FEDERAL MINISTRY OF HEALTH

Department of Public Health
National Tuberculosis and Leprosy Control Programme

National Tuberculosis, Leprosy and Buruli ulcer Management and control Guidelines

Sixth Edition

2014

FOREWORD

The National Tuberculosis, Leprosy and Buruli ulcer Control Programme (NTBLCP), a unit in the department of Public health, Federal Ministry of Health Nigeria is saddled with the mandate of controlling Tuberculosis, Buruli ulcer and Leprosy in Nigeria. Its goal is to reduce significantly the burden of these three diseases in line with the global target.

In the last five years, a lot has been achieved in this respect but more work needs to be done in order to reduce morbidity and mortality caused by these three diseases in our society. This call for innovations in TB diagnosis and treatment to improve the needed quality of services provided at all service points.

The sixth edition is an improvement over the previous fifth edition of the workers manual to provide an elaborate and comprehensive information related to the management and control of TB, Leprosy and BU. This guideline contains the technical and operational instructions for all health workers implementing activities to control and manage these diseases in Nigeria. It is developed primarily to provide technical assistance, guidance and key information on the NTBLCP implementation strategies to reduce transmission, morbidity and mortality of the three diseases mentioned above to a level that they are no longer a public health problem in Nigeria.

Lastly, in order to compliment the national public health response to Tuberculosis, Leprosy and Buruli ulcer, this guideline is to serve as a reference tool to provide standards and describes a widely accepted level of care that all practitioners, public and private, should seek to adhere to in managing patients who are affected by the three diseases.

I hope that this guideline will serve as a very useful tool for all health workers and health institutions, both government and private, in providing high quality care for patients with TB as well as TB/HIV co-infection, Leprosy and Buruli Ulcer.

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This guideline is indispensable for the effective implementation of the NTBLCP strategies. Its development is a collaborative work of the NTBLCP, partners and other stakeholders involved in the control of Tuberculosis, Leprosy and Buruli ulcer.

We wish to express our appreciation to all development partners, including: World Health Organization (WHO), members of the International Federation of Anti-Leprosy Association (ILEP) in Nigeria, KNCV Tuberculosis foundation, United States Agency for International Development (USAID), Global Fund (GF), the Academia and other Voluntary Organizations.

The experiences of the front line health workers were also invaluable and helped to determine the final content of the guideline.

Finally our appreciation goes to the Global fund, all TBL managers in the 36 States and the FCT, LGTBLS and all our technical partners for providing the field experiences which contributed to the finalization of this guideline.

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ACRONYMS

ACSM	Advocacy, Communication & Social Mobilization
AFB	Acid-Fast Bacilli
ADR	Adverse Drug Reaction
AIDS	Acquired Immune-deficiency Syndrome
ART	Anti-Retroviral Therapy
ARV	Anti-Retroviral
BU	Buruli Ulcer
CB-DOTS	Community Based-Directly Observed Treatment
CBO	Community-Based Organization
CCF	Chronic Cardiac Failure
CDC	Centre for Disease Control and Prevention, Atlanta, USA
CMS	Central Medical Stores
CPT	Co-trimoxazole Preventive Therapy
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment - Short course (WHO Strategy)
DST	Drug Susceptibility Testing
DR-TB	Drug resistant TB
DS-TB	Drug susceptible TB
FDC	Fixed-Dose Combination
GFATM	Global Fund to fight AIDS, TB and Malaria
HAD	HIV/AIDS Division
HBC	Home-based Care
HIV	Human Immuno-deficiency Virus
HF	Health Facility
HMIS	Health Management Information System
HRD	Human Resource Development
HSR	Health Systems Research
IEC	Information, Education and Communication
ILEP	International Federation of Anti-Leprosy Association
IPT-TB	Isoniazid Preventive Therapy for Tuberculosis
IUATLD	International Union Against Tuberculosis and Lung Diseases
KAP	Knowledge, attitude, practices
KNCV	Royal Netherlands Tuberculosis Association
MDR-TB	Multidrug Resistant TB
MDT	Multi-drug Therapy for Leprosy
NACP	National AIDS Control Programme
NGO	Non-Governmental Organization
NMCP	National Malaria Control Programme
NTBLCP	National Tuberculosis and Leprosy Control Programme
NHLS	National Health Laboratory Services
OI	Opportunistic Infection
OPD	Out Patient Department

OR	Operational research
PCP	Pneumocystis Pneumonia
PHC	Primary Health Care
PLHIV	People Living With HIV and AIDS
POD	Prevention of Disability
PTB	Pulmonary Tuberculosis
QA	Quality Assurance
STBLCO	State TB & Leprosy Control Officer (State TB & Leprosy Manager)
STBLCP	State TB & Leprosy Control Programme
STI	Sexually Transmitted Infection
TB	Tuberculosis
TB/HIV	Tuberculosis and HIV Co-infection
TB-IPT	Isoniazid Preventive Therapy for Tuberculosis
TBLS	Tuberculosis and Leprosy Supervisor
ToT	Training of Trainers
WHO	World Health Organization
XDR-TB	Extensively Drug Resistant Tuberculosis

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GENERAL OVERVIEW

1. BACKGROUND INFORMATION

Tuberculosis, Buruli ulcer and Leprosy diseases constitute major public health problems in Nigeria. In addition, the social stigma associated with these diseases further compounds the problem. In order to combat these challenges, the NTBLCP has a working road map which is centred on demand creation, provision of access and ensuring social re-integration of those affected by these diseases into the community.

As part of its strategies, services are provided in a comprehensive manner which ensures that TB, Buruli ulcer & Leprosy services are integrated into the existing health system infrastructure and general health care services in all the 774 Local government Areas in Nigeria. These services are implemented in collaboration with the HIV/AIDS control programme at various levels of health care, the private health providers and the community.

To create demand for services, the NTBLCP encourages community participation and ensures there is awareness creation through provision of information on the causes, transmission, diagnosis and treatment of the three diseases in the community. Accessibility is also ensured through continuous strategic expansion of treatment and diagnostic centres across the country in order to provide quality laboratory services, prompt treatment and rehabilitation services. Other areas like the control of TB in children and management of Drug resistant TB is also being given serious attention.

As at the end of 2013, there are over 5,300 TB service points and 1, 602 microscopy centres distributed across the entire country. The program is scaling up PMDT activities nationwide as a mix model with both hospital and community care for the patients. Equally there are various capacities for diagnosis and treatment of multi drug resistance tuberculosis, with two national reference laboratories and 6 zonal reference laboratories.

1.1 Structure of NTBLCP

NTBLCP is structured along the three tiers of government i.e. Federal, State and Local Government. The National level a unit in the Department of Public Health of the Federal Ministry of Health is responsible for policy development, tertiary care, mobilization and development of human and material resource and provision of technical support to State programmes.

The State TBL programmes coordinate TB activities, provide secondary care and provide technical management to programme implementation at the Local government level. The LGA is the operational level (basic management unit) of the NTBLCP.

The program benefits from the National TB and Leprosy Training Centre (NTBLTC) in Zaria, which is responsible for identifying the human resource needs for program implementation and for training various categories of health care staff to implement TB and Leprosy Control

activities. It also incorporates a referral hospital with a 140-bed capacity as well as the National TB Reference Laboratory.

1.2 GOAL, OBJECTIVES AND STRATEGIES OF THE PROGRAMME

1.2.1 Long-term goal

To reduce significantly the burden, socio-economic impact and transmission of Tuberculosis, Leprosy and Buruli Ulcer in Nigeria in line with the MDG and Stop TB Partnership Targets.

1.2.2 The general objectives

- To reduce the prevalence of tuberculosis, Leprosy and Buruli Ulcer to the level at which they no longer constitute public health problems in the country.
- To prevent and reduce the impairments associated with leprosy and Buruli Ulcer as well as provide appropriate rehabilitation for persons affected by both diseases.

1.2.3 Strategies

- Early case finding and proper case management.
- Comprehensive management of the long term physical and socio-economic effects of the three diseases.
- Integration of TBL and BU services into the general health services.
- Promoting Public-Public-Private partnerships (PPP).
- Behavioural Change Communication.
- Collaboration with bilateral and multi-lateral partners.
- Ensure functional commodities management system.
- Human Resource Development.

2. ROLES AND RESPONSIBILITIES IN TB, LEPROSY AND BURULI ULCER CONTROL

2.1 Roles and Responsibilities of government

2.1.1 Federal government

- Planning and policy development
- Coordinates all activities of TB, Leprosy and Buruli Ulcer control in the country.
- Provision of managerial and technical support for the States and Local government areas on TBL Control.
- Procurement and distribution of the National Tuberculosis and Leprosy Control Programme supplies (anti-tuberculosis, anti-leprosy and anti-lepra reaction drugs, laboratory equipment and reagents, stationery and transport etc.).

- Resource Mobilization for the implementation of the programme.
- Ensure Human Resources development for the TB programme.
- Collaborating with international, non-governmental organizations and voluntary agencies including private health establishments for TB control
- Organisation of periodic review and evaluation of the NTBLCP
- Surveillance data and information management

2.1.2 State government

- Management, coordination, and supervision of all programme activities at State and Local Government level.
- Provide facilities for the diagnosis and management of difficult TBL patients
- Support Order and distribute supplies to LGAs.
- Collect, collate and analyze data on leprosy and tuberculosis activities in the State and disseminate reports to the Federal and Local Governments, as well as other organizations and institutions as appropriate.
- Maintain active cooperation with NGOs supporting the State programmes.

2.1.3 Local government councils

- Managing and coordinating TB and Leprosy control activities within the LGA.
- Support the States in planning, organizing and conducting training programmes.
- Ensuring proper sputum collection and prompt transportation to the laboratory
- Perform routine diagnosis and management of difficult TBL patients.
- Ensure directly observed treatment (DOT) by health workers throughout the LGA in line with National guidelines.
- Keep up-to-date and accurate record of activities of TB and leprosy control activities in the LGA, including the LGA Central Registers.
- Maintain inventory management of programme supplies (drugs, laboratory supplies, records cards and forms) and distribute to all health units in the LGA.
- Establish and conduct health education activities.
- Undertake disability prevention and rehabilitation activities.
- Contact investigation and management.

2.2 Roles and Responsibilities of partners

2.2.1 Academic institutions (including schools of medicine, pharmacy, public health, and nursing):

- Provide tertiary care for TB in the community they serve
- Serve as models for TB risk assessments for patients, in-patient care and infection control practice
- Incorporate TB education ion their curriculum

- Function as repositories of expertise in the treatment and management of TB infection and disease
- Provide sites for TB education and training and clinical research as well as hospital and outpatient care
- Provide leadership in conducting research in diagnostics, drugs, and vaccines for TB infection and disease

2.2.2 Medical professional organizations/associations

- Provide training and education of their members and other health professionals on both clinical and public health aspects of the risk assessment, diagnosis, treatment, control, and prevention of TB disease
- Support the development or endorsement of guidelines, professional school curricula for TB control and TB training Fellowship programmes
- Provide support for adequate funding for TB control and research through public education campaigns

2.2.3 Civil Society/Community-based organizations (CBOs)

- Facilitate access to TB diagnosis, treatment and prevention services through partnership with the State and local government TB control programmes and public/private care providers
- Participate in support initiatives such as State and local government TB advisory committees
- Develop educational programmes for the target population in collaboration with public health agencies and educational institutions

2.2.4 The prisons

- Coordinate with the State or national TB programme to develop and maintain routine surveillance for TB data analysis and reporting to the programme
- Establish screening tools in collaboration with TB programme for routine testing of all symptomatic presumptive cases of tuberculosis
- Serve as sites for the treatment and care for all cases diagnosed in the facility
- Establish and strengthen referral linkages for patients who are in-mates to local government TB programmes after discharge
- Develop TB infection programs to protect inhabitants, detainees, staff and visitors from exposure to TB infection.
- Develop education programmes for staff and inmates regarding TB disease

2.2.5 Hospital (including all tertiary and Federal Medical Centres)

- Develop TB infection control policies and ensure that effective TB infection control measures are implemented in the facility
- Report data on presumptive or confirmed TB cases to their LGA and State TB and Leprosy control programmes
- Develop written policy and plan for prevention of the nosocomial transmission of TB disease in their facility

- Provide training and education of both medical as well as support staff of the institution on the prevailing diseases of the populations which they serve including tuberculosis
- Coordinate and prepare advanced arrangements with the local and perhaps the State government programmes for all TB patients on care who are discharged to the health facilities close to them

2.2.6 Partner organizations

- Collaborate with the NTBLCP in the implementation of TBL & BU activities in line with the NTBLCP implementation guidelines
- Provide Technical and/or Financial supports to the NTBLCP as the need may arise
- Ensure that organizational strategic and operational plan for the control of TB, Leprosy and Buruli ulcer speaks to the NTBLCP over all goals and objectives.

2.3 Job descriptions of key NTBLCP staff at all levels

2.3.1 National Co-ordinator (Head of the NTBLCP at the Federal Ministry of Health)

Qualification: Medical Officer with post-graduate training in Public Health
Responsible to: Head of Department of Public Health, Federal Ministry of Health

✓ **The National Co-ordinator is responsible for:**

- Co-ordination of all activities of TB, leprosy and buruli ulcer control in the country.
- Provision of managerial and technical support for the Zonal TBLCP Co-ordinators and the State TBL Control Officers.
- Procurement and distribution of the National Tuberculosis and Leprosy Control Programme supplies (anti-tuberculosis, anti-leprosy and anti-lepra reaction drugs, laboratory equipment and reagents, stationery and transport etc.)
- Resource mobilization for the implementation of the Programme
- Ensuring adequate Human Resources for the Programme
- Maintaining active collaboration with national and international, non-governmental organizations and voluntary agencies including private health establishments
- Organisation of periodic review and evaluation of the NTBLCP
- Performing any other duty that may be assigned

Programme Officers and other support staff of the Central unit will assist the National Co-ordinator.

2.3.2 State Tuberculosis and Leprosy Control Officer (STBLCO)

Qualifications: Medical Officer with post-graduate training in Public Health
Responsible to: Administratively to the Director of Public Health State Ministry of Health* and technically to the National Coordinator

✓ **The State TBL Control Officer's responsibilities include:**

- Management of TBL and BU control activities at the State level
- Management, coordination, and supervision of all programme activities at State and local government levels
- Assist in the diagnosis and management of difficult TBL & BU patients
- Order and distribute supplies to LGAs
- Collect, collate and analyse data on leprosy and tuberculosis activities in the State and disseminate reports to the Federal and Local Governments, as well as other organizations and institutions as appropriate
- Maintain active co-operation with NGOs supporting the State programmes
- Perform any other duties that may be assigned

2.3.3 The Local Government Tuberculosis and Leprosy Supervisor (LGTBLS)

Qualifications: Nurse, CHO, Environmental Health Officer or Senior CHEW with at least 5 year experience
Responsible to: Technically to the STBLCO; administratively to the HOD Health at the LGA headquarters

✓ **The Local Government TBL Supervisor is responsible for:**

- Managing and co-ordinating TB, leprosy and BU control activities in LGA
- Assisting the STBLCO in planning, organizing and conducting training programmes
- Ensuring proper sputum collection and prompt transportation to the laboratory
- Assisting in diagnosis and management of difficult TBL & BU patients
- Supervising treatment by other health workers throughout the LGA and ensure that the National guidelines are followed
- Keeping an up-to-date and accurate record of activities of TB, leprosy & BU control activities in the LGA, including the LGA Central Registers
- Ensuring that patients' record cards are properly filled and kept by the health unit staff
- Ordering supplies (drugs, laboratory supplies, records cards and forms) from the State level for the LGA and ensure their distribution to all health units
- Liaising with the PHC Co-ordinator in carrying out health education activities in the LGA
- Ensuring proper slide selection for blinded re-checking
- Undertaking activities for disability prevention and rehabilitation
- Performing any other duties that may be assigned

2.3.4 State Laboratory Quality Assurance Officer

Qualifications: Registered Medical Laboratory Scientist or technologist who has attended orientation course in TB microscopy.
Responsible to: The State TBL Control Officer

✓ **The State Laboratory Quality Assurance Officer is responsible for:**

- Setting up QA (Quality Assurance) system in the State in conjunction with the Control Officer
- Carrying out regular supervision to each of the laboratories aimed at ensuring that Standard Operating Procedures (SOP) are adhered to and also carry out on-the-job training
- Maintaining adequate stock of reagents and software to eliminate out of stock syndrome at the State level; Central reconstitution of laboratory reagents.
- Ensuring effective utilisation and care of reagents, equipment and materials meant for the programme
- Ensure quarterly requisition of laboratory stocks through the LGTBLS or MO in charge
- Together with the CO facilitate laboratory feedback and information dissemination quarterly meetings
- Organising training of for laboratory workers on programme procedures.
- Keeping records of work quarterly, and collating statistical data on workload (patient and smear)
- Perform any other duties that may be assigned
- Ensure quarterly requisition of laboratory stocks through the LGTBLS or MO in charge
- Taking part in all laboratory feedback and information dissemination meetings relating to NTBLCP

2.3.5 Laboratory worker at the health facility level

Qualifications: Registered Medical Laboratory Scientist, technologist or technician who has attended orientation course in TB microscopy.
Responsible to: Administratively to the Officer in charge of the health facility and technically to the LGTBLS, QA officer and the STBLCP.

✓ **The Laboratory worker at the health facility is responsible for:**

- Observing all standard operating procedures and basic safety measures for efficient and effective TB Microscopy, in all cases, as designed by the Programme
- Advising patients and other health workers on correct, safe sputum collection
- Preparing, staining and examining sputum and slit skin smears
- Ensuring prompt dispatch of results to the clinic in less than 72hrs from the receipt of specimen
- Recording findings and reports using the NTBLCP Information System
- Storing slides for quality control
- Creating and facilitating the practice of Internal Quality Control as an integral part of standard laboratory practice
- Maintaining effective communication with reference laboratory for the purpose of Quality Control and cooperating with them by preserving serially, all read Z.N. smears on quarterly basis

- Maintaining adequate stock of reagents and software to eliminate out of stock syndrome
- Ensuring effective utilisation and care of reagents, equipment and materials meant for the Programme
- Taking part in all laboratory feedback and information dissemination meetings

2.3.6 Medical Officer at the TBL Referral Hospital

Qualifications: Medical Officer
Responsible to: Administratively to the Medical Director in charge of the Hospital/Director of Medical Services/Chief Medical Officer and technically to the LGTBLS and the STBLCP

✓ **The Medical Officer is responsible for:**

- Attending to all referrals from the field
- Attending to non-referral patients coming to the hospital
- Ensuring that patients receive the treatment necessary for their disease conditions (both medical and surgical)
- Giving feedback to STBLCO on referred patients as well as new patients detected in the hospital
- Ensuring both medical and surgical general supplies are available at all times as allowed in the budget
- Supervising the various hospital departments for effective functioning
- Holding departmental and management meetings regularly
- Co-operating with other health institutions in the State
- Performing any other duties that may be assigned.

2.3.7 Physiotherapist

Qualifications: Registered Physiotherapist
Responsible to: Administratively to the Medical Officer in charge and technically to the LGTBLS and the STBLCP

✓ **The physiotherapist is responsible for:**

- Ensuring appropriate assessments of all patients and records (both in-patients and out-patients) attending physiotherapy
- Producing individual treatment plans based on clinical assessment and analysis
- Keeping appropriate records of all patients
- Educating and training the patients, specifically in the area of prevention of disability
- Co-ordinating self-care groups in the settlements around the hospital
- Administering, training and developing the Prevention of Disability (POD) programme in the Centre for both in-patients and out-patients
- Visiting the field areas of the centre and identifying areas that require intervention in the area of POD when requested by the STBLCO

- Facilitating the Field POD Programme through training of LGATBLS and General Health Workers when requested by the STBLCO
- Ensuring regular monitoring and evaluation of all activities within the department
- Day to day administration of the department and planning for development including departmental budgets
- Take part in relevant researching
- Performing any other duties that may be assigned

2.3.8 General Health Care Worker (GHCW): Nursing and Primary Health Care staff

Qualifications: Qualified Nurse, Community Health Officer, Community Health Extension Workers, Pharmacist and any other staff with minimal competency to perform this task.
Responsible to: Administratively to the Officer in charge of the hospital and technically to the LGTBLS and the STBLCP.

✓ **The General Health Care Worker's responsibilities include:**

- Identifying; Presumptive TB Cases, Leprosy and BU Suspects
- Ensuring TB diagnosis through appropriate specimen examination for bacteriology
- Diagnosis of Leprosy and BU cases
- Classifying TBL patients for treatment
- Administering and monitoring TBL treatment
- Carrying out examinations of household contacts of patients
- Filling completely and accurately all forms, cards and registers used in patient management
- Identify and refer all smear negative patients and children suspecting to be having TB to Medical Officers where appropriate
- Tracing and retrieving patients who interrupt treatment with collaboration with the LGTBLS and CBOs in the community
- Carrying out patient education on TBL
- Undertaking public enlightenment

IMPLEMENTING TUBERCULOSIS CONTROL ACTIVITIES

3. INTRODUCTION

Tuberculosis (TB) is a communicable disease caused by a type of bacteria known as Mycobacterium tuberculosis (commonly referred to as TB bacilli). The bacilli usually attack the lungs, causing pulmonary TB (PTB). TB bacteria can also attack other parts of the body such as the spine, lymph nodes, brain and kidneys; this is known as extra-pulmonary TB (EPTB).

3.1 Transmission

When individuals with infectious tuberculosis cough, sneeze, talk or spit, they expel TB bacilli into the air. TB is an airborne disease i.e. transmitted through the air by inhaling air contaminated with TB bacilli. Transmission is more intense in crowded, poorly ventilated spaces with little ambient sunlight as they increase the likelihood of inhalation of infectious TB bacilli present in the air.

If not treated, a person with active pulmonary TB disease will infect, on average, between 10 and 20 people every year. Persons infected by M. tuberculosis but who have no symptoms of TB disease have what is known as latent TB infection. After infection, TB bacilli can lie dormant in the body for many years. If the immune system is compromised as in the case of HIV infection, malnutrition or other conditions the TB bacilli can cause active disease.

Many factors influence the progression from infection to disease. The most important is HIV infection. Other factors include age, diabetes and cancer.

3.2 The targets for TB control in Nigeria

- To detect at least 70% of the estimated all forms of TB cases by 2020
- To achieve a treatment success rate of at least 90% for all new bacteriologically confirmed TB cases by 2020
- To eliminate TB as a public health problem (<= 1/1,000,000 population) by 2050

3.3 Strategy to Control Tuberculosis

The NTBLCP strategy to control TB is outlined in the new Strategic Plan (2015- 2020) in line with the new STOP TB strategy recommended by WHO. It is based on the following elements:

1. Pursuing high quality DOTS expansion and enhancement
2. Addressing TB/HIV, MDR-TB and other challenges
3. Contributing to health system strengthening
4. Involving all care providers
5. Engaging people with TB and affected communities
6. Enabling and promoting operational research

4. APPROACH TO DIAGNOSIS OF TUBERCULOSIS

Diagnosis of TB starts with early identification of a TB case and prompt initiation of treatment. This is important for TB control and reducing TB-related mortality, particularly in TB/HIV co-infected patients and other high risk groups. Diagnosis of tuberculosis depends on the identification of the tubercle bacilli in a clinical specimen OR a strong suspicion of TB based on sound clinical judgment.

4.1 Identifying a Presumptive Tuberculosis Case

4.1.1 Definition of Presumptive TB case

A Presumptive TB case (previously known as TB suspect) is a person who presents with symptoms or signs suggestive of TB. The most common symptom of pulmonary TB is productive cough for 2 weeks or more, which may be accompanied by other respiratory symptoms. However, any person living with HIV (PLHIV) is considered a presumptive TB case if he/she presents with cough of any duration. Other respiratory symptoms may include:

- Shortness of breath
- Chest pain
- Coughing up blood (haemoptysis)

There may be other constitutional symptoms such as;

- Loss of appetite
- Fever
- Weight loss
- Night sweats
- Tiredness

Tuberculosis cases are most frequently found among the following:

- patients who present themselves on their own initiative at a health facility with symptoms suggesting tuberculosis;
- those (especially children and young adults) living in the same household with smear-positive patients;
- those infected with HIV
- those found to have an abnormality that has the appearance of tuberculosis when a chest radiograph has been taken for clinical investigation of a sick patient
- those who live in crowded conditions, such as prisons
- those treated for TB in the past

Symptoms or signs due to Extra Pulmonary Tuberculosis (EPTB) depend on the site involved. Regardless of the site of disease, there are usually constitutional symptoms present such as fever, night sweats and weight loss.

Table 4.1: Symptoms of Tuberculosis Disease

Pulmonary	General: Pulmonary and Extra-pulmonary	Extra-pulmonary
• Cough • Coughing up sputum or blood • Pain in the chest when breathing or coughing	• Chills • Fever • Night sweats • Loss of appetite • Weight loss • Weakness or easy fatigability • Malaise (a feeling of general discomfort or illness)	• The symptoms depend on part of body affected by tuberculosis (TB) disease: • TB of the spine may cause pain or swelling in the back. • TB of the kidney may cause blood in the urine. • Meningeal TB may cause headaches, persistent fever, neck stiffness, vomiting, irritability, convulsions or loss of consciousness. • Lymphatic TB Lymphadenitis may cause swollen and non-tender lymph nodes, often at the base of the neck and may drain pus

4.2 Investigating a presumptive Tuberculosis case

4.2.1 Laboratory diagnosis of Tuberculosis

The laboratory diagnosis of TB rests mainly on the identification of the tubercle bacilli in a clinical specimen by using any of the following laboratory methods available; microscopy, culture or newer molecular tests e.g. GeneXpert MTB/RIF and line probe assays. Similarly, the laboratory diagnosis of TB begins with the collection of a quality clinical specimen which in the majority of cases is a sputum specimen, therefore proper specimen collection and prompt transportation to the laboratory should be ensured by all health staff.

Any of the commonly used methods such as; direct coughing up of sputum, nebulization/Sputum induction, gastric washing/aspirate and bronchoscopy may be used to collect a sputum specimen sample from an identified presumptive TB case where necessary.

4.2.1.1 Methods of collecting sputum specimen

i. Process of sputum collection using coughing up of sputum method

All presumptive PTB cases should be requested to submit two (2) sputum specimens using the 'spot-early morning' approach as described in table 4.2 below.

Table 4.2 Approach for sputum samples collection for smear microscopy

Day	Specimen number	Approach to specimen collection
Day 1	Sample 1	Patient provides an "on the spot" sample under supervision; Give the patient a sputum container to take home for an "early morning" sample the following morning
Day 2	Sample 2	Patient produces and brings the "early morning sample" to the clinic

A. Before collecting sputum specimen:

a) Health worker should educate and inform the presumptive TB Case on the following:
- The reason for collection of sputum
- That he/she will give 2 sputum specimens to be examined in a laboratory for TB germs
- That if the germs are seen the Presumptive TB Case will receive treatment and be cured

b) Health Worker should:
- Fill the 'NTBLCP Clinic Presumptive TB case Register' (TB suspect register)
- Fill a 'Request for Sputum Examination Form'
- Write the number of the patient on the side of the sputum container, according to the clinic Presumptive TB case Register;
- Ensure that sputum collection occurs in a well-ventilated area or outside, but in private and without others watching (the collection must be supervised).
- Ensure that the patient must be informed and understand the instructions for sputum collection (the supervisor must not stand in front of the patient).

c) Advise the patient to be very careful and direct the sputum into the container so as not to contaminate the outside of the container.

d) Ask patient to cough deeply (demonstration may be necessary);

e) Patient should spit the sputum carefully into the container to avoid contamination of the outside part;

f) If the specimen is not suitable, e.g. saliva, then repeat deep coughs to produce better sample.

B. During Collection of Sputum Specimen:

a) Ensure that patients who have chewed any food immediately before sputum collection have rinsed their mouth with water

a) Tell the patient that the best specimens come from deep inside the lungs after coughing, not from saliva

b) Demonstrate how to cough deeply

c) Instruct the patient to:
- Inhale deeply 2 to 3 times and to breathe out hard each time,
- Cough deeply from the chest
- Place the open container close to the mouth to collect the sputum
- Screw the lid tightly after producing sputum
- Return the sample to the laboratory where possible

d) The patient should spit the sputum carefully into the container to avoid contamination of the outside part; If the outside is contaminated, discard the container and repeat the collection with a fresh container
e) If the specimen is not suitable, e.g. saliva, then repeat deep coughs to produce better sample.
f) The volume of the sputum should be about 3 to 5 ml (equivalent to one tablespoonful).

C. After collecting sputum specimen:

a) Double check to ensure that the container is labelled properly,
b) The container should be firmly closed using the lid
c) Hands should be washed with soap and water
d) All sputum specimens should be sent to the lab immediately
e) In situations where sputum specimen cannot be move to the lab immediately,
f) Store sputum specimens preferably in a refrigerator or in a cool, safe and dark place.
g) Sputum specimens for microscopy culture should be sent to the laboratory within 5 days.
h) The specimens should be sent to the laboratory as soon as possible, not later than 24hours after collection
i) Each specimen should be accompanied with a completed sputum examination request form

D. Labelling of sputum specimen container:

a) It is important that sputum containers are labeled on the side of the cup and not on the cover, to avoid confusion in the laboratory.
b) The number on the sputum container is derived from the Presumptive TB case clinic register: Clinic code/Number of examination in the current month/current calendar month/number of specimen. Refer to the example below:

Example:

The 2 sputum specimens that were taken from a presumptive TB case at Maitama PHC in August, being the 50th patient that was screened that month, would be labeled:
MT/50/08/1
MT/50/08/2

E. Transportation of sputum specimens

a) Sputum specimens should be sent to the laboratory as soon as possible to ensure examination is done within 48 hours of collection.
b) All samples should be properly labelled.
c) Make sure that every specimen is accompanied with a laboratory request form and do not use the TB Request for Sputum Examination forms for wrapping specimens.
d) The dispatch register should be filled by the health worker delivering the sputum in the laboratory
e) If samples require transportation, they should be packed carefully, preferably in a transport box (3-level packaging) before transportation.

f) A cold chain should be maintained throughout the transportation process, especially when sending samples for culture.

Note

- Smear microscopy has good specificity for TB but has very low sensitivity in detecting TB in patients with non cavitary pulmonary disease or low bacillary load in sputum (e.g. HIV positive patients).
- Laboratory personnel should perform sputum examination the same day samples are submitted, aiming to return a result to the patient within 48 hours from the collection of the first sputum specimen.

Refer to manual on technical SOPs for TB laboratories in Nigeria.

ii. Process of Sputum collection using gastric aspirate method

In children who are unable to expectorate spontaneously, obtaining an aspirate of gastric fluid is a reasonable alternative to obtaining sputum. Gastric aspirates are safe and easy to perform early in the morning after an overnight fast. Two gastric aspirate specimens or one gastric aspirate specimen should be collected when examination by microscopy or GeneXpert MTB/RIF is needed respectively. As much as possible, sputum should be collected within 2 days and sent to the laboratory within 48 hours.

A. Patient Preparation

- Ideally the patient being prepared for an early morning gastric aspirate should sleep for at least six hours without interruption, and should not eat or drink anything overnight to prevent the stomach from emptying.
- The family should come to the clinic first thing in the morning.

B. Procedure for collection of gastric aspirate

- Place nasogastric (NG) tube in patient; use as large a bore NG tube as this is likely to be more comfortable for the child (minimum 10FG size). Avoid too deep a placement to prevent passage through the pylorus.
- The (stepwise) procedure for sample collection includes:
    - Aspirate the stomach contents and if less than about 10ml of mucus is aspirated, instill 20–30ml of sterile water into the tube and quickly withdraw. (Note: the organism is most viable when not exposed to saline or preservatives; the kind of sterile water used for infant feeding is fine).
    - Reposition the tube and/or the patient to maximize the yield of gastric contents.
- Place the gastric aspirates in a regular specimen cup, universal tube or a special bicarbonate-containing gastric aspirate tube, where available.
- Transport the specimen to the microbiology lab. If special bicarbonate containing tube or cup is not available, the lab must neutralize the stomach acid with bicarbonate within 1/2 hour.

iii. Process of Sputum collection using Nebulization/ Sputum induction method

This is an alternative method that can be used for sputum specimen collection especially in organized tertiary facilities where facility for nebulization is readily available. It is used to obtain sputum in patients with non- productive cough and easy to perform. It entails that patient inhales a saline mist which causes them to cough. Disadvantages includes; it requires special equipment, specimen may be watery and confused with saliva and may cause bronchospasm

iv. Process of Sputum collection using Bronchoscopy method

This method is used to obtain sputum when the patient cannot cough and gastric aspirate cannot be done. This invasive procedure needs some level of specialization and entails that a scope is passed through the mouth or nose to the diseased part of the lung to obtain sputum or lung tissue. The procedure must be done in a hospital by a specialist, requires special equipment and anaesthesia.

4.2.1.2 Laboratory methods for diagnosing Tuberculosis

i. Sputum Microscopy

Sputum smear microscopy still remain the primary test for the diagnosis of pulmonary tuberculosis (PTB) in Nigeria. Smear microscopy has good specificity for TB but has very low sensitivity in detecting TB in patients with non cavitary pulmonary disease or low bacillary load in sputum (e.g. HIV positive patients). Smears may be prepared directly from clinical specimens or from concentrated preparations using the two available staining methods (Ziehl-Nielsen staining or fluorescent Auramine staining) in the country to observe acid-fast bacilli.

Interpretations of Smear results

A sputum smear result is positive if at least one tubercle bacillus (acid-fast *OR* fluorescent) is detected on one or more sputum smears.

Figure 4.1 Interpretation of sputum Smear (AFB) Microscopy Result

Positive AFB Result:

Sample 1	Sample 2
+	+
+	Sc
+	0
Sc	0
0	+
Sc	Sc
Sc	0
0	Sc

Negative AFB Result:

Sample 1	Sample 2
0	0

Scanty refers to:

1-9 AFB per 100 oil immersion for ZN Staining

OR

<1 AFB per field for Auramine Staining

When recording, ensure to enter all AFB smear-positive results into the Tuberculosis Laboratory Register, on the TB treatment card and in the Facility treatment register in red ink.

ii. Molecular rapid test Methods

Currently in Nigeria, there are two PCR technologies available and both provide different information which is helpful in the management of TB. These includes; GeneXpert MTB/RIF which is useful for rapidly diagnosing TB and Line Probe assay which is useful for drug resistance confirmation and detects resistance to both Rifampicin and Isoniazid.

✓ GeneXpert MTB/RIF rapid testing

This is a new rapid molecular test. It requires only one clinical specimen and can detect both TB and rifampicin-resistance in less than 2 hours. The NTBLCP has prioritized the following for GeneXpert MTB/RIFMTB/RIF testing:

1. Known symptomatic contacts of confirmed DR-TB cases
2. Failure to Regimen 1 treatment
3. Failure to convert when AFB is repeated at month three (3) of Regimen 1 treatment
4. Retreatment cases (Relapse, Treatment after failure, Treatment after loss to follow-up, and other previously treated patients)
5. All patients with smear negative AFB result who remained symptomatic after a week course of broad spectrum antibiotics
6. PLHIV with symptoms of TB
7. Any health care staff with symptoms of TB who has not had TB before
8. All children with symptoms of TB
9. Extra-pulmonary TB (Where applicable)

✓ Line Probe Assays

These tests provide rapid diagnosis of drug resistant TB for direct testing on smear positive specimens and on isolates from solid and liquid culture. It simultaneously detects MTB complex and specific mutations in the *rpoB* gene conferring rifampicin resistance and mutations on the *katG* gene which is associated with higher levels of isoniazid resistance and *inhA* gene mutations which is associated with lower levels of isoniazid resistance.

Advantages of line probe assay includes; the detection of MTB and resistance to RIF & INH at the same time from one specimen, reduces time to diagnosis of MDR-TB to 7 days, it is specific for MTB complex and can differentiate MTB from other mycobacteria. Its use however is limited because; It cannot be used for monitoring patients on treatment (it does not distinguish between live and dead bacilli), therefore its use is limited to diagnosis, It is dependent on smear results, can only be performed on smear positive or culture positive sputum specimen, the test is labour intensive and is prone to contamination and human error and requires a lot of space (at least 3 separate rooms for the different steps)

iii. Culture Methods

Culture methods remain the cornerstone of bacteriologic confirmation of TB. It is more sensitive than smear microscopy, detecting a higher proportion of cases among patients with symptoms. Traditional culture uses a solid medium such as coagulated egg (e.g. Löwenstein-Jensen) or agar (e.g. Middlebrook 7H10) as a base. While solid media are simple and cost effective to use, there are few limitations such as; slow bacterial growth (3-4 weeks) and errors due to manual reading of results for which the development of more sensitive liquid medium culture techniques, has allowed for the more rapid detection of TB bacilli, within 7 to 14 days and automated systems are used to culture mycobacteria in liquid media. These systems use specialized vials/tubes which are inoculated with the patient's specimens.

Indications for sputum culture in Nigeria include:

- TB cases diagnosed as Rifampicin resistant on GeneXpert MTB/RIF for susceptibility testing of other drugs (i.e. all MTB detected Rifampicin resistant detected cases)
- MTB not detected cases who are AFB smear positive with persistent symptoms of TB; this is to exclude the presence of Non Tuberculous Mycobacteria.
- In unusual cases where despite a Rifampicin susceptible result the patient is failing treatment and treatment adherence is good and thus resistance to drugs other than Rifampicin is suspected.

Note that:

- Smear microscopy requires ~10,000 TB bacilli per ml of sputum to be detected/positive.
- GeneXpert MTB/RIF requires ~ 130 TB bacilli per ml of sputum for a positive result
- Culture can be positive with only ~10 - 100 TB bacilli per ml of sputum
- Liquid culture is more prone to contamination than solid culture

4.2.2 Other investigations for Tuberculosis in adults

i. Chest X-ray

The use of chest x-ray is very limited in the diagnosis of TB. All patient with smear negative sputum result whom after a 7-days course of broad spectrum antibiotics still remain symptomatic should be subjected to Xpert testing. However, its use in patients with suspected complication still remain important.

ii. Ultrasound

Ultrasound can be used as a supplementary investigation in the diagnosis of extra-pulmonary TB particularly abdominal and pericardial TB.

iii. Computerized Tomography (CT scan) and Magnetic Resonance Imaging (MRI)

The use of CT scan and MRI are not widely recommended because they are expensive but they have proved useful for imaging tuberculosis lesions. It provides more detailed images of body parts not easily seen on a standard x-ray. The CT scan may be of diagnostic value in;

a. Children and immune compromised people suspected to have TB but without any positive findings
b. Patients with normal or inconclusive chest x-ray where TB complications are suspected
c. Patients with extra-pulmonary TB

iv. Tuberculin skin test

The tuberculin test has limited value in clinical work, especially where TB is common. The test shows hypersensitivity to proteins of the TB bacillus, as a result either of infection with M. tuberculosis or induced by Bacille Calmette-Guérin (BCG) vaccination. A positive TST does not indicate TB disease, only infection. A negative result does not rule out the diagnosis of TB disease as various conditions, including HIV, may suppress the reaction.

v. Histological Test

In addition to a smear-positive microbiological evidence from the fine needle (lymph node) aspirate, histological features of a tuberculous lesion (from a fine needle aspirate specimen) also offers a convenient laboratory avenue for making a diagnosis of tuberculous lymphadenitis.

vi. Chemistry of cerebrospinal fluid

Rarely, features of tuberculous meningitis (i.e. elevated WBC with lymphocytic predominance, high protein and/or a low glucose concentration with or without identifying the tubercle bacilli on microscopy) are also considered a valid diagnostic tool.

