thickened/ tender nerve trunk**

**Pauci-Bacillary**

**Leprosy (PB)**

**Multi-Bacillary**

**Leprosy (MB)**

**Types of**

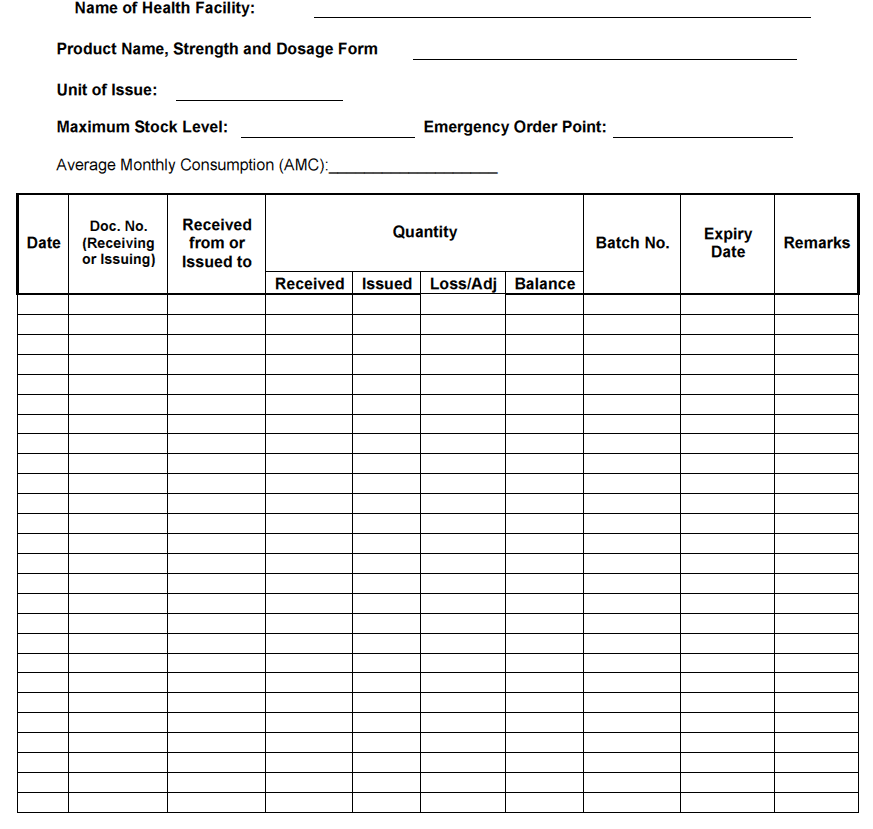
**Leprosy**

**Classifying Leprosy (bacteriologically)**

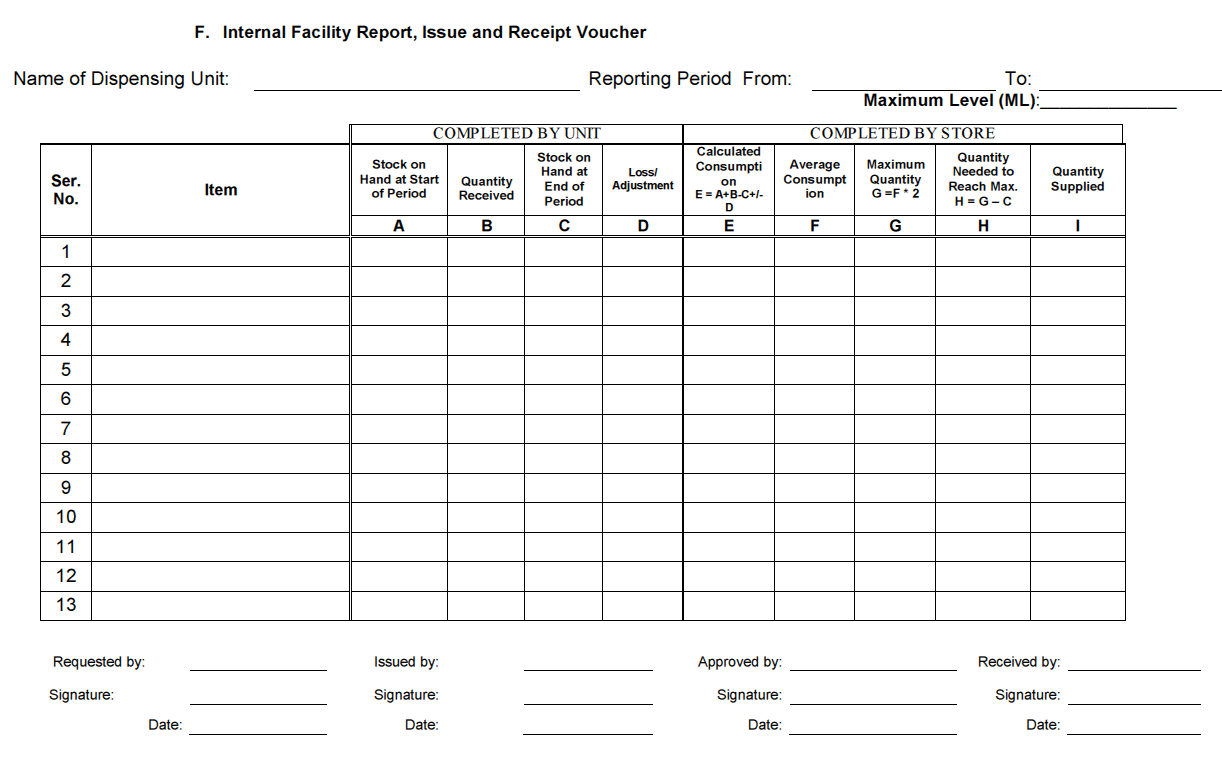
**Skin Smear-negative**

**Skin Smear-positive**

## Annex 7. Bin Card

 *Source: National SOP Manual for Pharmaceutical Logistics system in Ethiopia, March 2010.*

## Annex 8: Internal Facility Report and Receipt form

*Source: National SOP Manual for Pharmaceutical Logistics system in Ethiopia, March 2010.*

## Annex 9. List of standardized registers and formats in TBL and TB/HIV

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Forms and Registers | Data Content | Data recording point | Responsible person | Frequency of reporting |
| Unit TB register | Category of TB patient, treatment & lab. follow up, HIV screening status, treatment outcome, contact screening; presumed DR TB Screening, Treatment Adherence support. | HF (TB clinic) | Facility TBL focal persons | Routine |
| Unit Leprosy register | Leprosy Patient category, Disability grade, treatment follow up, treatment outcome | HF (TB clinic) | Facility TBL focal persons | Routine |
| AFB Lab register | AFB lab result of new & follow up cases | HF (Laboratory unit) | Lab staff | Routine |
| Presumed TB and treatment follow up TB Treatment follow-up card | Lab & Evaluation result, Treatment & Lab follow up, Treatment outcome | HP/Community | HEWs and treatment supporter | Routine |
