



**FEDERAL MINISTRY OF HEALTH
NIGERIA
DEPARTMENT OF PUBLIC HEALTH**

***NATIONAL TUBERCULOSIS AND LEPROSY
CONTROL PROGRAMME (NTBLCP)***

WORKERS' MANUAL – REVISED 5TH EDITION

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FOREWORD

Tuberculosis and Leprosy are ancient diseases that (unfortunately) still constitute major public health problems in Nigeria. In addition, the social stigma associated with these diseases further compounds the problem. It has been estimated that about 460,000 new TB cases and 5,000 leprosy cases occur yearly.

In the last five years, there has been significant reduction in the registered prevalence of leprosy with some evidence of reduced transmission. This has been attributed to increased and sustained controlled activities resulting in the elimination of the disease as a public health problem at national level in Nigeria. However, there are still endemic pockets at the sub-national level. The greatest challenge in leprosy control remains rehabilitation of a large number of ex-leprosy patients who have been cured of leprosy but have disabilities.

While the elimination target for Leprosy has been achieved nationally, progress toward the achievement global targets for TB control remains slow. The control and prevention of Tuberculosis in contemporary times has many faces and challenges. These among others include the impact of HIV/AIDS and the emergence of multi-drug resistant tuberculosis (MDR-TB). The HIV/AIDS pandemic is not only fuelling the burden of Tuberculosis but also poses great challenge to its diagnosis and management. The recorded HIV prevalence among TB cases in Nigeria is estimated at 27% (WHO, 2009).

Apart from the HIV/AIDS situation, the emergence of MDR-TB not only presents additional burden to the control of TB but is capable of obliterating all the gains of TB control over the years. Although the current burden is currently unknown, the WHO estimates MDR-TB rates of 1.8% of the new TB cases and 9.4% among re-treatment cases. Institution-based reported from 2006 to September 2009 showed that 97 MDR-TB cases have been notified so far in the country. This is certainly a tip of the ice-berg and it is hoped that the on-going TB drug drug resistance survey (DRS) will establish exactness in the burden of MDR-TB.

In response to the TB/HIV problem, the NTBLCP is collaborating with partners to scale up the TB/HIV collaborative activities in Nigeria. The ongoing scale up of ART sites is done in centres with existing DOTS services and it is also the policy of the NTBLCP to ensure that all ART sites have DOTS service.

The NTBLCP in collaboration with the National MDR-TB committee is also working relentlessly to institutionalize the programmatic management of MDR-TB including

routine surveillance. TB reference laboratories are being established to enhance access to culture and drug susceptibility testing (DST). Specialized treatment centres are also being established and treatment services will commence shortly following the approval by the Green Light Committee for the procurement of quality-assured second-line anti-TB drugs.

Furthermore, to achieve a robust TB control and prevention in the country, the Federal Ministry of Health, wholly adopted the global Stop TB Control Strategy in 2006. This strategy has further been modified in line with contemporary global realities.

The review of the 5th edition of the Workers' Manual is essentially to align our control efforts with the current global initiatives and consensus and national realities. It is hoped that this revised 5th edition of the Workers' Manual 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, TB/HIV co-infection, Leprosy and Buruli Ulcer.

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April 2010

ACKNOWLEDGEMENTS

The revised 5th edition of the Workers' Manual is an indispensable tool for the effective implementation of the National Tuberculosis and Leprosy Control Programme (NTBLCP). It contains the technical and operational instructions for all health workers implementing TB and Leprosy control activities and managing TB, TB/HIV, Leprosy and Buruli Ulcer diseases in Nigeria. I am informed that due cognisance of contemporary issues and initiatives have been well considered in this review exercise.

The enormous task of reviewing of the 5th edition of Workers' Manual would not have been successfully completed without the support of experts from different fields working in the programme mentioned in the list of contributors. We are indeed grateful for their assistance.

We wish to express our thanks to all development partners for their support of the effective implementation of activities of NTBLCP, including: World Health Organization (WHO), members of the International Federation of Anti-Leprosy Association (ILEP) in Nigeria, namely The Leprosy Mission Nigeria (TLMN), Netherlands Leprosy Relief (NLR), German Leprosy and TB Relief Association (GLRA) and the Damien Foundation Belgium (DFB); International Union Against TB and Lung Disease (IUATLD), Canadian International Development Agency (CIDA), Department for International Development (DFID), United States Agency for International Development (USAID), and other Voluntary Organizations.

Finally special thanks go to TBCAP, WHO and ILEP for co- financing the production of this Revised Workers' Manual and their technical support.