The WHO has recently reviewed data on the performance of serological tests for TB and has strongly recommended that these tests should NOT be used in the diagnosis of TB infection or disease.

Table 4.3: Specimens for diagnosis of EPTB

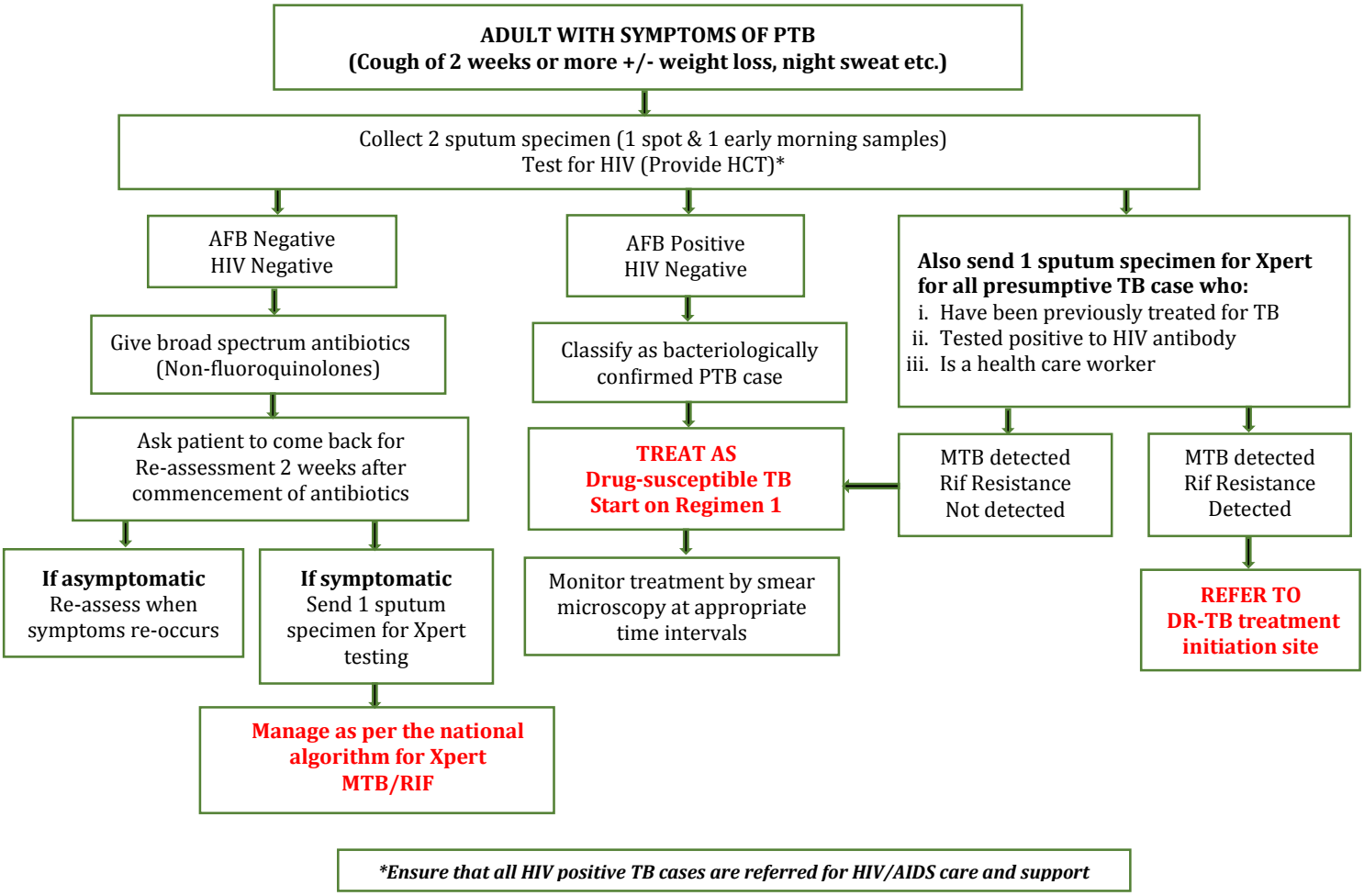
Suspected Diagnosis	Specimen Needed
Extra-pulmonary TB	Depending on the site, other clinical specimens may be necessary, such as: • Urine – Renal TB • Cerebrospinal fluid – TB of the meninges • Pleural fluid – TB of the lung pleural • Pus or other aspirated fluid – TB of the pleural, abdomen etc. • Biopsy specimens – TB of the lymph nodes

4.3 Management of an Adult Presumptive Pulmonary Tuberculosis Case

To ensure reduction in the transmission of TB, early identification of persons with symptoms of TB is an essential step in the management of a presumptive PTB case. Absence of fever or cough does not exclude a diagnosis of tuberculosis, particularly in patients with HIV or malnutrition. The revised NTBLCP guidelines describes the revised algorithms for TB diagnosis, drug susceptibility testing for Rifampicin and how to manage patients based on the test results.

Therefore, all individuals who present with symptoms of pulmonary TB should be managed in line with the National TB guideline as described in figure 4.2 and 9.1.

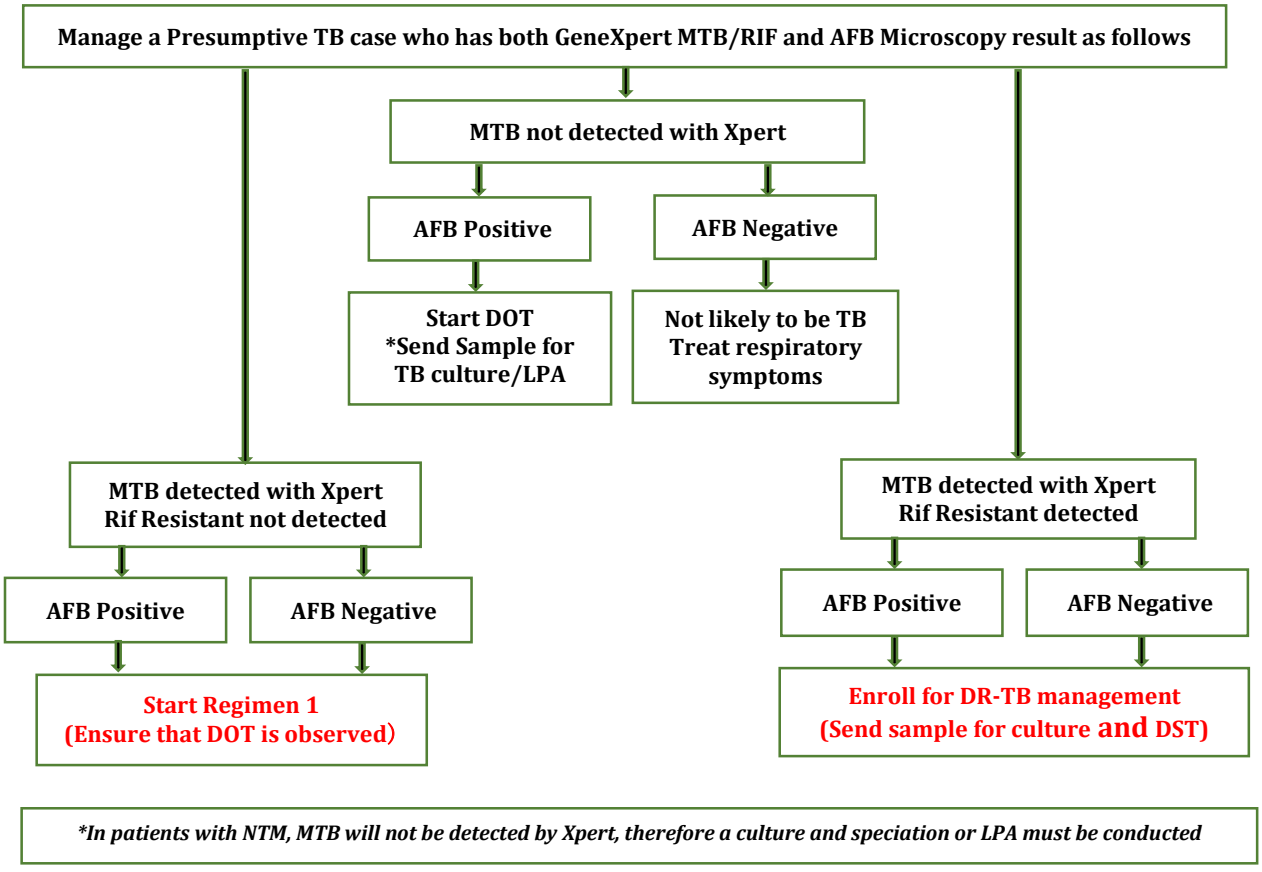
Fig. 4.2: Diagnostic algorithm for management of Presumptive PTB Cases



4.3.1 Interpreting a multiple bacteriological examination result for TB diagnosis

The new NTBLCP diagnostic algorithm allows for a presumptive TB case to have multiple bacteriological examination done for TB diagnosis in order to ensure early diagnosis and improve diagnosis. In most cases, this usually come as an AFB smear microscopy and an Xpert MTB/RIF examination. To avoid confusion in the interpretation of test results for the purpose of managing these patients, it is important to understand the interpretation of results when both AFB microscopy and Xpert test are done at the same time. Refer to figure 5.3 below on how to interpret bacteriological results when a presumptive TB case has both an AFB examination result together with a GeneXpert MTB/RIF result.

Figure 4.3: How to interpret AFB microscopy result together with Xpert MTB/RIF result



4.4 Approach to management of Presumptive EPTB Cases

Diagnosis of EPTB is based on at least one specimen with confirmed M. tuberculosis by smear microscopy, culture or histology. However, strong clinical evidence consistent with active EPTB, followed by a decision by a clinician to treat with a full course of tuberculosis chemotherapy may suffice in the absence of a bacteriological confirmation.

- **Any person suspected of having extra-pulmonary TB should be referred to a Medical Officer where appropriate samples and diagnostic methods will be used to make diagnosis.**
- **All patients suspected of EPTB should be offered HIV counselling and testing.**

Table 4.4: Approach to management of common EPTB case

Disease Site	Typical clinical presentation	Investigation
TB adenitis	• Asymmetrical, painless, non-tender lymph node enlargement for more than one month • +/- discharging sinus • Most commonly in neck area	• Fine needle aspiration when possible for culture and cytology • Lymph node biopsy for histology • TST usually positive - not necessary for diagnosis If axillary node enlargement on same side as BCG, consider BCG disease and refer or manage as applicable
Pleural TB	• Signs of respiratory distress • Reduced breath sound • Dullness on percussion • +/-chest pain Signs and symptoms are related to the degree of fluid in the pleural space	• Investigate for PTB • Chest X-Ray • Pleural tap* If pus in pleural tap, consider empyema and refer or manage as applicable.
TB meningitis	• Headache • irritability/abnormal behaviour • vomiting (without diarrhoea) • lethargic/reduced level of consciousness • Convulsions • Neck stiffness • Bulging fontanelle • Signs and symptoms of cranial nerve palsies	• Lumbar puncture and obtain CSF* for microscopy, GeneXpert MTB/RIF • CXR where applicable • Hospitalise for TB treatment and treat as per NTBLCP Guidelines
Miliary TB	• Non-specific symptoms • May be lethargic • Fever • wasted	• Chest X-Ray If chest X-ray is suggestive, treat as per NTBLCP guidelines
Abdominal TB	• Abdominal swelling with ascites • or abdominal masses	• Abdominal USS • Ascitic tap* • FNACs
Spinal TB	• Deformity of spine	• X-ray of the spine (Features of anterior wedge collapse of the spine)

	May have lower limb weakness/ paralysis/unable to walk	Treat as per NTBLCP guideline
Pericardial TB	• Signs and symptoms of cardiac failure • Distant heart sounds • Apex beat difficult to palpate	• CXR • Cardiac ultrasound • Pericardial tap* Treat as per NTBLCP guidelines and is an indicator for steroid
TB bone and joint	Swelling end of long bones with limitation of movement • Unilateral effusion of usually knee or hip	• X-ray bone/joint • Joint tap*

**Typical findings – straw coloured fluid, exudates with high protein, WBC predominantly lymphocytes on microscopy. Also do GeneXpert MTB/RIF or culture were applicable.*

5. APPROACH TO TREATMENT OF TUBERCULOSIS

5.1 Case definitions

5.1.1 TB Case

A TB case is a person who has been confirmed to have TB disease. It is classified as either bacteriologically confirmed or clinically diagnosed TB case.

A bacteriologically confirmed TB case: is a presumptive TB case from whom Mycobacterium tuberculosis complex is identified from a clinical specimen, either by smear microscopy, culture or WHO-approved rapid diagnostics (WRD) such as GeneXpert MTB/RIF.

In line with the introduction of the new NTBLCP algorithm for the management of presumptive TB cases in Nigeria, it is important to properly interpret all bacteriology results to ensure proper case definition of all presumptive TB cases who present with multiple bacteriological results. Refer to table 5.1 for the current interpretation of bacteriology results in Nigeria.

Table 5.1: Defining a TB case who present with multiple bacteriological results

Results	Definition	Comment
Xpert positive TB	MTB detected in at least one clinical specimen tested using GeneXpert MTB/RIF	This applies to both pulmonary and extra pulmonary specimen
Xpert negative TB	MTB not detected in at least one clinical specimen tested using GeneXpert MTB/RIF	This applies to both pulmonary and extra pulmonary specimen
Smear positive PTB	MTB detected using GeneXpert MTB/RIF and at least 1+ acid-fast bacilli (10-99 AFB per 100 oil immersion fields)* in at least one sputum smear microscopy	This is essential for contact investigation and monitoring the patient's response to treatment as well as confirming cure.
Smear negative PTB	MTB detected using GeneXpert MTB/RIF and at least two sputum smear microscopy negative for AFBs*	This may be used to monitor the patient's response to treatment
Culture positive TB	A positive culture result with or without an Xpert result.	This applies to both pulmonary and extra pulmonary specimen.
***This is essential for contact investigation and maybe used for confirming cure.**		

A clinically diagnosed TB case: is a presumptive TB case who does not fulfil the criteria to be considered bacteriologically confirmed but has been diagnosed with active TB by a health care worker (clinician or other medical practitioner) who has decided to treat the patient with a full course of TB treatment. This includes:

- Cases diagnosed on the basis of X-ray abnormalities that are consistent with active TB

- Suggestive histology and clinical picture suggestive of PTB or EPTB extra pulmonary cases without a laboratory confirmation.
- Histological and biochemical tests suggestive of TB

Clinically diagnosed cases subsequently found to be bacteriologically positive (before or after starting treatment) should be re-classified as bacteriologically confirmed.

5.1.2 Classification of TB Cases

Cases of TB are also classified according to the**:**

- Anatomical site of disease,
- Bacteriological results (including drug resistance)
- History of previous treatment
- HIV status.

5.1.2.1 Classification based on Anatomical site of disease

In general, recommended treatment regimens are similar, irrespective of the anatomical site of disease. Defining the site is important for recording and reporting purposes and to identify the more infectious patients – those with pulmonary involvement (who will be further subdivided by bacteriological status).

Pulmonary tuberculosis (PTB)

This is a form of tuberculosis that involves the lung parenchyma (tissues). Miliary tuberculosis is classified as pulmonary TB because there are lesions in the lungs as well.

Extra-pulmonary tuberculosis (EPTB)

This type of TB involves one or more organs other than the lung parenchyma, for example, the pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones and/or meninges. Both intra-thoracic tuberculous lymphadenopathy (e.g. involving the mediastinal and/or hilar lymph nodes) and tuberculous pleural effusion, when radiographic abnormalities in the lungs are absent, constitute cases of extra-pulmonary TB.

Patients with both pulmonary and extra pulmonary TB should be classified based on site of maximal disease involvement e.g. Miliary tuberculosis is notably the deadliest form of the disease, but is now classified as pulmonary TB because most lesions are in the lungs and treatment is with Regimen 1 as per NTBLCP guideline.

5.1.2.2 Classification based on Bacteriological results (including drug resistance)

Bacteriological status refers to the detection of M. tuberculosis by smear, culture or molecular methods, and to the detection of drug sensitive and drug resistant cases. Any case with a positive bacteriological result (microscopy, culture or molecular method) is defined as a ***"bacteriological positive TB case"***. If the bacteriological tests are all negative or not done, the case is defined as a ***"bacteriological negative TB case".***

TB cases are sub-classified as "smear-positive" or "smear-negative", which is useful because it best correlates with infectiousness.

- **Smear-positive pulmonary TB:** Patient with at least one sputum smear-positive sample (at least one AFB is found in at least one sputum sample: scanty results are considered as positive) +/- an Xpert positive result. Smear-positive patients are the most infectious and most likely to transmit the disease to people in their surroundings; as such, they have historically been the primary focus of infection control measures and contact tracing efforts.

- **Smear-negative pulmonary TB:** Pulmonary TB that are negative for AFB with an Xpert positive result and for whom a clinician prescribes anti-TB treatment. Therefore diagnosis of sputum smear-negative pulmonary tuberculosis should be based on the following criteria:
    - At least two negative sputum smears (including at least one early morning specimen) and
    - Lack of response to a trial of broad-spectrum antimicrobial agents.

      OR
    - Patient with AFB smear negative sputum that is culture or GeneXpert positive for mycobacterium TB

5.1.2.3 Classification based on History of previous treatment

TB cases can also be classified according to whether or not a patient has a new infection or has previously received TB treatment. It is important to identify previously treated patients because they are at increased risk of having drug-resistant TB. At the start of treatment, specimens for GeneXpert MTB/RIFMTB/RIF should be obtained from all previously treated patients.

1. **New patients:** A patient who has never had treatment for TB, or have taken anti-TB drugs for less than 4weeks. They may have Xpert, smear, culture positive/ negative PTB or EPTB. Patients with both pulmonary and extra pulmonary TB should be classified based on site of maximal disease involvement e.g. Miliary tuberculosis is notably the deadliest form of the disease, but is now classified as pulmonary TB because most lesions are in the lungs and treatment is with Regimen 1 as per NTBLCP guideline.

2. **Previously treated (Re-treatment) patients:** Are patients who have received 4 weeks or more of anti-TB drugs in the past. They may have Xpert, smear, culture positive/negative PTB or EPTB and are further classified by the outcome of their most recent course of treatment as follows:

    i. **Relapse patients:** Are patients previously treated for TB and were declared cured or treatment completed at the end of their most recent treatment episode and are now diagnosed with a recurrent episode of TB. These patients could be true relapses or a new episode of TB caused by reinfection.

    ii. **Treatment after failure patients:** are previously treated for TB and whose treatment failed at the end of their most recent treatment episode.

    iii. **Treatment after loss to follow-up patients:** are previously treated for TB and were declared Lost to follow-up at the end of their most recent treatment episode. (These were previously known as Return after default patients).

    iv. **Other previously treated patients:** are previously treated for TB but with an unknown or undocumented outcome for their most recent treatment episode, or do not fit into any of the categories listed above.

    v. **Patients with unknown previous TB treatment history:** are those who do not fit into any of the categories listed above.

    vi. **Transfer in patients:** A patient who has been diagnosed and registered for treatment in a facility in one LGA and is transferred to a facility in another LGA to continue treatment. The smear conversion and treatment outcome for this patient must be reported back to the facility that transferred the patient.

5.1.2.4 Classification based on HIV status

- **HIV-positive TB patients:** are patients with TB (bacteriologically confirmed or clinically diagnosed) who have a documented HIV-positive result (e.g. there is documented evidence of enrolment in HIV care such as enrolment in the pre-ART register or in the ART register once started on ART) or have a positive HIV result from testing conducted at the time of TB diagnosis.

- **HIV-negative TB patients:** are patients with TB (bacteriologically confirmed or clinically diagnosed) who have a documented negative HIV result from a test conducted at the time of TB diagnosis. HIV negative TB patients subsequently found to be HIV-positive should be re-classified as HIV-positive TB patients.

- **HIV status unknown TB patients:** do not have a documented HIV test result. If HIV-status is subsequently determined the patient should be re-classified as per the HIV test result.

5.2 Principle of treating Drug Susceptible TB (DS-TB)

5.2.1 Aims, Rationale and Current principle

5.2.1.1 Aims

The aims of treatment of tuberculosis are:

- To cure the patient of TB and restore quality of life and productivity
- To prevent death from active TB or its late effects
- To prevent relapse of TB
- To reduce transmission of TB to others
- To prevent the development and transmission of drug resistance
- To achieve all these with minimal toxicity.

5.2.1.2 Rationale

The rationale for adopting the new principle of treating susceptible TB in Nigeria with the current TB regimen is based on the susceptibility of the mycobacterium Tuberculosis to Rifampicin. In addition to this, other important factors considered includes:

- Availability of adequate logistics to access rapid molecular test by all
- The burden of retreatment TB cases of 8% among all New TB cases
- Drug Resistance pattern of 25 – 41% for streptomycin injection in Nigeria
- The current MDR-TB burden (estimated 2.9% new TB cases with MDR-TB and estimated 14% of retreatment TB cases with MDR-TB)
- Treatment success rate of 86% and 81% respectively among New Smear positive and retreatment TB cases.

5.2.1.3 CURRENT PRINCIPLE OF TREATING DS-TB IN NIGERIA

In order to ensure quality TB treatment and reduce drug resistance, the NTBLCP with collaboration with key technical persons in the control of TB in Nigeria has recommended based on scientific evidence the following for strict implementation:

- All previously treated TB patients should have immediate access to Xpert MTB/RIF in order to determine the correct treatment regimen to offer to the patient.
- All patient diagnosed to have Rifampicin susceptible TB should be managed with Rifampicin-based treatment regimen according to the NTBLCP guidelines.
- The repeat of Rifampicin based regimen should not be ***more than once*** except it is recommended based on culture and DST results.
- DOTS through patient centred approach must be ensured for all NTBLCP TB regimen.
- TB Treatment "trial" is prohibited and should not be used as a method of TB diagnosis.

5.2.2 Directly Observed Treatment (DOT)

DOT ensures that the TB patient takes the right drugs, in the right doses at the right times. The treatment supervisor watches the patient swallow the tablets throughout the whole course of treatment. Supervisors or "treatment supporters," can be health workers, volunteers, and trained members of the community or guardians.

- A patient-centred approach with proper communication between the patient and treatment supporter promotes patient education, good adherence and early identification of challenges with treatment (including side effects and clinical worsening).
- All treatment supporters should be chosen together with and should be acceptable to the patient.
- The need for good adherence and follow-up should be reinforced at all times.
- Patients should be reminded about the duration of treatment and common side effects.
- DOT allows the prompt detection and management of adverse drug reactions and clinical worsening of TB.

5.2.2.1 SOP for the engagement of Treatment Supporter for DOT

Steps

1. Educate patients and relatives/treatment supporter on importance of adhering to regular drug intake.
2. Provide information to the patient on the available treatment options:
    a. Daily Direct Observation of Treatment (DOT) at health facility
    b. Daily DOT by a treatment supporter at home. This involves 2 weekly visits to the health facility for drug collection.
3. If the patient chooses to involve a treatment supporter, take steps as outlined below.
4. Provide information to the patient on how to select a treatment supporter using the following criteria:
    a. Preferably a close relation of the patient (family/non family)
    b. Living within same house hold or walking distance of less than 500 meters from patients home
    c. Physically able to visit the facility
    d. Willingness of the individual to provide support to the patient.
5. Place patient on daily DOT treatment while waiting for **Treatment Supporter.**
6. Ask patient to invite treatment supporter to the health facility within a **period of 2 days.**
7. Provide health education to both patient and treatment supporter on the following:
    a. Basic information on TB and TB infection control (especially cough etiquette)
    b. Treatment duration (6 months) and number of tablets to take daily
    c. Intervals for sputum follow-up examination (2, 5 & 6 months)
    d. Possible side effects of anti TB drugs and need to report back to health facility in case of any complaints.
8. Discuss the roles and responsibilities of the treatment supporter:

a. Ensuring daily DOT
b. Ticking treatment supporter's card
c. Support patient to come to the health facility for drugs collection every 2 weeks
d. The patients and treatment supporter should return used (empty) blisters and treatment supporters card before another supply
e. Support patient to come to health facility for follow-up sputum examination and management of any side effect or complications
f. Inform health care worker in the event of opting out or becoming unavailable to provide treatment support.

9. Reconfirm the wiliness of the treatment supporter.
10. The treatment supporter and patient should sign an agreement on the appropriate section of the TB treatment card.
11. Add the name, address and phone number of the treatment supporter to the contact of the patient on the TB treatment card.
12. Ensure that the patient and treatment supporter agree on timing of drug intake and drug storage.
13. Provide treatment supporter with drugs (two weeks) drug and the treatment supporter's card.
14. The health care worker should review the treatment supporter's card and update TB treatment card during the 2- weekly visits as outlined below.
    a. Ensure that the section for engagement of TS on the treatment card is ticked
    b. Mark letter 'X' to signify that patient was given a dose and that DOT was observed by the GHCW.
    c. Then draw a straight line through the days (i.e. 13 days) in which drugs were collected on behalf of the patient.
    d. Patient treatment card each time the patient and TS come for drug refill.
    e. Mark letter 'X' or 'A' as appropriate on the line to update patient treatment card (this to ensure that adequate information is available on the patient treatment card always).
15. The treatment supporter and patient should discuss any challenges with health care workers.
16. Where available, CBOs in the community through their community volunteers should be used for tracing patients who interrupt treatment.

Note: The patient has the option to reconsider either the use of health care worker or treatment supporter for DOT at any point in time.

5.2.3 First line anti-TB drugs currently used in the NTBLCP

All TB drugs have varying properties. Below are common properties of the anti-TB drugs currently used in the treatment protocol of the NTBLCP. Refer to table 6.2 below.

- They may be bactericidal, bacteriostatic (sterilizing) or have the ability to prevent resistance.

- They differ in the ability to act against the various populations of bacilli found in a tuberculosis lesion:
    - Metabolically active bacilli, intermediately active bacilli, semi-dormant bacilli (persisters), which undergo occasional spurts of metabolism and dormant bacilli (that may become active).
    - Some TB drugs act best in an acid environment; others better at a more alkaline pH
- Bacilli occur both in extracellular spaces where the pH is usually neutral or alkaline and in intracellular spaces where it is acidic.

Table 5.2: Common properties of 1st line anti-TB Drugs currently used in the NTBLCP

Drug	Drug Property	Target Bacilli	ph	Site of Action
Isoniazid (H)	Bactericidal after 24 hours. High potency: kills >90% bacilli in first few days of treatment.	Rapid and intermediate growing bacilli	Alkaline and acid media.	Intracellular and extracellular
Rifampicin (R)	Bactericidal within 1 hour. High potency. Most effective sterilising agent.	All populations including dormant bacilli.	Alkaline and acid media.	Intracellular and extracellular
Rifabutin (Rfb)	Bactericidal within 1 hour. High potency. Most effective sterilising agent. A semi-synthetic derivative of rifamycin	All populations including dormant bacilli.	Alkaline and acid media.	Intracellular and extracellular
Pyrazinamide (Z)	Bactericidal with a low potency. Achieves its sterilising action within 2-3 months.	Slow growing bacilli.	Acid medium.	Intracellular bacilli only (macrophages)
Ethambutol (E)	Bacteriostatic. Low potency. Minimises the emergence of drug resistance	All bacterial populations.	Alkaline and acid media.	Intracellular and extracellular

These drugs are available in both loose and fixed dose combination (FDC) tablet e.g. 4FDC-RHZE, 3FDC-RHE and 2FDC-RH. Rfb is used in replacement of R in HIV/AIDS patients on 2nd line ART who developed susceptible TB.

5.2.3.1 Standard treatment protocols for treating drug-susceptible Tuberculosis in Nigeria

Two standardized treatment Regimen have been adopted for the treatment of all susceptible TB cases in Nigeria. These regimens include the following:

1. Standard six month treatment Regimen for all form of TB (PTB and EPTB cases – both new and previously treated) with the exception of TB meningitis and Osteo-articular TB cases.
    a. Regimen 1 for adult: **2(RHZE)/4(RH)**
    b. Regimen 1 for Children: **2(RHZ+E)/4(RH)**
2. Standard twelve month treatment Regimen for all cases of TB Meningitis (TBM) and Osteo-articular TB cases.

a. Regimen 2 for adult with TBM and Osteo-articular TB: **2(RHZE)/10(RH)**
b. Regimen 2 for children with TBM and Osteo-articular TB: **(RHZ+E)/10(RH)**

Table 5.3: Revised treatment guidelines for all TB cases in Nigeria

Type of TB Disease	Recommended Regimen		Length of treatment
	Intensive Phase	Continuation Phase	
PTB and all forms of EPTB except TB meningitis & Osteo-articular TB (spine, joints) in adults	2 RHZE	4 RH	6 months
TB meningitis and Osteo-articular TB (spine, joints) in adults	2 RHZE	10 RH	12 months
PTB and all forms of EPTB except TB meningitis & Osteo-articular TB (spine, joints) in children	2 RHZ+E	4 RH	6 months
TB meningitis and Osteo-articular TB (spine, joints) in children	2 RHZ+E	10 RH	12 months

R=rifampicin. H=isoniazid. Z=pyrazinamide. E=ethambutol
Numeral refers to number of months of the regimen e.g. 2 RHZE refers to two months of daily rifampicin, isoniazid, pyrazinamide and ethambutol

Note:

- Streptomycin is no longer used in the Regimen 1 and 2 of the NTBLCP but may be used in special situations such as in liver disease when Rifampicin and Isoniazid cannot be used.
- Intermittent regimens also not recommended.

The drugs come in fixed dose combinations and each Regimen are divided into two phases (intensive and continuation). Treatment principle is the same for both adults and children, although doses differ. Refer to the TB Paediatric sections for detail of anti TB drug used in children).

Previous TB treatment is a strong determinant of drug resistance. All previously treated patients (adult and children) should submit specimen for smear and GeneXpert MTB/RIF before initiation of treatment and should be managed as outlined in the algorithm for management of Presumptive TB Cases in Nigeria.

5.2.4 Regimen 1 (Six Months Regimen) for adult: 2(RHZE)/4(RH)

All Adults and children weighing more than 18kg diagnosed with Rifampicin susceptible TB (with the exception of TB meningitis and Osteo-articular TB) should be started on the Regimen 1 treatment for adult. During the intensive phase, 4 drugs (isoniazid, rifampicin, pyrazinamide, and ethambutol) are used to rapidly kill the tubercle bacilli and Infectious patients become less infectious within approximately 10-14 days of starting treatment. .

In the continuation phase, 2 drugs (isoniazid, rifampicin) are used, over a period of 4 months. The sterilizing effect of these drugs eliminates the remaining bacilli and prevents subsequent relapse.

DOT is observed throughout the period of treatment either through direct supervision by the health worker or through the engagement of a treatment supporter (**always refer to the SOP for the engagement of a treatment supporter**).

Table 5.4: Regimen and dosages for Adult with susceptible PTB/EPTB cases*

Regimen	Pre-treatment weight			
	>18-37 kg	38-54 kg	55-70 kg	> 70 kg
Intensive phase (2 months): • *Combined tablet of RHZE (150mg+75mg+400mg+ 275mg)*	2	3	4	5
Continuation phase (4 months): • *Combined tablet of RH* (150mg + 75mg)	2	3	4	5

*Refers to all PTB and EPTB cases with the exception of TB meningitis & TB of bones/joints

5.2.5 Regimen for adult with TB Meningitis and Osteo-articular TB (Twelve Months Regimen): 2(RHZE)/10(RH)

The six months treatment is as effective in extra-pulmonary as in pulmonary disease. However, in some instances of severe or complicated diseases like TB meningitis and TB of the bones or joints treatment may need to be extended to twelve months. The intensive phase remains two months and the continuation phase is prolonged to ten months.

Therefore all adults and children weighing more than 18kg diagnosed with Rifampicin susceptible TB of the meninges, bones and joints (TB meningitis and Osteo-articular TB) should be started on the Regimen 2 for treating TB meningitis and Osteo-articular TB as outlined in table 5.5.

DOT should be observed throughout the period of treatment either through direct supervision by the health worker or through the engagement of a treatment supporter ***(always refer to the SOP for the engagement of a treatment supporter).***

Table 5.5: Regimen and dosages for adults with TB meningitis and Osteo-articular TB

Regimen	Pre-treatment weight			
	>18-37 kg	38-54 kg	55-70 kg	> 70 kg
Intensive phase (2 months): • *Combined tablet of RHZE (150mg+75mg+400mg+275mg)*	2	3	4	5
Continuation phase (10 months): • *Combined tablet of RH (150mg + 75mg)*	2	3	4	5

Note:

- Patient who are put on Regimen 2 will need more RH because treatment is for 10 months
- The extra drugs (RH) needed should be taken from the supply box. Refer to table 18.1 to 18.4 for more details.

5.2.6 Adjunctive treatment use during TB treatment

i. Pyridoxine (Vitamin B6)

The use of Pyridoxine is recommended for all adults patients started on TB treatment to prevent peripheral neuropathy most commonly caused by Isoniazid. This should be made available to patient where ever it is available.

- Dose of Pyridoxine: 50mg daily
- If patient develops peripheral neuropathy at any stage during TB treatment, the dose can be increased to 50 – 100mg (up to maximum of 200mg) until the symptoms subside, then reduce to 50mg daily.

ii. Steroids (corticosteroids)

The use of corticosteroids is recommended in extra-pulmonary tuberculosis, particularly for TB meningitis and pericarditis. High dose steroid treatment for 2-4 weeks and the taper off gradually over several weeks depending on clinical progress is recommended. The response to treatment is assessed clinically. Note the following:

- Corticosteroids, in conjunction with anti-TB drugs, reduce the risk of death in TB meningitis and TB pericarditis.
- Patients with TB meningitis or TB pericarditis should be given corticosteroids (60mg for adults and 1mg/kg wt. (max 40mg) in children) for an initial period of 21 days followed by tapering off by 25% per week over four weeks.
- Either prednisolone or dexamethasone may be used.

Use of Steroids

Steroids have a supportive therapeutic effect and have been shown to improve survival in patients in specific forms of TB disease. Indications include:

- TB meningitis (decreased consciousness, neurological defects, or spinal block).
- TB pericarditis (with effusion or constriction).
- TB pleural effusion (when large with severe symptoms).
- Hypo-adrenalism (TB of adrenal glands)
- TB laryngitis (with life-threatening airway obstruction)
- Severe hypersensitivity reactions to anti-TB drugs
- Renal tract TB (to prevent ureteric scarring)
- Massive lymph node enlargement with pressure effects

Prednisolone dosage (first-line): 1-2 mg/kg/day (maximum dose of 60 mg) for three weeks, followed by a reduction regimen over three weeks.

5.2.7 Use of anti-tuberculosis drugs in special situations

The following special situations require an adjustment of standardised TB regimens:

TB/HIV and taking ART

- Rifampicin induces liver enzymes that reduce levels of nevirapine in the blood.
- All HIV-positive TB patients should receive an efavirenz- based regimen to minimize drug interactions with rifampicin.
- Refer to section 9.3 on TB/HIV for more details on the management of TB/HIV co-infection.

Pregnancy

- Isoniazid, rifampicin, pyrazinamide and ethambutol are safe in pregnancy.
- Pyridoxine supplementation is recommended for all pregnant and breastfeeding women receiving isoniazid.

Oral contraceptives

- Rifampicin reduces the effectiveness of the oral contraceptive pill.
- Health workers should advise patients on TB treatment to use barrier contraception like male or female condoms while on rifampicin.

Renal impairment and renal failure

- Ethambutol and pyrazinamide are cleared by the kidneys and should be reduced to three times per week in patient with poor creatinine clearance.

Table 5.6: Recommended dosages in patients with renal failure

Drug	Dose	Normal frequency	Frequency in renal failure
Pyrazinamide (Z)	25 mg/kg	Daily	3x/week
Ethambutol (E)	15 mg/kg	Daily	3x/week

Liver impairment and liver failure

- Isoniazid, rifampicin and pyrazinamide are recognized to be hepatotoxic.
- TB patients with active liver disease (i.e., those with jaundice or ascites) should not receive pyrazinamide or rifampicin.
- If the jaundice is acute and severe, then treat initially with only streptomycin and ethambutol.

Epilepsy

- Rifampicin induces liver enzymes that reduce levels of anticonvulsant medications (phenobarbital and phenytoin) in the blood.
- Increase the dose of the anticonvulsant and monitor the patient closely for increasing seizure frequency.

5.3 Monitoring TB treatment

Monitoring progress of tuberculosis patients while on treatment is an essential part of TB case management. This is to ascertain the effectiveness of treatment in killing M. Tuberculosis as well as assessing improvement in the patient's clinical State.

Monitoring of a TB patient while on TB treatment is done through the following methods:
a) Clinical assessment: This involve regular clinical assessment including weight assessment.
b) Drug intake: This is done through assessment of patient's records for regularity.
c) AFB Microscopy: It involves looking for AFB in sputum specimen at specified intervals.

5.3.1 Follow up using clinical assessment Monitoring

Most TB patients will start to show signs of improvement after 2 to 4 weeks of anti-TB treatment. However assessment for poor response should be carried out each time the patient comes to swallow or pick up his/her drugs in order to avoid "treatment failure".
Treatment failure suggests the possibility of DR-TB and needs careful assessment, therefore consider that treatment may be failing in any patient receiving anti-TB treatment if:

- No symptom resolution, or symptoms are getting worse
- Continuous weight loss
- Smear-positive at 2-month follow-up sputum test
- Laboratory evidence of Rifampicin resistance

All TB patients who are on treatment are expected to come to the health facility at specified intervals; at end of 2, 5 and 6 months. During these visits, health staff are expected to clinically assess patients to ascertain improvements in their health and to ensure that patients adhered to their treatments. Similarly, health staff are expected to weigh patients during these visits and ensure that the patient weight is recorded in the appropriate space on the treatment card.