| HMIS Health Center/Clinic/Hospital Quarterly Service Delivery report form | Information on TBL case finding and treatment outcome and TB/HIV collaborative activities | HF | Health facility HMIS/TB focal persons | Quarterly |
| WorHO /ZHD /RHB Quarterly Service Delivery report form | Information on TBL case finding and treatment outcome and TB/HIV collaborative activities by type of health facility | WoHO /ZHD / RHB health offices | HMIS/TB focal persons at respective health office | Quarterly |
| Lab request form | Lab exam request and result | HF | Health worker and lab technicians | Routine |
| Leprosy patient card & VMT and ST (follow-up) form | VMT/ST status | HF | Health worker at TBL clinic | At diagnosis and then on a quarterly basis |
| TB & Leprosy ID cards | Patient information, disease classification and category of patient and follow up dates | HF | Health worker at TBL clinic | Routine |
| TB & Leprosy transfer/referral forms | Details on TB & Leprosy patient treatment status and reason for referral | HF | Health Worker | Routine |
| Presumed TB cases referral form | Information on presumed TB case | HP | HEWs | Routine |
| HMIS HP Monthly Service Delivery report form | CBTC activity report (presumed TB case identified and referred) | HP | HEWs | Monthly |
| Report and Requisition Form | Drug/supplies consumption report and requisition | HF (drug store) | Health workers | Quarterly |

N.B.: ART & Pre-ART registers from ART clinic and PMTCT register are used for reporting of TB/HIV collaborative activities (IPT) in addition to the Unit TB register.