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GLOSSARY OF ABBREVIATIONS USED IN THIS BOOK

Abbreviation	Meaning
AFB	Acid-Fast Bacilli
AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-Retroviral Therapy
BCC	Behavioural Change Communication
BCG	Bacille Calmette-Guerin
CDC	Centers for Disease Control and Prevention
CHEW	Community Health Extension Worker
CHO	Community Health Officer
CIDA	Canadian International Development Agency
CPT	Cotrimoxazole Preventive Therapy
CTBC	Community TB Care
DFB	Damien Foundation – Belgium
DFID	Department For International Development
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment Short Course
EFZ	Efavirenz
EPTB	Extra Pulmonary Tuberculosis
EQA	External Quality Assurance
4FDC	Four Fixed Dose Combination
FMOH	Federal Ministry of Health
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHS	General Health Services
GCP	Good Laboratory Practice
GLRA	German Leprosy Relief Association
HCT	HIV Counselling and Testing
HIV	Human Immunodeficiency Virus
HOD	Head Of Department
IEC	Information Education and Communication
ILEP	International Federation of Anti-Leprosy Associations
IHVN	Institute of Human Virology Nigeria
IPT	Isoniazid Preventive Therapy
IRIS	Immune Reconstitution Inflammatory Syndrome
ISTC	International Standard for TB Care
IUATLD	International Union Against Tuberculosis and Lung Disease
LGA	Local Government Area
LGTBLS	Local Government Tuberculosis and Leprosy Supervisor
MB	Multi-Bacillary
M&E	Monitoring and Evaluation
MDR	Multi-Drug Resistance

MDT	Multi-Drug Therapy
MO	Medical Officer
NGO	Non-Governmental Organisation
NLR	Netherlands Leprosy Relief
NPI	National Programme on Immunization
NTBLCP	National Tuberculosis and Leprosy Control Programme
PAL	Persons Affected by Leprosy
PALH	Practical Approach to Lung Health
PB	Pauci-Bacillary
PHC	Primary Health Care
PLHIV	Persons Living With HIV/ AIDS
PMTCT	Prevention of Maternal To Child Transmission
PPM	Public Private Mix
PPP	Public-Public-Private Partnership
PTB	Pulmonary Tuberculosis
QAS	Quality Assurance System
RFT	Release From Treatment
SCC	Short Course Chemotherapy
SSS	Slit Skin Smear
ss+	Sputum smear positive
STBLCO	State Tuberculosis and Leprosy Control Officer
STD	Sexually Transmitted Diseases
SMOH	State Ministry of Health
ST	Sensory Test
TBL	Tuberculosis and Leprosy
TLMN	The Leprosy Mission Nigeria
USAID	United State Agency for International Development
VA	Visual Acuity
VMT	Voluntary Muscle Test
WHO	World Health Organisation
ZN	Ziehl Nielsen

CHAPTER 1 GENERAL OVERVIEW

1.1 INTRODUCTION

Tuberculosis and Leprosy constitute serious causes of high morbidity and mortality, especially in association with the HIV/AIDS epidemic. The social stigma associated with these diseases further compounds the problem

The national registered number of leprosy cases on register at the end of 2008 was 6,906 resulting in the prevalence rate of 0.46 per 10,000 people. Disability proportion among these cases was 14%. Though the elimination target has been achieved at the national level, however, leprosy remains a problem in a few states.

Concerning Tuberculosis, Nigeria ranked 4th among the 22 high burden countries for TB in the world and the 1st in Africa with a 2007 estimate of 460,000 new cases occurring per year. A total 90311 of all forms of TB cases were notified from the 37 States in 2008. 55% of the 83,263 new cases detected were smear positive (46,026). The TB burden is further compounded by the high HIV prevalence of 4.4% in the country. The recorded HIV prevalence among TB patients increased from 2.2% in 1991 to about 27% in 2008. HIV is the most powerful risk factor for developing TB disease.

The effort of the Federal Government of Nigeria in the fight against these diseases is being supported by the following development partners: World Health Organization (WHO), The Leprosy Mission Nigeria (TLMN), Netherlands Leprosy Relief (NLR), German Leprosy and TB Relief Association (GLRA), Damien Foundation Belgium (DFB), International Union Against TB and Lung Diseases (IUATLD), Canadian International Development Agency(CIDA), Department for International Development (DFID), United States Agency for International Development Agency (USAID), TB Control and Assistance Program (TBCAP), Centers for Disease Control and Prevention (CDC) and other voluntary organization for the effective implementation of the NTBLCP.

1.2 ORGANISATION OF HEALTH SERVICES IN NIGERIA

Health care services in Nigeria are provided at 3 levels namely: Primary, Secondary and Tertiary. The Local Government level is responsible for primary level of care, State Government for secondary level of care and provision of technical guidance to the LGAs, and the Federal Government is responsible for the tertiary level of care as well as policy formulation and technical guidance to the State level.

In 1993, the Federal Government established the National Primary Health Care Agency to render direct technical support to the implementation of primary health care activities at the LGA Level. The Agency operates from 6 (six) zonal offices across the nation.

The private sector, non-governmental organizations, and local communities also provide considerable services at all the levels of health care. The private sector accounts for about 50% of health care delivery in the country.

1.3 THE NATIONAL TB AND LEPROSY CONTROL PROGRAMME FRAMEWORK

The Federal Government of Nigeria established the National Tuberculosis and Leprosy Control Programme in 1988 within the Department of Public Health in the Federal Ministry of Health. It is headed by the National Coordinator who is supported by a team of medical officers, laboratory scientists and other support staff. Similarly, the State TB and Leprosy Control Programme (STBLCP) is located within the Department of Public health or Primary Health Care in the respective State Ministries of Health. Each STBLCP team comprises of a medical Officer as the State TB/Leprosy Control Officer and 2-3 TBL Supervisors (TBLS).

Each of the 774 LGAs has a Local Government TB/Leprosy Supervisor (LGTBLS) who provides technical guidance to the implementation of activities at the peripheral health facilities in the LGA.