5.3.2 Follow up using drug intake

Drug monitoring is assessed through patient's records for regularity. Health worker should:

- Ensure that patient drug records are regularly updated to avoid treatment interruption and to allow for proper follow up.
- Ensure that patient treatment card is updated during each patient visit. Indicate on the treatment card whether DOTS was observed or whether patient missed their drugs while at home.
- Use the patient treatment support card to update the patient treatment card by marking 'X' or 'A' on the line drawn when patient collected his/her drugs. This will help to provide adequate information on the regularity of a TB patient drug intake even in the absence of the patient treatment support card. Also refer to section 6.2.21 above for more details on updating patient treatment card.

5.3.3 Follow-up using sputum smear microscopy

All patients who had sputum examined for AFB at diagnosis **must** be followed up using smear microscopy. ***One sputum smear examination taken as early morning sample*** is done at different points during treatment. Follow the flow chart in Figure 6.1 for details:

Figure 5.1: Algorithm for monitoring using AFB smear microscopy

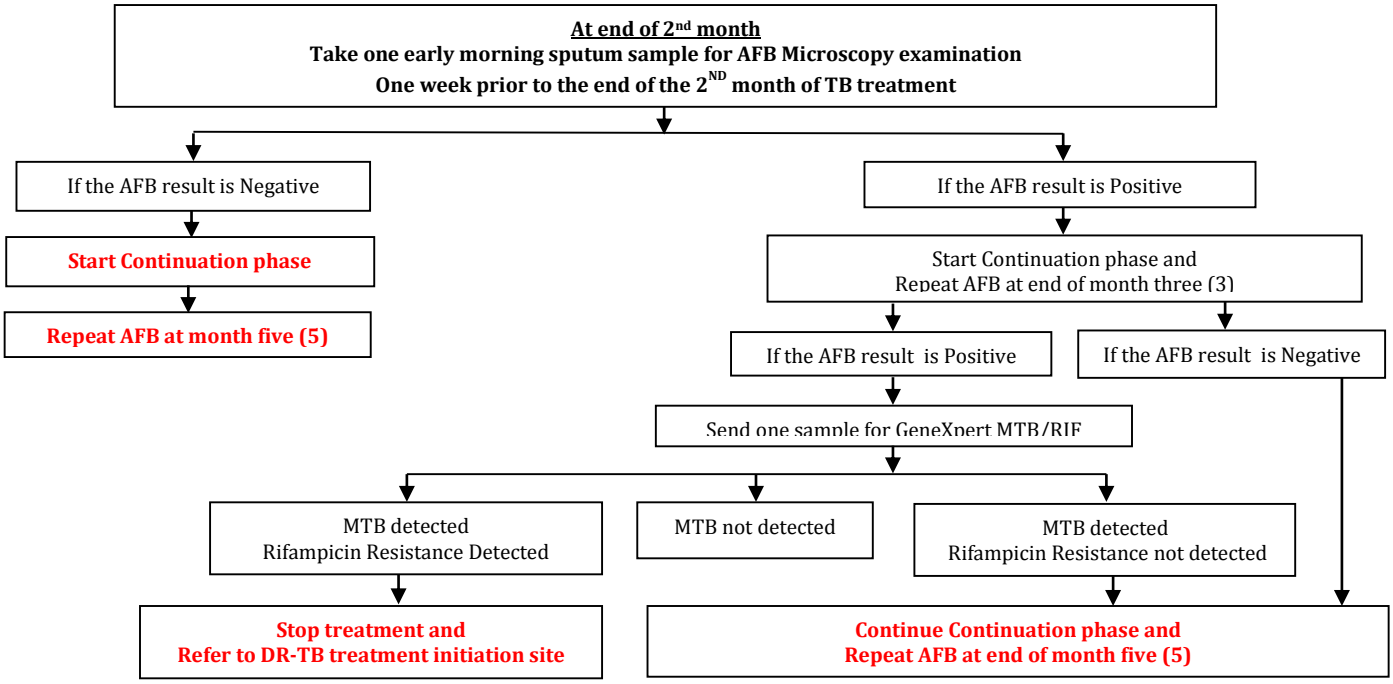
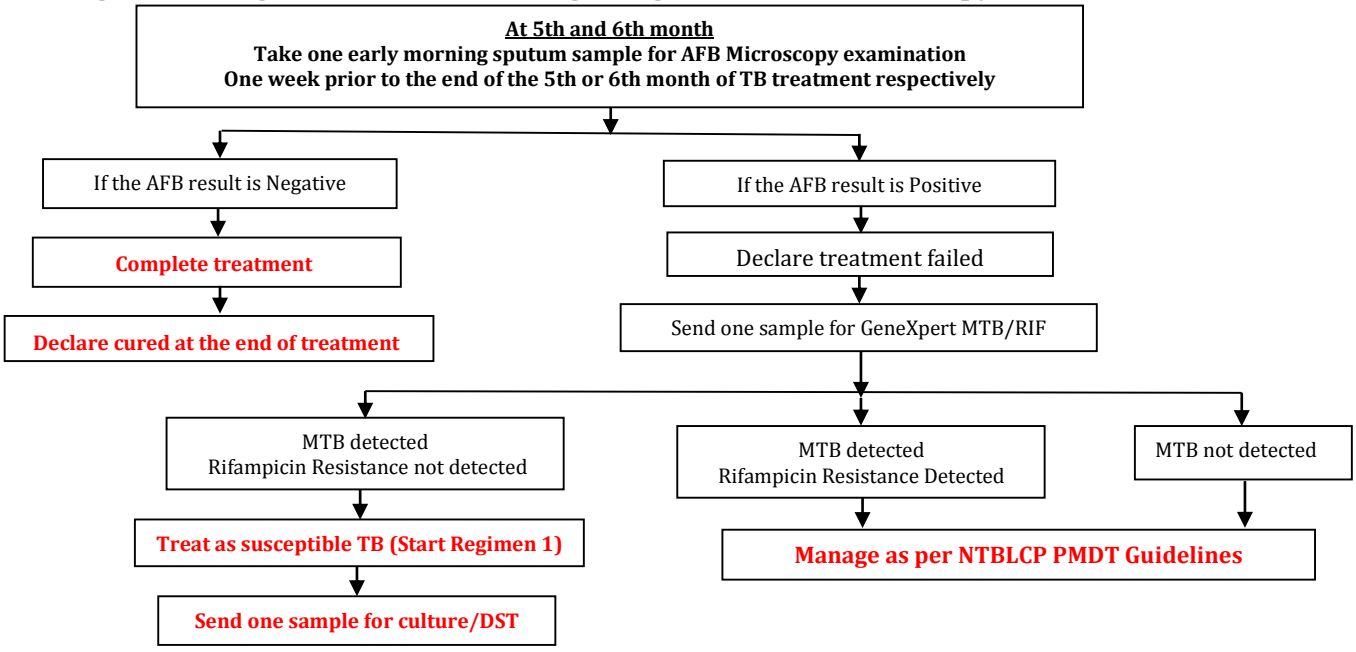


Figure 5.2: Algorithm for monitoring using AFB smear microscopy



5.4 Treatment interruption

Treatment adherence of every TB case is absolutely essential in order to cure the patient and prevent Drug Resistant TB (DR-TB). Therefore, in order to ensure that all TB patients started on anti-TB complete their treatment, all effort should be made by the DOTS provider to bring back any patient who interrupts treatment and a report of the action(s) taken should be attached to the treatment card.

5.4.1 Managing interruption of treatment in adults

During enrolment of patient, the health worker should record and confirm the patient's address, other relevant addresses such as those of family members and if possible, the patient's or a family member's mobile phone number in case the need to contact or track the patient arises.

Should a TB patient miss a scheduled appointment, action must be taken within three days of the date the patient was due for his or her scheduled appointment or drug collection. It is the responsibility of the LGTBLS to ensure a sound default-tracking plan is in place and implemented at LGA level. Where applicable, it is the responsibility of the GHCW, the LGTBLS and the CBOs in the community/community volunteers and/or other stakeholders to locate a patient who has interrupted treatment.

Table 5.7: Managing treatment interruption.

Length of interruption	Do a smear?	Result of smear	Length of treatment	Action to be taken
< 1 month	No	-	-	• Continue Rx and prolong to compensate for missed doses
1-2 months	Yes (2 samples)	Negative or EPTB	-	• Continue Rx and prolong to compensate for missed doses
		If 1 or more positive	< 5 months	• Continue Rx and prolong to compensate for missed doses
			>5 months	• Collect and send sample for GeneXpert MTB/RIF • Treat patient according to GeneXpert MTB/RIF result.
2 or more months	Yes (2 samples)	Negative or EPTB	-	• Clinical decision on individual basis whether to restart or continue treatment, or no further treatment
		If 1 or more positive	-	• Collect and send sample for GeneXpert MTB/RIF • Treat patient according to GeneXpert MTB/RIF result.

5.5 Transferring a TB patient while on TB treatment

5.5.1 Managing transfer-in and transfer-out

When a patient transfers out to another treatment facility, it should be indicated in the facility/LGA central TB register and ensure you do the following.

- All transferred out patient should be given drugs that will last them for only two weeks and their remaining drugs should be returned back to the supply box in the health facility where they started treatment
- Similarly, all transferred out patients should be given their drugs from the supply box on arrival to their new treatment centre provided they have a properly filled referral/transfer form
- The date of transfer-out and the new treatment facility must be indicated in the transfer-out form.
- A copy of the transfer-out form must accompany the patient and must be sent to the GHCW of the receiving LGA and hence the new treatment facility.
- A copy of each transfer-out form must be kept at the original treatment unit in a special transfer-out folder.
- When patients transfer in from another facility, they should be registered in the facility/LGA central TB register.
- The patient's treatment outcome must be entered in the facility/LGA central TB register and results must be communicated to the original treatment unit.

5.6 Recording outcome of treatment

Within the NTBLCP, the outcome of treatment of all TB cases is evaluated quarterly using Tuberculosis cohort report forms. As part of routine surveillance and assessing programme performance of the NTBLCP, it is vital that accurate recording of treatment outcome results are entered in the TB registers and treatment cards for ALL patients.

Treatment cards for patients who have completed treatment, died or lost to follow-up must be kept safely and in chronological order in the health facility for 5 year period at least before discarding.

At the end of treatment, results of chemotherapy should be recorded according to treatment outcome in the patient treatment card as defined in the table 5.8 below.

Table 5.8: Definitions of treatment outcomes[a]

Cured:
A DR-TB patient who completed treatment without evidence of failure and has three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase.
Treatment completed:
A TB patient who completed treatment but without evidence of cure or failure (there is no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion are negative either because they were not done or because results were not available).

Treatment Failure:
A TB patient whose sputum smear or culture is positive at month 5 or later during treatment.
Died:
A TB patient who dies for any reason before starting or during the course of treatment.
Lost to follow-up:
A TB patient whose treatment was interrupted for two consecutive months (eight weeks) or more.
Not evaluated:
A TB patient for whom no treatment outcome is assigned. (This includes cases "transferred out" to another treatment unit and where the treatment outcome is unknown to the reporting unit).
Treatment success:
The sum total of bacteriologically diagnosed TB cases cured and those who complete their treatment without a bacteriological confirmed result.[b]
Moved to 2nd-line treatment register:
Patients who became MTB detected/RIF Resistance detected at any point of their treatment and whom are moved to CAT IV treatment[c] (Note that the LGTBLS should receive confirmation from the unit providing second-line treatment that the patient has indeed started second-line treatment before noting this in the facility treatment register).

[a] These definitions apply to pulmonary smear-positive and smear-negative patients, and to patients with extra-pulmonary disease. Outcomes in these patients need to be evaluated separately.

[b] For smear- or culture-positive patients only.

[c] These patients are excluded from first line treatment outcome cohort calculations.

5.7 Management of contacts of TB case

A contact investigation is the process of identifying, examining, evaluating, and treating all persons who are at risk for infection with Mycobacterium tuberculosis due to recent exposure to a newly diagnosed or suspected case of pulmonary, laryngeal, or pleural tuberculosis (TB).

The following are the highest priority contacts for evaluation in the NTBLCP:

- Contacts of an index case of TB especially children aged <6years
- Contacts with known or suspected immuno-compromised persons, particularly HIV infection
- Contacts of patients with MDR/XDR tuberculosis

Refer to section 7.4 below.

5.8 Management of common TB-related complications

The management of common TB-related complications are outlined in Table 4.1.
Any of the following symptoms may also suggest complications in TB case

- Coughing blood (Haemoptysis)
- Spontaneous Pneumothorax

- Pleural effusion
- Cor Pulmonale
- Destructive lung disease
- Seizures
- Altered or loss of consciousness
- Tingling/abnormal sensations in the extremities
- Inability to walk or weakness in lower limbs
- Swelling over the back
- Impaired vision

If any of the following severe/dangerous symptoms or signs is present, the patient should be referred urgently to the hospital for expert management.

Table 5.9: Common TB-related complications and their basic management

Complication	Management
Haemoptysis (coughing up blood)	• Admit patient to hospital for oxygen, blood transfusion and intubation if bleeding is severe. • Put the patient on the lateral position. • Request chest x-ray to rule out conditions such as invasive aspergillosis or bronchiectasis.
Pleural effusion or empyema	• This may subside with TB treatment alone but sometimes drainage is necessary to relieve symptoms of dyspnoea. • All empyema should be drained
Spontaneous pneumothorax	• Admit patient to hospital for placement of a chest tube and drainage with an underwater seal.
Paraplegia (may be due to spinal TB)	• Refer the patient to the hospital. Surgery may be needed
Cold abscesses and suppurating fistulae	• Drainage of abscesses
TB pericarditis	• High doses of steroids (see Table 6.7) • Cardiac tamponade (i.e. distress associated with shock) may necessitate pericardial aspiration by an experienced clinician.

5.9 Adverse (side) effects of anti-TB drugs

Most TB patients complete their treatment without any significant adverse drug effects. However, a few patients do experience adverse effects. It is therefore important that patients be clinically monitored during treatment so that adverse effects can be detected promptly and managed properly.

The following should be considered when commencing a patient on treatment to prevent or reduce the effect of adverse drug reaction:

- Educate patients on how to recognize the symptoms of common side effects and urge them to report if they develop such symptoms
- Ask about symptoms of side effects each time patients come to collect drugs.
- If a patient develops any side effect, manage as outlined in Table 5.10 and 5.11.
- Adverse reactions to drugs should be recorded on the TB Treatment Card.
- A reporting form for adverse drug reaction (ADR) must also be completed and sent according to guidelines.

Table 5.10: Symptom-based approach to managing major side effects of R, H, Z and E

Side effects	Drug(s) probably responsible	Management
Major side effects: Stop responsible drug(s) and refer to clinician urgently		
Skin rash with or without itching	H, R, Z	Stop anti-TB drugs and refer to the Medical Officer
Jaundice (other causes excluded), hepatitis	H, Z, R	Stop anti-TB drugs and refer to the Medical Officer
Visual impairment (other causes excluded)	E	Stop ethambutol and refer to the Medical Officer
Shock, purpura, acute renal failure	R	Stop rifampicin and refer to the Medical Officer

Table 5.11: Symptom-based approach to managing minor side effects of R, H, Z and E

Side effects	Drug(s) probably responsible	Management
Minor side effects: Continue anti-TB drugs, check doses		
Anorexia, nausea, abdominal pain	Z, R, H	Give drugs with small meals or just before bedtime;
		Advise patient to swallow pills slowly with small sips of water; If symptoms persist or worsen, refer to hospital
Joint pains	Z	Non-steroidal anti- inflammatory (e.g. Ibrufen) or paracetamol
Burning/numbness in the hands/ feet	H	Pyridoxine 50 -100mg daily
Orange/red urine	R	Reassure, counsel patients before starting treatment, encourage increase fluid intake.
Drowsiness	H	Reassurance. Give drugs before bedtime
Flu syndrome (fever, chills, malaise, headaches, bone pains)	Intermittent dosing of Rifampicin	Change intermittent to daily rifampicin administration (Intermittent doing is not use in Nigeria)

5.9.1 Process of re-introducing anti-TB drugs after an adverse reaction

Once the reaction has resolved, anti-TB drugs are reintroduced one by one, starting with the drug least likely to be responsible for the reaction (rifampicin or isoniazid) at a small challenge dose, such as 50 mg isoniazid (3). The dose is gradually increased over 3 days.

The procedure is to observe if the patient tolerates a full dose of isoniazid before adding rifampicin, then evaluate if the patient tolerates a full dose of rifampicin before introducing pyrazinamide, and so on. A reaction after adding in a particular drug identifies that drug as the one responsible for the reaction. Refer to Table 5.12 for further guidance on reintroduction of anti-TB drugs.

Table 5.12: Challenge doses used in managing ADR

Drug	Day	Dose 1	Dose 2	Dose 3
Isoniazid (H)	1	50mg		
	2		300mg	
	3			300mg
Rifampicin (R)	4	75 mg		
	5		300 mg	
	6			Full dose
Pyrazinamide (Z)	7	200 mg		
	8		800 mg	
	9			Full dose
Ethambutol (E)	10	100 mg		
	11		400 mg	
	12			Full dose

Note:
The drugs at the top of the table are the least likely to cause a reaction, and should be reintroduced first while those at the bottom of the table are most likely to cause a reaction.

5.9.2 Pharmacovigilance

Pharmacovigilance is the Science and activities relating to the detection, assessment, understanding, response and prevention of adverse drug reactions (ADRS) and other potential medicine-related problems.

5.9.2.1 What to do when you suspect Adverse Drug Reaction

When a health worker suspect any signs or symptoms of Adverse Drug Reactions in a person who is on anti-TB drugs, do the following:

a. Interview and examine the patients
b. Document your findings in the patient treatment card
c. Take appropriate action as outlined in tables 5.10 and 5.11 above. Some patients may have to be transferred out to the hospital.

d. Complete the Adverse Drug Reaction (ADR) form for the patient.
e. Duely completed form must be submitted to the LGTBLS who must ensure that the form gets to the designated NAFDAC officer in their LGA.

Copy of the Adverse Drug Reaction (ADR) Reporting form MUST be filled for all side effects noticed in a TB patient.

6. DIAGNOSING TUBERCULOSIS IN CHILDREN

6.1 Identifying a Child who is a Presumptive TB Case

6.1.1 History findings (Symptoms) of TB in children

In general, the identification of presumptive TB cases in children remains a daunting task especially in view of the well-known difficulty in obtaining sputum from children in the under-five (5) age bracket Obtaining a comprehensive history of the illness from the care giver/patient taking special cognizance of a positive history of TB symptoms:

a. Below are important symptoms to consider in children with presumptive TB
b. Cough of 2 weeks or more with or without a wheeze associated with weight loss with or without haemoptysis in adult household contact(s)
c. History of fever with or without night sweats
d. Poor weight gain or unexplained weight loss
e. Failure to thrive
f. Positive History of contact with an adult with TB symptoms in the last 2 years
g. Features of hypersensitivity to the tubercle bacilli e.g. red eye associated with white speck(s) at the border of the cornea
h. Erythematous rash over the shins
i. Loss of appetite
j. Reduced playfulness/fatigue
k. Behavioural changes (irritability, confusion or agitation)
l. History of death attributable to HIV/AIDS in any member of the patient immediate family is also suggestive with corroborative historical data.
m. Of all the historical data required in identifying a presumptive TB case in children, a positive history of TB symptoms in a close household contact (frequently adults and the aged) remains the single most important.

6.1.2 Physical findings (signs) to be explored in a presumptive TB child

A. General physical examination

a. Chronically ill
b. Wasted
c. Febrile
d. Palor
e. Oedema
f. Enlarged lymph nodes around the neck greater than 2cm in diameter
g. Phlyctenular Keratoconjunctivitis (PKC) (red eye associated with white speck(s) at the border of the cornea)
h. Erythema Nodosum (EN) rash at the distal lower extremities (erythematous rash over the shins)

B. Anthropometric Examination

a. Weight
b. Underweight (60-80% of normal body weight)
c. Marasmic (< 60% of normal body weight)
d. Height
e. Stunted (Height < 90% of the expected)
f. Mid-Upper Arm Circumference
g. Children 1 – 5 years: Normal range – 13.5 – 17cm.
h. Skin fold thickness
i. this is measured over the triceps muscles

C. Other systemic examination may reveal abnormalities depending on the system diseased e.g.

a. Abdominal distension with or without ascitis and/or hepatospleno megally
b. In addition the presence of gibbus (angulation of the spine) with or without weakness of the lower extremity in a child with consistent features of the disease is highly suggestive

If any of the above symptoms and signs is found in a child, health care provider should manage child as outlined in figure 7.1 and 7.2.

6.2 Investigating a Presumptive TB Child

6.2.1 Laboratory Diagnosis of pulmonary Tuberculosis in Children

The laboratory investigation of a child with symptoms of TB who can produce sputum specimen is the same as that for adult as described above. However obtaining sputum specimen in younger children may be difficult since children usually swallow their sputum hence the need to use other methods of specimen collection such as; Nebulization/Sputum induction, Gastric washing/aspirate and Bronchoscopy to obtain sputum specimen may be necessary. Refer to section 4.2 above for more details.

6.2.2 Ancillary Investigation of TB in Children

Ancillary investigative clues and laboratory investigations towards making a diagnosis of primary TB in children includes:

1. Mantoux test:

A positive Mantoux test (tuberculin skin test) indicates infection with M. tuberculosis but does not necessarily indicate disease.

- Interpretation:

- 4mm = negative
- 5 – 9mm = borderline
- >5mm = positive in HIV patient + severe malnutrition (marasmus, kwashiokor)
- >10mm = positive in all other children irrespective of the BCG vaccination

2. Chest X-ray:

Chest X-ray remains an important tool for diagnosis of TB in children. It needs to be of good quality and interpretation depends on the expertise of the person reading them. Because CXR changes are often non-specific and may be completely normal in the HIV-infected or malnourished child, it should not be used alone to diagnose TB disease in children.

The following abnormalities on Chest X-ray are suggestive of TB in a child:

- Enlarged hilar lymph nodes and opacification in the lung tissue
- Widened mediastinum due to enlarged lymph nodes (this is the most common x-ray abnormality in children with TB).
- Scattered markings may present across the lungs fields on x-ray following dissemination, miliary disease
- Cavitation (tends to occur in older children)
- Pleural or pericardial effusion – though seen on CXR – are forms of extra pulmonary TB that tend to occur in older children (> 5 years of age)

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.

3. HIV Test:

A positive HIV test is also required to identify a TB/HIV co-infection.

- Any child who is a presumptive TB case should have an HIV test
- A positive HIV test also directs the need for other HIV-related care for the child and possibly other family members

4. Histological Test (Fine Needle Aspiration - FNA):

In children with large, palpable cervical lymph nodes, collection of an aspirate offers a convenient way of collecting samples for microscopy, culture and histology. The aspirate can be smeared onto a slide and sent for microscopy where culture is not available.
In addition to a smear-positive microbiological evidence from the fine needle (lymph node) aspirate, histological features of a tuberculous lesion (from a fine needle aspirate specimen) also offers a convenient laboratory avenue for making a diagnosis of tuberculous lymphadenitis.

5. Chemistry of cerebrospinal fluid (Lumbar Puncture - LP)

Lumbar Puncture should be performed by a competent medical officer on any child in whom TBM is suspected and repeated on a child failing to respond to standard treatment for bacterial meningitis. Suspect TBM if the CSF demonstrates:

- A spider web appearance after 30mins

- An elevated WBC count with a lymphocytic predominance
- A high protein level and/or a low glucose concentration

An absence of bacilli on microscopy does not exclude a diagnosis of TBM. TB culture is of particular value when there is a concern regarding drug resistance. The probability of obtaining a positive TB culture result increases when more than one sample is taken.

6.3 Managing a presumptive TB Child

It is important that all presumptive TB cases be identified early and investigated without delay. The current approach to diagnosis of TB in HIV-infected children is similar to that recommended for HIV-uninfected children and that all children with symptoms of TB should produce clinical specimen for GeneXpert MTB/RIF and those who can cough up sputum should also have AFB smear microscopy done to allow for their follow up during their treatment.

The NTBLCP has recommended two approaches for the diagnosis of any child identified with symptoms of TB in Nigeria. Refer to figure 6.1 and 6.2 below for more details.

- The first algorithm describes the steps involved in the diagnosis of PTB in children who can cough up sputum specimen for examination. The sputum must be examined using both AFB smear microscopy and GeneXpert MTB/RIF.
- The second algorithm describes the steps involved in the diagnosis of all forms of TB in children when:
    - here is no clinical specimen available for examination
    - Gastric aspirate
    - Other clinical specimen from a presumptive EPTB cases e.g. CSF are available for examination.

The available clinical specimen should be examined using GeneXpert MTB/RIF.

Figure 6.1: Algorithm for diagnosis of PTB in children whose sputum is available

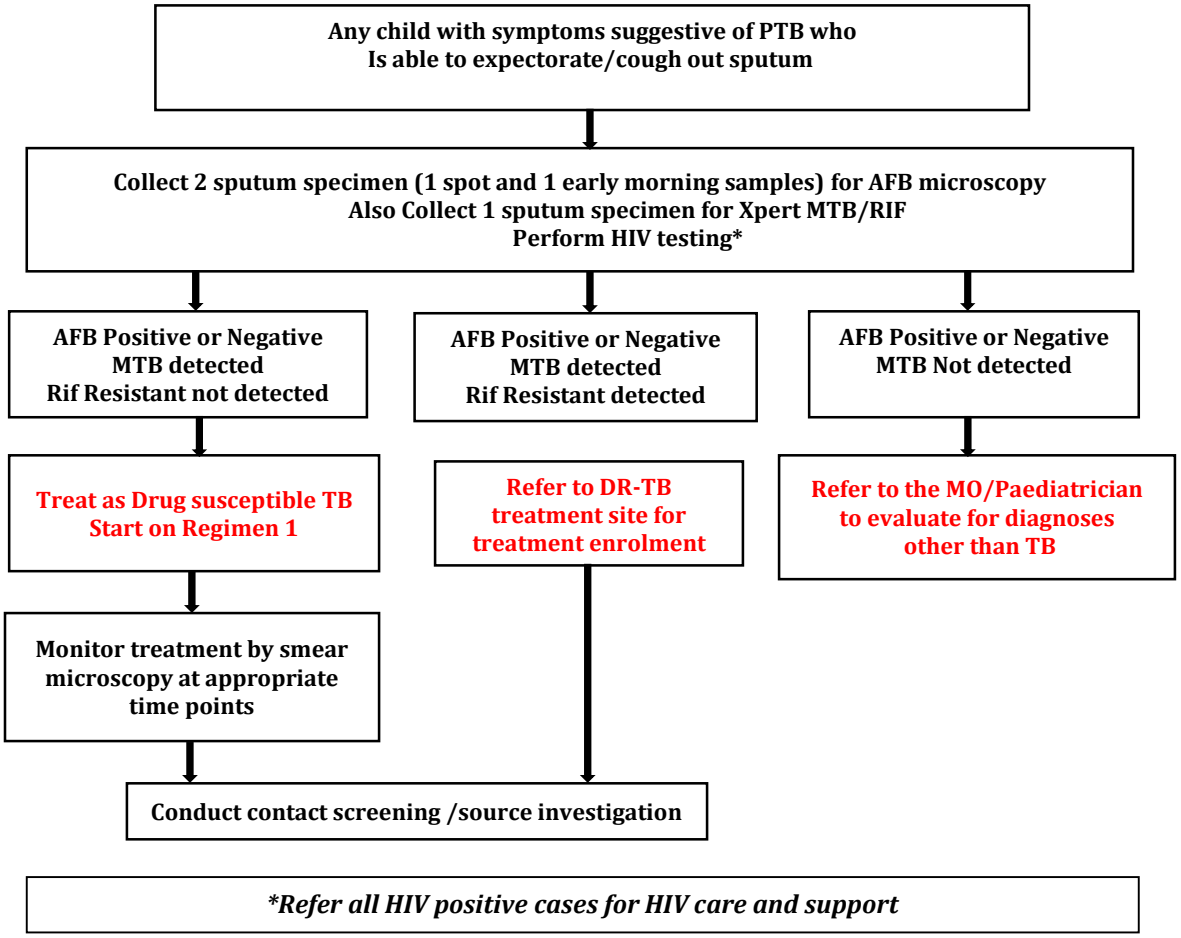
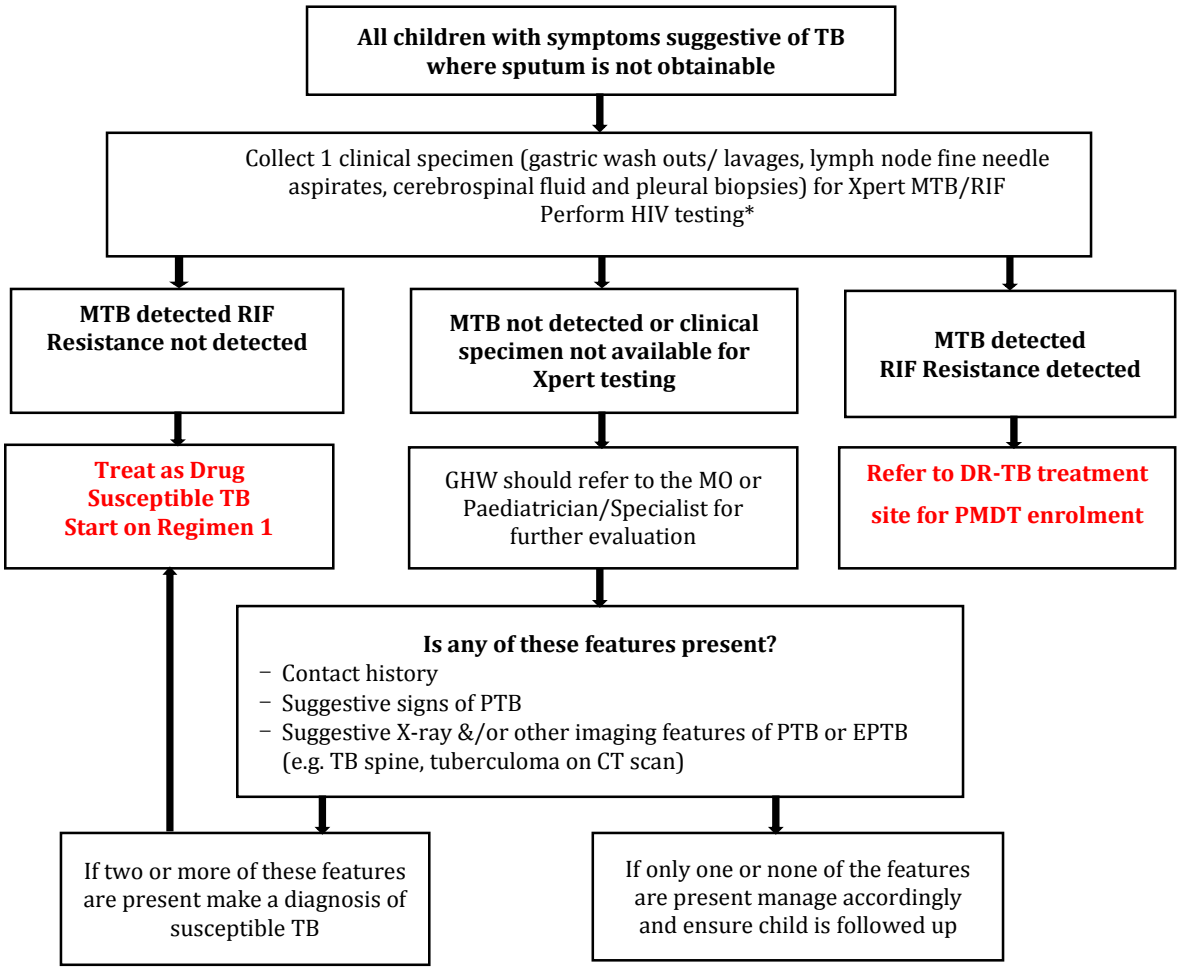


Figure 6.2: Algorithm for diagnosing TB in children where sputum is not obtainable



6.3.1 Clinical Diagnosis of Extra-Pulmonary Tuberculosis

Extra-pulmonary TB is common in children and presentation varies with age. Symptoms vary depending on site of disease and are characteristically persistent, progressive and may be associated with weight loss or poor weight gain

Clinical assessment in all cases should consider:

- History of contact Time lapse from exposure to disease presentation can be quite variable; shorter for young children with disseminated disease, longer for other forms that present in school-aged children
- Sputum for smear microscopy if cough and sputum is available
- HIV test

6.3.1.1 TB adenitis

Tuberculous lymphadenitis is the commonest form of EPTB in children, usually representing around 10% of total child TB case load. Enlargement of regional lymph nodes occurs after infection via lymphatic drainage from the site of infection. TB adenitis may or may not be associated with other symptoms of TB. Sinus and discharge may develop.

The cervical lymph nodes are the commonest site of clinical presentation. The usual age of presentation is 2-10 years.

Lymph node enlargement due to TB is typically:

- Large (>2 x 2 cm) i.e. visibly enlarged not just palpable.
- Painless and asymmetrical - often Multiple, discreet or matted
- Persistent (>1 month) and not responsive to other treatment such as antibiotics

TST (if available) usually strongly reactive but not necessary for diagnosis. Fine needle aspiration for culture and histology should be done whenever possible.

7. ADMINISTERING TB TREATMENT IN CHILDREN

7.1 Classification of a child with TB

The classification of a TB case in children is the same as for adults. Refer to section 6.6 above for details.

7.2 Treatment of TB in Children

The principle of TB treatment in children is essentially the same as that of adult except that the dosages differs. Refer to section 5.2 for more details.

In order to assign the correct treatment regimen and dosages to a child with TB, the health provider must ask about the following Information:

- History of anti-TB treatment for one month or more
- Age
- Pre-treatment weight (and at each follow-up visit)
- Pregnancy status (ask for last menstrual period in adolescents)
- History of HIV status
- History of taking any of these medications; anti-epileptic drugs, corticosteroids, anti-retroviral treatment, oral treatment for diabetes or oral anticoagulants and birth control medications (If yes to any of these medications, refer to the medical officer before commencing treatment.)

It is important to monitor the child's weight at every clinic visit and among other things do the following:

- Nutritional support should be provided for malnourished children
- Breastfeeding infants and children should continue to breastfeed while receiving anti-TB treatment
- Pyridoxine is not routinely given but is recommended for severely malnourished and HIV-infected children

Table 7.1: TB Paediatric drug and dosages

Drug	Dosage (mg/kg)	Range (mg/kg)	Maximum dose (mg/day)
Isoniazid (H)	10	7 – 15	300
Rifampicin (R)	15	10 – 20	600
Pyrazinamide (Z)	35	30 – 40	2000
Ethambutol (E)	20	15 – 25	1200

7.2.1 Standard treatment protocols for treating drug-susceptible Tuberculosis in children

Two standardized treatment Regimen have been adopted for the treatment of all children diagnosed with susceptible TB in Nigeria. These regimens include the following:

1. Standard six month treatment Regimen for all children with all form of TB (PTB and EPTB - newly diagnosed or previously treated PTB disease) with the exception of TB meningitis and Osteo-articular TB.
   a. Regimen 1 for Children: **2(RHZ+E)/4(RH)**
2. Standard twelve month treatment Regimen for all children with TB meningitis and Osteo-articular TB.
   a. Regimen 2 for children with TBM and Osteo-articular TB: **(RHZ+E)/10(RH)**

Table 7.2: Regimen and dosages for children with susceptible PTB/EPTB cases*

Daily Regimen	Weight			
	< 5 kg	5-9 kg	>9-13 kg	>13-18 kg
Intensive phase (2 months)				
• *Combined tablets of RHZ (60 mg+30 mg+150 mg)*	1	2	3	4
• *Ethambutol tablet (100mg)*	1	2	3	4
Continuation phase (4 months)				
• *Combined tablets of RH (60 mg + 60 mg)*	1	2	3	4

Refers to all PTB and EPTB cases with the exception of TB meningitis & TB of bones/joints

Table 7.3: Regimen and dosages for children with TB meningitis and Osteo-articular TB

Daily Regimen	Weight			
	< 5 kg	5 - 9 kg	>9 - 13 kg	>13 - 18 kg
Intensive phase (2 months)				
• *Combined tablets of RHZ (60 mg+30 mg+150 mg)*	1	2	3	4
• *Ethambutol tablet (100mg)*	1	2	3	4
Continuation phase: (10 months)				
• *Combined tablets of RH (60 mg + 60 mg)*	1	2	3	4

7.2.2 Use of Pyridoxine (Vitamin B6) in children

Pyridoxine (vitamin B6) protects against isoniazid-induced peripheral neuropathy. It is not routinely given but is recommended for severely malnourished and HIV-infected children. The recommended dose is 25 mg/ day until treatment is completed.

7.3 Engagement of Treatment supporter for children

7.3.1 Identifying patients/caregivers who need treatment supporters

Currently the intensive and continuation phase of all the first line treatment regimen in Nigeria is Rifampicin based. In order to ensure that TB treatment is observed, some patients/caregivers might require the assistance of treatment supporter for the duration of anti-TB treatment to ensure adherence to their treatment. Some of the patient who fell under this category include:

- Children living with caregivers who are unable to understand instructions
- Children living with caregivers who are unable to present to health facilities as requested on account of ill-health, work or other conditions.
- Children without an identified caregiver e.g. children in remand homes or orphanages where assigned caregivers may vary.