## Annex 10. Key Indicators in TBL and TB/HIV Prevention and Control

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Indicators to be monitored and reported to National TB Program(NTP) | | | | | | |
|  | TB |  |  | | |  |
| S. No. | Indicator definition | Calculation and Data Source | Frequency | | | Remark |
|  | Tuberculosis | | | | | |
| 1 | Tuberculosis case detection rate (all new forms of TB):  the percentage of all new forms of TB (New and relapse) cases notified among the total number of TB cases estimated to occur | *Numerator:* all forms of TB (New and Relapse cases) detected during reporting period.  *Denominator:* Estimated number of all new forms of TB cases in the population during the same reporting period  *Data Source:* *TB Unit Register* | | Quarterly/ Annual | | Estimated number of all new forms of TB cases of the country is calculated annual using estimate of annual incidence of TB cases. Source of this figure is Global TB report published every year. |
| 2 | Tuberculosis re-treatment rate:  The Proportion of re-treatment TB Cases (Relapse, Treatment –after -failures Treatment –after -lost to follow up & other previous treated with unknown or undocumented treatment outcome) among all forms of TB cases detected in the reporting period | *Numerator*: Total number of retreatment TB cases  *Denominator*: Total number of all forms of TB cases registered during reporting period  *Data Source: TB Unit Register* | | Quarterly/ Annual | |  |
| 3 | Cure rate for bacteriologically confirmed new PTB cases:  The percentage of a cohort of new bacteriologically confirmed PTB cases that were cured as demonstrated by bacteriologic evidence in the reporting period. | *Numerator:* number of cohort of new bacteriologically confirmed PTB cases registered during specified cohort period and *cured*  *Denominator*: Total number of new bacteriologically confirmed PTB cases registered in the same cohort period  *Data Source: TB Unit Register* | | Quarterly/ Annual | |  |
| 4 | Treatment Success Rate (TSR) among new bacteriologically confirmed PTB cases:  Proportion of new bacteriologically confirmed PTB cases registered during specific cohort period that successfully completed treatment, whether with bacteriologic evidence of success (“cured”) or without (“treatment completed”). | *Numerator:* Number of cohort of new bacteriologically confirmed PTB cases registered during the same period of the previous year that were cured plus the number completed treatment.  *Denominator:* total number of new bacteriologically confirmed PTB cases registered in the same cohort period  *Data Source: TB Unit Register* | | Quarterly/ Annual | |  |
| 5 | Treatment success/ treatment completion rate among clinically diagnosed new TB cases:  Percentage of new clinically diagnosed (EPTB and P/ Negative TB) cases registered during specific cohort period that successfully completed treatment. | *Numerator:* Number of new clinically diagnosed cohort of TB cases registered during the same period of the previous year that completed the treatment.  *Denominator:* The total number of new clinically diagnosed TB cases registered during the same cohort period  *Data Source: TB Unit Register* | | Quarterly/ Annual | |  |
| 6 | Death rate among all forms of TB cases:  The percentage of a cohort of all forms (New and relapse) of TB cases registered in a specified period that died during treatment, irrespective of the cause. | *Numerator:* The number of all forms of new TB cases registered in the same period of the previous year that died during treatment, irrespective of the cause  *Denominator:* The total number of all forms of new TB cases registered during the same cohort perio  *Data Source: TB Unit Register* | | Quarterly/ Annual | |  |
| 7 | Lost to follow up rate among all forms of TB cases: The percentage of a cohort of all new forms of TB cases registered in a specified period that interrupted treatment for more than 2 consecutive months | *Numerator:* The number of all new forms of TB cases registered in the specific cohort period that interrupted treatment for more than two consecutive months  *Denominator:* The total number of all new forms of TB cases registered during the same cohort period  *Data Source: TB Unit Register* | | Quarterly/ Annual | |  |
| 8 | TB case Detection through community TB care: The percentage TB cases (all forms) referred by the community health extension workers among all TB cases notified during a specified reporting period. | Numerator: Number of registered TB cases (all forms) initially referred by the community to a health facility for diagnosis during the reporting period  *Denominator:* Total number of all forms of TB cases registered during same reporting period  *Data Source: TB Unit Register* | | Quarterly/ Annual | | This indicator helps to acknowledge the contribution of HEWs in TB case detection. Their contribution is calculated from the number TB cases registered in TB unit register and it is not from presumed TB cases referred for diagnosis |
| 9 | TB treatment support through community TB care:  The percentage of cohort of TB patients (all forms) who received support for treatment adherence from community health extension workers. | *Numerator:* Number of cohort TB cases (all forms) provided treatment observation (DOT) by the Community health extension workers  *Denominator:* The total number of all forms of TB cases registered during the same cohort period  *Data Source:* TB Unit Register | | Quarterly/ Annual | | HEWs are expected to monitor treatment adherence of TB patients who are in their catchment area.  Stable TB patients living nearby to HPs, and those initially referred by HEWs are expected to receive DOT at HPs. |