1.3.1 Programme Objectives

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

1.3.2 Strategies

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

1.3.3 National Tuberculosis and Leprosy Training Centre.

1.3.3.1 Mandate

The National Tuberculosis and Leprosy Training Centre, Zaria was established in January, 1991 as the Human Resource Development unit of the National TB & Leprosy Control Programme. The Centre provides training and medical services. The second National Tuberculosis Reference Laboratory is also situated at the Centre.

The mandate of the centre is as follows:

- Training manpower for the National TBL Control programme (NTBLCP).
- Provision of TB, TBHIV and Leprosy services (diagnostic, chemotherapy etc.)
- Operational research relating to TB, HIV and Leprosy.

1.3.3.2 Strategic Directions

- Increase focus on decentralisation of trainings to the field.
- Increase focus on material and tools development
- Integrate HIV/AIDS into standard courses of the centre
- Expand the pool facilitators by using program managers from the field and partners
- Maintain active learning methodology for training of participants
- Start electronic learning environment
- Coordination of all training activities in the field.
- Maintain referral facility for TB, HIV/AIDS and Leprosy.
- Emphasis on rehabilitation of leprosy patients
- Stimulate research activities for the NTBLCP

1.3.4 Job Descriptions of Key NTBLCP Staff

1.3.4.1 National Coordinator (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:

- Coordinates all activities of TB, Leprosy and Buruli Ulcer control in the country.
- Provision of managerial and technical support for the Zonal TBLCP Coordinators 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.
- Ensure 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.

Medical and other support staff of the National Coordinator's Office will assist the National Coordinator

1.3.4.2 State TBL Control Officer (STBLCO)

Qualifications: Medical Officer with post-graduate training in Public Health

Responsible to: Director of Public Health, State Ministry of Health.

The State TBL Control Officer's responsibilities include:

- Management of TBL activities at the State level.
- Management, coordination, and supervision of all programme activities at State and Local Government level.
- Assist in the diagnosis and management of difficult TBL 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 cooperation with NGOs supporting the State programmes.
- Perform any other duties that may be assigned

1.3.4.3 The Local Government TBL Supervisor (LGTBLS)

Qualifications: CHO, Nurse, Environmental Health Officer or Senior CHEW with at least 5 years 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 coordinating TB and Leprosy 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 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 and leprosy control activities in the LGA, including the LGA Central Registers. Ensure 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 Coordinator in carrying out health education activities in the LGA.
- Undertaking activities for disability prevention and rehabilitation.
- Performing any other duties that may be assigned

1.3.4.4 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 QA Officer is responsible for:

- Setting up QA system in the State in conjunction with the Control officer.
- Carry out regular supervision to each of the laboratories aimed at ensuring that 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.

1.3.4.5 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: The Officer in charge of the health facility.

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 within 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.

1.3.4.6 Medical Officer at the Referral Hospital

Qualifications: Medical Officer

Responsible to: Medical Director in charge of the Hospital/Director of Medical Services/Chief Medical Officer

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
- Cooperating with other health institutions in the state
- Performing any other duties that may be assigned.

1.3.4.7 Physiotherapist

Qualifications: Registered Physiotherapist

Responsible to: Medical Officer in charge

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.
- Coordinating self-care groups in the settlements adjacent 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.

1.3.4.8 General Health Staff: Nursing and Primary Health Care staff.

Qualifications: Registered Nurse, Community Health Officer, Community Health Extension Workers

Responsible to: Medical Officer in charge of the hospital, Officer in charge of health facility or PHC coordinator as may be appropriate.

The General Health Worker's responsibilities include:

- Identifying TB suspects
- Ensure TB diagnosis through sputum examination
- Diagnosis of Leprosy
- 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.
- Trace and retrieve patients who interrupt treatment
- Carry out patient education on TBL
- Undertaking public enlightenment

The following are the components of the STOP TB strategy and implementation approaches.

2.3.1 Pursue high-quality DOTS expansion and enhancement

- Political commitment with adequate and sustained financing
- Early case detection through quality-assured bacteriology
- Standardized treatment with supervision and patient support
- An effective drug supply and management system
- Monitoring and evaluation system, and impact measurement

2.3.2 Address TB/HIV, MDR-TB and the needs of the poor and vulnerable population

- Scale-up collaborative TB/HIV activities
- Scale - up prevent and control multi-drug resistant TB
- Address the needs of TB contacts, poor and vulnerable population (prisoners, refugees, other high-risk groups and special situations)

2.3.3 Contribute to health system strengthening based on primary health care

- Help improve health policies, workforce development, financing, supplies, service delivery and information.
- Strengthen infection control in health services, other congregate settings and house holds
- Upgrade laboratory networks and implement innovations that strengthen systems, including the Practical Approach to Lung Health (PAL)
- Adapt innovations from other fields and sectors and foster action on social determinants of health

2.3.4 Engage all care providers

- Involve all public, voluntary, corporate and private providers through Public-Public, and Public-Private Mix (PPM) approaches
- Promote use of International Standards for Tuberculosis Care (ISTC)

2.3.5 Empower people with TB and communities through partnership

- Pursue advocacy, communication and social mobilization
- Foster community participation in TB care, prevention and health promotion
- Promote use of Patients' Charter for Tuberculosis Care

2.3.6 Enable and promote research

- Conduct Programme-based operational research and introduce new tools into practice
- Advocate for and participate in research to develop new diagnostics, drugs and vaccines

2.4 IDENTIFYING TUBERCULOSIS SUSPECT

Tuberculosis (TB) is a chronic, infectious disease caused by bacteria generally referred to as '*Mycobacterium tuberculosis complex*'. Almost every organ in the body can be affected, but involvement of the lungs accounts for more than 80% of TB cases. TB affecting the lungs is called *Pulmonary Tuberculosis* (PTB), while that affecting other organs is called *Extra-pulmonary TB* (EPTB).