7.3.2 Steps in engaging a treatment supporter for a child on TB treatment

1. Describe to the patient the following criteria for selecting a treatment supporter:
    i. Preferably a close relation to the patient (family/non family)
    ii. Living within same household or at walking distance of less than 500 meters from patient's home
    iii. Physically able to visit the facility
    iv. Willingness of the individual to provide the needed support to the patient
2. Place the patient on daily DOT while waiting for the treatment supporter
3. Ask the patient to invite the treatment supporter to the health facility within a *period of 2 days*
4. Provide health education to both patient/caregiver and treatment supporter on the following:
    i. Basic information on TB and TB Infection Control (especially cough etiquette)
    ii. Treatment duration and number of tablets to take daily
    iii. Sputum follow-up examination (2, 5 and 6 months)
    iv. Possible side effects of anti TB drugs and the need to report back to health facility in case of any complaints
5. Discuss the roles and responsibilities of the treatment supporter:
    i. Ensuring daily DOT
    ii. Tick the Treatment Supporters Card
    iii. Support the patient to come to the health facility for drugs collection *every 2 weeks*
    iv. The patient and treatment supporter should return used (empty) blisters and Treatment Supporters Card before another supply
    v. Support the patient to come to the health facility for follow-up sputum examinations and management of side effects or complications
    vi. Inform the health care worker in case of unavailability of the treatment supporter

vii. Reconfirm the willingness of the treatment supporter
viii. The treatment supporter and patient should sign an agreement on the remark line of the TB Treatment Card
ix. Document the name, address and phone number of the treatment supporter as the contact of the patient on the Patient TB Treatment Card.
x. Ensure that the patient and treatment supporter agree on timing of drug intake and drug storage
xi. Provide the treatment supporter with drugs (two weeks) and the Treatment Support Card
xii. Complete the front page of the Treatment Support card and demonstrate to treatment supporter on the completion of the TS card, especially on his specific roles of only ticking drug administration.
xiii. Health care worker to complete all appropriate section of the patient treatment card and block dates not applicable for the months on treatment.
xiv. The health care worker should review the Treatment Support Card and update patient TB Treatment Card during the 2-weekly visits
xv. The treatment supporter and patient should discuss any challenges with health care worker
xvi. Where available a community volunteer should be used for supervision and defaulter tracing

7.4 Managing contacts of tuberculosis patients

Contact investigation is considered an important activity, both to find persons with previously undetected tuberculosis and persons who are candidates for treatment of latent tuberculosis infection. Unfortunately, lack of adequate staff and resources in many areas makes contact investigation a challenging task. This inability to conduct targeted contact investigations results in missed opportunities to prevent additional cases of tuberculosis, especially among children. Whenever possible, the following should be evaluated for TB:

- All children with symptoms suggestive of tuberculosis
- All children aged <6years who are in close contact with an infectious TB case
- All children contacts with known or suspected immunocompromised States, particularly HIV infection
- All children contacts of patients with MDR/XDR tuberculosis

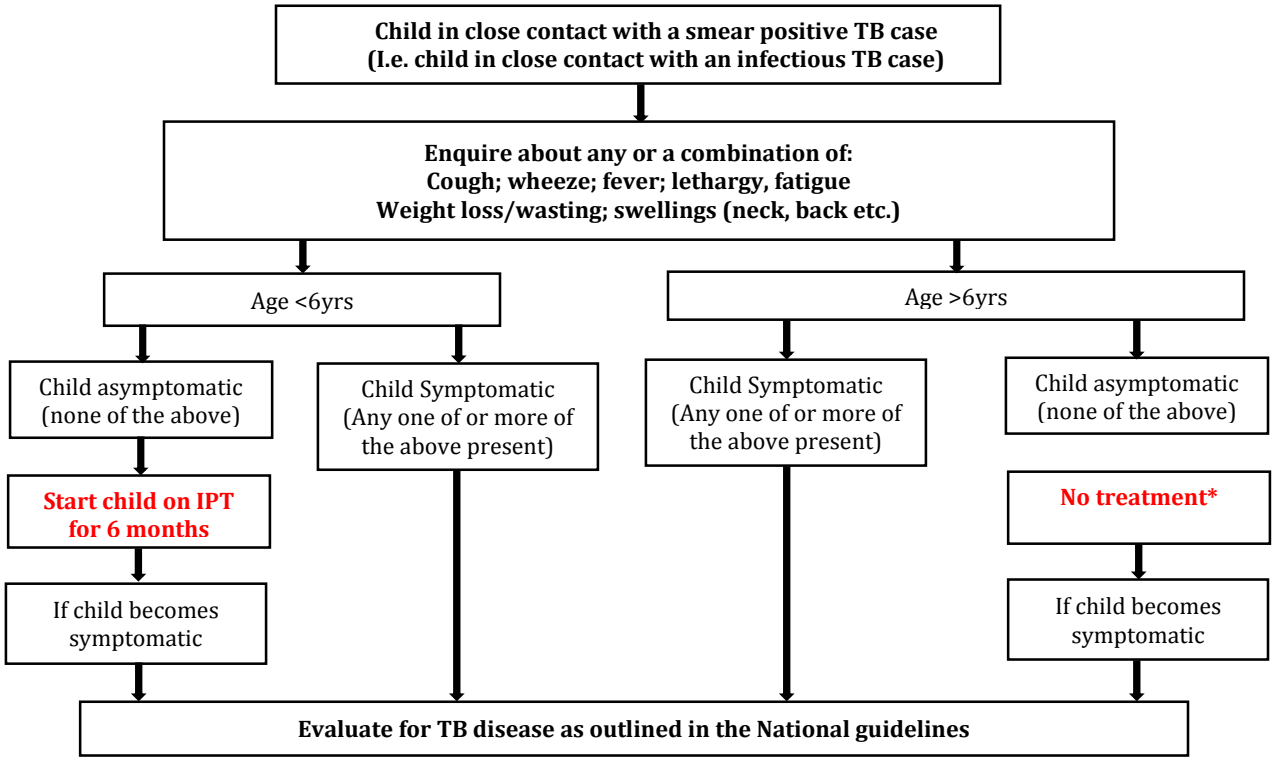
7.4.1 Priority contacts to be screened for TB

The highest priority contacts for evaluation in the NTBLCP are:

- Children aged <6years who are *close contacts* of an infectious index TB patient
- All persons of any age known to have HIV infection

For all children aged <6years who are in close contact with an infectious index TB case should be managed as outlined in figure 7.1 below and record should be entered into the register for management of under 6 contacts of smear positive cases.

Figure 7.1: Approach to evaluating a child for IPT



7.4.2 Administering Isoniazid prophylaxis for children

Children <6 years of age and persons of any age with HIV infection who are close contacts of an infectious index TB patient and who, after careful evaluation by medical officer, do not have active tuberculosis, should be treated for presumed latent tuberculosis infection with isoniazid.

Steps for initiating IPT

- Ask all smear positive TB patient to bring all children who have come in contact with them for screening
- Screen all children <6yrs who came in contact with a smear positive TB case or all children who are HIV positive irrespective of their age as outlined in figure 7.1 above.
    - If symptoms of tuberculosis are present manage as outlined in figure 6.1 and 6.2 above.
    - If symptoms of tuberculosis are absent, preventative treatment should be given, regardless of whether BCG vaccination has been given in the past.

- Ensure availability of INH for the duration of 6 months before commencing clients on IPT, pre-pack the 6 months dosages at the commencement of therapy to be dispensed monthly to enhance compliance.
- Weigh the child every month and the dosage administered should be adjusted accordingly.
- IPT appointment date should be aligned with that of ART to reduce frequency of visits
- Complete necessary INH Prophylaxis Register, and complete INH Appointment Card. (See INH prophylaxis Treatment register for PLHIV, and INH Prophylaxis card in the annex.)
- Staple this card to the treatment card of the smear positive contact of the child.

Table 7.4: Dosage of INH Prophylaxis for children under 6 years

Weight in kg	INH dosages in mg/day	INH in tablet/day
<2.5	25	¼
2.5 – 5.0	50	½
6.0 – 10.0	100	1
11.0 – 25.0	150	1½

Steps for monitoring a child on IPT

- During monthly drug refills, monitor patient for development of active TB (clinical assessment of signs and symptoms of active TB)
- Ask for side-effects; the commonest side-effect is peripheral neuropathy (numbness/tingling sensation of extremities); If present give Pyridoxine (25 mg/day)
- Check for jaundice; If present stop IPT and refer to medical officer for assessment
- Check for abdominal pain, nausea vomiting, yellowish urine and eyes; If present refer to medical officer to rule out active liver disease
- Check for allergic skin eruptions; If present refer to the medical officer
- Evaluate adherence and counsel appropriately
- Any client who did not come a week after his/her IPT appointment day should be tracked and managed appropriately

If patient develops symptoms suggestive of active TB during the course of IPT:

- Discontinue IPT,
- Assess for active TB,
- Commence DOTS if confirmed or refer to medical officer.
- Assess for ART/re-assess for ART failure

7.4.3 Management of IPT missed appointment

For any HIV infected child who missed appointment:

- Trace clients/care giver
- Solve the reason for missed appointment
- Offer adherence counseling
- Manage as outlined in table 7.5 below

Table 7.5: Management of IPT missed appointment

Length of interruption	Evaluate for TB	Outcome of TB evaluation	Action
< 8 weeks	Yes	Confirmed TB	Discontinue IPT commence DOTS
		No TB	continue him/her on IPT and prolong to compensate for missed doses
> 8 Weeks	Yes	Confirmed TB	Discontinue IPT, commence DOTS
		If no active TB	re-start IPT for 6 months

7.4.4 Infants exposed to a mother with TB

i. If a mother is diagnosed with TB before the third trimester of pregnancy, is taking TB medications with good adherence and is clinically well:

- Examine the new born for signs of disease. If the baby is well, no action is required.
- Refer all other household children <5 years of age to the TB clinic for clinical assessment.

ii. If a mother is diagnosed with TB in the third trimester of pregnancy or shortly after delivery:

- Examine her baby closely for symptoms and signs of disease.
- If the baby is well, commence isoniazid (H) prophylaxis at 10 mg/kg/day and continue for 6 months, followed by BCG immunization two weeks after completing isoniazid, as BCG is a live vaccine, isoniazid will kill the vaccine and prevent an effective immune response from developing.
- If the baby is not well and has signs/symptoms suggestive of TB disease, then evaluate for TB.

7.4.5 BCG vaccine and BCG Disease

Bacille Calmette-Guerin (BCG): is a live, attenuated vaccine and is routinely given to neonates in Nigeria in the first week of life. BCG may be associated with injection-site abscesses, adenitis, and (very rarely) with disseminated disease. Infants with advanced HIV infection are at particular risk of BCG-related complications.

The presence of right-sided axillary or regional lymph nodes in a young child or infant indicates possible BCG disease and an immune-compromised State. This most commonly presents in the two years of life after BCG vaccination. It requires further evaluation. Refer to experienced clinicians if BCG disease is suspected.

Infants need to be reviewed monthly after commencing isoniazid. Infants' weights must be checked monthly and their isoniazid dosages increased accordingly.

7.4.6 Outcomes for the Isoniazid prophylactic treatment

Health workers should ensure that all children started on IPT treatment are evaluated after completing their treatment and are a treatment outcome. The following are the available treatment outcome that can be assigned to a child who was started on treatment.

1. Completed treatment
2. Loss to follow-up
3. Not evaluated
4. Died
5. Developed active TB.

7.5 Monitoring of TB treatment in Children

7.5.1 Method of Monitoring

Monitoring progress of tuberculosis patients while on treatment is an essential part of TB case management. This is to ascertain the effectiveness of treatment in killing M. Tuberculosis as well as assessing improvement in the patient's clinical State.

- HIV- uninfected children: are monitored monthly during intensive phase and 2-monthly in continuation phase.
- HIV-infected children: are monitored at 2 weeks and at 4 weeks following commencement of anti-TB treatment and then monthly thereafter.

Refer to section 5.3 for more details.

Following up a child using Clinical assessment

Below are important practical points to be considered when assessing a child receiving treatment for TB during follow-up visits.

- For each visit ensure anthropometric examinations are carried out, these includes:
  - Weigh the child at each follow-up, document
  - Height
  - Mid-Upper Arm Circumference (Children 1-5 years: Normal range; 13.5 – 17cm).
  - Skin fold thickness -this is measured over the triceps muscles
- Adherence for the full course of treatment may be a challenge.
- Explain and emphasize to care-giver and child why they must take the full course of treatment even if they are feeling better
- Note risk factors for poor adherence such as distance/transport; orphan (especially if mother has died) or primary care-giver unwell; adolescents
- Education and adherence support especially TB/HIV
- Explain that anti-TB drugs in children are well tolerated and safe.

Important practice points for monitoring a child on treatment

- Weigh the child at each follow-up, document and do not adjust dosages.
- Adherence for the full course of treatment may be a challenge.
  - Explain and emphasize to care-giver and child why they must take the full course of treatment even if they are feeling better
  - Note risk factors for poor adherence such as distance/transport; orphan (especially if mother has died) or primary care-giver unwell; adolescents
  - Education and adherence support especially TB/HIV
- Explain that anti-TB drugs in children are well tolerated and safe.
- Chest X-ray is not required in follow-up if the child is responding well to anti-TB treatment
- Regularly look for signs of poor response to treatment

Poor Response to Treatment

Most children with TB will start to show signs of improvement after 2 to 4 weeks of anti-TB treatment. In looking for poor response in children on anti-TB

- Assessment should be carried out as Stated above.
- Poor adherence is a common cause of "treatment failure".
- Treatment failure is more common in HIV-infected children.
- Treatment failure suggests the possibility of MDR TB and needs careful assessment.
- Consider imminent treatment failure if child is receiving anti-TB treatment and:
  - No symptom resolution, or symptoms are getting worse
  - Continuing weight loss
  - Smear-positive at 2- month follow-up sputum

Note:

- If a child stops anti-TB treatment for more than 2 weeks in the intensive phase or more than 2 months in the continuation phase and becomes symptomatic, then restart Regimen 1.
- If a child stops anti-TB treatment for less than 2 weeks in the intensive phase or less than 2 months in the continuation phase and becomes symptomatic, then continue current regimen and make up for missed doses.

7.6 Case holding

As in the management of an adult TB case, it is important that all children continues and completes treatment uninterrupted. Case holding implies that a patient on anti-TB treatment is monitored by a health care provider to ensure that he/she continues and complete his/her treatment uninterrupted. Health Workers should do all that is humanly possible to ensure that patients complete treatment in the required time.

7.6.1 Managing Treatment Interruption

Any child who has not come to receive his/her treatment for two consecutive days either in the intensive or continuation phase should be regarded as having interrupted treatment and therefore be traced. In children whose caregivers do not return to collect their drugs two days after the expected date of return are regarded as having interrupted treatment. All effort should be made to bring the child back on treatment and a report of the defaulter-tracing visit should be attached to the treatment card.

Actions to be taken in patients who interrupt Anti-TB Treatment

- General action
- Trace patient
- Solve the cause of interruption
- Continue treatment and prolong it to compensate for missed doses

Manage all children who cannot produce sputum as described in table 7.6 below

Table 7.6: Management of treatment interruption in children who cannot produce sputum

Length of interruption	Clinical assessment	Action
< 2 weeks (intensive) < 2months (continuation)	Not Symptomatic	Continue Rx and prolong to compensate for missed doses
	Symptomatic	Continue Rx and prolong to compensate for missed doses
> 2 weeks (intensive) > 2months (continuation)	Not Symptomatic	Continue Rx and prolong to compensate for missed doses
	Symptomatic	If on Six months or twelve months Regimen Restart the same regimen respectively

- **Treatment adherence of every child is absolutely essential in order to cure the patient and prevent Drug Resistant TB (DR TB)**
- **For children who can produce sputum; Apply steps for management of interruption as described in section 3.5 of implementing TB control activities in adults**

7.6.2 Treatment Outcomes

All bacteriologically confirmed and clinically diagnosed tuberculosis cases that were started on TB treatment should be assigned an outcome. It is very important that treatment outcomes are reported for all children that receive TB treatment as per standard category. Treatment outcome for children is the same as assigned to adults.

Refer to section 5.6 above for details.

8. APPROACH TO MANAGEMENT OF TUBERCULOSIS AND HIV CO-INFECTION

Tuberculosis (TB) and the Human Immunodeficiency Virus (HIV) are among the 10 leading causes of death in Nigeria and indeed Africa. While HIV fuels the TB epidemic in immuno-compromised individuals, TB is the most common cause of death among People Living with HIV/AIDS (PLHIV).

8.1 Facts about TB and HIV Interaction

- Infection with HIV leads to progressive destruction of the body's immune system. Therefore persons who are infected with HIV are more prone to TB disease than those without HIV infection when infected with TB.
- Similarly, HIV reduces the protection provided by the immune system and enables TB bacilli to multiply unchecked, facilitating rapid progression to active TB disease whereas a strong immune system usually prevents the development of TB disease following infection with TB bacilli.
- In Africa, HIV prevalence among tuberculosis patients is approximately 38%, while in Nigeria about 23% of TB patients are HIV-positive.

8.2 Impact of HIV on TB

- High HIV prevalence is associated with increased newly diagnosed TB cases. This is because HIV infection increases susceptibility to new TB infections and accelerates the progression from Latent TB infection (LTBI) to active TB disease.
- Most HIV patients with TB often present with atypical TB symptoms and are particularly associated with an increased number of smear-negative PTB and EPTB cases.
- When HIV-positive patients develop PTB, the number of bacilli present in the sputum is fewer than in HIV-negative patients. This makes diagnosis by conventional sputum microscopy difficult among this group of patients.
- Furthermore, studies have shown that up to 17% of new TB cases are acquired from smear-negative cases; therefore it is important to identify and treat smear-negative cases early in order to break the cycle of TB transmission in the community and health facilities.
- Also, HIV infection increases TB-associated morbidity, mortality and may increase the proportion of those of them with worse treatment outcomes for TB when compared with HIV-negative TB patients.
- Adverse reactions to anti-TB drugs are also more frequent in TB/HIV co-infected patients compared to HIV negative TB patients and may lead to interruptions of treatment among these patients.

8.3 Collaboration and coordination between the TB and HIV programmes

8.3.1 Goals and Objectives of TB/HIV collaborative activities

8.3.1.1 Goal

The Goal for the TB/HIV collaborative activities in Nigeria is to decrease the burden of TB and HIV in people at risk or affected by both diseases.

8.3.1.2 Objectives

The objective of TB/HIV collaboration is to:

1. To establish and strengthen the mechanisms of collaboration and joint management between HIV programmes and TB-control programmes for delivering integrated TB and HIV services preferably at the same time and location.
2. To reduce the burden of TB in people living with HIV, their families and communities by ensuring the delivery of the Three I's for HIV/TB and the early initiation of ART in line with the National guidelines.
3. To reduce the burden of HIV in patients with presumptive and diagnosed TB, their families and communities by providing HIV prevention, diagnosis and treatment.

8.3.2 Integrated TB/HIV Services

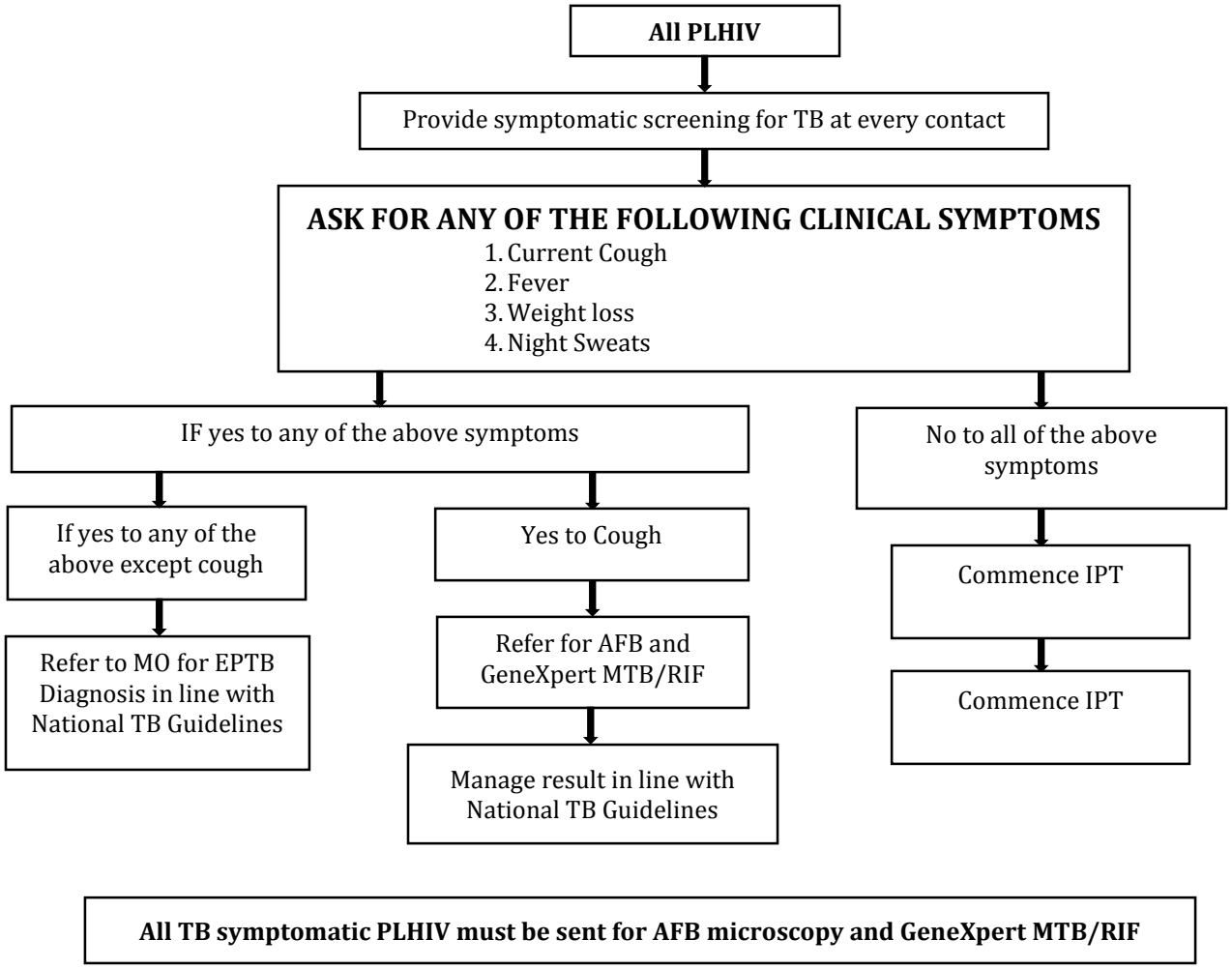
Controlling TB/HIV requires collaboration and coordination between the TB and HIV programmes at all levels. Service integration should include referral of TB cases and presumptive TB cases between TB and HIV services, partial provision of joint TB/HIV services, or full integration of the TB and HIV/AIDS services in a clinic. In order to minimize the burden to the patient it is recommended that the patient receives both TB and ARV medicines from one health facility nearest to his/her home or workplace. ARV drug collection should therefore be made accessible in health facilities that also offer TB therapy, or vice versa.

Examples of integrated TB/HIV services include:

- Provider-initiated HIV testing and counselling (PITC) of TB patients,
- Provision of co-trimoxazole preventive therapy (CPT),
- Early initiation of ART in HIV-infected patients with TB,
- Screening of all HIV-positive persons for active TB, and
- Provision of isoniazid preventive therapy (IPT) to PLHIV who are eligible (see section 7.4 above).

HIV-related tuberculosis is associated with unfavourable/poor TB treatment outcomes such as treatment failure and death. It is therefore imperative to rapidly identify and treat TB cases among PLHIV. In order to achieve this objective, all adults and adolescents **living with HIV** should be clinically screened for TB as recommended in figure 8.1 below.

Figure 8.1: Algorithm for TB screening among Adult living with HIV



8.3.3 Integrated TB/HIV Services expected to be provided to a TB/HIV co-infected patient

1. Provider-initiated HIV testing and counselling (PITC) for TB patients

- All presumptive TB cases and TB cases should be offered HIV counselling and testing by health workers. HIV testing should be carried out if:
    - HIV status is unknown
    - Was previously reported as negative in the past 3 months
    - Was refused or opted out of during the patient's previous visit.
    - A patient reports having been previously tested for HIV but has no documented evidence of this fact.
- All HIV- positive TB patients are entitled to quality HIV treatment, care and support services.
- It is important to note that HIV testing in Presumptive and diagnosed TB cases is provider-initiated (PITC).

- Health workers should continue in offering PITC to all TB patients who opted out of HIV testing.
- Health workers should encourage HIV-positive TB patients to invite their partners and children for TB screening and provide access to HCT services.

2. Provision of co-trimoxazole preventive therapy (CPT)

- All HIV-positive TB patients should be started on CPT to reduce the occurrence of opportunistic infections.
    - If possible, CPT should be started on the same day that the patient's HIV-positive status is determined.
    - The recommended dosage for trimethoprim-sulphamethoxazole (cotrimoxazole) is 960mg daily for adults and 60mg/kg for children not exceeding 960mg.
    - Contraindications to cotrimoxazole include:
        - Known severe drug reaction to sulphur-containing drugs,
        - Severe anaemia,
        - End-stage renal disease.
        - First trimester of pregnancy

Refer to the national HIV treatment guidelines and NTBLCP SOP on CPT for further information.

3. Provision of antiretroviral therapy in HIV infected TB patients

- Antiretroviral therapy improves survival in HIV-positive patients.
- Regardless of CD4 count, all TB/HIV co-infected patients should be started on ART as soon as possible and within the first 8 weeks of starting TB treatment.
- If the TB/HIV co-infected patient is clinically stable, ART and TB treatment may be started concurrently.

4. Provision of INH Preventive Therapy (IPT)

IPT has been shown to be beneficial in certain settings in preventing morbidity and mortality from TB. INH preventive therapy should be given to all HIV positive individuals in whom active TB has been excluded (also refer to section 5.4 above for administration of IPT in children)

- To exclude active TB:
    - Ask the patient about cough, chest pain, fever, night sweats and weight loss etc.
    - Check for lymph node enlargement
    - Those with the above symptoms/signs should not be considered for IPT
    - Do sputum smear examination for AFB and GeneXpert MTB/RIF
    - Manage result as per National TB guidelines
    - Refer clients with other symptoms other than cough to the medical officer for further evaluation

Dosages for IPT

- Adult: 300mg/day for six months.
- Children: 10mg/kg/day to a maximum of 300mg/day for six months

5. Overlapping ARV and TB drug side effects

Concurrent use of ARVs and TB drugs has potential for added toxicity. The most common causes of skin rashes are pyrazinamide, isoniazid and rifampicin. ARVs such as Nevirapine and Efavirenz are also known to cause skin rashes. These overlapping side effects make it difficult to identify the causative drug when a patient is receiving treatment for both TB and HIV con- currently. Patients on both treatments need a thorough history and clinical assessment to establish which drug is responsible for the side effects.

Table 8.1: Drug interactions between ARVs and anti-TB drugs

Drug	Interactions with	What to do?
AZT	Cotrimoxazole, pyrimethamine	Check WBC and HB
3 TC	Cotrimoxazole: 3TC level increased	NIL (well tolerated)
D4T	With drugs that cause neuropathy: INH, phenytoin, Ethambutol	Use with caution or avoid
NVP	ketoconazole, rifampicin	Do not use
EFZ	carbamazepine, cisapride, ergot derivatives (ergotamine), ketoconazole Phenobarbital, phenytoin benzodiazepines Rifampicin Oral contraceptives	Do not use! Only short term use possible Increase dosage to 800mg OD if tolerated! Use dual protection
LPV/r	rifampicin, ergot derivatives, benzodiazepine, Phenobarbital phenytoin ketoconazole, itraconazole, carbamazepine, calcium channel blockers Oral contraceptives decreased effectiveness	Do not use! Use with caution Dual protection essential
ABC	Alcohol	Avoid
DDI	Ethambutol Ketoconazole, doxycycline or ciprofloxacin (if buffered formulations)	Avoid! Take 2 hours before or after meals

8.3.4 Immune reconstitution inflammatory syndrome (IRIS)

An HIV-positive patient's condition could worsen within the first 6 months of starting ART because of IRIS. IRIS is as a result of recovery of the body's immune system. There are two common IRIS scenarios:

- An unmasking of an occult OI,
- A paradoxical symptomatic relapse or worsening of a prior infection that was seemingly diagnosed and treated successfully.

Before starting ART, counsel TB patients about the possibility of a temporary worsening of symptoms.

- If a patient develops IRIS while on anti-TB treatment and ART, seek the advice of a senior ART provider or medical specialist. There is no need to stop or change TB or ARV treatment. Confirm that the patient adheres to his or her medication regimen as prescribed. Admit severe cases to hospital.
- If treatment with steroids is indicated:
    - Give dexamethasone 8 – 16 mg/day (divided into twice daily dosing) or prednisolone 1 mg/kg body weight (once daily) for 14 – 21 days.
    - After 14 – 21 days, rapidly taper the steroids over a 10 – 14 day period while monitoring for recurrence and/or worsening of symptoms.
- Consider TB treatment failure or DR-TB if the patient's condition worsens despite having received one or more months of anti-TB treatment.

- **Occasionally a TB/HIV co-infected patient may experience a temporary worsening of TB symptoms soon after beginning ART and TB treatment. IRIS should be considered as a potential cause of such clinical worsening.**
- **Signs and symptoms include: high fever, lymphadenopathy, and worsening CXR findings.**
- **Other causes of clinical worsening should be ruled out before making a diagnosis of IRIS; these include undiagnosed TB disease, cryptococcal meningitis and Kaposi Sarcoma.**
- **Patients with advanced AIDS who start ART late are at the greatest risk of developing IRIS.**
- **Any patient with symptoms of IRIS at primary health care facility should be referred to secondary or tertiary health facility for care**

8.4 Approach to Managing TB and HIV in Children

The current approach to clinical diagnosis of TB in HIV-infected children is similar to that recommended for HIV-uninfected children (see Figure 7.1 and 7.2 above). It is recommended that HIV-infected children be treated with the same TB treatment regimens and for the same duration as those for HIV-uninfected children. Always ensure that:

- Those children who are co-infected are referred to the ART clinic for HIV treatment and care.
- HIV-infected children should also be started on ART as soon as the TB treatment is commenced.
- ART is started on the same day as TB treatment if the child is stable.
- ART is commenced for all HIV-infected children and infants with any form of TB.
- Children must be followed up regularly and must be started on co-trimoxazole preventive therapy (CPT) as described above.
- Patients must be weighed at regular intervals.

9. APPROACH TO MANAGEMENT OF DRUG RESISTANT TUBERCULOSIS (DR-TB)

9.1 Introduction

The emergence of resistance to drugs used to treat TB and particularly multi-drug resistant TB (MDR-TB) and XDR-TB poses an obstacle to effective TB control at both national and global levels. Resistance arises from both service and patient-related factors in the management of the disease, ranging from poor, inadequate supervision; poor quality of drugs; inadequate dosing, drug combinations, and duration of treatment; poor training of health staff; and poor adherence by patients.

9.2 Definitions

9.2.1 DR-TB Case

A patient is considered to be a drug resistant TB case if only there is a laboratory confirmation of resistance to one or more anti- tuberculosis drugs.

9.2.2 Classification of Tuberculosis based on drug resistance

TB cases are classified in categories based on drug susceptibility testing in clinical isolates confirmed to be Mycobacterium tuberculosis:

1. **Mono-resistance:** Is resistance to one first-line anti-TB drug only

2. **Poly-resistance:** resistance to more than one first-line anti-TB drug, other than both isoniazid and rifampicin

3. **Multidrug-resistance (MDR):** resistance to at least both isoniazid and rifampicin

4. **Extensive drug resistance (XDR):** resistance to any Fluoroquinolone, and at least one of three second-line injectable drugs (Capreomycin, kanamycin and Amikacin), in addition to multidrug resistance

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, in the form of mono-resistance, multidrug resistance, poly-drug resistance or extensive drug resistance.

9.2.3 Programmatic classification of a DR-TB case

Programmatically a DR-TB case could also be classified based on previous exposure to anti-TB drugs.

- **Drug resistance among new cases:** Is the presence of resistant strains of MTB in the clinical isolates of a newly diagnosed patient who has never received anti-TB drugs or has received treatment with them for less than one month
- **Drug resistance among previously treated cases:** Is the presence of resistant strains of MTB in the clinical isolates of a patient who has previously received at least one month of anti-TB drugs.

9.3 Management of a presumptive DR-TB Case

Diagnosis of a DR-TB case begins with the identification of a presumptive DR-TB case. It is important to identify presumptive DR-TB cases, confirm diagnosis and initiate appropriate treatment in a timely manner.

9.3.1 Identifying presumptive DR-TB cases

The identification of a presumptive TB case should be done early to ensure prompt diagnosis and appropriate treatment in order to prevent the disease from spreading to others. The NTBLCP has considered the following patients as the priority presumptive DR-TB cases in Nigeria:

i. All known symptomatic contacts of a confirmed DR-TB case
ii. Any failure to Regimen 1 treatment
iii. Any failure to convert when AFB is repeated at month three (3) of Regimen 1 treatment
iv. All Retreatment cases
    a. Relapse
    b. Treatment after failure
    c. Treatment after loss to follow-up
    d. Other previously treated patients
v. Child with TB that is not responding to first line therapy despite adherence(assessed after about 4 weeks of treatment in the absence of alternative diagnosis)
vi. Extra-pulmonary TB cases in which specimen could be collected for Xpert testing such as collection of cerebrospinal fluid (CSF) for examination as in TB meningitis.

These patient categories require urgent intervention to prevent further damage to their lungs and spread of the disease. Health care workers should ensure that the following services are provided:

- Any presumptive DR-TB case identified should be requested to submit 1 sputum specimen for GeneXpert MTB/RIF and managed as outlined in figure 9.1 below.

Figure 9.1: Diagnostic Algorithm using GeneXpert MTB/RIF

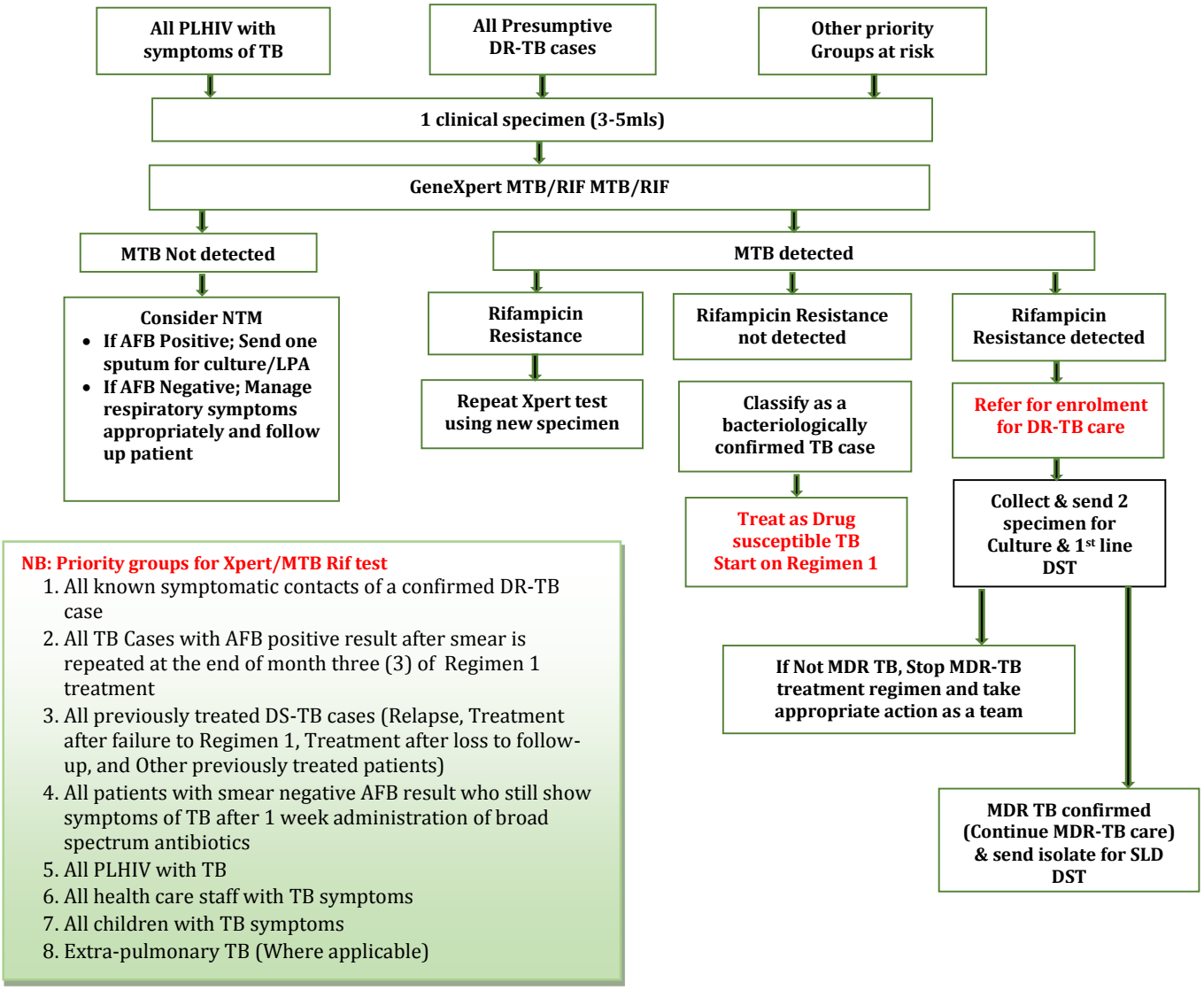


Table 9.1: Sputum collection and transportation for Xpert-MTB/RIF

STEP	ACTION
1.	1. Contact the TBL supervisor prior to collecting specimen for Xpert-MTB/RIF for transportation of the sputum sample 2. Ensure that the request form is correctly filled with all patient information (identifiers)
2.	3. Clearly label the side of the sputum cup (not the lid) with patient's name, ID number and date of collection before giving the cup to the patient
3.	4. Instruct patient to: • Rinse mouth with clean water • Take 3-4 deep breaths, holding breath for 3-5 seconds after each inhalation

	• Cough after the last inhalation, emptying the sputum into the sputum cup, with care taken not to contaminate the outside of the cup 5. Educate patient on cough etiquette and hygiene (TB IC)
2	1. Collect one sputum specimen from the patient using the normal sputum cup 2. Sputum specimen should be produced in an open, well ventilated space not in the laboratory or offices 3. Ensure that the sputum cup screw cap is tightly closed 4. Wipe the outside of the cup with cotton wool soaked in tuberculocidal disinfectant (Phenol, Lysol, bleach)
5.	5. Inspect specimen for quality and volume, the recommended volume of sputum specimen *is at least 3 to 5 mls*
6.	6. Send collected specimen in a sputum collection box e.g. "coolers" to the Xpert-MTB/RIF laboratory alongside the completed sputum request form not more than two days after collection

All sputum samples for Xpert-MTB/RIF must be sent to designated laboratories.

Table 9.2: Sputum collection and transportation for culture & DST

STEP	ACTION
1.	1. For sample collection outside the DR-TB Treatment Centre, contact the TBL supervisor prior to collecting specimen for culture and DST for logistics 2. Ensure that the request form is correctly filled with all patient information (identifiers)
2.	3. Clearly label the sides of the falcon tubes (not the lid) with patient's name, ID number and date of collection before giving out to patients
3.	4. Instruct patient to: Rinse mouth with clean water, take 3-4 deep breaths, holding breath for 3-5 seconds after each inhalation and cough after the last inhalation, emptying the sputum into the falcon tube, with care taken not to contaminate the outside of the tube
4	5. Collect two spot sputum specimen from each patient at least one hour apart in sterile leak-proof (50ml) falcon tubes 6. All sputum specimens should be produced in an open and well ventilated space not in the laboratory or offices 7. Ensure that the falcon tube screw cap is tightly closed 8. Wipe the outside of the tube with cotton wool soaked in tuberculocidal disinfectant (Phenol, Lysol, bleach)
5	9. Inspect specimen for quality and volume, the recommended volume of sputum specimen *is 3-5 mls*
6	10. Store the specimen at 2-8^{o}C and ship to reach the lab within three days 11. Package collected specimen for transport to the culture and DST laboratory using SOP on specimen transportation

All sputum samples for culture and DST must be sent to designated MDR TB laboratories in good condition away from sunlight.