| 10 | TB Case Detection through Private sectors:  The percentage of all forms of TB patients diagnosed and notified with TB who were initially referred by private/Non-Governmental health facilities during reporting period. | *Numerator:* Number of TB cases (all forms) referred &/or diagnosed and on DOT through private health facilities during the reporting period  *Denominator:* Total number of TB cases (all forms) registered during reporting period.  *Data Source: TB Unit Register and private health facilities report from HMIS system* | | Quarterly/ Annual | | This indicator shows the contribution of private sectors in TB diagnosis and treatment. While calculating this indicator, in addition to TB patients registered in TB unit register as a contribution of PPM sites, those patients who are diagnosed and being treated in PPM sites for more than one month and report by private Health facilities should be included in the numerator. |
| 11 | AFB Microscopy centers (HF) with adequate EQA performance:  Proportion of Health facilities(both public and private) participating in EQA that showed concordance of 95% on EQA blind rechecking results | *Numerator:* Number of AFB Microscopy Centers (HC and Hospitals) with 95% concordance result on EQA blind rechecking during the previous quarter  *Denominator:* Total number of laboratory with AFB Microscopy service (Hospital and HCs) that are participated on EQA during the same quarter  *Data Source: Administrative report(check feedback report at health facility level)* | | Quarterly/ Annual | | Woreda health offices are responsible to report this indicator by looking into the blind rechecking feedback of health facilities participated in EQA during previous quarter. |
| 12 | Presumptive MDR TB cases with result for drug susceptibility testing(DST):  Proportion of presumptive MDR TB cases for whom DST is performed for at least rifampicin during the specified period | Numerator: Number of presumptive MDR TB for whom DST is performed for at least rifampicin during previous reporting Quarter  Denominator: Total number of cases eligible for drug susceptibility testing according to national policy during the same period  *Data Source: TB Unit Register* | | Quarterly/ Annual | | Previous reporting period for this indicator indicates the reporting quarter before current reporting period |
| 13 | MDR cases detected:  Number of MDR/RR-TB cases Detected during the reporting period. | Numerator :Number of MDR/RR-TB cases detected during reporting period  Denominator: NA  *Data Source: TB Unit Register* | | Quarterly/ Annual | | All Confirmed MDR/RR-TB cases diagnosed at the facility should be recorded on Unit TB register (-even if they did not receive treatment) before linked to MDR TICs. These cases should be reported at the end of the quarter as MDR/RR TB cases detected. |
| 14 | MDR/RR-TB cases enrolled on Second Line Drugs (SLDs):  Number of MDR/RR-TB cases started on second-line anti-TB treatment regimen during the reporting period | Numerator: Number of MDR/RR-TB cases registered and started on a prescribed MDR-TB treatment regimen during reporting period  Denominator: NA  Data Source: *MDR TB Register* | | Quarterly/ Annual | | This indicator is only reported by MDR TIC when the patients enrolled to SLD |
| 15 | MDR TB Treatment six month interim result:  A cohort of MDR/RR-TB cases for whom six month interim result has been determined ( negative, positive, died, LTFU, and not evaluated) among those enrolled on second-line anti-TB treatment during the year of assessment | Numerator: Number of cohort of MDR-TB cases enrolled on second-line anti-TB treatment for whom six month Interim result ( negative, died, LTFU and not evaluated) has been determined during reporting period  Denominator: Number of MDR-TB cases initiated on second-line anti-TB treatment regimen during a same cohort period.  Data Source: *MDR TB Register* | | Quarterly/ Annual | | This indicator is only reported by those MDR TB TICs initiating SLD for the patients not the MDR TB TFCs. |
| 16 | Final outcome MDR-TB cases: A cohort of MDR-TB cases for whom final outcome (cured, completed, failed, died, lost to follow up, not evaluated) has been determined among those enrolled on second-line anti-TB treatment during the year of assessment | Numerator: Number of cohort of MDR-TB cases enrolled on second-line anti-TB treatment during reporting period for whom final outcome (cured, completed, failed, died, lost to follow up, not evaluated) has been determined  Denominator: Total number of MDR-TB cases enrolled on second-line anti-TB treatment during the same cohort period.  Data Source: *MDR TB Register* | | Quarterly/ Annual | | This indicator is only reported by those MDR TB TICs initiating SLD for the patients is no the MDR TB TFCs. |
| 17 | Leprosy case detection rate : Proportion of new leprosy cases detected among eligible population in a specified area | Numerator: Total number of leprosy cases detected during reporting period  Denominator: Estimated number of population in the catchment area  Data Source: *Leprosy register* | | Quarterly/ Annual | |  |