The most important source of infection is an untreated Pulmonary TB (PTB) patient. When such a person coughs, spits or sneezes, tiny droplet nuclei containing the tubercle germ are released. Transmission is through inhaling these droplet nuclei.

2.4.1 Identifying Pulmonary TB (PTB) Suspects

The commonest symptom of PTB is persistent cough lasting 2 weeks or more, which is usually accompanied by one or more of the following symptoms:

- Weight loss
- Tiredness
- Fever
- Night sweats
- Chest pain
- Shortness of breath
- Loss of appetite
- Coughing up blood

Any person coughing for 2 weeks or more, with or without the above symptoms should be suspected of PTB.

2.4.2 Identifying Extra-pulmonary TB suspects

A person with Extra-pulmonary TB will show symptoms depending on the affected organ and some general symptoms (weight loss, persistent fever, night sweats).

Sites and Symptoms of EPTB

ORGAN AFFECTED	SYMPTOMS
Vertebral spine	Back pain, swelling on spine
Bone	Long standing pain and swelling of the bone
Joints	Painful joint swelling, usually affecting one joint
Kidney and urinary tract	Painful urination, blood in urine, frequent urination, lower back pain(loin pain)
Upper respiratory tract (larynx)	Hoarseness of voice, pain on swallowing
Pleural membrane of lungs	Chest pain, difficulty in breathing, fever

Meninges of the brain	Headache, persistent fever, neck stiffness, vomiting, irritability, convulsions, loss of consciousness.
Lymph node	Painless swelling of the node, may drain pus
Skin	Longstanding ulcer despite antibiotic treatment, draining pus

Any person suspected of Extra-pulmonary TB should be referred to a Medical Officer for diagnosis. If the patient is also coughing, sputum should equally be examined.

2.4.3 Suspecting TB in Children

Tuberculosis should be suspected in children with any or combination of the following symptoms:

- Low grade fever not responding to malaria treatment
- Night sweats
- Loss of weight
- Loss of appetite
- Failure to thrive
- Lymph node swellings
- Joint or bone swellings
- Angle deformity of the spine
- Listlessness
- Neck stiffness, headache, vomiting (TB meningitis)

Any child suspected of having TB should be referred to a Medical Officer for diagnosis.

2.5 DIAGNOSIS

The diagnosis of tuberculosis rests mainly on the identification of the tubercle bacilli by sputum smear microscopy. Any individual suspected of having Tuberculosis disease should be requested to submit three (3) sputum samples for examination.

2.5.1 Procedure for Sputum Collection

2.5.1.1 Educating the TB Suspect

Inform the TB Suspect that:

- He/she will give 3 sputum specimens to be examined in a laboratory for TB germs
- If the germs are seen the suspect will receive treatment and be cured

2.5.1.2 Before collection of sputum, the General Health Worker should:

- Explain to the patient the reason for collection of sputum;
- Fill the 'NTBLCP Clinic Sputum Register'
- Fill a 'Sputum Examination Request Form'
- Write the number of the patient on the side of the sputum container, according to the clinic Sputum Register;
- Ensure that patients who have chewed any food immediately before sputum collection have rinsed their mouth with water;
- Ensure that the sputum collection takes place in a well-ventilated place or in an open air space;
- Where possible ensure some privacy to the patient;
- Ensure that no one is standing near the patient during sputum collection.

2.5.1.3 Collecting Sputum Samples:

- Ask the patient to inhale deeply and cough from within (demonstration may be necessary);
- The patient should spit the sputum carefully into the container to avoid contamination of the outside part;
- If the specimen is not suitable, e.g. saliva, then repeat deep coughs to produce better sample.

The three sputum samples for smear microscopy should be collected and submitted within 24 hours following the schedule below:

Day	Sample	Explanation
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
	Sample 3	Patient provides another “ on the spot ” sample under supervision

2.5.1.4 After Sputum Collection:

- The container should be firmly closed using the lid;
- Hands should be washed with soap and water;
- Sputum specimens should be stored preferably in a refrigerator or in a cool, dry and dark place, e.g. a cupboard;
- The General Health Worker must arrange for specimens to be sent to the laboratory as soon as possible, not later than one week after collection;
- Each specimen should be accompanied with a completed 'Sputum Examination Request Form'
- Where and when applicable, the Sputum Dispatch Register (NTBLCP/TB3) should be filled by the health worker delivering the sputum to the laboratory.

2.5.2 Labelling the Sputum Container

It is important that sputum containers are labelled on the **side** of the cup and not on the cover, to avoid confusion in the laboratory.