9.4 Management of DR-TB in Nigeria

Early diagnosis and appropriate treatment remains the cornerstone of TB control and as such health care workers should ensure that patients are detected early and giving appropriate treatment through DOTS. Appropriate treatment through DOT will ensure:

- Cure for the patient
- Reduction of transmission of resistant strains of TB bacilli to other persons
- Prevention of further development of resistance

9.4.1 Treatment delivery model in Nigeria

In order to ensure that DR-TB cases are promptly and appropriately treated, the NTBLCP has adopted a mixed treatment delivery model:

1. Initiation of treatment in a treatment centre which entails that:
    a. Patients are admitted into the ward to commence the initial part of the intensive phase of treatment.
    b. Ambulatory treatment are provided to patients at the nearest DOT Clinic for the remaining duration of treatment after discharge from the treatment centre.
    c. Specialized clinical services are provided to the patient as at when needed
2. Initiation of DR-TB treatment in the community which entails that:
    a. DR-TB patients are commenced on treatment while in their homes through the use of a treatment supporter (Both phases of treatment are provided at the community throughout their treatment)
    b. Specialized clinical services are provided to the patient as at when needed

9.4.2 DR-TB Treatment Regimen in Nigeria

The current national DR-TB treatment regimen is designed based on the recognition of five groups of anti-TB drugs as shown in table 9.3. This treatment regimen could either be individualized or standardized based on the resistant pattern and DST result of the clinical isolates in that environment.

In line with WHO/IAUTLD recommendation and available local evidence, Multidrug-resistant TB in Nigeria is currently treated with a standardized second-line anti-TB drugs for a minimum period of 20 months.

- Standardized second-line anti-TB drugs for Nigeria is **8km-Z-Cs-Lfx-Pto/12 Lfx-Cs-Pto**
    - **8 months of Intensive phase:** which represents the period the injectable agent, i.e. Kanamycin is used in addition to pyrazinamide, Cycloserine, Levofloxacin and Prothionamide
    - **12 months of continuation phase:** which is the period after the injectable is stopped and the other four drugs mentioned above are continued.

Table 9.3: Grouping system of anti-TB drugs

Grouping	Drugs/Codes
Group 1: **First-line oral anti-TB drugs**	Isoniazid (H); Rifampicin (R); Ethambutol (E); Pyrazinamide (Z). Rifabutin (Rfb).
Group 2: **Injectable anti-TB drugs**	Kanamycin (Km);Amikacin (Am); Capreomycin (Cm); Streptomycin (S)
Group 3: **Fluoroquinolones**	Levofloxacin (Lfx); Moxifloxacin (Mfx); Gatifloxacin Gfx
Group 4: **Oral bacteriostatic second-line anti-TB drugs**	Ethionamide (Eto); Prothionamide ((Pto); Cycloserine (Cs); Terizidone (Trd); P-aminosalicylic acid (PAS); P-aminosalicylic-Na
Group 5: **Anti-TB drugs with uncertain efficacy**	Clofazimine (Cfz); Linezolid (Lzd); Amoxicillin/Clavulanate (Amx/Clv); Thiacetazone (Th);Clarithromycin (Clr); Imipenem/Cilastatin (Ipm/Cln), Bedaquiline (Bdq), Delamanid (Dlm); High dose isoniazid (High dose H)

Refer to the Guidelines for the Programmatic and Clinical Management Of Drug Resistant Tuberculosis in Nigeria.

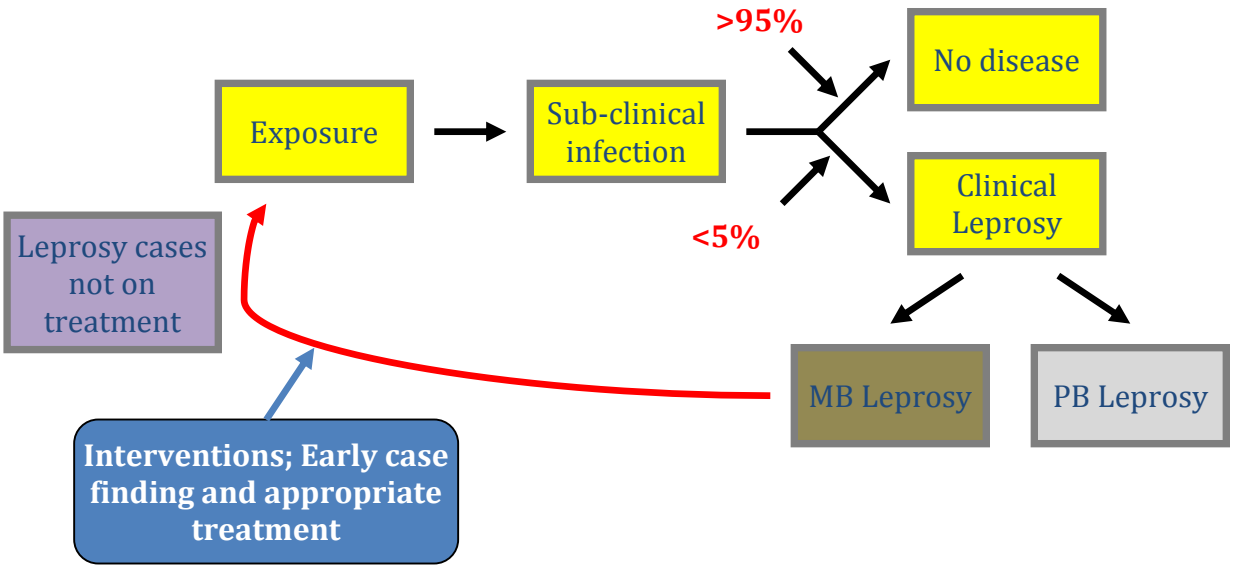
IMPLEMENTING LEPROSY CONTROL ACTIVITIES

10. INTRODUCTION

Leprosy remains a disease of major public health challenge in Nigeria despite the existing interventions and services for the control of leprosy. Over the years the weak capacity for leprosy as well as inadequate quality of care for leprosy has continually undermined the country's earlier attainment of the WHO elimination target of less than one case per 10,000 in 1989. An average of 4,000 leprosy cases are reported annually in the last ten years with relatively high proportion of children and many patients are diagnosed late with obvious deformities and disabilities. Leprosy services are provided in an integrated manner by general health workers in public and private health facilities in all 774 LGAs. These Leprosy services are supported by the World Health Organisation (WHO) globally and in-country mainly by the International Federation of Anti –Leprosy Associations (ILEP).

Leprosy is a chronic, infectious disease that mainly affects the skin, peripheral nerves and mucous membrane of the upper respiratory tract. It is caused by a bacterium called Mycobacterium Leprae. Transmission is thought to be through droplets from coughing and sneezing. The most important route of exit is through nasal discharge. The incubation period (that is the period between infection and appearance of the first symptom or sign of disease) is variable, two to five years in PB disease but much longer, five to ten years in MB disease.

Figure 11.1: Transmission Cycle of Leprosy



10.1 GOAL FOR LEPROSY CONTROL

To reduce the prevalence and socio-economic burden associated with leprosy in Nigeria to such a level that it is no longer a public health problem.

10.1.1 Objectives

1. To ensure early case detection such that the rate of new cases with grade 2 disability per 100,000 population is reduced by at least 35% by the end of 2015 compared to the baseline at the beginning of 2010.
2. To ensure 100% Multi-Drug Therapy (MDT) coverage for all patients in need of MDT.
3. To ensure that the provision of rehabilitation needs are mainstreamed into the existing socio-economic and physical rehabilitation services at the State and national levels.

10.1.2 LEPROSY CONTROL STRATEGY

1. Early case-finding and proper treatment.
2. Management of contacts (including household contacts)
3. (Re-) introduce quality-assured slit skin smear microscopy
4. Targeted active case-finding campaigns (mini-Lecs)
5. BCG vaccination.
6. Strengthen leprosy control activities in areas with high proportions of grade 2 disability and children, among new cases.
7. Promote the use of community-based rehabilitation to improve the quality of life of persons and families affected by leprosy.
8. Focused integration of leprosy control into the general health care services, this will involve designated skin clinic days in designated facilities.
9. Increase surveillance for resistant strains of M. leprae.
10. Apply cost-effective advocacy and communication methods to improve community awareness, acceptance and involvement to combat stigma and discrimination against person and families affected by leprosy.
11. Institute effective referral systems from the peripheral health facilities to designated skin clinics and referral centres.
12. Post-MDT surveillance.

- **Leprosy is curable with drugs**
- **Drugs are available free through the NTBLCP.**

11. CASE DETECTION STRATEGIES

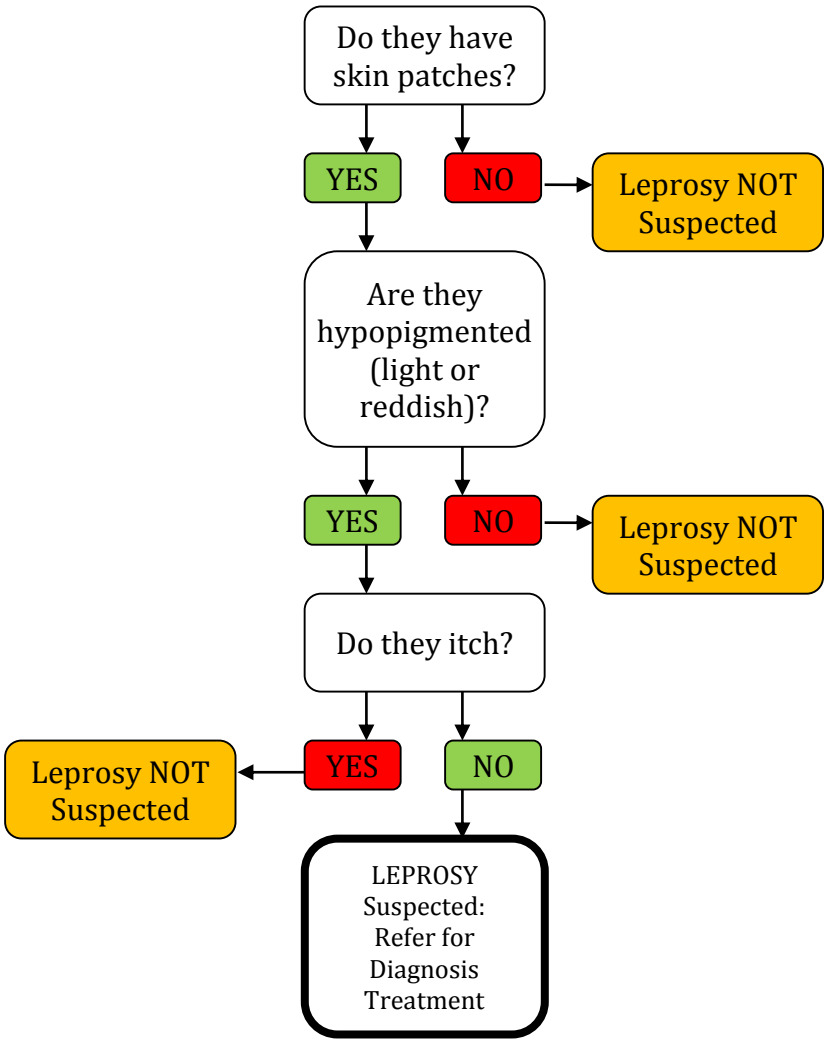
Leprosy case detection is based on both passive and active case finding.

11.1 Suspecting Leprosy

When should leprosy be suspected?

Leprosy usually starts as a patch on the skin, but it can also affect the nerves and damage them. If not properly treated, this nerve damage can lead to problems in the face, hands and feet – but if taken care of, most permanent damage can be prevented. Refer to figure 12.1.

Figure 11.1 Guides for Managing Leprosy Suspects at the Primary Health Centre Level



Leprosy should be suspected in people with any of the following symptoms or signs:

- **light (hypo-pigmented) or reddish patches on the skin (the most common sign of leprosy);**
- **loss or decrease of feeling in the skin patches;**
- **numbness or tingling of the hands or feet;**
- **weakness of the hands, feet or eyelids;**
- **painful or tender nerves;**
- **swelling of or lumps in the face or earlobes;**
- **Painless wounds or burns on the hands or feet.**

11.2 Managing Leprosy Suspects

The following actions are the necessary steps needed to be followed whenever a leprosy suspect is identified which will in turn helps to improve case detection:

- Good history taking;
- Physical examination of the patients (skin, peripheral nerves and general assessment); and
- Laboratory examination of slit skin smears for cases that cannot be diagnosed by clinical signs.

11.2.1 Talk to the Person (History Taking)

i. **Previous medical history:** Find out as much as you can about the previous medical history of the patient. Allow adequate time to talk to patients.
   - They are the people who know their bodies best.

ii. **Duration of skin patches:** How long has the skin patch been there? How did it start? Has it changed?
   - Leprosy patches usually appear slowly

iii. **Itching & Pain:** Do the patches itch? Is there pain?
   - Leprosy patches do not itch and are usually not painful unless complicated (Leprosy reaction)

iv. **Sensation:** Does the person have unusual sensations in his/her hands or feet, such as numbness, tingling or a burning feeling?
   - Unusual sensations in the hands or feet can be suggestive of leprosy

v. **Muscle weakness:** Does the person think that his/her hands or feet have become weaker? Does he/she have problems with holding or lifting things and with moving his/her hands and feet?
   - Losing strength of the muscles of the eyes, hands or feet, can be a sign of leprosy

vi. Does the person have any painless cuts or injuries on their hands or feet?

vii. Has the person experienced any social problems?
- This may be more likely if the person already has some deformity due to leprosy

11.2.2 Physical Examination

The first sign of leprosy is often a patch of skin that is lighter in colour than the surrounding skin. Although the majority of leprosy patients have straightforward skin lesions which are easy to see, experienced workers know that there is a great variety in the skin lesions of leprosy. Some skin lesions are very diffuse and difficult to distinguish from normal skin, in these cases the other symptoms and signs become important. Any skin patch could be leprosy.

Any person suspected of having leprosy should be examined systematically in the following order:

- Talk to the person
- Examine and test their skin patches
- Feel the nerves
- Examine the hands and feet
- Decide whether a slit skin smear is needed (referral to another clinic or hospital may be needed for this)

11.2.2.1 Examine the Skin

Conditions for proper skin examination

- Good natural light source
- Privacy
- Inform the person about the process and reasons for the examination
- Examine the whole body from head to toe in a systematic order

Look for pale/red skin lesions

- Leprosy lesions are usually lighter than the surrounding skin (macula)
- They may be reddish in colour and can have a raised edge (plaque)
- Leprosy lesions can also be solid and raised (papules and nodules)

Look for loss of sensation in the skin patches

- Leprosy patches usually have a loss of feeling to cotton wool. Check to see if the person can feel anything when you touch the skin patches with cotton wool.

Cotton wool test for loss of feeling

- **Before you start, show the person what you are going to do**
- **Use a wisp of cotton wool**
- **Educate and demonstrate to the patient with his/her eyes open**
- **Ask the patient to close his/her eyes or he/she should be blindfolded while carrying out the procedure**

- **Touch normal skin above the patch, then touch the centre of the skin patch then touch normal skin below the patch with the wisp of cotton wool**
- **Ask the patient to touch the area if he/she feels the touch**
- **If the person cannot touch where the cotton wool touched on the skin patch, that is a cardinal sign of leprosy**

Note:

- It is difficult to demonstrate loss of sensation in a lesion on the face, due to the complexity of nerve supply in the face. Also, non-leprosy scaly lesions may be insensitive to the cotton wool test.
- Record findings on the NTBLCP leprosy record card.

A person who present with a hypo-pigmented or reddish skin lesion with definite loss of sensation is diagnostic of leprosy

11.2.2.2 Feel the Peripheral Nerves

Feel the nerves

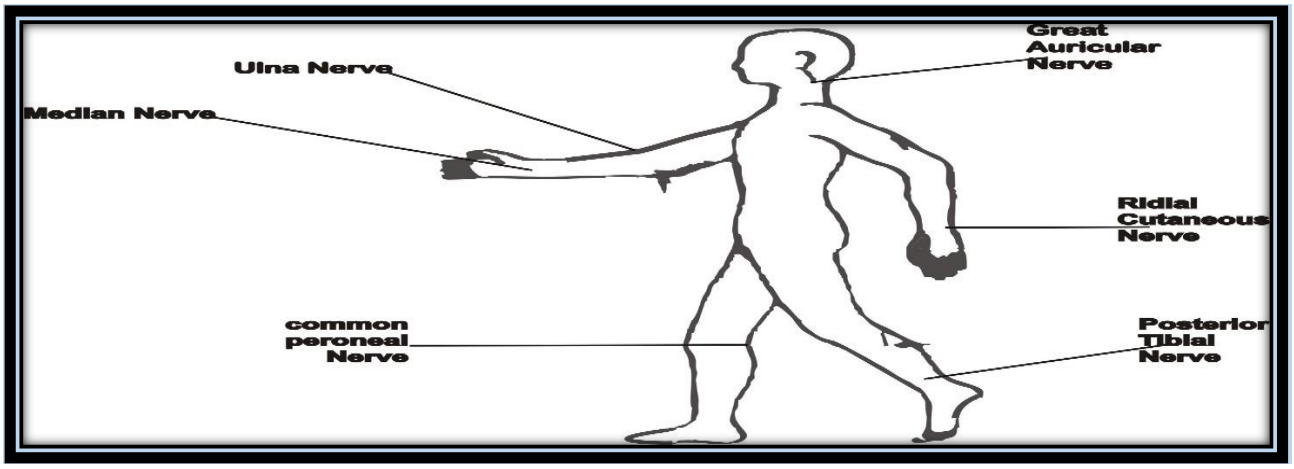
- Leprosy-affected peripheral nerves are usually enlarged

Examine for signs of nerve damage in the eyes, hands and feet

- Enlarged peripheral nerves can be a sign of leprosy. Examination of the peripheral nerves is an important part in the examination of a person suspected of having leprosy, but requires experience and should be done only by staff specifically trained to do it.

Nerves which are commonly enlarged are

- **Great Auricular nerve** on the side of the neck, below the ear, it is sometimes visibly enlarged: gently feel it to make sure it is the nerve (solid) and not one of the veins in the neck (full of fluid).



These should be gently palpated for enlargement. The palpation is a practical skill that must be learned and practiced in a training session as follows:

- Use the pulp of two or three fingers
- Roll the nerves gently over underlying surface to get an impression of the size, consistency and tenderness
- Always compare left and right
- Nerve enlargement **alone** should be interpreted with caution.

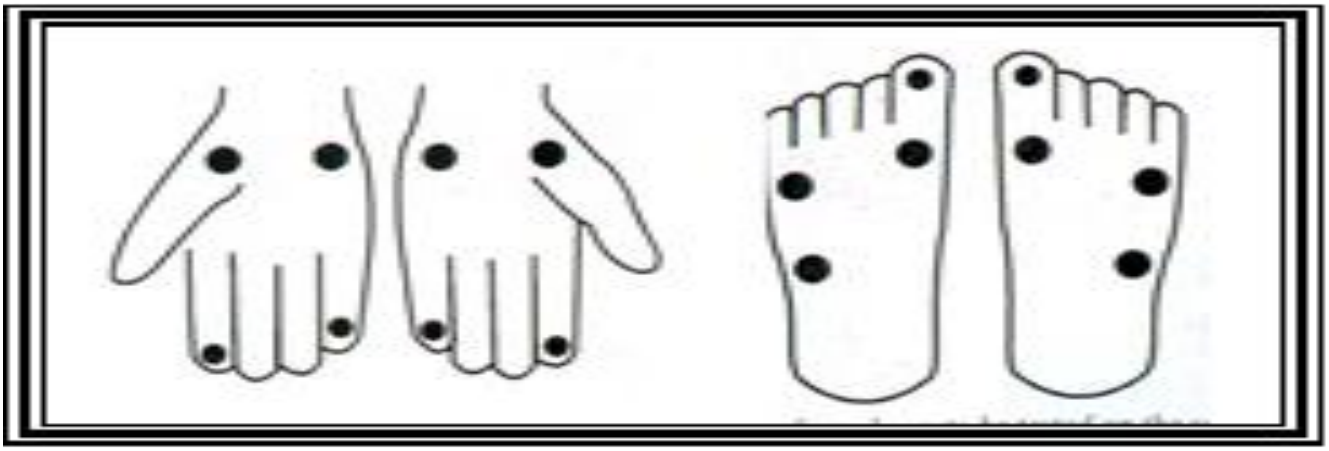
Definite nerve enlargement with loss of sensation or muscle weakness in the area supplied by the nerve is diagnostic of leprosy

11.2.2.3 Examine the eyes, hands and feet for nerve damage (VMT/ST) and other disability

Dryness, loss of feeling or weakness (autonomic, sensory or motor neural deficit) are usually seen. A person with loss of feeling can injure himself or herself without realizing it, which is why people with leprosy often get wounds and ulcers. Loss of feeling is rare in other diseases, so it can help to confirm the diagnosis of leprosy.

- **Check the Eyes**
  - Check the Visual Acuity of each eye separately using an eye chart; if no chart is available, ask the person to count fingers at 6 metres; if the person cannot read the top line of the chart, or count fingers at 6 metres, they are visually impaired and have ***grade 2 disability*** in that eye.
  - Look for an inability to close one or both eyes (lagophthalmos) and check for normal strength of eye closure
  - Look for any redness of the eye

- **Check for Sensation on Hands and Feet**
  - Check the sensation on the palms of the hands and the soles of the feet, using a ballpoint pen.
  - Explain the test to the patient
  - Ask them to close or cover their eyes
  - Touch the skin very lightly with the ballpoint
  - Ask the patient to point to the place you touched
  - Test a minimum of four points on each hand and foot
  - Note any areas where the pen is not felt by marking with a red cross ”X”
  - Note areas where the pen is felt by marking with a blue tick “√”



Note: In the palm of the hand, the ***ulna nerve*** supplies the side with the little finger. The part with the thumb, index and middle fingers is supplied by the ***median nerve***. The sole of the foot is supplied by the ***posterior tibial nerve***.

- **Check for Muscle Weakness Function in the Hands and Feet**

Hands

i. **Thumb up (tests the median nerve)**
   - ask the person to put out their hand, palm up and wrist hyper-extended
   - support their hand in your hand
   - ask them to point the thumb towards their own nose
   - test the strength of the thumb to stay in that position

ii. Little finger out (tests the ulna nerve)
- ask the person to put out their hand, palm up and wrist hyper-extended
- support their hand in your hand
- ask them to move the little finger out
- test the strength of the little finger to stay in that position

Feet

i. Foot up (tests the peroneal nerve)
- ask the person to sit down
- support the person's lower leg in your hand
- ask them to point the foot up to the roof
- test the strength of the foot to stay in that position

Muscle strength is recorded as "Strong" (S), "Weak" (W) or "Paralyzed" (P).

12.2.5 Slit Skin Smear Examination

Most leprosy cases can be diagnosed clinically, however, slit skin smear is recommended for difficult and ambiguous leprosy suspects and such individuals should be referred to designated facilities.

A suitably equipped laboratory with well-trained staff is required for this test. Leprosy skin smear services could be made available in selected units (leprosy referral centres only).

A positive skin smear in an untreated individual is diagnostic of leprosy.

11.3 LEPROSY DIAGNOSIS

11.3.1 Leprosy Case

If leprosy is recognized in its early stages, it can easily be treated and it will not cause the disabilities that most people think of when they hear the word 'leprosy'. Many of the social problems associated with leprosy could also be avoided by treating cases early.

A reasonable degree of certainty is required before making the diagnosis of leprosy. A suspect should not be registered as a case, because wrong diagnosis of leprosy has many consequences.

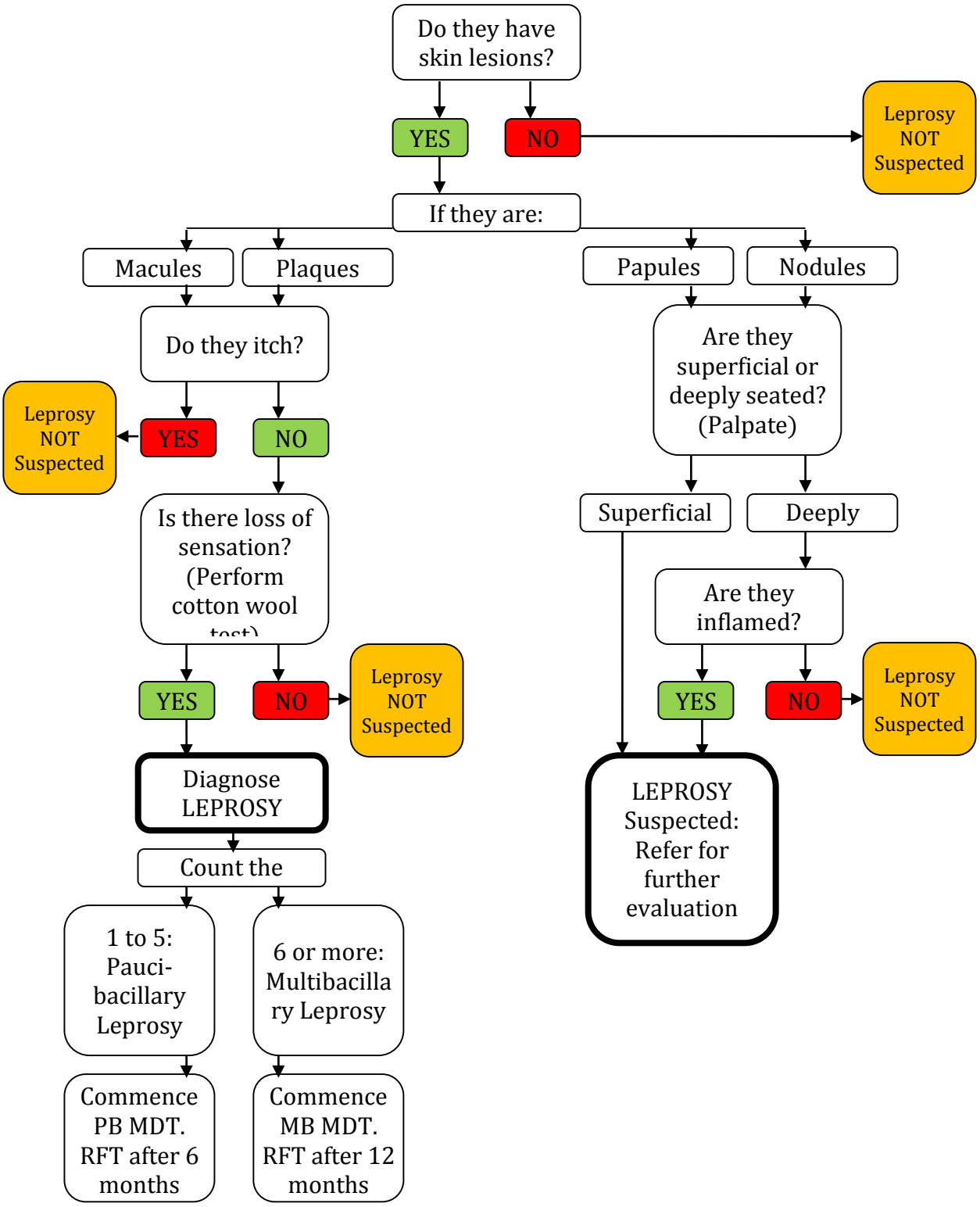
Leprosy is diagnosed by finding at least one of the following cardinal signs:

- Definite loss of sensation in a pale (hypo-pigmented) or reddish skin patch
- A thickened or enlarged peripheral nerve, with loss of sensation and/or weakness of muscles supplied by that nerve
- The presence of acid-fast bacilli in a slit skin smear (SSS)

- **A case of leprosy is a person with clinical signs of leprosy who requires chemotherapy (MDT).**
- **Therefore start treatment immediately, subject to locally agreed validation mechanism**

Once you have made a diagnosis of leprosy you must start treatment immediately, however be careful; other conditions can look like leprosy.

Figure 11.2: Guide for Leprosy Case Management at the Secondary Health Care Level



11.3.2 Differential Diagnosis of Skin Lesions

If you are not sure about the cause of the skin lesion, check with the list of possible skin diseases below:

- **Pityriasis Versicolor:** Lesions are hypo-pigmented but without loss of sensation and often itch. Give an anti-fungal ointment for 6 weeks.

- **Ringworm (Tineasis):** Lesions are well defined areas of hypopigmentation with white scales but without loss of sensation. There is itching. Give an anti-fungal ointment for 6 weeks.

- **Vitiligo:** Completely depigmented areas of skin with clear, flat edges without loss of sensation,refer to a medical officer.

- **Leukoderma:** There is localized loss of pigmentation of the skin. May occur after any number of inflammatory skin conditions, burns, intra-lesional steroid injections, post-derm abrasion, etc; Refer to a medical officer.

- **Birthmarks:** Lightly or deeply pigmented areas of different sizes that are present from birth without loss of sensation. Reassure the patient.

- **Granuloma Multiforme (Mkar Disease):** Initially there is itch in a patch, which gradually develops into a hypopigmented, fine papular ring, with central depigmentation, without loss of sensation.

- **Onchocerciacis (River Blindness):** Thickened skin, very itchy nodules, areas of scratch marks, and hypopigmentation. Slit skin smears for acid fast bacilli are negative. Nodules usually on bony prominences. Skin snip for microfilaria may be positive. Treat or refer.

- **Neurofibromatosis:** Multiple nodular lesions, which are soft and may be pendulant (hanging). The peripheral nerves are not involved. Skin smears are negative. Sometimes the disease manifests itself as scattered coffee brown (café au lait) spots and patches. Refer.

- **Psoriasis:** Hypo-pigmented plaques with silvery scales. Slight scratching on the surface reveals micro bleeding. Refer.

11.3.2.1 IN CHILDREN

The two most common dermatological conditions that should be differentiated from leprosy are:

- Pityriasis Alba: Present over the face and upper neck. Asymptomatic, hypopigmented rounded or oval patches variable in size with the margins sharply demarcated, covered with fine adherent scales. Sometimes the patches are erythromatous and elevated. Responds well to tar ointments or refer.

- Nutritional Deficiencies: These deficiencies cause hypopigmentation usually on the cheek; single or multiple, ill-defined, hypopigmented patches together with other features of avitaminosis such as glossitis, angular stomatitis and pharynoderma. These patches will clear with administration of vitamins. Give dietary advice.

After completing the history and examination of the skin, nerves and other organs, decide whether the patient has leprosy or not. If in doubt, re-examine one to three months later or refer to the nearest TB/Leprosy referral centre for further diagnostic tests.

If the diagnosis of leprosy is confirmed, record your findings on the Leprosy Record Card (NTBLCP/LEP 1).

11.3.3 Contact Tracing

The health worker should ask all newly diagnosed patients to bring along their household contacts for examination at the clinic. If possible, a home visit to the patient's compound can be arranged and the screening done there.

- Examine all contacts as soon as possible after diagnosis of the patient and record in the Contact Register
- Advise contacts to look regularly for suspicious lesions on their skin and/or signs of nerve-function impairment. If they find them, they should report to the clinic.

11.3.3.1 Health Education at Diagnosis

Educate the patient and relatives about the following:

- The disease, its cause and prospects
- The disease is curable and treatment is free
- The need to bring their household contacts for examination
- The treatment duration
- The importance of monthly attendance and daily intake of the drugs
- What can be expected from the treatment regarding skin lesions and existing impairments
- Patient should know about the signs and symptoms of lepra-reaction and the importance of immediate self-reporting if there is (increase of) nerve function loss or nerve pain
- If there is definite nerve function loss at diagnosis, the importance of self-care to prevent (further) impairments

Obtain feedback from patient at the end of the health talk:

- Ask patient to recall facts
- Identify possible problems and deal with them appropriately

12. MANAGEMENT OF A LEPROSY CASE

12.1 CLASSIFICATION OF LEPROSY

12.1.1 Functional/Clinical Classification

There are two types of leprosy namely – paucibacillary (PB) and multibacillary (MB) leprosy. The type of leprosy in an individual can be determined on the basis of counting the number of skin lesions and nerves affected:

Table 12.1: Classification of Leprosy

Lesion	Paucibacillary	Multibacillary
Number of SKIN LESIONS (with sensory loss)	1-5 lesions	6 or more lesions
Number of nerve INVOLVEMENT (demonstrated by either thickness, loss of sensation or muscle weakness)	Only 1 nerve involved	Two or more nerves involved

Note:

i. Where Slit Skin Smear was done, if positive patient is classified as MB
ii. If there is doubt about the classification, the patient should be classified as MB and treated with MB-MDT
iii. Any patient with more than one nerve involvement but less than five skin patches should be classified as MB.

12.1.2 Case Categorization for Leprosy Patients

New Case:
A person who has never taken any leprosy treatment before (DDS or MDT)

Relapse After PB:
A person who has completed a six-month course of PB-MDT but is now reporting back with active leprosy that has been confirmed by the STBLCO/MO designated

Relapse After MB:
A person who has completed a twelve-month course of MB-MDT but is now reporting back with active leprosy that has been confirmed by the STBLCO/MO designated

Re-Admission after DDS:
A person who was treated with DDS monotherapy and is now reporting with signs of active leprosy

Transfer-in:
A person on MDT transferred from one LGA/State to another

Treatment after Default:
A person who started MDT (PB or MB) BUT DID NOT COMPLETE THE COURSE within the stipulated period of time who is now reporting with signs of active leprosy

12.2 TREATMENT OF LEPROSY

It is the policy of the Federal Ministry of Health to treat leprosy patients with Multi Drug Therapy (MDT) as recommended by WHO. The effectiveness of MDT is well known and relapses are very few. MDT cures the patient within a short period of time and interrupts the transmission of the disease rapidly.

12.2.1 WHO Recommended MDT Regimens

The treatment for leprosy is simple. It is available free, and the drugs are supplied in special packs that contain the correct dose for one person for four weeks. All that is needed is to decide which course of treatment the patient needs and to make sure that they take it regularly.

The experience of the WHO MDT regimens has been positive. Since the start of implementation in 1983, more than eight million patients have been treated throughout the world and few side effects of MDT have occurred. The two type of leprosy are treated as explained below:

PB patients: should receive one blister pack of PB MDT every 28 days for a period of 6 months (TOTAL 6 BLISTERS). The intake of drugs on every day of collection must be supervised.

- These 6 blisters should be completed within a maximum period of 9 months.
- After completing 6 blisters the patient should be released from treatment (RFT)

MB patients: should receive one blister of MB MDT every 28 days for a period of 12 months (TOTAL 12 DOSES), intake of drugs on every day of collection must be supervised.

- These 12 blisters should be completed within a maximum period of 18 months.

12.2.2 Stopping MDT

MDT is a fixed duration therapy.

- When 6 doses of PB-MDT have been completed stop the treatment, and remove the patient from the Register as treatment completed
- When 12 doses of MB-MDT have been completed stop the treatment, and remove the patient from the Register as treatment completed

Prior to release from MDT the health worker should examine the patient and record all clinical findings on the back page of the Patient Record Card.

12.3 Treatment Outcome

Treatment completed

- Any person who has completed a full course of either PB or MB MDT

Default

- Any person who has missed appointments and is unable to complete treatment within the time limit
- For PB – missing 4 cumulative months renders it impossible to complete treatment within 9 months
- For MB – missing 7 cumulative months renders it impossible to complete treatment within 18 months

Died

- Any person who died before completing his MDT

Transferred out

- Any person who is transferred to another LGA or State to continue his/her

Guidelines for patient education at the time of discharge:

- **Inform patient that:**
- **Now he/she has completed the MDT regimen, he/she is now cured**
- **He/she should come back to report if any of the symptoms or signs of reaction appear**
- **He/she should inform the people in the community about the signs and symptoms of leprosy and that it is curable**
- **He/she should persuade any suspect to report to the clinic for screening**

12.4 Side-Effects of Anti-Leprosy Drugs

Serious side-effects of leprosy treatment are rare. However, interview patients and examine for signs of side effects of medications at each clinic visit.

Common problems you may find are:

- Side-effects of the drugs
- Signs of new nerve damage or inflammation (reaction)
- New social problems related to leprosy

Serious side-effects of Leprosy treatment are rare. The table below outlines the common side-effects and actions to take if they occur.

Table 12.2: Common side-effects and actions to take if side effect of MDT occur.

SIDE-EFFECTS/COMPLAINTS	POSSIBLE CAUSE	ACTION
The urine may stain slightly reddish for a few hours after taking the supervised dose. The skin may in the course of months gradually turn brownish-black and show dryness.	Rifampicin Daily Clofazimine for (MB patient)	This is harmless and should be explained to the patient at the start of MDT.
Itching and skin rashes, even the skin may start to peel off and the patient will feel very ill.	Typical for a (serious) allergic reaction due to Dapsone	It will disappear within a few months after completing MDT, but the patient should be informed when starting MDT.
Jaundice often accompanied by lack of appetite, nausea and vomiting.	Either Rifampicin or Dapsone	The patient should stop taking the Dapsone and come to the (LGA) TBL clinic if he has rash only or go immediately to the TBL hospital if more severely ill. The PB patients should receive daily 50 mg Clofazimine and a monthly dose of 300mg as a substitute for Dapsone. MB patients continue with Rifampicin and Clofazimine in the usual dosage. Stop MDT and refer to the TBL referral hospital.
The patient may experience nausea vomiting and diarrhoea.	Clofazimine	Abdominal complaints may spontaneously disappear, but if they continue, the patient needs to be referred for further examination and management at the TBL referral hospital.
A patient may quite suddenly develop chills, fever, headache and bone pains, in a few hours followed by a weak, quick pulse (shock) and renal failure.	Rifampicin	This flu-like syndrome needs urgent hospital treatment. Stop Rifampicin.
Tiredness and shortness of breath.	Anaemia, a known side-effect of Dapsone	This is often a dose-related effect and treatment with Dapsone can be continued with half or a quarter of the daily dose.