| 18 | Grade II disability rate among new cases of leprosy :  The proportion of new cases of leprosy with disability grade II at the time of diagnosis. | Numerator: Total number of new leprosy cases having disability grade II at time of diagnosis during reporting period  Denominator: Total number of new leprosy cases detected during the same period  Data Source: *Leprosy register* | | Quarterly/ Annual | |  |
| 19 | Leprosy treatment completion rate : the percentage of a cohort of leprosy cases registered in a specified period that successfully completed treatment | Numerator: The number of leprosy cases registered for treatment and completed treatment successfully during specified cohort period  Denominator: The total number of leprosy cases registered during the same cohort period  Data Source: *Leprosy register* | | Quarterly/ Annual | |  |
| 20 | HIV screening for TB patients:  The proportion of TB patients enrolled in DOTS who are tested for HIV | Numerator: The number of TB patients enrolled in DOTS who are tested for HIV in the quarter  Denominator: The total number of TB patients enrolled in DOTS during the same period  Data Source: *TB Unit Register* | | Quarterly/ Annual | |  |
| 21 | TB Screening for HIV positive Clients:  Proportion of clients enrolled in HIV care whose TB status was assessed and recorded during their last visit | Numerator: Number of clients enrolled in HIV care whose TB status was assessed and recorded in their last visit during the reporting period  Denominator: Total number of adults and children enrolled in HIV care and seen for care in the reporting period.  Data Source: *Pre ART & ART register PMTCT register* | | Quarterly/ Annual | |  |
| 22 | Anti-Retroviral Therapy (ART) for HIV positive TB patients:  Proportion of HIV-positive TB patients who are started on or continue previously initiated ART during their TB treatment. | Numerator: All HIV-positive TB patients, registered over the reporting period, who Received ART (are started on or continue previously initiated ART).  Denominator: Total number of HIV-positive TB patients registered during the reporting Period.  Data Source: *TB Unit Register* | | Quarterly/ Annual | |  |
| 23 | INH Preventive therapy (IPT) for HIV positive clients:  Proportion of the total number of newly enrolled HIV-positive people started on IPT during the reporting period | Numerator: Number of HIV positive individual newly enrolled in HIV care who started on (are given at least one dose of) IPT during reporting period  Denominator: Total number of IPT eligible HIV positive clients newly enrolled in to HIV care during the reporting period.  Data Source: Tally sheet in HIV and PMTCT unit | | Quarterly/ Annual | |  |
| 24 | Co-trimoxazole preventive therapy during TB treatment for PLHIV  Proportion of HIV-positive TB patients who are started on or continue previously initiated CPT during reporting period | Numerator: Number of HIV-positive TB patients, registered over the reporting period, starting or continuing CPT treatment during reporting period.  Denominator: Total number of HIV-positive TB patients registered during the reporting period.  Data Source: *TB Unit Register* | | Quarterly/ Annual | |  |
| Additional Indicators to be Monitored at Regional / District/ Woreda level | | | | | | |
|  | Community TB |  |  | | Remark | |
| 1 | Health posts implementing packages of community TB care activities:  Proportion of health posts being provided full package of community TB care services. | Numerator: Number of HPs implementing packages of community TB care activities.  Denominator: Total number of HPs  Data Source: Administrative report from HPs and community TB logbooks | Quarterly/ Annual | | A package of community based TB care as defined by National CBTC guideline. | |
| 2 | Presumed TB cases who are smear positive:  Percentage of presumed TB cases referred from HPs to Health facilities for diagnosis and who are diagnosed TB (bacteriologically confirmed TB cases). | Numerator: Number of bacteriologically confirmed TB cases identified among presumed TB cases referred for diagnosis during specified period.  Denominator: Number of presumed TB cases identified and referred to Health facilities for diagnosis during the same period  Data Source: Administrative report from HPs and community TB logbooks | Quarterly/ Annual | |  | |
| TB Laboratory | | | | | | |
| 1 | TB microscopy units submitting slides for rechecking  Percentage of all TB microscopy units for which slide rechecking results, are available. | Numerator: Number of TB microscopy units for which slide rechecking results are available during a specified period  Denominator: Total number of units performing TB smear microscopy during the same period  Data Source: Administrative report from HFs and woreda health offices | Quarterly/ Annual | | This indicator does not measure the quality of smear microscopy at the laboratories; it simply measures whether quality checks are being done.( it is a proxy for measuring the existence of a complete QA system for laboratory control) | |
| Leprosy | | | | | | |
| 1 | All leprosy case detected( N+O+R+D)  Total number of leprosy cases detected ( N+O+R+D)during reporting period | Numerator: Total number of leprosy cases detected ( New +relapse + lost to follow up and Other ases)during reporting period | Quarterly/ Annual | |  | |