The number on the sputum container is derived from the 'TB Clinic Sputum Register' as follows:

Clinic code / Number of examination in the current month/ month/ number of specimen

For example, the 3 sputum specimens that were taken from a suspect at Alafara Clinic in August, being the 56th patient that was screened in the month, would be labelled:

1st specimen - A/56/08/1

2nd specimen - A/56/08/2

3rd specimen - A/56/08/3

Every sputum sample should be taken to the laboratory, even if only one or two samples could be collected from a suspect.

2.5.3 Labelling of Slides for TB Laboratory Microscopy

For reasons of ease of reference and standard operation, there is need to code label ZN slides in each centre to achieve uniformity. The codes are determined as follows:

State: As in this Workers' Manual (page 157)

Local Government Area: As approved by the STBLCP

Laboratory unit number:	As approved by STBLCP
Year of Operation:	International Calendar, last two digits only
Laboratory Serial No:	As adopted by Standard Laboratory Practice. Obtainable from laboratory Register. Universally starts from 01 in January and ends on 31 st December each year.
Specimen No:	Identified appropriately
E.g.	
01/01/01/08 100-1	Abia State, Aba South LGA, Lab unit 1, in year 2008 Lab serial number 100, Sample 1.

2.5.4 Interpretation of Results

The results of sputum can either be negative or positive. Positive includes: scanty (exact number of bacilli seen), 1+, 2+ and 3+.

If at least two sputum specimens are positive for acid-fast bacilli (AFB), the patient is classified as smear-positive TB. Detailed interpretation is as described in the flow chart (Management of TB Suspect) with actions to take.

Explanation of indices on the flow chart:

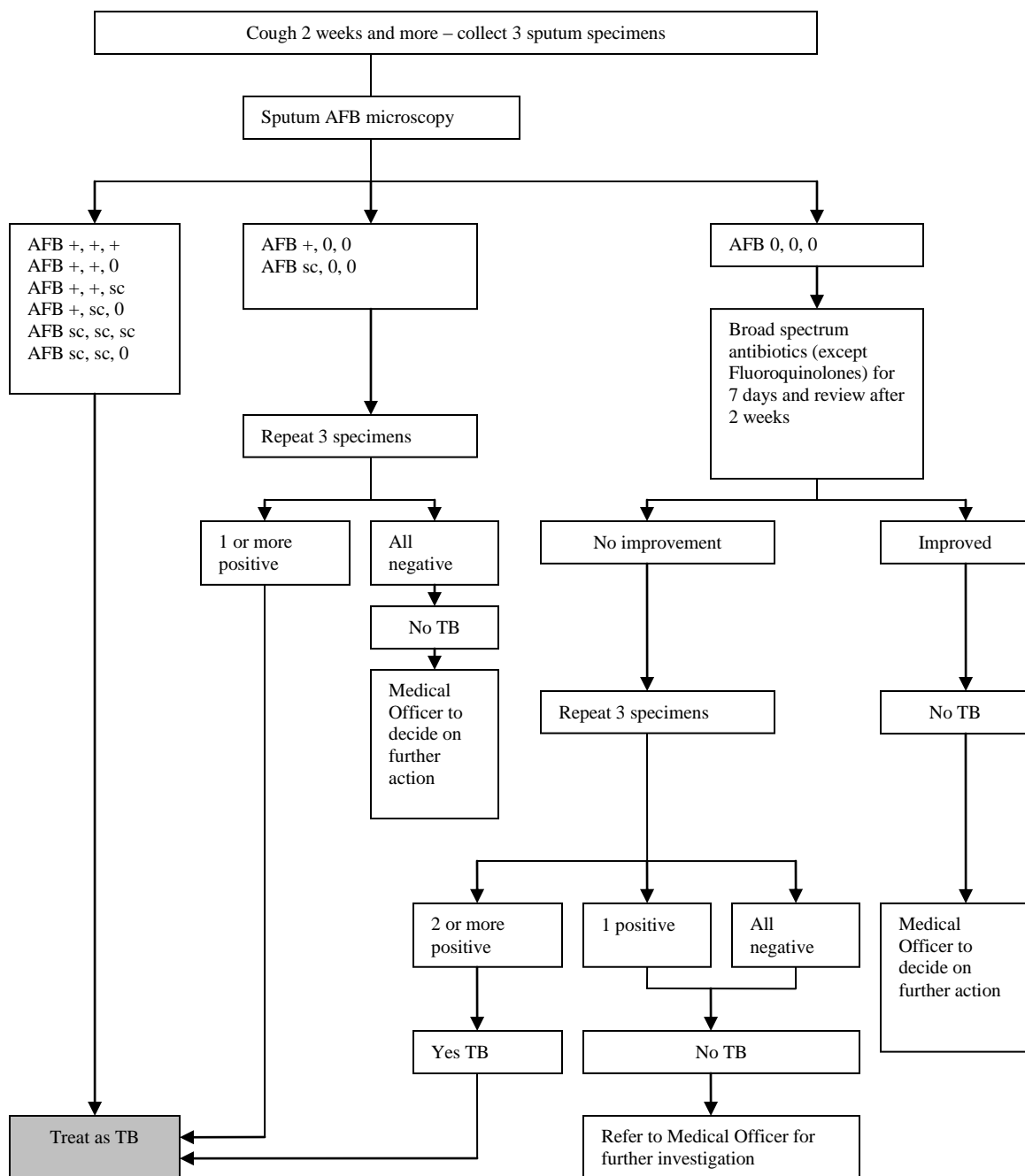
- + means a positive sputum result: usually expressed in grades 1+, 2+ or 3+;
- sc means a scanty positive sputum result;
- O means a negative sputum result

Remark 1: If a patient is critically ill, he should immediately be referred to a Medical Officer after sputum has been taken.