12.5 Treatment Interruption and Defaulter Prevention

- Health workers should do all that is possible to prevent interruption of treatment as well as ensure that treatment is completed within the shortest possible time. In order to obtain good case holding it is necessary to:
- Give effective patient education

- Administer drugs regularly
- Provide accessible places for drug collection
- Be flexible in drug supply to compensate for seasonal factors - e.g. accessibility of rural clinics during the rainy season
- Identify and treat complications and side effects promptly
- Operate an effective defaulter retrieval system (see below)
- Carry out regular clinical review of patients; including Voluntary Muscle Test/Sensory Test and discussion of findings with the patient
- Have a good attitude. Rude and unhelpful staff discourages patients from attending clinics
- Discuss with patients showing concern for psycho-social effects of leprosy
- Instruct patient about the prevention of impairments and disabilities; self-care etc.
- Refer patients with complications according to the guidelines
- Offer comprehensive medical care for the treatment of concurrent ailments

FLEXIBLE MDT DELIVERY

- **Services must be organized to be convenient to patients rather than to the health workers.**
- **This may include using 'proxy supervisors' (e.g. village head) or the dispensing of more than one-month supplies of blister calendar packs of MDT**

The dates when the patient has to attend should be recorded in advance on the appointment schedule. If the patient does not attend on the appropriate date, get information about him from the other patients. If possible, send a reminder to the patient. But if (s)he does not turn up after 28 days, a health worker should visit him at home to find out his/her reason for non-attendance. Complete the Defaulter Retrieval Form. Appropriate further action should then be taken.

12.5.1 Defaulter Retrieval

PB Patients

Any PB patient who misses four (4) cumulative months of treatment cannot complete treatment within the 9-month period, and should be removed from the register, recorded as ***default.***

- **Action:**
  - Go and find the patient
  - Re-assess the patient and look for signs of active leprosy
  - If there are signs of active leprosy, then re-register as 'treatment after default' and start treatment again
  - If there is no sign of active leprosy, do not start treatment again. Re-assess patient every six months for 2 consecutive years.

MB Patients

Every MB patient who misses 7 months of treatment cannot complete treatment within the 18-month period, and should be removed from the register, recorded as ***default***.

- **Action**:
  - Go and find the patient
  - Re-assess the patient and fill in a new Leprosy Record Card
  - Re-register as 'treatment after default' and start treatment again

13. PREVENTION OF IMPAIRMENTS AND DISABILITIES (POID)

13.1 Aims of POID

Impairment and disabilities are a cause of great concern in leprosy because they often bring physical, psychological and socio-economic suffering to people and families affected by leprosy. Prevention of impairments and disabilities in leprosy is therefore a high priority in leprosy control.

The aims of POID are as follows

- Prevention of new impairments
- Prevention of deterioration of existing impairments

Impairment: is an abnormality of structure or function in any part of the body e.g. loss of sensation of the cornea, ulcer of the thumb, weak eyelid, fixed claw, dropped foot etc.

Disability: is partial or complete limitation of doing something that is normal for people of your age, sex and culture (activity limitation) e.g. difficulty in reading a book, inability to hold a hoe tightly because of mobile claw etc.

13.2 Monitoring Impairments

It is important to monitor and assess the status of impairment in a patient at any point during and after treatment. This enables a health worker to take appropriate actions to prevent further deterioration of the impairment status of the patient.

Table 13.1: The Impairment Grading is done according to the table below:

IMPAIRMENT GRADE	HANDS AND FEET	EYES
0	No loss of sensation No visible deformity	Blinking normally No redness No evidence of visual loss
1	Loss of sensation or muscles weakness No visible deformity	Loss of spontaneous blink Vision 6/60 or better(Can count fingers at 6 metres)
2	Visible deformity present with (e.g. ulcer, clawing etc.)	Lagophthalmos; Iridocyclitis Corneal scarring/ulcer Vision worse than 6/60(Inability to count fingers at 6 metres)

In order to summarise the impairments, the following tests must be completed:

- Full eye examination
- Voluntary Muscle Test
- Sensory Test
- Impairment charting

The system has a grading scale of "0, 1 and 2". Each eye, hand and foot is graded separately. The highest grade for the eyes, hands and feet are entered into the appropriate boxes on page 1 of the Leprosy Record Card and in the LGA MDT Register.

For example:

	E	H	F
Right	2	0	2
Left	0	1	2

E = Eye
H = Hand
F = Foot

The highest number seen over the six boxes should be taken as the Maximum Grade. In the above example therefore the maximum score is 2. **The impairment grade for this patient should be recorded as 2**.

The WHO impairment grading has its limitations. Though deterioration may have occurred, the impairment grading at beginning/during treatment may remain the same at the end of treatment. In the example below the patient has loss of sensation on both feet at registration; by RFT he had ulcers on his feet.

Grade at registration:

	E	H	F
Right	2	0	1
Left	0	0	1

Grade at end of treatment (RFT)

	E	H	F
Right	2	0	2
Left	0	0	2

WHO grade = 2 **WHO grade = 2**

It can be seen that the WHO maximum grade has not changed, even though the patient has deteriorated, so we need a more sensitive tool for monitoring. The EHF sum score is more sensitive.

13.2.1 EHF Sum Score

The sum of all six numbers is called the EHF sum score. This can be used to monitor the progress of the patient from starting MDT to being released from treatment. A higher sum score means more impairment, therefore deterioration.

For example:

At Registration:

	E	H	F	Total
R	2	0	1	3
L	0	0	1	1
Total	2	0	2	4

EHF score = 4

At end of treatment

	E	H	F	Total
R	2	0	2	4
L	0	1	2	3
Total	2	1	4	7

EHF score = 7

The patient has deteriorated between registration and release from treatment.

13.3 Preventing Impairments and Disabilities

13.3.1 Leprosy Reaction

Leprosy is not usually a painful disease. But sometimes a person with leprosy will experience pain and discomfort. This happens because the body reacts against the presence of the leprosy bacilli. These reactions are the main cause of nerve damage and disability in leprosy.

13.3.1.1 Recognising Lepra-reaction

Lepra-reaction is an acute inflammatory process, therefore, look for the following signs: Leprosy reactions can happen at any time during the illness: before, during or even after release from treatment.

- Redness
- Swelling
- Heat
- Pain/tenderness
- Loss of function

Table 13.2: Signs of reaction in Leprosy

BODY PART	Look/Feel for
Skin	Red patches Raised/swollen patches Tender patches and new skin patches may re-appear
Nerves	Pain or tenderness in a nerve New loss of sensation New muscle weakness
Eye	Pain or redness in the eye New loss of sensation (loss of ability to blink) New weakness of eye closure

There are two types of reaction. Use the table below to differentiate the two types.

Table 13.3: Type 1 Leprosy Reaction:

Body Part Affected	Mild	Severe
SKIN	*Red, raised and tender skin lesions* (except on the face)	Ulcerating skin lesions Red, raised *facial lesion*
NERVES	No nerve tenderness	*Painful or tender* and enlarged nerves on palpation Red, raised patch *on or around any peripheral nerve*
VMT	No change	*Recent change in VMT* (less than 6 months duration) Muscle weakness in eyes, hands, feet
ST	No change	*Recent change in ST*(less than 6 months duration) Change in sensation in one or more points in any one hand or foot
EYES	Not affected	*Sudden lagophthalmos* (inability to close the eye) *Sudden loss of corneal sensation* (loss of automatic blink)
GENERAL BODY CONDITION	Good general condition	Fever and malaise can occur in the acute phase only
SYSTEMIC EFFECTS	No effect	*Joint pain*due to enlarged nerves

Table 13.4: Type 2 Reaction

Body Part Affected	Mild	Severe
SKIN	Appearance of red, raised sub-cutaneous nodules (and patches) Few crops of nodules No nerve tenderness	Ulcerating sub-cutaneous nodules Painful or tender and enlarged nerves on palpation
VMT	No change	Recent change in VMT (less than 6 months duration) Muscle weakness in eyes, hands, feet
SENSORY TEST (ST)	No change	Recent change in ST(less than 6 months duration) Change in sensation in one or more points in any one hand or foot
EYES	No effect	Painful eyes with redness around the cornea, fear of light, excessive tearing and diminished vision
GENERAL BODY CONDITION	Patient in good general condition	Fever and malaise common and prolonged
SYSTEMIC EFFECTS	No effect	Orchitis - painful, testicular swelling Dactylitis - painful, swollen joints, hands and feet Renal involvement (blood in the urine)

13.3.1.2 Treating Reactions

Treatment of Mild Reaction (Type I or Type II)

- Mild reaction should be treated by general health care workers in the field as follows:
- Aspirin 600mg (2 tablets of 300mg) 4 times daily x 1 week
- Chloroquine 150mg base (1 tablet) twice daily for 1 week
- If the patient cannot tolerate Aspirin, replace with Paracetamol 1g (2 tablets) 3 times daily for 1 week
- Re-examine the whole body after 1 week and record findings in the leprosy treatment form. If there are still signs of reaction, repeat for another week.
- Re-examine the whole body after another week and record findings in the leprosy treatment form, if no improvement or if there is deterioration treat as severe reaction.

Treatment of Severe Reactions (Type I or II)

Field management of severe reactions (type I or II) is no longer acceptable. Treatment of severe reactions (type I or II) should be done in the referral centres where they can be closely monitored.

- **Treatment of Severe Type I Reaction**

Severe type 1 reactions can be treated with a standard course of Prednisolone. Prednisolone is a potent corticosteroid drug. As the drug may also worsen various other conditions, treatment of these conditions should be started immediately, but need not be finalized before the start of treatment with Prednisolone.

Table 13.5: Management of other conditions that worsen lepra-reaction

Condition	Treatment
Worm infestation **Diarrhoea with blood / mucus suggestive of dysentery**	Mebendazole 100mg BD x 3 days Metronidazole 400mg TDS x 7 days
Conjunctivitis	Chloramphenicol eye drops 1-2 drops QID x 5 days
Scabies	Benzyl Benzoate applied after bath x 3 nights

- **If you notice corneal ulcer; refer immediately to the nearest eye clinic. Do not give steroids!**
- **If you suspect stomach ulcer; refer to the nearest leprosy hospital and do not give steroids!**

Educate patients before start of prednisolone

Before the start of treatment with Prednisolone, give the patient an explanation as follows:

- Importance of completing treatment of other conditions while on the steroid
- Daily and continued Prednisolone to the end of the course is essential
- The expected duration of the course (12 weeks or 24 weeks)
- The arrangements for examination and drug collection every two weeks
- Possible side effects of Prednisolone
    - Moon face appearance
    - Excessive thirst and urinating
    - Steroid induced acne
    - Abdominal discomfort
    - Predisposition to infection
    - Weakness of the bones
- Exacerbation of previously undetected tuberculosis
- Increase in blood pressure
- The need to report immediately if pain, loss of feeling or weakness increases, or if general illness and/or fever occurs

Standard prednisolone regimen

Prednisolone is given orally, every morning as a single dose, either in pre-packed blister packs or in counted 5mg tablets after food

Table 13.6: Duration of Treatment

Daily Dose	Duration of Treatment	
	PB	MB
40mg	2 weeks	4 weeks
30mg	2 weeks	4 weeks
20mg	2 weeks	4 weeks
15mg	2 weeks	4 weeks
10mg	2 weeks	4 weeks
5 mg	2 weeks	4 weeks
Total	12 weeks	24 weeks

Patients who do not improve within four weeks after the start of Prednisolone or who deteriorate at any time of the treatment have to be referred to the nearest TB/Leprosy referral centre. There the Prednisolone dosage can be varied according to the clinical judgement of the Medical Officer.

During the course of Prednisolone, do a full examination at least every two weeks; this includes VMT/ST and nerve palpation. All findings must be recorded on the Reaction Monitoring form. This form must be attached to the Leprosy Treatment Card.
If a patient fails to collect his/her next dosage of Prednisolone, he/she should be retrieved immediately and reassessed (VMT/ST and Nerve palpation). If there are signs of deterioration as compared to the previous examination then start again with a full course of Prednisolone starting from 40mg. If there is no deterioration then complete the treatment.

A course of Prednisolone can only be given twice in the field, otherwise refer the patient to the referral Hospital. In the hospital, severe type I cases may be given higher doses of Prednisolone than 40mg according to the Medical Officer's findings.

Any person on Prednisolone whose nerve function deteriorates (either sensory or muscle strength) must be referred to the TB/L hospital

A patient who is on MDT and develops a reaction requiring treatment with Prednisolone should continue with MDT. Alongside the steroids, other measures, especially rest are important. This will include splinting the joints where the nerves are located.

Treatment of Severe Type II Reaction

All cases of severe type II reaction are to be treated in the hospital. **All cases of severe type II reaction are managed on individual basis**. This is based on the Medical Officer's interpretation of clinical findings.

In general, Clofazimine and Prednisolone are started at the same time. The Prednisolone dose can be started at doses higher than 40mg daily and quickly tapered down while the Clofazimine should be started at the same time at 300mg and maintained at that dose until

there is clinical improvement. Then the Clofazimine is tapered down to 200mg, then 100mg, and then 50mg before discontinuing. This may take a long time – often many months.

Alongside chemotherapy, rest is essential, and this includes splinting of all affected joints. The joints are splinted for 24 hours daily until the acute phase is over, then the splint can be removed each day for gentle passive exercises, and then replaced. Thereafter, active exercise can be encouraged on the advice of the Medical Officer.

Analgesics and sedatives are also important.

Weekly VMT/ST is essential to closely monitor nerve function to identify early changes immediately.

Blood/Urine sugar levels will also need to be monitored to check for further complications of high doses of steroids.

If there is iritis/iridocyclitis (type II reaction of the eye), give mydriatic agents (atropine) as well.

Always Remember that:

- **Severe type II reaction must not be treated in the field, it can be life-threatening and disabling**

When treating severe reactions, the medical officer should look out for the following:

- Deep ulcer(s)
- Nerve abscess
- Corneal Ulcer
- Keratitis (hazy cornea)
- Acute iritis /iridocyclitis – painful red eye
- Pregnancy
- Tuberculosis or any other severe infectious disease
- Nerve damage which developed two years or more after release from MDT
- Recent history of stomach ulcer
- History of diabetes
- General illness and/or fever
- Complications of Prednisolone
- Hypertension

13.3.2 Components of POID

There are various ways through which impairments and disabilities can be prevented in leprosy patients. These are:

1. Early case detection and effective treatment with MDT
2. Preservation of nerve function
3. Preservation of vision
4. Training of patients in self-care
5. Provision of protective wear
6. Proper management of ulcers

13.3.2.1 Early Case Detection and Effective Treatment with MDT

This topic has been discussed extensively in section 11 above.

13.3.2.2 Preservation of Nerve Functions

It is important that all health workers are trained to identify and treat nerve damage. The single most significant way of preserving nerve function is in diagnosing and managing lepra-reactions correctly and promptly, therefore it is necessary to carry out baseline and monthly nerve assessments (VMT/ST).

13.3.2.3 Preservation of Vision

Eye Examination

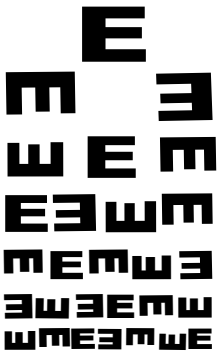
Tools needed:

- Vision chart (E chart)
- Patient record card
- Pen torch
- Ruler

A. Visual acuity (VA):

The patient's visual acuity should be tested using an E chart at a distance of 6 metres. Test one eye at a time, right eye first.

If the patient's VA is worse than 6/60 refer to the nearest eye clinic for further investigation and management.



After the right eye, test the left eye.

To test visual acuity (VA) accurately, you need an E-chart as shown here and a well-lit area. The chart should be hung up on a wall where it can be clearly seen. (That is, not crowded in between posters and pictures).

The person should stand 6 metres away from the chart in order to read the letters.

i. Test the right eye first

The person should cover his left eye with his hand and reading from top to bottom, indicate which way the 'fingers' of the E are pointing. The person should keep reading until he can no longer see the direction correctly.

If the person cannot even see the biggest E at the top, then he should stand at 5 metres and try again. If not then he should stand at 4 metres, 3 metres etc. down to 1 metre. If he cannot see at 1 metre then the E chart cannot be used to test his VA.

After the right eye, test the left eye.

B. Recording the Result:

The result is recorded as a fraction. E.g. **6/60**

The top number is the distance from the E chart – that is 6 metres

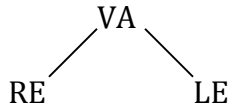
The bottom number is the number written underneath the last line read clearly – that is 60 (the very top line)

The visual acuity results at 6 metres for each line are shown below:

6/60; 6/36; 6/24; 6/18; 6/12;
6/9; 6/6

6/6 being normal vision, 6/60 meaning that the person can read at 6 metres what other people can read at 60 metres (impaired vision).

The results for each eye are written together as below:



In this case both eyes have normal VA

6/6 6/6

Visual acuity should be assessed at first contact with a patient, and at least every year for follow up patients. In addition, any time a person complains of eye problems or symptoms of reaction, the VA should be re-assessed.

Regular VA testing can assist in the detection of preventable blindness at an early stage.

C. Pen Torch:

VA test should be followed up by ***full eye examination*** with a pen torch

i. Lids

- The lids should be symmetrical (same right and left) and should both be able to close fully on light closure. The lids should be able to remain closed when some resistance is put on them (VMT)
- Lagophthalmos is the inability to close the eye fully, so that there is a lid gap
- A person with a facial patch is at risk of reaction, and especially of damage to the facial nerve leading to lagophthalmos
- The eye lids should both lie against the eyeball. If the upper eyelid is turning in, that is called entropion, if the lower eyelid is falling down and out is called ectropion

ii. Lashes

- The upper lashes should be pointing out and up, the lower lashes pointing out and down; both the upper and lower lashes point away from the eye
- Eyelashes touching the eyeball is abnormal and is called trichiasis

iii. Conjunctiva

- The conjunctiva is white in the normal eye
- If it is red, there is a problem

The table below will help you to diagnose the eye complication when you notice redness of the conjunctiva.

Table 13.7: Diagnosis of eye complications in redness of the conjunctiva

EYE COMPLICATION	REDNESS	PAIN	BLURRED VISION	PUPIL REACTION
NORMAL	No	No	No	Good/ brisk
REDNESS DUE TO LAGOPHTHALMOS, ECTROPION/ ENTROPION	Yes, near the lower conjunctiva	No	No	Good
CONJUNCTIVITIS	Yes, with discharge	Foreign body sensation	No	Good
CORNEAL ULCER	Yes, near white spot on cornea	Yes	Usually yes	Usually good
ACUTE IRITIS	Yes, around the cornea, no discharge	Yes	Usually yes	Poor

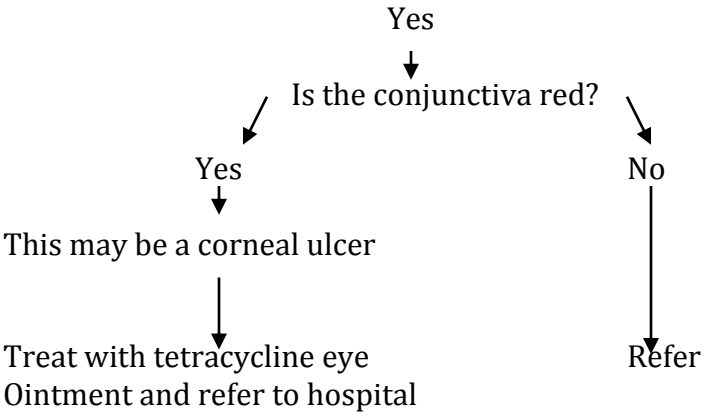
iv. Cornea

- Shine the torch onto the eye from the side
- The cornea should be clear like glass, smooth and shiny

Is the cornea smooth and shiny?

If no, treat with tetracycline eye ointment and refer to an eye clinic

Is there a white spot on the cornea?



v. Iris and Pupil

- You need to be in a darkened room to examine the iris and pupil
- Shine the torch from the side
- The iris should be brown and should not be perforated (iris atrophy)
- The pupil should be round

- Is the pupil round in shape? If no, refer to an eye clinic
- The pupil should be 'greenish' in colour
- Is the pupil white? If yes (cataract), refer to an eye clinic
- The pupil should be about 2mm
- Is the pupil wide and not reacting to light? If yes, refer to an eye clinic
- Does the pupil react quickly when you shine your light on the eye and then remove it?
- No? Refer to an eye clinic

Common Eye Problems and Actions to Take

i. Lagophthalmos less than six months:

- Protective glasses
- Tetracycline eye ointment
- Systemic steroids immediately

ii. Lagophthalmos more than six months <5mm:

- Protective glasses
- Tetracycline eye ointment
- Artificial tears (if available)

If the eye can close fully when closed forcefully

- Cover eye when sleeping at night
- Regular inspection of the eye
- Self-care training

If the eye cannot be closed fully when forcefully closed

- Exercise: Forced eye closure at least 3 times a day for 5 seconds x 20 repetitions
- Exercise: Passive eye

iii. Lagophthalmos more than six months >5mm:

- Refer for surgery

iv. Tiny Pupil

- Dilate with atropine and refer to an eye clinic

v. Acute Iritis: Redness around the cornea

- Dilate with atropine
- Glasses (sunshades)
- Refer immediately to TBL Referral Centre for steroids

vi. **Loss of Corneal Sensation (no blink) – less than six months**

- Protective glasses
- Tetracycline eye ointment
- Prednisolone
- Self-care training
- *If associated with facial patch then refer to TBL Referral Centre*

vii. **Loss of Corneal Sensation (no blink) – more than six months**

- Protective glasses
- Tetracycline eye ointment
- Self-care training
- Blink exercises

viii. **Conjunctivitis**

- Wash face and clean with water carefully 3 times daily
- Tetracycline eye ointment
- *Refer if no improvement in 2 days*

ix. **Acute Keratitis (white/hazy cornea with red conjunctiva)**

- Tetracycline eye ointment
- Refer to eye clinic immediately

x. **Corneal Ulcer (white spot on cornea with red conjunctiva – may have a discharge with pain and diminished vision)**

- Tetracycline eye ointment
- Dilate with atropine
- Refer to eye clinic immediately
- ***Note:*** *Do not give steroid (Prednisolone)*
-

xi. **Trichiasis (lashes rubbing the eyeball) less than 5 lashes**

- Remove lashes with forceps
- Give Tetracycline eye ointment

xii. **Trichiasis (lashes rubbing the eyeball) more than 5 lashes**

- Tetracycline eye ointment
- Refer to eye nurse or referral hospital

13.3.2.4 Training of patients on Self-Care

Patients should be trained and empowered to take care of the simple problems at home, and encourage to form self-care groups. All leprosy patients (upon registration) should be provided with a copy of a self-care manual 'I CAN DO IT MYSELF' after proper introduction.

Educate patients on:

Eye Care

1. Inspect the eye in a mirror daily for redness, injuries or discharge
2. Washing of eyes with clean water and removal of foreign objects
3. Blink frequently to keep the eyes moist and exercise the lids
4. Wear a hat or sunglasses to prevent dust or foreign objects from getting into the eye in case of lagophthalmos
5. Use a sheet to cover eyes at night

Hands

1. Inspect daily for signs of injury
2. Use appropriate protective wear for domestic/occupational work e.g. hand gloves/padding during work
3. Daily soaking, scrubbing and oiling for dryness and cracks
4. Daily soaking and cleaning of wounds using water with salt
5. Use clean cloth to cover open wounds
6. Practice simple hand exercises to prevent stiffness of the fingers

Feet

1. Inspect daily for signs of injury
2. Use appropriate protective foot wear
3. Daily soaking, oiling and cleaning of ulcers
4. Use clean cloth to cover open wounds
5. Ensure adequate rest of foot with an ulcer e.g. use crutches
6. Practice simple exercises if there is foot drop

General

1. In case of burns and blisters report to health facility immediately
2. General hygiene – cleanliness of the body and environment
3. Good appropriate nutrition
4. Support children going to school
5. Support women and children to access general health care services

13.3.2.5 Provision of Protective and Assistive Devices

Provide protective wears to all people affected by leprosy who have loss of feeling on their feet or ulcers, hands and inability to close their eyes.

Protective footwear and sunglasses are available free of charge from the leprosy control programme. If a person does not find them acceptable, (s) he can be advised on the features of protective footwear, so that they can find their own footwear:

- Cushioned soft insole
- Hard under sole to prevent penetration of nails
- Adjustable straps
- Heel support

People with very deformed feet may need to be supplied with special moulded footwear. A number of leprosy hospitals around the country are able to make this footwear at subsidised prices (or even free of charge in some places).

People with dropped foot may benefit from straps attached to their footwear and fastened around their knees to hold the toes up and prevent them catching on the ground and being injured.

Patients with plantar ulcers should be provided with crutches.

13.3.2.6 Proper Management of Ulcers of

A. Identify causes of ulcers:

The underlying factor in ulcer development is nerve damage, discuss with patients to identify common causes, examples are:

- Walking too far and holding tools for too long without resting, which results in the formation of blisters
- Wearing badly fitted shoes which results in blisters
- Thorns, stones etc. entering the hands and feet unnoticed
- Burns going unnoticed
- Neglect of small injuries which leads to further damage and larger wounds

B. Assessing Ulcers:

Table 13.8: Simple procedure to follow when assessing ulcers

ASK	**When did the problem start?** **How did it start?** **What does the patient think is the cause?**
LOOK	How is the patient moving around? (restrictions, limping, drop foot, signs of pain) What does the area near the wound look like? (colour, swelling, clean, blisters) What footwear is the patient wearing? (hard, soft, covered shoe, slippers, sandals in good condition, well–fitting)
TOUCH	Is the hand or foot warm? **Feel it with the back of your hand. Feel near the ulcer and also further away to compare the temperature in different places. Heat can indicate infection** Is the hand or foot swollen? **Is there pitting oedema? If yes, these are signs of infection** **CAREFULLY EXAMINE FOR SIGNS OF EARLY TARSAL DISINTEGRATION:** **(Collapsed foot – leading to flat/boat-shaped foot).** Unilaterally swollen, hot foot with or without ulcers. Pitting oedema on the dorsum (top) of the foot Is there tenderness? **This could indicate a localised infection** Check the position and mobility of joints - the fingers, the toes, the ankle and knee, the wrist and elbow

Using a Probe
Health workers should always examine ulcers using a probe (even sterilised bicycle spokes will do the job!). With probes we can:

- Differentiate if an ulcer is superficial or deep
- Find out where a sinus ends
- Whether there is bone, joint or soft tissue etc. in the sinus

C. Managing Ulcers

The three basic rules of ulcer management are:

- REST – the single most important factor in healing wounds is to rest the affected area
- CLEAN – dirty wounds will never heal!
- COVER – keep out dirt, flies etc.

Simple Home Based Care

- Patients and their families can manage simple, superficial ulcers:
- Rest can be achieved with simple means:
    - Hands – Slings; Splints
    - Feet – Bed rest; Crutches; Moulded footwear
- Clean with bar soap and water every day. If the wound is very dirty, put a handful of salt into the water
- Cover the wound (old cloth that is torn into strips, washed and ironed can be used as bandages in the home)
- Teach the patient to identify and report immediately to the nearest health centre if there are any signs of infection (sepsis):
    - Swelling of the hand/foot
    - Warmth of the hand/foot
    - Sudden loss of function – recent neuritis is excluded
    - Purulent discharge
    - Offensive odour

All septic/complicated ulcers should be referred to a hospital for treatment.

IF SIGNS OF EARLY TARSAL DISINTEGRATION ARE PRESENT REFER TO THE TB/LEPROSY HOSPITAL IMMEDIATELY (the only way to treat early tarsal disintegration is to apply full contact Plaster of Paris for 6 months).

Hospital-based Care – for deep and/or complicated wounds
Again the basic principles apply, but obviously aseptic techniques are used.

Rest Using Wheelchair; Crutches or walking frames; Plaster of Paris with Bohler iron or wooden rocker

Preventive and Rehabilitative surgery can remove prominent bones and pressure points

Clean May be done in the theatre – debridement

Antibiotics may be needed

Cover Gauze and bandages

Criteria for Referral of Patients with Ulcers:
The following should never be managed at home or in a field clinic but should be referred immediately:

- Hot, swollen hands or feet with or without wounds
- All complicated ulcers - where bones, tendons, ligaments etc. are involved in the wound
- High risk ulcers:
    - 5th metatarsal base ulcers
    - Heel ulcers that are deep
- Chronic and/or recurrent ulcers
- Long-standing, lower leg ulcers where surgery, excision, skin graft or other kinds of resurfacing, may be of value
- Amputation stumps with ulcers
- Septic ulcers
- Ulcers suspected of malignant degeneration

D. Preventing Ulcers

The patient needs to accept that it is his/her responsibility to prevent further wounds. It is not the responsibility of the health workers, however we should ensure that:

- The patient needs to understand the general causes of ulcers
- The patient needs to understand the cause of the first wound and know specifically how to avoid this in the future
- Following the healing of an ulcer, the patient should go through a time of graduated walking with regular inspection of the wound site
- Protective sandals are worn at all times and protective gloves when working
- The patient carries out basic skin care and inspects his/her hands and feet everyday

It is important to realise that:

- **Wounds are not always caused by neglect.**
- **The condition of the person's foot may have so badly deteriorated over time that occasional wounds are inevitable.**
- **Such patients should be referred to the hospital for assessment for rehabilitative surgery and/or special footwear.**

13.4 POST-MDT SURVEILLANCE

Post-MDT surveillance is important to help pick-up post-RFT reactions, reactivation, and particularly relapse.

13.4.1 Follow up Visits

After RFT, there should be follow up visits at six month intervals for a minimum of (2 years for PB and 5 years for MB leprosy) or thereafter. During such visit the doctor will look out for the following:

- Relapse
- Reaction (Type I or Type II)
- Reactivation.

13.4.1.1 Relapse

Several definitions have been proposed for relapse in leprosy. WHO defines relapse as "A patient who successfully completes an adequate course of MDT, but who subsequently develops new signs and symptoms of the disease either during the surveillance period (2 years for PB and 5 years for MB leprosy) or thereafter."

The diagnostic criteria for relapse are: Clinical criteria

- increase in size and extent of existing lesion(s)
- appearance of new lesion(s)
- infiltration and erythema in lesions that had completely subsided
- nerve involvement (thickening or tenderness)

Differences between Type I Reaction and Relapse

It is often a diagnostic dilemma to differentiate true relapse from a late Type I reaction in a PB case. Many studies on PB leprosy show falsely high relapse rates, possibly because of the inclusion of cases that are probably reactions and not really relapses. Some of the features that will help in differentiating these two conditions are given in the table below.

Table 13.9: Common features that differentiate Type 1 reaction from a relapse

Feature	Reversal Reaction (Type I Reaction)	Relapse
Time	Usually within 6 months from RFT; in recurrent reaction, up to 2 years	1 year or more after RFT
Type		
Skin Lesion	Increased erythema, swelling, tendernesss on pressure, succulent consistency; edema of hands/feet	Increase in extent and number of lesions, no tenderness, rubbery consistency; edema of hand and feet rare.
Ulceration	Seen in severe reactions	Not seen
New Lesions	Few, same morphology	Many
Nerves	Acute painful neuritis; nerves exquisitely tender; nerve abscess; sudden paralysis of mucles and increase in reactions	New nerves involved; no spontaneous pain; tenderness on pressure; sensory and motor deficits slow and creeping
Respond to Systemic Steroids	Complete subsidence of lesions in 2-4 weeks; remain subsided with 2-month therapy	No response

Differences between Type II Reaction - Erythema Nodosum Leprosum (ENL) and Relapsed papules and nodules

Papules and nodules that occur as part of relapse in the MB spectrum should be differentiated from ENL nodules. The most important point of difference is that ENL nodules are tender and evanescent, unlike lepromatous nodules. Additional differences are listed in the table below.

Table 13.10: Common features that differentiate ENL nodules from a relapsed nodule

Feature	ENL	Relapsed Papules and Nodules
Onset	Sudden	Insidious
Constitutional Symptoms	Present	Absent
Physical Signs	Nodules are tender, warm, erythematous, blanchable on pressure and superficially located	Non-tender, not warm, do not blanch, involve full thickness of skin

Relapse vs. Reactivation

Reactivation of lesions occurs due to treatment failure, i.e. premature termination of treatment or gross irregularity in treatment either due to non-compliance or irregular supply of drugs. Reactivation occurs soon after subsidence of the disease while relapses occur after complete and sustained subsidence of the disease.

Management of Relapse

Relapsed cases of leprosy should be identified and put back on chemotherapy as soon as possible to prevent further disability and transmission of infection. Factors that should be considered in choosing an appropriate regimen are:

- Type of leprosy (PB or MB)
- Previous treatment

Type of leprosy
PB cases usually relapse as PB, and MB cases as MB. However, PB cases occasionally relapse as MB and such cases should receive MB-MDT.

Previous therapy
- Patient previously treated with dapsone monotherapy - standard WHO MDT is sufficient.
- Patient previously treated with clofazimine monotherapy - standard WHO MDT is sufficient (clofazimine resistance is extremely rare).

13.5 REHABBILITATION

The key objective of the NTBLCP is to ensure that leprosy rehabilitation is mainstreamed into State and national rehabilitation programs and services using the principles of community based rehabilitation as recommended by ILO and WHO. Community Based Rehabilitation (CBR) is a strategy within general community development for the rehabilitation, equalization of opportunities, and social inclusion of all people with disabilities.
The STBLCO and their TBL Supervisors should ensure appropriate linkages between their programmes and the relevant rehabilitation services in their States.

IMPLEMENTING BURULI ULCER CONTROL ACTIVITIES

14. INTRODUCTION

14.1 Definition

Buruli ulcer (BU) is a chronic, indolent, necrotizing infectious disease of the skin caused by Mycobacterium ulcerans, the third most common Mycobacterial disease in humans after tuberculosis (M. tuberculosis) and leprosy (M. leprae). The disease is curable, but is a public health problem by the high prevalence rate in affected areas and also because of its debilitating nature. More than 25% of cases are permanently deformed and disabled mainly due to late diagnosis and case management.

The distribution of the disease is patchy, that is, irregular, often in relatively inaccessible areas. It is now confirmed that Nigeria is a BU endemic country and many States are affected, particularly those in the southern belt and States neighbouring Benin Republic and Cameroon (November 2006).

The disease affects all age groups. However, children less than 15 years of age (range of 2-14 years) are predominantly (more than 70%) affected, especially the impoverished inhabitants of remote rural areas. There are no sex differences, and no race exempted.

14.2 Risk factors for BU

These are possible risk factors for BU

- Residence near slow-flowing rivers/streams or marshy
- lowland areas
- Contact with marshy environment e.g. through occupational
- activities
- Environmental changes and degradation through various
- forms of land-use
- Pricks or abrasions of the skin
- Predisposing skin diseases

14.3 Goal

The overall goal of BU control is to reduce the morbidity, disabilities and socio-economic consequences caused by the disease.

14.3.1 General objectives

i. The general objective of BU is to:
ii. Detect and treat early active cases of BU
iii. Provide appropriate care (antibiotics, surgery and prevention of disabilities) including referrals according to standardised guidelines

iv. Ensure BU patients with disabilities receive appropriate rehabilitative care
v. Include BU as part of the integrated disease surveillance system
vi. Promote relevant research on the epidemiology, diagnosis, treatment and prevention of BU
vii. Advocate and mobilise resources for the programme

14.3.1.1 Specific Objectives for Buruli Ulcer Control in Nigeria

i. To increase the case-detection rate of non-ulcerative forms to 80%
ii. To provide treatment for all active cases of Buruli ulcer detected by passive case detection between 2009 and 2015
iii. To provide rehabilitation for 10% of patients with disabilities caused by Buruli ulcer detected between 2009 and 2015
iv. To train 80% of health workers operating in areas in which the disease is endemic

14.3.2 STRATEGIES

14.3.2.1 Strategies adopted from the GLOBAL BURULI ULCER INITIATIVE (GBUI)

i. Capacity building to improve accuracy of clinical diagnosis of Buruli Ulcer.
ii. Laboratory confirmation of Buruli Ulcer cases through quality assured methods (AFB microscopy and Polymerase Chain Reaction (PCR) methods.
iii. Standard antibiotic treatment regimen according to National guidelines with appropriate documentation.
iv. Wound management of Buruli Ulcer including Skin Grafting
v. Prevention and Management of Disability including rehabilitation.
vi. Supervision, monitoring and evaluation

15. APPROACH TO MANAGEMENT OF BU DISEASE

15.1 Identifying a BU Suspect

It is necessary to identify Buruli ulcer (BU) cases, especially in the early stages of the disease, in order to provide treatment and avoid disabilities. Early identification of Buruli ulcer Suspect is based on a combination of:

- History of residence in an endemic area
- Travel/visit to an endemic area
- Features of the lesion at onset
- Clinical impression based on signs and symptoms

Any individual with the following conditions should be identified as a BU suspect

- With a painless swelling
- Or an ulcer or a scar consistent with the clinical definitions,
- Living in or having visited a BU endemic area.
- Most lesion(s) on the limbs (60% on the lower limb)
- Most patients are children under 15 years of age
- No constitutional symptoms (fever, malaise), except in
- complicated cases
- No associated enlarged lymph nodes.

15.2 CASE DIAGNOSIS

15.2.1 General principles for diagnosing BU

- Any patient coming from an endemic area and showing lesions or a scar such as described below should be clinically considered as a Buruli ulcer case until proven otherwise
- The clinical diagnosis of Buruli ulcer should be supported both by history and physical examination
- It should be conducted by a physician, nurse or a trained health worker
- It should be confirmed by a laboratory test if possible

15.2.1.1 Methods of diagnosing BU

1. Clinical Diagnosis

The clinical diagnostic process consists of:

- history
- physical examination

There are 3 clinical forms BU:

- pre-ulcerative forms (papule, nodule, plaque and oedematous lesion)
- ulcer
- scar

Table 15.1 Main differentiating features of the three types of BU

Lesion	Characteristics
Papule:	Painless raised lesion, less than 1 cm in diameter situated in the skin. It may be itchy.
Nodule	Painless, palpable, firm lesion, often itchy, 1-2 cm in diameter, situated in the sub-cutaneous tissues, usually attached to the skin. A nodule may be mobile over the

	underlying tissues (especially in the early stages). The skin over a nodule is often hypopigmented (lighter).
Plaque	Painless, visibly well-demarcated, and elevated indurate lesion, more than 2 cm in diameter, with irregular edges. The surface may be reddish or hypopigmented.
Non-ulcerated oedematous	Diffuse, firm, non-pitting swelling of a part of the body, with ill-defined margins. It may be painful, with or without colour change.
Ulcer	Relatively painless wound with a necrotic floor, undermined edges and oedematous hyper-pigmented (darkened) surrounding skin.
Scar (inactive case)	a scar with a history of a painless swelling that developed into a typical Buruli ulcer healing with or without deformity. The scar may be depressed, usually with an irregular star shape. Note: take care to exclude burns scars which may look similar – the history of burns should clarify the case.

Multiple active lesions

A patient may have two or more lesions at the same time. The lesions may be at the same stage of development e.g. all nodules, or may be at different stages, e.g. a plaque and an ulcer.