## Annex 11: Sample Transportation SOP

|  |  |  |  |
| --- | --- | --- | --- |
| Standard Operating Procedure (SOP) for Collection , Handling , Packaging and Transportation of Sputum Sample for TB | | | |
| **Title: Collection , Handling , Packaging and Transportation of Sample for TB** | | | |
| Written by:  Lab Quality officer | signature | Effective Date: |  |
| Approved by:  TB Lab Head | signature | Revised Date: |  |
| Laboratory area |  |

PURPOSE

This standard operating procedure (SOP) provides the general technical requirements and Operational guidelines for the proper collecting, packing, and shipping of sputum specimen samples to a culture and drug susceptibility testing (DST) laboratory for analysis for MDR TB. This SOP includes the guidance and regulatory requirements that ensure proper collecting, packing, and shipping of sputum samples classified as “hazardous material”

**GENERAL CONSIDERATION**

Potential hazards associated with the planned tasks are thoroughly evaluated prior to conducting laboratory activities. The laboratory safety manual provides a description of potential hazards and associated safety and control measures. Personnel wear gloves while performing the procedures described in this SOP. Specifically, gloves are

worn while preparing, handling and packing samples. Protocols for sample temperature maintenance and sample packing are applicable to collection of samples. The intent is to ensure that samples arrive at the laboratory in good condition both physically intact and appropriately preserved.

**MATERIALS**

Falcon Tube

Cetylpyridinium chloride

Triple package

Absorbent cotton swab

**SAMPLE TYPE**: Sputum

**AMOUNT**: 3-5 ml\*

**COLLECTION**:

two purulent /muco purulent early morning and spot sputum specimen for culture and DST

one purulent /muco purulent (Non bloody) spot sputum specimen for Xpert MTB/RIF

**STORAGE**: Store the sputum specimen at 2 to 8oC up to 5 days

**TRANSPORT**: Use triple packaging and the sample must reach to the testing site within 5 days after collection

**STABILITY**: Cold chain must be maintained using Ice pack and the Ice pack must be changed at the transit site after 12 hours.

**SPECIMEN REJECTION**:

* Specimen is unlabeled or mislabeled.
* Specimen without request form.
* Specimen name and request form does not match.
* Specimen container breakage or leakage.
* Specimen not collected in an appropriate container

\*Ideally a sputum specimen should have a volume of 3- 5ml, although smaller quantities are acceptable if the quality is satisfactory

**SAFETY PRECAUTIONS**

* Patients should produce sputum in sputum coughing designated area
* Avoid shaking of the tube
* Wear gown and glove when handling the sputum