Remark 2: If only one or two sputum samples could be collected from a suspect and only one of these specimens is positive, the patient should be traced and asked to produce additional sputum specimens.

2.5.5 Management of TB Suspect

Management of TB suspects (page 16)



Note:

- HIV positive clients with one sputum sample positive should be considered as TB cases.**

2. HIV positive clients with three smear negatives samples should be referred to medical officer immediately for further evaluation (using X-ray).

2.5.6 Guidelines and Procedures for Educating Patients and their Family at Time of Diagnosis

Inform patient / family about/that:

- The sputum result and the type of disease diagnosed
- The cause of TB and how it is transmitted
- The disease is curable, provided the correct drugs are taken for 8 month without a break
- Number and types of drugs to take
- The need to bring symptomatic contacts for screening (the family should know the signs and symptoms of TB and be willing to bring any suspect and also to support the patient to be regular on the treatment).
- The patient is no longer infectious if he takes his/her treatment regularly.
- Duration and how the nature of the treatment will be at the hospital/clinic and at home
- Symptoms will disappear but must continue to take the drugs as directed, if not the disease will come back in a worse form
- How to collect drugs on work-free days, inaccessible time etc.
- Importance of the support of the family to ensure strict compliance by the patient.
- Signs and symptoms of possible side effect of drugs and what to do (Examples: Skin rash, joint pains, yellow eyes, poor vision, imbalance, and red discoloration of urine). All these should be reported immediately.
- Sputum examination will be conducted at the end of months 2, 5, and 7 to determine the effect of the drugs taken. However, if the result still shows the germs, the treatment may change.

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

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

2.5.7 Diagnosis of TB in Children

The diagnosis of TB in children can be very difficult owing to the wide range of symptoms. Sputum cannot often be obtained from children and in any case it is often negative even on culture. Symptoms in children are not typical. The diagnosis should therefore be based on clinical findings (especially failure to thrive or weight loss), family history of contact with a smear positive case, X-ray examination and tuberculin testing, culture (if available and non-response to broad spectrum antibiotic treatment.

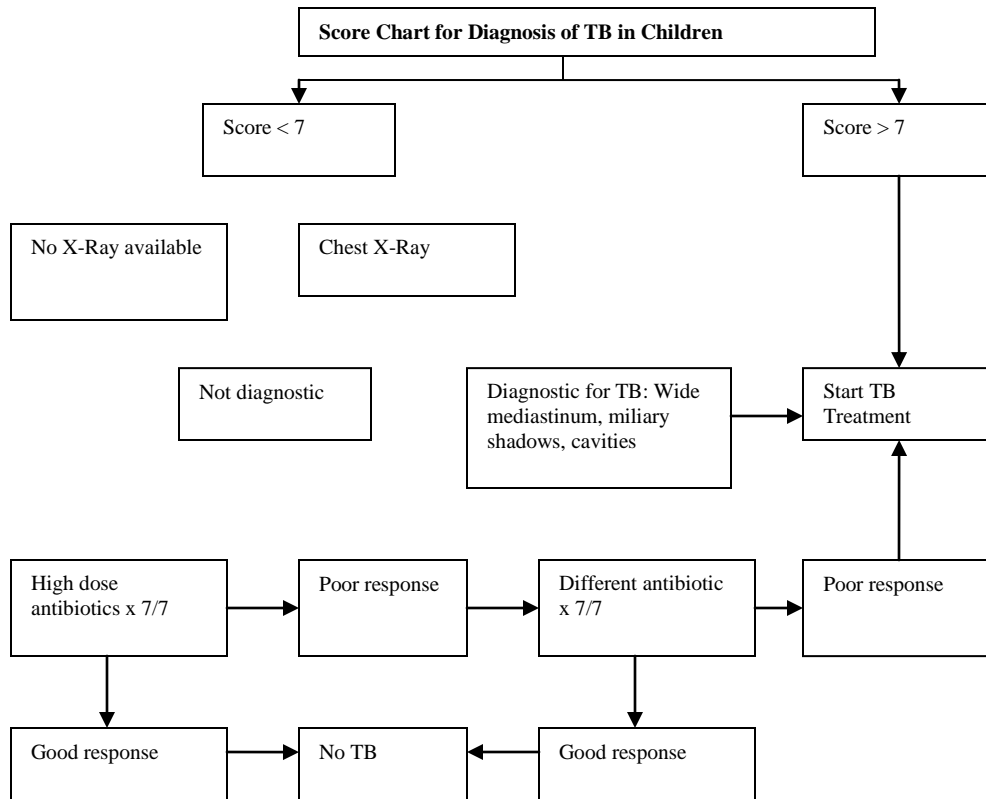
A score chart below can help to reach the diagnosis of tuberculosis. Older children who are able to cough up sputum should go through the same assessment as adults using smear microscopy as the "gold standard".