2. Laboratory Diagnosis

Laboratory exams that are available for diagnostic confirmation are (ranging from the simplest non-specific to the most complex and specific):

- Examining a smear after staining by the Ziehl-Nielsen method
- A culture
- Histopathology
- Polymerise chain reaction (PCR).

Collecting samples

- **For microbiology (direct examination, culture and PCR):**
  - In case of non-ulcerative lesions, the sample will be taken at the middle of the lesion;
  - In case there is an ulcerated lesion, the samples may be obtained at the detachment of edges, by taking multiple samples of secretions on swab and tissue particles by excision;

- **For histopathology**
  - The sample is to be a particle taken from the area located between the healthy skin and the diseased skin and moving toward the subcutaneous skin tissue.

Note:

At health centre level, only the Ziehl-Neelsen stained smear exam may be done. However, samples of secretions or tissues will be taken, correctly identified, preserved and sent to higher levels of reference for other laboratory tests.

Preserving and transporting samples
For samples to be sent to microbiology (direct examination, culture and PCR), they will be preserved either in cool condition at 4°C (in a refrigerator - avoiding freezing); For samples to be sent to histopathology, preservation will be assured by using a 10% formol solution.

15.3 CASE DEFINITION

15.3.1 Definitions

15.3.1.1 A BU Case

A confirmed case of BU is a BU suspect that has been confirmed by one or more of the following laboratory tests:

- Demonstration of acid fast bacilli (AFB) in a smear from the lesion
- A positive culture of M. ulcerans from the lesion.
- Characteristic histopathology on a tissue specimen from the lesion
- Positive polymerise chain reaction-based (PCR) test for M. ulcerans on a specimen from the lesion.

15.3.1.2 Recurrent Case

A recurrent case of BU is one which has been treated (antibiotics and/or surgery), declared cured and presenting later less than one year after the healing with an active form of BU confirmed by clinical and/or a laboratory test A recurrent must be considered as a failure of the previous treatment. All lesions occurring after 12 months of cure should be considered as new cases of BU.

15.3.1.3 Complicated BU Cases

If any of the forms of BU described in 15.3.1.1 above is associated with any of the following conditions, it is considered as complicated BU disease and should be referred for specialist care.

- Secondary bacterial infection
- Abscess formation
- Tetanus
- Moderate to severe bleeding (more bleeding than is associated with normal wound dressing)
- Extensive lesion (larger than the size of the patient's palm)
- Osteomyelitis

- Formation of sinus(es)
- Contractive deformities of joints e.g. fixed joints, excessive scarring
- Amputation of a digit or a limb
- Destruction of an organ, e.g. an eye
- Malignancy (Cancer)
- Any located head and neck, perineum, genitalia, maxilla, hand, breast and lesions that span the joints.

15.4 CASE MANAGEMENT

15.4.1 General principles of managing a BU case

- Treat it as early as possible
- Ensure full compliance with antibiotic treatment
- Avoid cross-infections
- Promote rapid healing
- Prevent complications and treat them in case they happen
- Prevent recurrence

Always Remember

- **In BU known endemic area, treatment must start before laboratory confirmation of the diagnosis.**

15.4.2 Modes of treatments

1. Combination of Rifampicin (10mg/kg body weight) and Streptomycin or Amikacin (15mg/kg body weight) daily direct observation for 8 weeks
2. Sterile
3. Surgery (debridement, excision, skin grafting)
4. Prevention of disability (POD)

15.4.3 Procedures to be applied in case management

15.4.3.1 In case of simple active forms

- **Papules, nodules and ulcerations of ≤ 5 cm. in diameter**
    - Treatment with Rifampicin-Aminoglycoside only for 4 to 8 weeks

- **Plaques, oedemas and ulcerations of more than 5 cm in diameter**
    - Treatment with Rifampicin-Aminoglycoside during 4 weeks, followed by surgical treatment if needed and then 4 weeks treatment of combined specific antibiotics

15.4.3.2 In a facility without a medical officer:

- Apply dressing to keep the lesion clean for active forms;
- Start specific combined antibiotic regimen (rifampicin-aminoglycoside)
- Transfer patients to higher reference levels.

15.4.3.3 Referral will be indicated in one or more the following conditions

- Extensive plaques or oedemas;
- Extensive ulcerative lesions;
- Deep lesions in contact with the bone;
- Localized lesions on the head, neck, genital organs, chest, fingers or joints;
- Patients in generally poor condition.
- Association of other systemic conditions (sickle cell disease, diabetes, renal failure etc.)

15.5 Monitoring during the treatment

- Regular dressing of the wound;
- Prevention of disused atrophies ;
- Physiotherapy
- Assessment of vital signs
- Management of an associated disease.

Table 15.2: Roles of the various Levels in Case Management Process

Facilities	Management Activities
Health post/Dispensary	Case suspicion Appropriate referral of suspicious cases Dressing non-BU wounds
Health centres without a Medical Officer	Clinical diagnosis of the cases Dressing all wounds Combined antibiotics (rifampicin-aminoglycoside) Appropriate referral of BU cases

Health centres with a Medical Officer	Above-mentioned activities of health centre without a doctor Excision of nodules, papules or small Ulcers of ≤ 2 cm in diameter Anti-tetanus coverage Appropriate referral of other BU cases Ziehl-Neelsen and send samples Management of complicated cases, if feasible Reconstructive surgery of complications, if feasible Culture and histopathology, if possible (If not, Ziehl-Neelsen and send samples)
Tertiary/ Referral Facility	Above mentioned activities of intermediate hospital plus
	Management of complicated cases
	Reconstructive surgery of complications
	Physiotherapy
	Culture, PCR and histopathology

16. PREVENTION OF DISABILITY (POD)

16.1 Essential Interventions to Prevent Disability (POD)

POD takes teamwork and commitment and persons affected by BU are assessed and monitored regularly to determine what POD intervention/treatment are needed

16.1.1 The essentials of POD

- Early diagnosis and treatment of the infection
- Wound and skin care (Safe handling of wounds and contaminated materials by health worker and caregiver, facilitate wound healing, control oedema, manage scars and adhesions)
- Minimize pain (treat infection, control oedema, remove bandages carefully, give analgesics, provide adequate positioning & splinting and avoid forceful movement).
- "Anti-deformity" positioning / splinting (prevent soft tissue and joint contractures and manage existing contractures)
- Exercise and activity (prevent and manage soft tissue and joint contracture and control oedema)
- Self-care education (empower and encourage independence and participation)
- Refer when necessary
    - If the condition is worse
    - If interested in other more complex rehabilitation interventions

16.2 Suggested preventive measures

Based on the identified risk factors, the following primary preventive methods can be recommended:

- Preventing M. ulcerans entry through the skin
- Environmental manipulation

- Vaccination by BCG
- Socio-economic development
- Excision of pre-ulcerated lesions to minimize duration of healing and deformity due to the disease
- Education on post-surgery complications must be emphasised

Preventing entry of *M. ulcerans* through the skin

- **Keeping the skin clean**
- **Preventing breaks in the skin**
- **Taking good care of breaks in the skin and skin disease**
- **Minimizing contact with pre-disposing environments**

NB.
After completing antibiotic treatment, patient should be followed up for at least 10 months to confirm cure, assess possible complications and observe any recurrences.

LOGISTIC MANAGEMENT SYSTEM OF THE NTBLCP

17. MANAGING MEDICINES AND OTHER SUPPLIES

17.1 The Purpose of Medicine Management

Good medicine management is essential in ensuring that patients get their drugs whenever they need it. The purpose of why medicine should be properly managed is to:

1. Maintain the quantity of medicines in the facility at approved levels. For example at the beginning of the quarter or at the time of fresh supply it should be 5 MOS; as the quarter progresses, it should reduce progressively down to about 2 MOS at the end of quarter or before another supply.
2. Avoid wastages. Wastage refers to any situation in which medicine or other commodities are removed from inventory for any reason other than that it being given to the patient. This can be due to expiry, damage, deterioration, contamination or theft.
3. Avoid stock out. Stock out is any situation whereby medicine or other commodities are not available at the facility for immediate use whenever patients need them.
4. Give the right dosing & right dispensing. This entails that every patient are classified correctly and placed in the correct weight band; the quantity of medicine and other commodities are calculated and issued correctly for the required duration of treatment as stipulated in the guidelines.
5. Ensure patient safety. It is the responsibility of both patient and caregiver to watch out for any "out of normal" experience the patience might have in the course of treatment. The effect may put the patient at risk or lead to treatment failure.
6. Maintain the quality of medicine & packaging. This is essential in order to ensure that the potency of medicine is maintained while in storage or until consumed by the patient.

17.1.1 What to do in order to achieve the above-listed purposes

The overall objective of medicines management is to satisfy the patient/client's needs. This entails that medicine should be "seated" at the facility at the right quantity of the right medicines, of acceptable quality, at the right time, place and cost waiting for patients to arrive and not the other way round.

The Pharmacist (or General health Care worker as the case may be), is responsible for ensuring that all medicines in routine use are available and at all times. Apart from medicines, other health products such as diagnostics, recording and reporting (R&R) materials are available as well.

17.2 Responsibilities

17.2.1 Responsibilities of the pharmacist or GHCW in the management of commodities

In ensuring that all medicines in routine use are available and at all times and he/she must familiarize him/herself with the NTBLCP Logistics guidelines in order to be able to:

1. ***Receive items delivered to the facility by inspecting items physically for wholesomeness;*** completeness as listed in the delivery voucher; long expiry dates and endorsing the delivery voucher after satisfying self of the delivery.

2. ***Ensure that the storage room is conducive for medicines according to the guidelines on storage;*** arrange received items properly to prevent physical damage and contamination; follow the First to Expire, First to go Out (FEFO) rule.

3. ***Visually inspect medicines & packaging***. Should routinely look out for signs of defect in the medicines or their packages while on storage. Whenever tablets begin to change colour or solutions unusually deposit solids; the GHCW should report and stop issuing the medicine.

4. ***Use Regime guide correctly to determine dosage and quantities***. Based on weight on first visit, the GHW should be able to classify the patient on correct weight band and determine the correct number of tablets/blisters required to complete treatment.

5. ***Manage Patient kits and the supply box.*** The GHCW should be able to bundle into kits any regimen supplied in loose blisters or tablets. He/she should be able to adjust the kit for patients that fall outside the average weight band (38-54kg) using the supply box. The latter is a container for storing any loose fraction of a medicine. Patient kit one has two supply boxes – one for RHZE and the other for RH loose blisters. He/she should be able to enrich the supply box when it does not contain enough loose drugs: Take one full kit and split into 6 blisters of RHZE and 12 blisters of RH, follow the Regimen guide to add or remove from it to adjust to patient needs.

6. ***Use the stock cards and other records for all products and update them for all transactions.*** Records are tools for capturing data. Examples of records include the Stock card, delivery voucher and the RT form. Records generally remain at the facility where they are used

NOTE:

- Records are instruments of transparency – such that claims can be verified
- Records MUST be true to fact on the ground so as not to mislead i.e. they must reflect logistics related events during the quarter, position of stocks such as at the beginning and at the end of the quarter.
- The quality of recording should reflect the skill level of the DOTS provider.
- The PICKnPACK defines "Medicine" as "cash in tablet form". Like cash, all drugs/commodities collected MUST be retired.

- The only place to retire medicines is at the DOTS sites or microscopy centres.
- The only person authorized to retire medicines is the DOTS provider or Microscopist.
- The Only means authorized to retire is to enter quantities in stock cards as issued to or used for named patients /TB suspects that can be traced from records in that facility.
- Records must be preserved for a minimum of 5 years

7. ***Use supply box stock cards. Patient kit Regimen 1 should have 3 stock cards:*** PK1, RHZE and RH; The Paediatric Kit should have 4 stock cards; - Paediatric PK, RHZ, E and RH. Whenever, the quantity of loose fractions in supply box is enough to form a new kit, you should consider to re-kit and enter in PK1 card under "adjustment".

8. ***Return medicines whenever there is a need to.*** When you find out that you are overstocked of a medicine and it is likely to expire unused, you may need to return it to the State store through the supervisor or carrier. Follow the guideline for returning or transferring medicines to complete the RT form. To know when you should return an item, you must know how to calculate the MOS and MOS cover.

9. ***Borrow from or transfer to a sister facility whenever there is a need to.*** The act of collecting from or giving to a sister facility (located within same LGA) is called adjustment. You can only give out when you are sure you will not run out of stock. Similarly, you can only request from a sister facility when your stock level falls below the emergency order point of 1 MOS and your supervisor is not reachable immediately. In either case, you must use the RT form as provided for in the guideline.

10. ***Make an emergency Order whenever there is a need.*** Emergency ordering is initiated to prevent stock outs. Whenever the stock level falls below the 1 MOS before the end of the quarter, you should find any means possible to communicate to the supervisor or the State logistics officer if the former is not reachable. You may also consider reaching out to any of your sister facilities that have more than enough if the State team is not responding. The QRRIF should be prepared to make this request. But if you cannot send across the QRRIF, use text messages, the receiver may enter the information in the QRRIF before delivering with the delivery voucher.

11. ***Carry out a physical inventory.*** The GHCW should be able to count by hand the total quantity of usable stock in the facility at any point in time. It should be carried out more often if the stock level is known to be falling below the MIN (2-3 MOS). Counting more often when your stock is low lets you know in advance when you need emergency ordering. This task is mandatory at the end of each quarter, and should be carried out to determine the opening balance for next quarter and how long it will last before fresh supply will arrive.

12. ***Rule-Off stock cards.*** At the end of each quarter, it is important to identify the last working day of that quarter and mark the line of last entry in the stock card. Done

correctly, it will provide you with ready-made data to use for the QRRIF. To do this, follow the steps outlined below:

- Below the rule-off line, sum all the data for the quarter e.g. "Beginning Balance", total received in quarter, total issued to patients & supply box, total losses/gains/adjustments and physical balance"
- Enter each of them under the appropriate column.
- Separate total received & total issued with a slash (/), enter quantity received first.
- Under voucher number, enter the total number of patients registered in facility in quarter under review.
- Enclose the number of patients in brackets to indicate that it captures human beings, not medicines.

13. ***Determine stock position in MOS.*** The GHCW should, at any point in time, be able to tell how long available medicines in facility would last. This is necessary to avoid the embarrassment of suddenly realizing that the medicine level has hit emergency level or worse still, has finished. The facility management may want to ask questions like;- Do we have too much, too little or just enough? This will, in turn, provide the basis to make decisions.

14. ***Report and Order using the QRRIF:*** The QRRIF, short for Quarterly Report, Requisition and Issue Form can be classified as a report in the sense that it contains data converted into information and sent to a higher level. Hence reports could also be described as forms on which data are moved from a lower level to a higher level. As the name implies, the QRRIF also serves as a requisition and can be used for issuing when the requisition gets to the State store. They are filled by DOTS providers and Microscopist and sent to LGTBLS. Note the following:

- Reports (QRRIFs) should be correctly filled with data contained in the records.
- QRRIFs should contain all the information required according to the design.
- The QRRIF should be reviewed by the LGTBLS and DOTS provider at site.
- All QRRIFs in LGA should be ready at the end of the quarter before the State review meeting.
- The review meeting is NOT meant for completing the QRRIF, rather to review its content with State and provide feedback.

15. ***Determine the quantity to order:***

Steps:

- Establish the number of TB patients treated last quarter for each treatment category.
- Estimate the average monthly consumption by dividing the quantity issued within the previous quarter by 3.
- Multiply the average monthly consumption by 5 to determine maximum stock quantity required for a quarter.
- Determine the physical inventory (stock on hand) by checking the quantity of each of the drugs in stock (in the store).
- Deduct the physical inventory from the maximum stock quantity to determine the quantity to order

Quantity to order = Maximum stock quantity - stock on hand

16. ***Monitor patient Safety & Expected Outcome of Medicine Use.*** Patient's safety is an important component of good drug management system, therefore the GHCW should:

- Educate the patient on the usual or likely reactions to expect from the use of a medicine
- Sensitize the patient to report to him/her any "unusual" experience
- Actively look out for, find, manage, record and report to the LGTBLS any "out of normal experience" associated with the use of medicines, including treatment failure
- Should complete the yellow (pharmaco-vigillance) form correctly and submit to the LGTBLS.

17. ***To determine stock position always in order to foresee stock out and in enough time for action to be taken to prevent it:*** The GHW should be able to:

a. Determine how long available stock will last (expressed in Months of Stock MOS)
b. Know how to interpret MOS values and what action to take or not to take e.g.
    - 1MOS or less = (Emergency): Place emergency order immediately
    - 2-3 MOS = (Below Min): Count stock more frequently
    - 3-5MOS = (ok): Keep in view
    - Above 5MOS = (over-stock):
        - Over-stock? Check if you have space for it and that the storage temperature is conducive. Notify the supervisor in case another facility is in immediate need for it.
        - Check expiry date to be sure it will not expiry before use; to be sure of your calculation, use the method of MOS Cover below.
        - Calculate MOS Cover: The actual number of months your stock will last before it expires e.g. if the MOS is 8 and the medicine will expire in 6months time i.e. Remaining Shelf Life (RSL) of medicine. Then, you are actually covered for only 6 months, not 8.
        - Determine quantity to return (in MOS): [MOS] –[MOS Cover]
        - I.e.8-6 =2MOS. Actual quantity = [2] X [AMC]

18. ***Routinely conduct visual inspection of medicines on the lookout for obvious signs of spoilage:*** The GHW should:

- Use the NTBLCP storage guidelines to maintain storage points at recommended condition.
- Arrange and issue medicines according to the FEFO (First expire, First out) rule.
- Conduct visual inspection of all products on storage in search for obvious signs of damage or deterioration such as colour change, appearance of growths, deposits forming, etc.
- Know what action to take or not to take based on an observed anomaly. For instance,
    - Stop issuing and report to LGTBLS if colour change is noted;
    - Recommend to the management to start rodent control if rats had bitten off some tablets or packages or rodents excreta observed etc.

- Repair roofs or floor if water is penetrating
- Check cooling systems if thermometer reading is showing high temperature.

19. ***Assess self on data-quality and how well Patient kits were used.*** Past usage of TB medicines can be assessed by comparing the quantity of patient kits dispensed with the number of new patients registered in the quarter. The indicator is called the 10-PATIENTS Index. It describes the estimated quantity of Patient kit that should be used for every 10 patients in that facility. The acceptable range is from 9-11. Any number far outside the range should be verified. The GHW should:
    - Use the previous quarter data to determine if the right quantities of patient kits have been used and the right entries made in the stock cards (for kits) and register (for patients). To be sure, he should use the 10-PATIENT Index method.
    - The 10-PATIENT Index value will be far outside the range of 9 – 11 if :
        - Number of Patient data in register is incorrect
        - Number of Patient Kits entered in Stock card is wrong
        - The right doses were not used
        - Patient kits actually lost, damaged or stolen are recorded as issued to patients.
        - Too many Kits were issued to the supply box than actually needed.
        - Many overweight clients are diagnosed rightly or wrongly as TB patients.
        - 10-Patient Index = Quantity of Kits Used x 10
        - No of patients reported
        - The GHCW knows what to do or not to do based on the result obtained - for instance:
        - Cross check all the possible causes listed above such as the entries in stock card and patient register are correct.
        - Lab procedures, reagents and equipment (microscopes) may be checked as well.

18. DEFINITIONS AND PARAMETERS

18.1 Operational considerations in Stock holding:

The NTBLCP makes no compromises for stock outs. However, for some sites, a balance is usually sought between keeping medicines endlessly in a facility in the expectation of patients and the loss of such medicines to expiry or redundancy. This relates to very low yielding sites. For such sites, the PICKnPACK does not allocate stocks automatically. It is usually left at the discretion of the State team & LGTBLS to decide whether or not to keep stock in such sites.

Luckily, the TB programme is organized in such a way that the LGTBLS has fore knowledge of, and actually registers every patient to be put on treatment in the LGA. He knows how medicines can be mobilized from nearby facility or from the State store before the arrival of the patient. Drug allocation is, thus, at the discretion of the LGTBLS and DOTS provider. If the need arises, medicines should be transferred from sister facilities using the RT form or from

State store. For these very considerations, the following operational definitions apply to stock holding in NTBLCP

18.1.1 Stock Out

Stock out is a situation whereby a listed medicine or health product is not available in the facility at any point in time for use.

- Please note that some facilities do not register some categories of patients such as children, CAT 11 or MDRTB. Such facility would not be expected to have the corresponding stocks in their stores.

18.1.1.1 Stock out (Technical)

A situation whereby a listed medicine or health product is not available in a facility and yet no patient was delayed or denied access to such medicine; i.e. patients notified within the period were served with medicines from nearby sources.

Note:
Means OF Verification (MOV): Central register indicates that all patients notified were placed on treatment and timely too.

18.1.1.2 Stock Out (Programmatic)

A situation whereby a listed medicine or health product is not available in a facility and one or more patients notified within the period were not placed on treatment or on time.

Note:
Means OF Verification (MOV): Central register indicates that not all patients notified were placed on treatment or on time.

18.1.2 Very Low Yielding (VLY) Facility

This is a logistics classification, it refers to a facility that notifies 1 or 2 patients in a quarter. The implication is that such a facility may or may not notify any patient in subsequent quarters and it will be wasteful keeping medicines in wait at such sites.

18.1.3 Inventory Control System

- **Forced ordering:** meaning that every facility is required to review stock at end of every quarter and place order in order to push stock levels up to the maximum.

- **Re-supply period:** Every quarter (3 months)

- **Stock Levels:** Max stock: 5MOS; Min stock: 2MOS; EOP: 1MOS

- **Lead Time:** 3-4 days using the Pre-Depot Replenishment (PDR) Strategy: All depot facilities (central, zonal and State stores) are replenished before the quarter ends. As new quarter begins, facilities come with QRRIF and draw stock immediately from

State stores. QRRIFs are analyzed within the 2 days of State review meetings. Medicines reach the facility through the LGTBLS or carrier next day.

18.1.4 Use and management of supply box

The current NTBLCP patient kit is designed for patient within the standard weight band of 38- 54kg (i.e. patient that take only three tablets daily). However, there are situations when patients weight fall outside this weight band necessitating the need to create a supply box. Section 19.1.4.1 explains in details steps to take when creating a supply box.

18.1.4.1 How to create a supply box

In the event of a patient with weight outside the standard weight band of 38- 54kg (i.e. patient that take only three tablets daily), an adjustment is required and the following steps are required:

1. Take a full (complete) Stop TB kit from the facility store;
2. write Supply Box on the outside of the kit;
3. Separate the content of the kit in to RHZE and RH;
4. Open a stock card for each of this drugs i.e. RHZE and RH respectively
5. Other steps may include:
    - Any extra blisters you removed when adjusting the patient boxes can be placed in the Supply Box
    - Any additional blisters you need for adjusting the kits, you can take from the Supply Box according to the schedule in section 18.1.4.2

18.1.4.2 Managing Patient KIT for new, retreatment PTB Cases and Extra-pulmonary TB cases

The current patient kit is factory customized to accommodate patient with weight within the standard weight band of 38- 54kg (i.e. patient that take only three tablets daily). However, in some circumstances the patient weight falls outside the standard weight band and hence there is need for kit adjustment.

In order to ensure that all patient put on treatment get the right regimen and dosages, the Logistic team of the NTBLCP has developed a simple SOP for kitting drugs when the need arises. This SOP helps to guide health staff on how to adjust kits either when the weight band falls above or below the standard weight band.

Refer to table 18.1 to 18.4 below for how to package patient kit whenever the need arises.

Table 18.1: How to package patient kit when using Regimen 1 for Adult TB Cases: 2RHZE/4RH

6 months Regimen for Adults: Total Number of Blisters for Full course of treatment					
Regimen	**Pre-treatment weight in kg**				**NUMBER OF BLISTERS IN ONE KIT**
	> 70	**55 – 70**	**38 – 54**	**>18 – 37**	
Intensive phase (2 months): Combined tablet of RHZE **(150mg+75mg+400mg+ 275mg)**	**10**	**8**	**6**	**4**	**6 Blisters**
ADD OR REMOVE BLISTERS TO ADJUST DOSAGE	**Add**	**Add**		**Remove**	
	4	**2**		**2**	
Continuation phase (4 months): Combined tablet of RH **(150mg + 75mg)**	**20**	**16**	**12**	**8**	**12 Blisters**
ADD OR REMOVE BLISTERS TO ADJUST DOSAGE	**Add**	**Add**		**Remove**	
	8	**4**		**4**	

Table 18.2: How to package patient kit when using Regimen 2 for Adult TBM/OA TB Cases: RHZE/10RH

12 months Regimen for Adults: Total Number of Blisters for Full course of					
Regimen	**Pre-treatment weight in kg**				**NUMBER OF BLISTERS IN ONE KIT**
	> 70	**55 – 70**	**38 – 54**	**>18 – 37**	
Intensive phase (2 months): Combined tablet of RHZE **(150mg+75mg+400mg+ 275mg)**	**10**	**8**	**6**	**4**	**6**
ADD OR REMOVE BLISTERS TO ADJUST DOSAGE	**Add**	**Add**		**Remove**	
	4	**2**		**2**	
Continuation phase (10 months): Combined tablet of RH **(150mg + 75mg)**	**50**	**40**	**30**	**20**	**12**
ADD OR REMOVE BLISTERS TO ADJUST DOSAGE	**Add**	**Add**	**Add**	**Add**	
	38	**28**	**18**	**8**	

Table 18.3: How to package patient kit when using Regimen 1 for child TB Cases: 2RHZE/4RH

Regimen	Pre-treatment weight in kg				NUMBER OF TABLETS IN ONE KIT
	>13 – 18	>9 – 13	5 – 9	<5	
Intensive phase (2 months): Combined tablet of RHZE **(150mg+75mg+400mg+ 275mg)**	**224**	**168**	**112**	**56**	**168 Tablets**
ADD OR REMOVE TABLETS TO ADJUST DOSAGE	**Add**		**Remove**	**Remove**	
	56		**56**	**112**	
Continuation phase (4 months): Combined tablet of RH (150mg + 75mg)	**448**	**336**	**224**	**112**	**336 Tablets**
ADD OR REMOVE TABLETS TO ADJUST DOSAGE	**Add**		**Remove**	**Remove**	
	112		**112**	**224**	

Table 18.4: How to package patient kit when using Regimen 2 for child TBM/OA TB Cases: 2RHZE/102RH

Regimen	Pre-treatment weight in kg				NUMBER OF TABLETS IN ONE KIT
	>13 – 18	>9 – 13	5 – 9	<5	
Intensive phase (2 months): Combined tablet of RHZE **(150mg+75mg+400mg+ 275mg)**	**224**	**168**	**112**	**56**	**168 Tablets**
ADD OR REMOVE TABLETS TO ADJUST DOSAGE	**Add**		**Remove**	**Remove**	
	56		**56**	**112**	
Continuation phase (10 months): Combined tablet of RH (150mg + 75mg)	**1120**	**840**	**560**	**280**	**336 Tablets**
ADD OR REMOVE TABLETS TO ADJUST DOSAGE	**Add**	**Add**	**Add**	**Remove**	
	784	**504**	**224**	**56**	

- Be careful to always place the blisters on the correct side of the Supply Box, so as not to mix RHZE or RHE blisters. When a Supply Box is empty, prepare a new Supply Box as described above, discarding the old one
- Any blister sheets remaining inside patient kits from patients who have defaulted, died or were transferred out should also be placed in the Supply Box and used for adjusting other patient kits in your TB centre, unless instructed otherwise by your supervisor or the NTP Guidelines.
- Open stock cards to manage individual drugs (RHZE, RH, RHE etc.) for the supply box

19. STORAGE AND MANAGEMENT PROCEDURES

Health facility drugs and other medical supplies are kept in the health facility's drug storeroom, which should be well kept and managed by a designated responsible staff member. Good storage and management procedures are important for anti-TB drugs.

19.1 Stock Management

In order to ensure continuous availability of quality and ready to use drugs at all time, the GHCW must ensure that:

- Stocks of anti-TB drugs are kept safe in the main storeroom, which should be locked when not in use.
- Drugs and other commodities should not be kept directly on the floor
- Fire prevention measures are implemented.
- The temperature, light and humidity in the main storeroom should be kept moderate by increasing ventilation, and repairing any roof leaks quickly.
- Storage conditions can be improved by some simple measures using fans, air vents or windows to increase ventilation, direct light can be prevented from entering the room by hanging curtains or painting the window glass.
- No one should eat, drink or smoke in the storeroom. Do not keep food or drink in the storeroom. This will help to keep the storeroom clean and free of pests and rodents.
- Stocks of anti-TB drugs in the storeroom (in individual patient drug boxes or stocked by type of drug) should be placed on shelves by expiry date: the drugs that expire soonest should be in front and those that expire later should be behind.
- When taking drugs off the shelf, use those expiring first (First-to- expire, First-out (FEFO)
- Return expired drugs or excess stock to the RLTCO for onward transmission to the regional pharmaceutical stores using the combined requisition and issue note book
- Maintain a stock cards/tally cards for each drug and strength and this should be kept next to that drug on the shelf.

MONITORING AND EVALUATION SYSTEM OF THE NTBLCP

20. INTRODUCTION

M&E is an important management tool which is essential for successful programme management and coordination. It plays an important role in the day-to-day management of health programmes, it provides information and insight needed for both routine and strategic programme planning including decision making at all times.

A good M&E system should help in providing indication of how well goals and objectives have been achieved and whether activities have been undertaken as planned, or whether services are effective in reaching programme goals. It can also be used to address weaknesses in programme design and implementation.

21. NTBLCP M&E SYSTEM

The M&E system of the NTBLCP is established to ensure a smooth programme implementation and management at all levels. It is designed to provide an on the spot snapshot of the entire programme in terms of its current performance, implementation progress towards programme targets, epidemiological trend of disease burden and programme accountability in line with international best practices.

The NTBLCP M&E system encompasses the central unit of the NTBLCP, the States and the LGA and focuses on three main aspects; programme management, monitoring and evaluation. To take advantage of this system, all TBL and BU managers (central unit staffs, STBLCOs, LGTBLS and Partners) at all level need to have a thorough understanding of the content and process of NTBLCP monitoring and evaluation system to enable them plan adequately and use available information to improve their programme planning, decision-making and programme implementation process.

21.1 Programme management

To ensure effectiveness of programme implementation, the NTBLCP has put in place a number of programme review exercises to help provide periodic evaluation and objective assessment of programme progress against intended objectives. There are quarterly programme review meetings at all levels (Planning cell meeting at the national level, Programme zonal and State level review meetings) with the singular purpose of providing periodic opportunity to review all planned programme activities, its progress towards set targets and use the result to inform key programme decisions where necessary. Data from these various review meetings are also important source of information to aid improvement in programme management.

21.1.1 Monitoring

Monitoring is the routine reporting of data on programmes implementation and performance. This entails the routine tracking of key elements of programmes performance through careful record keeping and regular reporting. The NTBLCP monitoring system focuses on activity implementation and results achieved against set targets. It is set in such a manner to continuously help to ask key questions such as;

- Is the programme being implemented according to the plan?
- Are there any changes in program resources or service utilization?
- Are there any weaknesses in the implementation of the program? and
- Where are the opportunities to improve program performance?

This is done through proper record keeping and periodic reporting of routine activities at all levels using standardized NTBLCP tools. Refer to table 21.1 and 21.2 for common NTBLCP Recording and Reporting tools.

21.1.2 Supervision

Supervision involves guiding staffs when they carry out their assigned task with the purpose of improving their performance against agreed standards. Apart from monitoring programmes, the NTBLCP has also provide various supervisory platforms at all levels with the intension of improving the performance of all staffs involved in programme implementation. There are quarterly supervisions which are jointly conducted by the Central unit staffs, Partners and zonal officers to State control programmes. Similarly, the State control programmes and the LGTBLS are expected to provide quality and supportive supervisory oversights to the LGA and health facilities respectively.

Supervisors at all levels are encouraged to develop and keep to their Supervisory schedules, while the LGTBLS is expected to visit any facility in their LGA at least once in every two weeks and make their supervisory reports available to the State TBL control team. Currently, technology aided (the use of smart phones/tablets with downloaded customized supervisory checklist) supervisory system has been introduced at all levels to ensure effectiveness and a standardized solution-oriented supervision at all times.

21.1.3 Evaluation

Evaluation is the periodic assessment of programme performance with particular focus on the effectiveness of interventions, efficiency in resource utilization and the level of impact achieved. Evaluation also helps to assess progress towards operational targets and epidemiological objectives. It relies on routine data generation and information from other sources such as routine surveillance and survey data.

The NTBLCP evaluation system is in place not only for surveillance purposes but also serve to provide routine information for efficient management of the programme and uses a quarterly, annually and sometimes a biannual evaluation system e.g. Quarterly and Annual statistical report on treatment outcomes.

21.1.3.1 Surveillance

Surveillance is the routine collection of epidemiological data (i.e. disease outcomes) to track trends in disease incidence or prevalence over time. It aims to provide timely information which will form the bases for public health decisions, and for the planning, implementation, and evaluation of public health policies and practices.

The NTBLCP operates both an active and a passive surveillance system. The active surveillance involves the reviews of clinical records, community health surveys and disease specific prevalence surveys e.g. the 2012 TB prevalence survey. In the other hand, the passive surveillance involves the detection of cases whenever they seek healthcare i.e. system is put in place to detect cases as they present in various health facilities across the country.

This system works through building the capacity of health service providers to routinely collect data on the numbers, basic demographics and diagnoses of patients seen using already standardized designed NTBLCP recording and reporting tools. ***Although surveillance data is an important data source for M&E, surveillance should not be confused with, or substituted for, actual programme monitoring as explained in section 21.1.2 above.***

22. NTBLCP DATA MANAGEMENT SYSTEM

The NTBLCP Monitoring & Evaluation system starts from the community and peripheral health facility units to the Central Unit of the programme. The health facilities (Public and Private) within each Local Government Area serve as the primary data collection points where the daily activities in the facility are recorded using a series of tools designed by the Programme. The health worker at the health facility has the primary responsibility of ensuring that all components of these varied forms are completed accurately and correctly and at specified and appropriate time intervals.

At the Local Government level, data generated from all health facilities providing DOTS, MDT and BU services are regularly updated at specified time intervals and collated quarterly by the Local Government TB and Leprosy Supervisor (LGTBLS). The LGTBLS provides oversight of the facility health worker, keeps custody of the Basic Management Unit (BMU) Register (Local Government Central Register) and ensures that all patients started on treatment are accurately captured on the electronic data management system e.g. the e-tb manager. This electronic system captures relevant information on patients initiated on treatment in health facilities during the reporting quarter. Currently data collection is manual at the facility, but fully electronic at the LGA level and above.

The State M&E officer should ensure that data validation exercise are carried out in all LGA in their States (visit at least one LGA annually) through regular onsite data verification (OSDV) exercise. Similarly the M&E unit of the central unit should ensure that quarterly

OSDV and biannual data quality assessment exercise are conducted to facilities and LGAs in at least six challenged State per quarter and biannually respectively.

22.1 Information flow

22.1.1 Reporting and Recording system

All patient information is collected at facility level using the facility based primary information collection tools e.g. Specimen examination request form for TB and patient treatment card. The health staff should ensure that the primary tools are used to update the Register for presumptive TB case and the facility treatment register on a regular (daily) basis respectively. After ensuring completeness and correctness, the LGTBLS should then transfer all these information into the e-tb manager during each patient registration period.

Quarterly reports are generated from the e-tb manager through the management module and made available for programme use at all levels. Similarly, validated data should feed into the DHIS2 tool for FMoH and partners use. The electronic data management system was necessary to help the NTBLCP address issues of data quality, workload, and data access, timeliness of information, management of complex data, data analysis and reporting among other challenges.

Timely reporting is central to effective programme management. TBL reporting is done on a quarterly basis, therefore all programme managers should be guided by the NTBLCP recommended timelines for data reporting and management as outlined below:

1. All LGTBLS should ensure that their LGA quarterly reports are ready for reporting by the end of the 1st week of every new quarter.
2. Similarly, all STTBLCO should ensure that their State quarterly reports are ready for reporting by the end of the 2nd week of every new quarter.
3. The M&E unit of the central unit should provide data quality feedback to all State programmes at least one week after submission of State data but not later than the end of the 3rd week of every new quarter.
4. Consequently, the M&E unit of the central unit on behalf of the National coordinator of the NTBLCP, should ensure that the national TBL and BU quarterly reports are available for dissemination (including DHIS) by the end of the 4th week of every new quarter.
5. Case finding data is due at the end of every quarter for DS-TB, DR-TB, Leprosy and BU.
6. Smear conversion data for DS-TB is due 3 months after the end of every quarter (one quarter behind the reporting quarter)
7. Treatment outcome data is due 9 to 12 months after the end of the quarter.

Table 21.1 below shows are key M&E tools use for DOTS, DOTS Plus (PMDT), Leprosy and BU in the NTBLCP.