**PROCEDURES**

**SPUTUM SPECIMEN COLLECTION PROCEDURE**

**Instruct the patient**

* To collect in a separate, ventilated room or preferably outdoors/ produce sputum in sputum coughing designation area/
* To Keep both hands on hips, cough forcibly and collect sputum in the mouth
* To spit the sputum carefully into a wide-mouthed, unbreakable, leak proof container and close the lid tightly. Example Falcon tube
* To collect 3–5ml in volume, although smaller quantities are acceptable if the quality is satisfactory.
* To collect two sample for culture or one sputum sample for GeneXpert

***Consider the following for collection***

* Sample containers are pre-labeled before sample collection, and the labels are protected from the sample matrix by using water proof labels or by covering with clear tape
* Laboratory personnel should label each specimen container with the unique identification number and date of collection
* Give labelled falcon tube to the patient
* Check the quantity, quality and cross check the number with the request form when receive
* Keep in the refrigerator or at room temperature until transport (depending on the time /date transport)

**SPUTUM SAMPLE PACKAGING AND SHIPMENT**

* Obtain samples in the laboratory-specified containers and verify the completeness of the sample identification information on the label and keeping record.
* Verify custody seals on sample containers and/or bags are intact and have been initialed and dated.
* If packaging aqueous samples or using wet ice for temperature preservation, place a garbage bag or liner in the cooler.
* Place samples in re-sealable plastic bags and then into the cooler. If appropriate, place a temperature blank in the center of the cooler.
* Place ample amounts of wet ice contained in doubled re sealable bags inside the garbage bag/liner in cooler. As needed, place bubble wrap or other inert packing material around the garbage bag/liner in the cooler. Note: Blue Ice is used for temperature maintenance for particulate matter sample media.
* Seal the garbage bag/liner with duct tape. This is to ensure that if the contents were to spill that the garbage bag/liner would contain the spill.
* Permanent marker to write number on the label.
* Sample custodian or designee relinquishes the samples on the COC record by signing their name and providing the date and time that the samples were packed.
* Write the shipper’s tracking number (such as courier and courier air bill number) on the COC form when a commercial courier is used.

**Triple Packaging Materials**

All specimens should be appropriately packaged within a triple packaging system: primary, secondary and outer packaging and should contain all relevant documentation:

|  |  |
| --- | --- |
| **Primary Receptacle:** | |
| [http://t0.gstatic.com/images?q=tbn:ANd9GcTsFRslZd41u31IvUHsy8dE8-HsWSYg4T1HWWJov5fKV58hLAiP](http://www.google.com/imgres?imgurl=https://static.fishersci.com/images/F14776-01~wn.jpg&imgrefurl=http://www.fishersci.com/ecomm/servlet/fsproductdetail_10652_661347_29104_-1_0&h=351&w=144&sz=8&tbnid=y5oUobqBshrWoM:&tbnh=93&tbnw=38&prev=/search?q=falcon+tubes+50+ml&tbm=isch&tbo=u&zoom=1&q=falcon+tubes+50+ml&usg=__MvF0szPOD5In_DbbvpOAjnhrkpY=&hl=en&sa=X&ei=05VEUNHgDIXTtAbN5IDQBQ&ved=0CEsQ9QEwCA&dur=3248)IMG_0835 | A primary watertight, leak-proof receptacle containing the specimen. The receptacle is packaged with enough absorbent material to absorb all fluid in case of breakage. |
| **Secondary Packaging:** | |
|  | A second durable, watertight, leak-proof packaging is used to enclose and protect the primary receptacle(s). |
| **Outer packaging.** | |
| IMG_0835 | Secondary packaging is placed in outer shipping packaging with suitable cushioning material. Several cushioned secondary packages may be placed in one outer packaging. Outer packaging protects their contents from outside influences, such as physical damage, while in transit. Each completed package is normally required to be marked, labeled and accompanied with proper documentation. |

Safety warnings to be written on the tertiary container

Sputum and other specimens suspected to contain infectious Mycobacteria or other infectious agents are classified as “Infectious substance, Category B’’.

The shipping name labeled on containers with such specimens is “BIOLOGICAL SUBSTANCE, CATEGORY B”.

Infectious substances in Category B are assigned to a specific UN number: UN 3373.

Label the safety box with the words “BIOLOGICAL SUBSTANCE, CATEGORY B” and the UN number: UN 3373

1. [↑](#footnote-ref-1)