Table 22.1: KEY NTBLCP Recording tools used at the facility level

Patient records: Update on a daily and weekly basis				
S/N	**M&E formats**	**Data requirement**	**Site of use**	**Frequency of entry**
NTBLCP	**NTBLCP Recording tools for Drug Susceptible TB activities**			
TB 01	Clinic Presumptive PTB case Register (Used for both DS-TB & DR-TB)	Records of patients presenting with cough of 2 weeks or more. Records of all patients sent for Xpert testing	DOTS facility	Every time clients present themselves for exams.
TB 02	Specimen Examination Request Form for TB	Results of AFB smear microscopy, GeneXpert MTB/RIF and culture/DST	DOTS facility	Each time clients present themselves for examinations at the facility.
TB 03	TB specimen Dispatch/Shipment Form (Used for both DS-TB & DR-TB)	Movement status of specimen	DOTS facility	When moving samples
TB 04	Laboratory register for smear microscopy and Xpert MTB/RIF	Results of AFB smear microscopy and Xpert MTB/RIF	Laboratory	Each time clients present themselves for examinations at the AFB/Xpert lab.
TB 05	TB Patient Treatment Card	Patients primary information, treatment records and progress	DOTS facility	Each time a DS-TB Case is diagnosed.
TB 06	TB Patient Treatment Appointment Card	Patient's treatment appointment records	DOTS facility	Each time a DS-TB Case is diagnosed.
TB 07	TB Patient Treatment Supporter card	Patient's daily treatment records at home or at the community level	Home/Community	Each time a TS is engaged for a DS-TB Case.
TB 08	TB LGA/Facility Register (Basic Management Unit Register) – Used at both the LGA and Facility level	Patients primary information, treatment records and progress	DOTS facility/LGA	Each time a DS-TB Case is diagnosed.
TB 09	INH Prophylaxis Card	Daily records and progress of INH in-take	DOTS facility	Each time a client is placed on IPT.
TB 10	Register for the management of under 6 contacts of bacteriological positive TB Case	Daily records and progress of INH in-take	DOTS facility	Each time a client is placed on IPT.
TB 11	TBL/HIV Referral & Transfer Form	Patient's up-to-date treatment status	DOTS facility	Each time a client needs to be referred or transfer to another service point.
TB 12	TB Community Referral form	Records of presumptive TB Cases referred from the community	Community	Each time a presumptive TB Cases is identified in the community.
TB 13	TB Community Referral Register	Records of presumptive TB Cases referred from the community	Community	Each time a presumptive TB

				Cases is referred for examination.
TB 14	Treatment Interruption Tracing Form	Records of actions taken to retrieve TB Patients who interrupt treatment	DOTS facility	Each time a DS-TB Case interrupts treatment.
NTBLCP Recording tools for Drug Resistant TB activities				
DR 01	Laboratory register for AFB smear microscopy/culture and drug susceptibility testing (DST)	Results of smear/Culture and DST	Laboratory	Each time clients present themselves for exams at the AFB/Culture & DST lab.
DR 02	DR-TB Patient Referral/Transfer Form	Patients details, Facility referring and facility discharged to	DOTS facility/ DR-TB Treatment centre	Each time a DR-TB patient is being referred or Transferred from one service point to another.
DR 03	DR-TB Patient Treatment Card	Patients primary information, treatment records and progress	DOTS facility/ DR-TB treat ment centre	Each time a DR-TB Case is being enrolled for treatment.
DR 04	DR-TB Patient appointment/Hand Card	Patients details of daily intake of drugs, follow-up lab results, details of referring sites	LGA/DOTS facility/DR-TB treatment centre	At enrolment for treatment
DR 05	DR-TB Treatment Register	Patients primary information, treatment records and progress	DOTS facility/DR-TB treatment centre	Each time services are provided
DR 06	Discharge form (from DR-TB Treatment centre to DOTS Facility)	Patient's treatment and referral details.	DR-TB treatment centre	Each time a DR-TB patient is being discharged from the treatment centre.
NTBLCP Recording tools for Leprosy activities				
LEP 01	Leprosy Treatment Record Card	Patients treatment records and progress	MDT facility	Monthly
LEP 02	Leprosy Treatment appointment Card	Patients treatment records and progress	MDT facility	Monthly
LEP 03	Leprosy Central Register	Patients treatment records and progress	MDT facility	Monthly
LEP 07	Leprosy Reaction Management Register	Details of Newly detected cases of leprosy reaction	Health facility/LG	Weekly/Monthly
NTBLCP Recording tools for LMIS activities				
LMIS 01	Delivery Voucher	Evidence and details of delivery of Drugs or Commodities	National, Zonal and State Levels	Each time delivery of Drugs or Commodities are being carried out.
LMIS O2	Stock Card	Details of transaction of Drugs or commodities	All levels	Each time a transaction is being executed.

LMIS 03	Record for Returning/Transferring (RT) form	Details of Returning or Transferring of Drugs or commodities	Facility Levels	Each time Drugs or Commodities are being Returned or Transferred.
LMIS 04	QRRIF for LAB	Details of Quarterly Facility, LGA or State lab consumables utilization and request	All Levels	At the end of every quarter or when an emergency order is executed.
LMIS 05	QRRIF for DRUGS	Details of Quarterly Facility, LGA or State Drugs /Commodities utilization and request	All Levels	At the end of every quarter or when an emergency order is executed.
LMIS 06	QRRIF for R&R TOOLS	Details of Quarterly Facility, LGA or State R&R tools utilization and request	All Levels	At the end of every quarter or when an emergency order is executed.
	Adverse Drug Reaction (ADR) form	Details of symptoms and signs of adverse drug reactions	Facility/LGA Levels	Each time there is an adverse reaction to any drug.

Table 22.2: NTBLCP Recording and Reporting tools used at the LGA/State/National level

E-tb manager register (Electronic): Update on a daily and weekly basis				
S/N	**M&E formats**	**Data requirement**	**Site of use**	**Frequency of entry**
NTBLCP	**NTBLCP Recording and Reporting tools for Drug Susceptible TB activities**			
TB 15a	LGA Quarterly Report on TB Case Finding Form	Report on TB cases detected in a quarter by category	LGA/State/ Zonal/ National	Quarterly, Annually
TB 15b	Quarterly Summary form for presumptive TB cases & TB cases - case finding by LGA/Facility	Report on Presumptive and TB cases detected in the quarter under review by category	LGA/State/ Zonal/ National	Quarterly, Annually
TB 16	Quarterly Report On Sputum Conversion	Report on treatment outcome of TB cases started on treatment 3-6 months earlier	LGA/State/ Zonal/ National	Quarterly, Annually
TB 17	Quarterly TB Cohort Report Form	Report on treatment outcome of TB cases started on treatment 9-12 months earlier	LGA/State/ Zonal/ National	Quarterly, Annually
TB 18	Quarterly report on newly established DOTS & Microscopy centres	Report of all newly established DOTS and Microscopy centres in the quarter under review	LGA/State/ Zonal/ National	Quarterly, Annually
TB 19	Quarterly quality assurance report	Report on EQA activities in the quarter under review	State/Zonal/ National	Quarterly, Annually
NTBLCP Recording and Reporting tools for Leprosy & BU activities				
LEP 04	Quarter/Annual Leprosy Statistical Report	Report on Leprosy cases detected in a quarter by category	LGA/State	Quarterly, Annually
LEP 05	Quarterly Report on Leprosy Case finding Form	Report on Leprosy cases detected in a quarter by category	LGA/State	Quarterly, Annually

LEP 06	Quarterly Leprosy Cohort Report Form	Report on treatment outcome of Leprosy cases started on treatment 12-24 months earlier	LGA/State/ Zonal/ National	Quarterly, Annually
NTBLCP Recording and Reporting tools for Drug Resistant TB activities				
DR 07	Quarterly GeneXpert Summary form	Details of Laboratory activities using Xpert machine	State/Zonal/ National	Quarterly
DR 08	MD (X)R-TB monthly notification form	Details of DR-TB Case Notification	LGA/State/ Zonal/ National	Monthly
DR 09	Quarterly Report on DR-TB Cases Registration (Include suspect).	Details of DR-TB Case Notification	LGA/State/ Zonal/ National	Quarterly
DR 10	Six Month Interim Outcome Assessment	Details of patient culture & DST result after 8 months of treatment	LGA/State/ Zonal/ National	Quarterly
DR 11	Annual Report of Treatment Outcome of Category IV Regimen	Details of patient treatment outcome at end of treatment	LGA/State/ Zonal/ National	Annually

22.2 Programme monitoring indicators

22.2.1 Calculating indicators

It is important to monitor the success of TB, Leprosy and BU case detection and treatment activities. This involves:

- Keeping good records at the health facilities
- Reviewing health facility records regularly
- Compiling data
- Analysing key indicators related to TBL & BU case detection and treatment.

Refer to table 21.1 and 21.2 for recording and summary reporting tools used for the calculation of TBL & BU indicators:

Indicator: is determined by dividing a numerator (top number) by a denominator (bottom number) to obtain a proportion. It may be expressed as a percentage if multiplied by 100.

22.2.2 Analysing indicators

It is not just enough to calculate indicators. Analysis and interpretation of the data must also be done.

- Comparing the actual proportion achieved with the expected or desired proportion.
- Comparing results achieved from one quarter to the next.
- It is helpful to keep a line graph of the facility performance on the wall Report Form

The tables below give a summary of Key NTBLCP programme monitoring indicators for DRS-TB, DR-TB and Leprosy:

Table 22.3: TB case Notification indicators

S/N	Indicator	Description	Formula	Source
DRUG SUSCEPTIBLE TB				
1	TB Cases (all forms) notification rate	The number of TB cases notified for every 100,000 population.	**Numerator:** Total TB patients reported in a year (× 100,000) **Denominator:** National population in the same year.	NTBLCP annual report
2	TB case (all forms) detection rate	The total number of TB cases detected among the estimated TB cases.	**Numerator:** Annual number of new TB cases notified **Denominator:** estimated number of new TB patients.	NTBLCP annual report
3	Proportion (%) of bacteriological diagnosed TB (all forms) cases	Total number of all forms of TB cases diagnosed by bacteriological tests (Xpert, smear or culture) among total number of all forms of TB cases notified.	**Numerator:** Total number of all forms of TB cases diagnosed by bacteriological tests (Xpert, smear or culture) **Denominator:** Total number of all forms of TB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
4	Proportion (%) of bacteriological diagnosed new TB cases	Total number of new TB cases diagnosed by bacteriological tests (Xpert, smear or culture) among total number of TB (new and retreatment) cases notified.	**Numerator:** Total number of new TB patients diagnosed by bacteriological tests (Xpert, smear or culture) **Denominator:** Total number of TB (new and retreatment) cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
5	Proportion (%) of bacteriological diagnosed new pulmonary TB cases	Total number of new PTB cases diagnosed by bacteriological tests (Xpert, smear or culture) among total number of TB (new and retreatment) cases notified.	**Numerator:** Total number of new PTB cases diagnosed by bacteriological tests (Xpert, smear or culture) **Denominator:** Total number of TB (new and retreatment) cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
6	Proportion (%) of new smear positive pulmonary TB cases	Total number of new PTB cases diagnosed by AFB smear microscopy among total number of TB (new and retreatment) cases notified.	**Numerator:** Total number of new PTB cases diagnosed by AFB smear microscopy **Denominator:** Total number of TB (new and retreatment) cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports

7	Xpert positivity rate	Total number of GeneXpert MTB/RIF test with MTB detected results among total GeneXpert MTB/RIF tests conducted.	**Numerator:** Total number of GeneXpert MTB/RIF test with MTB detected results **Denominator:** Total number of GeneXpert MTB/RIF tests conducted over the same period.	GX Alert/ NTBLCP quarterly Xpert summary reports
8	Proportion (%) of all TB cases notified as a result of active case-finding	Total number of all forms of TB cases notified as a result of active case search among total number of all forms of TB cases notified.	**Numerator:** Total number of all forms of TB cases notified as a result of active case search **Denominator:** Total number of all forms of TB cases notified.	E-tb manager/ NTBLCP quarterly TB case finding reports
9	Proportion (%) of children with TB notified	Total number of children (0-14yrs) with TB notified among total number of all forms of TB cases notified.	**Numerator:** Total number of children (0-14yrs) with TB notified **Denominator:** Total number of all forms of TB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
10	Proportion (%) of under 6 child contacts of bacteriological diagnosed PTB cases screened for TB.	Total number of under 6 child contacts of bacteriological diagnosed PTB cases screened for TB among total number of under 6 child contacts of bacteriological diagnosed PTB cases.	**Numerator:** Total number of under 6 child contacts of bacteriological diagnosed PTB cases screened for TB. **Denominator:** Total number of under 6 child contacts of bacteriological diagnosed PTB cases over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
11	Proportion (%) of under 6 child contacts of bacteriological diagnosed PTB cases placed on IPT.	Total number of under 6 child contacts of bacteriological diagnosed PTB cases placed on IPT among total number of eligible under 6 child contacts of bacteriological diagnosed PTB.	**Numerator:** Total number of under 6 child contacts of bacteriological diagnosed PTB cases placed on IPT. **Denominator:** Total number of eligible under 6 child contacts of bacteriological diagnosed PTB.	E-tb manager/ NTBLCP quarterly TB case finding reports
12	Proportion (%) of all presumptive TB cases examined who were referred from the community	Total number of all presumptive TB cases examined who were referred from the community among total number of presumptive TB cases examined.	**Numerator:** Total number of all presumptive TB cases examined who were referred from the community. **Denominator:** Total number of presumptive TB cases examined over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
13	Proportion (%) of all form of TB cases referred from the community	Total number of all form of TB cases referred from the community among total number of all forms of TB cases notified.	**Numerator:** Total number of TB cases referred from the community **Denominator:** Total number of all forms of TB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
DRUG RESISTANT TB				
1	Proportion (%) of all presumptive DR-TB cases examined using rapid tests according to the national diagnostic algorithm	Total number of all presumptive DR-TB cases examined using rapid tests according to the national diagnostic algorithm among total number of presumptive DR-TB cases notified.	**Numerator:** Total number of all presumptive DR-TB cases examined using rapid tests according to the national diagnostic algorithm. **Denominator:** Total number of presumptive DR-TB cases notified over the same period.	E-tb manager/ NTBLCP quarterly DR-TB case finding reports
2	Proportion (%) of all presumptive DR-TB cases diagnosed	Total number of all presumptive DR-TB cases diagnosed using rapid tests	**Numerator:** Total number of all presumptive DR-TB cases diagnosed	E-tb manager/ NTBLCP quarterly DR-

	using rapid tests according to the national diagnostic algorithm	according to the national diagnostic algorithm among total number of presumptive DR-TB cases examined.	using rapid tests according to the national diagnostic algorithm. **Denominator:** Total number of presumptive DR-TB cases examined.	TB case finding reports

Table 22.4: Case holding Indicators for TB

SUSCEPTIBLE TB				
S/N	**Indicator**	**Description**	**Formula**	**Source**
1	Proportion (%) of TB cases managed by treatment supporters	Total number of TB cases managed by treatment supporters while on TB treatment among total number of TB cases who was started on TB treatment.	**Numerator:** Total number of TB cases managed by treatment supporters while on TB treatment **Denominator:** Total number of TB patients who started TB treatment over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
2	Proportion (%) of New smear positive TB cases who had sputum conversion from smear positive to smear negative AFB at end of 2nd month of their TB treatment	Total number of New smear positive TB cases who had sputum conversion from smear positive to smear negative AFB at end of 2nd month of their TB treatment among total number of New smear positive TB cases who were started on TB treatment	**Numerator:** Total number of New smear positive TB cases who had sputum conversion from smear positive to smear negative AFB at end of 2nd months of their TB treatment **Denominator:** Total number of New smear positive TB cases who were started on TB treatment over the same period.	E-tb manager/ NTBLCP quarterly sputum conversion reports
3	Proportion (%) of smear positive re-treatment TB cases who had sputum conversion from smear positive to smear negative AFB at end of 2nd month of their TB treatment	Total number of New smear positive re-treatment TB cases who had sputum conversion from smear positive to smear negative AFB at end of 2nd month of their TB treatment among total number of smear positive re-treatment TB cases who started TB treatment.	**Numerator:** Total number of smear positive re-treatment TB cases who had sputum conversion from smear positive to smear negative AFB at end of 2nd month of their TB treatment **Denominator:** Total number of smear positive re-treatment TB cases who started on TB treatment over the same period.	E-tb manager/ NTBLCP quarterly sputum conversion reports
DRUG RESISTANT TB				
1	Proportion of culture-positive MDR-TB cases who have a negative culture at the end of eight months of treatment – Eight month interim treatment outcome	Total number of MDR-TB cases who had sputum conversion from culture/smear positive to culture/smear negative at end of 8th month of their treatment among total number of MDR-TB cases started on treatment	**Numerator:** Total number of MDR-TB cases who had sputum conversion from culture/smear positive to culture/smear negative at end of 8th month of their treatment. **Denominator:** Total number of MDR-TB cases started on treatment over the same period	E-tb manager/ NTBLC DR-TB quarterly eight month interim reports
2	Proportion (%) of diagnosed DR-TB cases started on treatment	Total number of confirmed DR-TB patients started on treatment among total number of confirmed DR-TB patients notified.	**Numerator:** Total number of confirmed DR-TB patients started on treatment **Denominator:** Total number of confirmed DR-TB patients notified over the same period.	E-tb manager/ NTBLCP DR-TB quarterly case finding reports

3	Proportion (%) of confirmed DR-TB cases started on treatment in the community.	Total number of confirmed DR-TB patients started on treatment in the community among total number of confirmed DR-TB patients started on treatment.	**Numerator:** Total number of confirmed DR-TB patients started on treatment in the community. **Denominator:** Total number of confirmed DR-TB patients started on treatment over the same period.	E-tb manager/ NTBLCP DR-TB quarterly case finding reports

Table 22.5: TB/HIV indicators

S/N	Indicator	Description	Formula	Source
SUSCEPTIBLE TB				
1	Proportion (%) of presumptive TB cases with known HIV status	Total number of presumptive TB cases with known HIV status among the total number of presumptive TB cases notified	**Numerator:** Total number of presumptive TB cases with known HIV status **Denominator:** Total number of presumptive TB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
2	Proportion (%) of TB cases who had an HIV test result recorded in the TB register (known status)	Total number of TB cases who had an HIV test result recorded in the TB register among total number of TB patients notified	**Numerator:** Total number of TB cases who had an HIV test result recorded in the TB register **Denominator:** Total number of TB patients notified over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
3	Proportion (%) of notified TB cases with HIV positive test result recorded in the TB register	Total number of notified TB cases with HIV test result recorded in the TB register among the total number of TB cases notified	**Numerator:** Total number of notified TB cases with HIV test result recorded in the TB register **Denominator:** Total number of notified TB cases over the same period	E-tb manager/ NTBLCP quarterly TB case finding reports
4	Proportion (%) of registered HIV-positive TB patients placed on co-trimoxazole preventive therapy (CPT) during TB treatment	Total number of registered HIV-positive TB patients placed on co-trimoxazole preventive therapy (CPT) during TB treatment among total TB cases with HIV positive test result recorded in the TB register	**Numerator:** Total number of registered HIV-positive TB patients placed on co-trimoxazole preventive therapy (CPT) during TB treatment. **Denominator:** Total number of with HIV positive test result recorded in the TB register over the same period.	E-tb manager/ NTBLCP quarterly TB case finding reports
5	Percentage of HIV-positive registered TB patients who are commenced on anti-retroviral therapy (ART) during TB treatment	Total number of HIV-positive registered TB patients who are commenced on ART during ART during TB treatment among total TB cases with HIV positive test result recorded in the TB register.	**Numerator:** Total number of HIV-positive registered TB patients who are commenced on ART during TB treatment. **Denominator:** Total number of total TB cases with HIV positive test result recorded in the TB register over the same period	E-tb manager/ NTBLCP quarterly TB case finding reports
6	Proportion (%) of death of HIV-	Total number of HIV-positive registered TB cases who died among total TB cases with HIV	**Numerator:** Total number of HIV-positive registered TB cases who died	E-tb manager/ NTBLCP

	positive registered TB patients	positive test result recorded in the TB register.	Total number of HIV-positive registered TB cases who died. **Denominator:** Total number TB cases with HIV positive test result recorded in the TB register.	quarterly TB cohort reports
DRUG RESISTANT TB				
1	Proportion (%) of notified DR-TB cases with HIV positive test result recorded in the DR-TB register	Total number of notified DR-TB cases with HIV test result recorded in the DR-TB register among the total number of DR-TB cases notified	**Numerator:** Total number of notified TB cases with HIV test result recorded in the DR-TB register **Denominator:** Total number of notified DR-TB cases over the same period	E-tb manager/ NTBLCP quarterly DR-TB case finding reports
2	Proportion (%) of registered HIV-positive DR-TB patients placed on co-trimoxazole preventive therapy (CPT) during DR-TB treatment	Total number of registered HIV-positive TB patients placed on co-trimoxazole preventive therapy (CPT) during DR-TB treatment among total DR-TB cases with HIV positive test result recorded in the DR-TB register	**Numerator:** Total number of registered HIV-positive DR-TB patients placed on co-trimoxazole preventive therapy (CPT) during DR-TB treatment. **Denominator:** Total number of with HIV positive test result recorded in the DR-TB register over the same period.	E-tb manager/ NTBLCP quarterly DR-TB case finding reports
3	Proportion (%) of HIV-positive registered DR-TB patients who are commenced on anti-retroviral therapy (ART) during DR-TB treatment	Total number of HIV-positive registered DR-TB patients who are commenced on ART during ART during TB treatment among total DR-TB cases with HIV positive test result recorded in the DR-TB register.	**Numerator:** Total number of HIV-positive registered DR-TB patients who are commenced on ART during DR-TB treatment. **Denominator:** Total number of total DR-TB cases with HIV positive test result recorded in the DR-TB register over the same period	E-tb manager/ NTBLCP quarterly DR-TB case finding reports

Table 22.6: Treatment outcome Indicators for New Smear-Positive PTB cases

S/N	Indicator	Description	Formula	Source
1	Proportion (%) of new smear-positive PTB cases Cured (Cure rate)	Total number of new smear-positive PTB cases that are smear negative in the last month of treatment and on at least one other occasion among total number of new smear-positive pulmonary TB cases notified.	**Numerator:** Total number of new smear-positive PTB cases that are smear negative in the last month of treatment and on at least one other occasion. **Denominator:** Total number of new smear-positive pulmonary TB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
2	Proportion (%) of new smear-positive PTB cases who completed their treatment	Total number of new smear-positive PTB cases that completed treatment but did not meet the criteria for cure or failure among total number of	**Numerator:** Total number of new smear-positive PTB cases that completed treatment but did not meet the criteria for cure or failure	E-tb manager/ NTBLCP quarterly TB cohort reports

	(Treatment completion rate)	new smear-positive PTB cases notified.	**Denominator:** Total number of new smear-positive PTB cases notified over the same period.	
3	Proportion (%) of new smear-positive PTB cases who were successfully treated (Treatment success rate)	Total number of new smear-positive PTB cases that were cured and those that completed treatment but did not meet the criteria for cure or failure among total number of new smear-positive pulmonary TB cases notified.	**Numerator:** Total number of new smear-positive PTB cases that were cured and those that completed treatment but did not meet the criteria for cure or failure **Denominator:** Total number of new smear- positive pulmonary TB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
4	Proportion (%) of new smear-positive PTB cases who were lost to follow-up (Loss to follow-up rate)	Total number of new smear-positive PTB cases that interrupted treatment for 2 consecutive months or more among total number of new smear-positive pulmonary TB cases notified.	**Numerator:** Total number of new smear-positive cases that interrupted treatment for 2 consecutive months or more **Denominator:** Total number of new smear- positive pulmonary TB cases registered.	E-tb manager/ NTBLCP quarterly TB cohort reports
5	Proportion (%) of new smear-positive PTB cases that died (Death rate)	Total number of new smear-positive PTB cases who died from any cause while on TB treatment among total number of new smear-positive pulmonary TB cases notified.	**Numerator:** Total number of new smear-positive PTB cases who died from any cause while on TB treatment **Denominator:** Total number of new smear-positive pulmonary TB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
6	Proportion (%) of new smear-positive PTB cases that failed treatment (Treatment failure rate)	Total number of new smear-positive PTB cases who remain or became smear-positive at end of 5th month of their TB treatment or after among total number of new smear- positive PTB cases notified.	**Numerator:** Total number of new smear-positive PTB cases who remain or became smear-positive at end of 5th month or after **Denominator:** Total number of new smear- positive PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
7	Proportion (%) of new smear-positive PTB cases that was transferred-out (Transferred-out rate)	Total Number of new smear-positive PTB cases notified that were transferred to another LGA/State or country and for whom the treatment outcome is unknown among total number of new smear-positive PTB cases notified.	**Numerator** Total Number of new smear-positive PTB cases notified that were transferred to another LGA/State or country and for whom the treatment outcome is unknown **Denominator:** Total number of new smear- positive PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
8	Proportion (%) of new smear-positive PTB cases that was not evaluated	Total number of new smear-positive PTB cases that have no outcome at the end of their treatment among total number of new smear- positive PTB cases notified.	**Numerator:** Total number of new smear-positive PTB cases that have no outcome at the end of their treatment **Denominator:** Total number of new smear- positive PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
9	Proportion (%) of new smear-positive PTB cases that was moved to 2nd-line treatment register	Total number of smear-positive PTB cases who became MTB detected/RIF Resistance detected at any point of their treatment and whom are moved to 2nd-line treatment register among total number of new smear- positive PTB cases notified.	**Numerator:** Total number of smear-positive PTB cases who became MTB detected/RIF Resistance detected at any point of their treatment and whom are moved to 2nd-line treatment register **Denominator:** Total number of new smear- positive PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports

Table 22.7: Treatment outcome indicators for re-treatment PTB cases

S/N	Indicator	Description	Formula	Source
1	Proportion (%) of re-treatment PTB cases Cured (Cure rate)	Total number of re-treatment PTB cases that are smear negative in the last month of treatment and on at least one other occasion among total number of re-treatment PTB cases notified.	**Numerator:** Total number of re-treatment PTB cases that are smear negative in the last month of treatment and on at least one other occasion. **Denominator:** Total number of n re-treatment PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
2	Proportion (%) of re-treatment PTB cases who completed their treatment (Treatment completion rate)	Total number of re-treatment PTB cases that completed treatment but did not meet the criteria for cure or failure among total number of re-treatment PTB cases notified.	**Numerator:** Total number of re-treatment PTB cases that completed treatment but did not meet the criteria for cure or failure **Denominator:** Total number of re-treatment PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
3	Proportion (%) of re-treatment PTB cases who were successfully treated (Treatment success rate)	Total number of re-treatment PTB cases that were cured and those that completed treatment but did not meet the criteria for cure or failure among total number of re-treatment PTB cases notified.	**Numerator:** Total number of re-treatment PTB cases that were cured and those that completed treatment but did not meet the criteria for cure or failure **Denominator:** Total number of re-treatment PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
4	Proportion (%) of re-treatment PTB cases who were lost to follow-up (Loss to follow-up rate)	Total number of re-treatment PTB cases that interrupted treatment for 2 consecutive months or more among total number of re-treatment PTB cases notified.	**Numerator:** Total number of re-treatment PTB cases that interrupted treatment for 2 consecutive months or more **Denominator:** Total number of re-treatment PTB cases registered.	E-tb manager/ NTBLCP quarterly TB cohort reports
5	Proportion (%) of re-treatment PTB cases that died (Death rate)	Total number of re-treatment PTB cases who died from any cause while on TB treatment among total number of re-treatment PTB cases notified.	**Numerator:** Total number of re-treatment PTB cases who died from any cause while on TB treatment **Denominator:** Total number of re-treatment PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
6	Proportion (%) of re-treatment PTB cases that failed treatment (Treatment failure rate)	Total number of re-treatment PTB cases who remain or became smear-positive at end of 5th month of their TB treatment or after among total	**Numerator:** Total number of re-treatment PTB cases who remain or became smear-positive at end of 5th month or after	E-tb manager/ NTBLCP quarterly TB cohort reports

		number of re-treatment PTB cases notified.	**Denominator:** Total number of re-treatment PTB cases notified over the same period.	
7	Proportion (%) of re-treatment PTB cases that was transferred-out (Transferred-out rate)	Total Number of re-treatment PTB cases notified that were transferred to another LGA/State or country and for whom the treatment outcome is unknown among total number re-treatment PTB cases notified.	**Numerator** Total Number of re-treatment PTB cases notified that were transferred to another LGA/State or country and for whom the treatment outcome is unknown **Denominator:** Total number of re-treatment PTB cases re-treatment PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
8	Proportion (%) of re-treatment PTB cases that was not evaluated	Total number of re-treatment PTB cases that have no outcome at the end of their treatment among total number of re-treatment PTB cases notified.	**Numerator:** Total number of re-treatment PTB cases that have no outcome at the end of their treatment **Denominator:** Total number of re-treatment PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
9	Proportion (%) of re-treatment PTB cases that was moved to 2nd-line treatment register	Total number of re-treatment PTB cases who became MTB detected/RIF Resistance detected at any point of their treatment and whom are moved to 2nd-line treatment register among total number of re-treatment PTB cases notified.	**Numerator:** Total number of re-treatment PTB cases who became MTB detected/RIF Resistance detected at any point of their treatment and whom are moved to 2nd-line treatment register **Denominator:** Total number of re-treatment PTB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports

Table 22.8: Treatment outcomes indicator for all forms of TB cases

	Indicator	Description	Formula	Source
1	Proportion (%) of bacteriologically diagnosed all forms of TB cases successfully treated	Total number of bacteriologically diagnosed all forms of TB cases that were cured and those that completed treatment but did not meet the criteria for cure or failure among total number of all forms of TB cases notified.	**Numerator:** Total number of bacteriologically diagnosed all forms of TB cases that were cured and those that completed treatment but did not meet the criteria for cure or failure **Denominator:** Total number of all forms of TB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
2	Proportion (%) of bacteriologically	Total number of bacteriologically diagnosed new TB cases that were	**Numerator:** Total number of bacteriologically diagnosed new TB cases that were cured and those that	E-tb manager/ NTBLCP quarterly TB cohort reports

	diagnosed new TB cases successfully treated in private facilities.	cured and those that completed treatment but did not meet the criteria for cure or failure in private facilities among total number of all forms of TB cases notified in private facilities.	completed treatment but did not meet the criteria for cure or failure in private facilities **Denominator:** Total number of all forms of TB cases notified in private facilities over the same period.	
3	Proportion (%) of children with bacteriologically diagnosed TB who were successfully treated	Total number of children (0-14yrs) with bacteriologically diagnosed TB that were cured and those that completed treatment but did not meet the criteria for cure or failure among total number of children (0-14yrs) with bacteriologically diagnosed TB notified.	**Numerator:** Total number of children (0-14yrs) with bacteriologically diagnosed TB that were cured and those that completed treatment but did not meet the criteria for cure or failure **Denominator:** Total number of children (0-14yrs) with bacteriologically diagnosed TB notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports
4	Proportion (%) of children placed on IPT who successfully complete prophylaxis	Total number of children placed on IPT who successfully complete prophylaxis among total number of children started on IPT	**Numerator:** Total number of children placed on IPT who successfully complete prophylaxis **Denominator:** Total number of children started on IPT over the same period	E-tb manager/ NTBLCP quarterly IPT cohort reports
5	Proportion (%) of all form TB cases supported by TS throughout their TB treatment who were successfully treated	Total number of all form TB cases supported by TS throughout their TB treatment who were that were cured and those that completed treatment but did not meet the criteria for cure or failure among total number of all form TB cases notified.	**Numerator:** Total number of TB patients (all forms) supported by TS throughout their TB treatment who were that were cured and those that completed treatment but did not meet the criteria for cure or failure **Denominator:** Total number of all form TB cases notified over the same period.	E-tb manager/ NTBLCP quarterly TB cohort reports

Table 22.9: Treatment outcomes at the end of 20th month indicators for DR-TB cases

S/N	Indicator	Description	Formula	Source
1	Proportion (%) of MDR-TB cases cured (MDR TB cure rate)	Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that was cured at the end of the 20th month of treatment among total number of culture positives cases initiated on 2nd line anti-TB treatment	**Numerator:** Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that was cured at the end of the 20th month of treatment **Denominator:** Total number of culture positives cases initiated on 2nd line anti-TB treatment over the same period.	E-tb manager/ NTBLCP quarterly DR-TB interim outcome reports
2	Proportion (%) of MDR-TB cases declared treatment completed (MDR-TB	Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that were declared treatment completed at the end of the 20th month of	**Numerator:** Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that were declared treatment completed at the end of the 20th month of treatment **Denominator:** Total number of	E-tb manager/ NTBLCP quarterly DR-TB interim outcome reports

	treatment completion rate)	treatment among total number of culture positives cases initiated on 2nd line anti-TB treatment.	culture positives cases initiated on 2nd line anti-TB treatment over the same period.	
3	Proportion (%) of MDR-TB cases successfully treated (MDR-TB treatment success rate)	Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that were cured and declared treatment completed at the end of the 20th month of treatment among total number of culture positives cases initiated on 2nd line anti-TB treatment.	**Numerator:** Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that were cured and declared treatment completed at the end of the 20th month of treatment **Denominator:** Total number of culture positives cases initiated on 2nd line anti-TB treatment over the same period.	E-tb manager/ NTBLCP quarterly DR-TB interim outcome reports
4	Proportion (%) of MDR-TB cases that failed treatment (MDR-TB treatment failure rate)	Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that failed treatment at the end of the 20th month of treatment among total number of culture positives cases initiated on 2nd line anti-TB treatment.	**Numerator:** Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that failed treatment at the end of the 20th month of treatment **Denominator:** Total number of culture positives cases initiated on 2nd line anti-TB treatment over the same period.	E-tb manager/ NTBLCP quarterly DR-TB interim outcome reports
5	Proportion (%) of MDR-TB cases that died (MDR-TB death rate)	Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that died from any cause while on treatment at the end of the 20th month of treatment among total number of culture positives cases initiated on 2nd line anti-TB treatment.	**Numerator:** Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that died from any cause while on treatment at the end of the 20th month of treatment **Denominator:** Total number of culture positives cases initiated on 2nd line anti-TB treatment over the same period.	E-tb manager/ NTBLCP quarterly DR-TB interim outcome reports
6	Proportion (%) of MDR-TB cases loss to follow-up (MDR-TB lost to follow-up rate)	Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that was lost to follow-up at the end of the 20th month of treatment among total number of culture positives cases initiated on 2nd line anti-TB treatment.	**Numerator:** Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that was lost to follow-up at the end of the 20th month of treatment. **Denominator:** Total number of culture positives cases initiated on 2nd line anti-TB treatment over the same period.	E-tb manager/ NTBLCP quarterly DR-TB interim outcome reports.
7	Proportion (%) of MDR-TB cases transferred-out (MDR-TB transferred-out rate)	Total number of MDR-TB cases initiated on 2nd line anti-TB treatment transferred-out at the end of the 20th month of treatment among total number of culture positives cases initiated on 2nd line anti-TB treatment.	**Numerator:** Total number of MDR-TB cases initiated on 2nd line anti-TB treatment transferred-out at the end of the 20th month of treatment. **Denominator:** Total number of culture positives cases initiated on 2nd line anti-TB treatment over the same period.	E-tb manager/ NTBLCP quarterly DR-TB interim outcome reports
8	Proportion (%) of MDR-TB cases still on treatment	Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that are	**Numerator:** Total number of MDR-TB cases initiated on 2nd line anti-TB treatment that are still on treatment	E-tb manager/ NTBLCP quarterly DR-

		still on treatment at the end of the 20th month of treatment among total number of culture positives cases initiated on 2nd line anti-TB treatment.	at the end of the 20th month of treatment. **Denominator:** Total number of culture positives cases initiated on 2nd line anti-TB treatment over the same period.	TB interim outcome reports

Table 22.10: Leprosy Indicators

S/N	Indicator	Description	Formula	Source
1	Grade 2 Disability rate	Rate of new cases with grade 2 disability per 100,000 pop per year. i.e. Disability Grade 2 rate : A/B	**Numerator:** A = Rate (Number of cases with Grade 2 disability among new cases/ Total Number of new cases of new cases. **Denominator:** B = CDR (l Number of new cases in a year x 100,000/Total Population.	E-tb manager/ NTBLCP quarterly Leprosy case finding reports
2	Registered Prevalence rate	Total number of Leprosy cases (old and new case left on register at the end of the year) per 10,000 population	**Numerator:** Total number of Leprosy cases (old and new case left on register at the end of the year. **Denominator:** 10,000 of the population.	E-tb manager/ NTBLCP Annual Leprosy case finding reports
3	Child proportion	Total number of child leprosy cases detected among total number of new leprosy cases detected	**Numerator:** Total number of child leprosy cases detected. **Denominator:** Total number of new leprosy cases detected over the same period.	E-tb manager/ NTBLCP quarterly Leprosy case finding reports
4	Female Proportion	Total number of female leprosy cases detected among total number of new leprosy cases detected	**Numerator:** Total number of female leprosy cases detected. **Denominator:** Total number of new leprosy cases detected over the same period.	E-tb manager/ NTBLCP quarterly Leprosy case finding reports
5	Proportion (%) of a cohort of MDT patients that completed treatment as prescribed (MDT Completion Rate)	Total number of leprosy cases who completed MDT among total number of leprosy cases who were started on MDT over the same period.	**Numerator:** Total number of leprosy cases who completed MDT treatment x 100 **Denominator:** Total number of leprosy cases Started on MDT over the same period.	E-tb manager/ NTBLCP quarterly Leprosy cohort reports
6	Proportion (%) of a cohort that defaulted from treatment (Defaulter rate)	Total number of leprosy cases who defaulted while on MDT among total number of leprosy cases who were started on MDT.	**Numerator:** Total number of leprosy cases who defaulted while on MDT x 100% **Denominator:** Total number of leprosy cases who were started on MDT over the same period.	E-tb manager/ NTBLCP quarterly Leprosy cohort reports

7	Proportion (%) of a cohort of MDT patients with a worse EHF score at RFT	Total number of Cases with worse EHF score at RFT among total number of Leprosy cases Registered for MDT over the same period.	**Numerator:** Total number of Cases with worse EHF score at RFT x 100% **Denominator:** Total number of Leprosy cases Registered for MDT over the same period.	E-tb manager/ NTBLCP quarterly Leprosy cohort reports
8	Proportion (%) of a cohort of RFT patients with a worse EHF score at end of care (or period)	Total number of Cases with worse EHF at the end of care (or period) among total number of Leprosy cases Registered for MDT over the same period.	**Numerator:** Total number of Cases with worse EHF at the end of care (or period) x 100% **Denominator:** Total number of Leprosy cases Registered for MDT over the same period.	E-tb manager/ NTBLCP quarterly Leprosy cohort reports
9	Proportion (%) of registered cases on MDT	Total number of Leprosy cases on MDT among total number of Leprosy cases registered over the same period.	**Numerator:** Total number of Leprosy cases on MDT among total number of Leprosy cases Registered x 100% **Denominator:** Total number of Leprosy cases registered over the same period.	E-tb manager/ NTBLCP quarterly Leprosy cohort reports
10	Proportion (%) of a cohort of MDT patients that completed treatment as prescribed (MDT completion rate)	Total number of a cohort of MDT patients that completed treatment as prescribed among total number of Leprosy cases started on MDT over the same period.	**Numerator:** Total number of a cohort of MDT patients that completed treatment as prescribed x 100% **Denominator:** Total number of Leprosy cases started on MDT over the same period.	E-tb manager/ NTBLCP quarterly Leprosy cohort reports
11	Proportion (%) of general facilities where MDT is provided by general health workers (Level of integration of leprosy service)	Total number of general facilities where MDT is provided by GHCW among total number of health Facilities in the area over the same period.	**Numerator:** Total number of general facilities where MDT is provided by GHCW x 100% **Denominator:** Total number of health Facilities in the area over the same period.	E-tb manager/ NTBLCP quarterly Leprosy cohort reports

ANNEXES

23. REFERENCES

1. Francis J. Curry National Tuberculosis Center http://www.nationaltbcenter.ucsf.edu/catalogue/epub/downloads/GAP/GA Patient_Prep.pdf
2. WHO Treatment of Tuberculosis guidelines(for adult and children), 4th edition
3. Tuberculosis Reader, University of London, September 2013 v.3
4. WHO TB/HIV Clinical Manual, 2nd edition
5. International Standard for Tuberculosis Care, 3rd edition
6. South Africa ntcp_adult_tb_guideline 2014 edition
7. Guidance for national tuberculosis programmes on the management of tuberculosis in children 2nd edition
8. Leprosy Review, Volume 83, number 2 June 2012

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