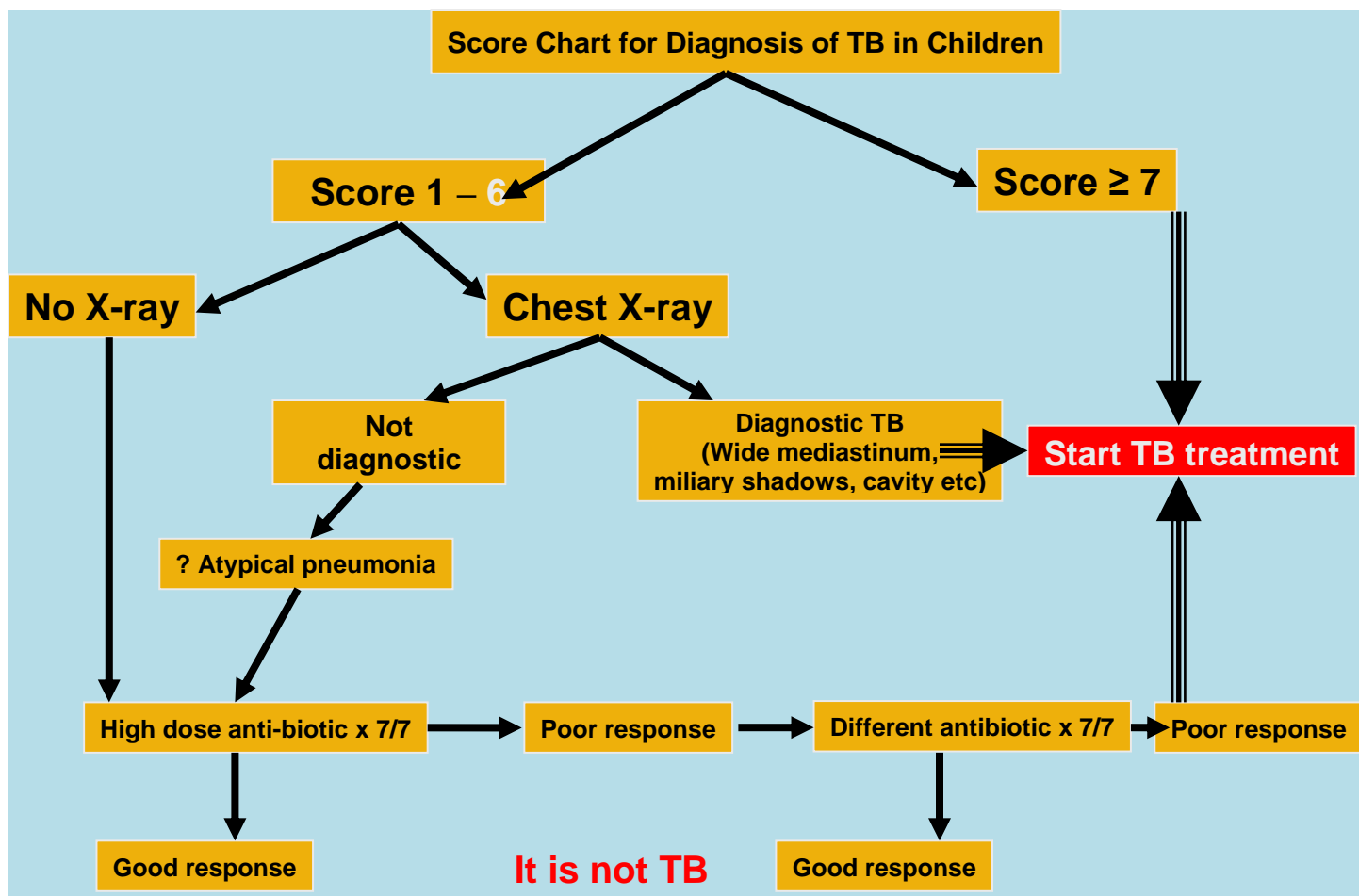
2.5.7.1

Score Chart for the Diagnosis of Tuberculosis in Children

SCORE IF SIGN OR SYMPTOM IS PRESENT						
	0	1	2	3	4	Score
GENERAL FEATURES						
Duration of illness	Less than 2 weeks	2-4 weeks		More than 4 weeks		
Failure to thrive or weight loss	Weight gain		No weight gain		Weight loss	
TB contact	None	Reported not proven		Proven Smear+ /EP	Proven Smear+	
Tuberculin test				Positive		
Malnutrition				Not improved after 4 weeks		
Chronic infant disease		Recurrent		No response to antibiotics		
LOCAL FEATURES						
Chest x-ray				TB suggestive feature like infiltration, cavity or hilar lymphnodes		
Lymph nodes				Cervical, sub-mandibular		
Swelling of bone or joint				Suggestive feature on X-ray		
Ascitis			Without abdominal mass	With abdominal mass		
Meningitis				Chronic C.N.S. signs		
Angle deformity of the spine					X-ray feature	
TOTAL SCORE						

A score of 7 or more indicates a high likelihood of tuberculosis





2.6 CLASSIFICATION OF TB PATIENTS - CASE DEFINITIONS

In order to prescribe appropriate treatment, case definitions according to history of previous treatment are important. TB patients are classified as follows:

- 2.6.1 **New Case (N):** A patient who has never had treatment for TB or who has taken anti-TB drugs for less than *four weeks*.
- 2.6.2 **Relapse (R):** A TB patient who previously received treatment and was declared cured or completed a full course of treatment and has once again developed sputum **smear-positive** TB

- 2.6.3 Treatment failure (F):** A smear positive patient who while on treatment remained, or became smear positive again *five months or later* after commencement of treatment
- 2.6.4 Return after default (RAD):** A TB patient who completed at least four weeks of **Category 1** treatment and returned smear positive after at least **8 weeks** of interruption of treatment
- 2.6.5 Transfer in (T.I.):** A TB patient already registered for treatment in one LGA/State who is transferred to another LGA/State where s/he continues treatment.
- 2.6.6 Other (O):** A TB patient who does not fit into one of the above case definitions. For example:
- A patient who has been treated for TB outside the NTBLCP (network) for more than four weeks and is smear-positive.
 - A patient who previously received treatment and was declared cured or completed a full course of treatment and is again diagnosed by a Medical Officer as sputum smear negative TB.

A patient who previously received treatment but outcome of treatment is un-known and now smear positive. A patient who remains smear positive after completing re-treatment regimen(cat 2) usually refers as chronic case and should be consider as MDR suspect see section ----- MDR suspect.

2.7 ADMINISTERING TB TREATMENT

Tuberculosis is curable, provided patients are detected early and treated promptly according to the NTBLCP guidelines. Once a TB patient has been properly classified, the appropriate treatment regimen should be prescribed.

2.7.1 Directly Observed Treatment (DOT)

Effective treatment is achieved through Directly Observed Treatment (DOT), which means that the patient swallows the tablets under the supervision of a health worker or designated treatment supporter (family or community member). Therefore the health workers should ensure that patients receive treatment in health facilities closest to the patient's home. Refer if necessary.

At the time of diagnosis, the General Health Worker should:

- Complete a 'TB treatment card' (NTBLCP/TB5) and a 'TB appointment card' (NTBLCP/TB6) for every diagnosed patient according to the NTBLCP guidelines
- For smear negative and extra-pulmonary patients, attach the Medical Officer's report to the treatment card.

During next visit to facility, the LGTBLS enters information on all newly-diagnosed patients in the 'LGA TB Central Register' (NTBLCP/TB7) according to the NTBLCP guidelines

2.7.2 Treatment Regimen

The following 1st line drugs are used within the NTBLCP for TB treatment:

R: Rifampicin	H: Isoniazid	E: Ethambutol
Z: Pyrazinamide	S: Streptomycin	

These drugs are presented as loose or in fixed-dose combinations (FDC)

Types of treatment regimens: Categories 1 and 2

1. **Category 1 regimen Adult: (2RHZE/6EH or 2RHZE /4RH)** for new cases (CAT 1)
2. **Category 1 regimen Children: (2RHZ/4RH)** for new cases (CAT 1)
3. **Category 2 regimen Adult: (2SRHZE/1RHZE/5RHE)** for relapses, failures, RAD and others - Retreatment chemotherapy (CAT 2)
4. **Category 2 regimen Children: (2SRHZE/1RHZE/5RHE)** for relapses, failures, RAD and others - Retreatment chemotherapy (CAT 2)
5. **Regimen for Multi-Drug Resistance TB see MDR section**

A treatment regimen consists of two phases:

1. *The initial intensive phase:* This consists of 2 months of fully supervised daily administration of drugs in new cases (CAT 1). This phase extends to 3 months in retreatment cases (CAT 2).
2. *The continuation phase:* This consists of **6 months (EH) or 4months (RH)** of monthly drug collection for new cases (Cat. 1), and is usually self-administered treatment for EH, while patients on RH should be observed daily. For retreatment cases (CAT 2), the continuation phase is **5 months** and treatment administration should be supervised daily.

Prescribing anti-tuberculosis drugs

Information required in prescribing correct treatment regimen dosages is:

- Pre-treatment weight (this weight is used to determine the dosage required throughout the **entire** treatment): *Use the drug table with the weight-bands to determine dosage*
- Pregnancy (ask for last menstrual period): *Avoid streptomycin in pregnancy*
- Age: *Avoid Ethambutol for children less than 6 years*

Ask if the patient is taking birth control medications, anti-epileptic medications, corticosteroids, antiretroviral treatment and oral treatment for diabetes or oral anticoagulants.

IF ANSWER IS "YES" TO ANY OF THE ABOVE REFER TO THE MEDICAL OFFICER.

2.7.3 Treatment Regimens: Fixed Dose Combinations (FDC)

2.7.3.1 ADULTS

Category 1 Regimen for New Cases): 2RHZE/6EH or 4RH

Regimen	Pre-treatment weight			
	> 70 kg	55-70 kg	38-54 kg	30-37 kg
Intensive phase: daily <i>supervised</i> for 2 months Combined tablet of RHZE (150mg + 75mg + 400mg + 275mg)	5	4	3	2
Continuation phase: daily for 6 months (monthly collection) Combined tablet of EH (400mg + 150mg) *OR	3	3	2	1
Continuation phase: daily <i>supervised</i> for 4 months Combined tablet of RH (150mg + 75mg)	5	4	3	2

Remark: If the patient weighs less than 30 kg, he should be given loose tablets.

Category 2 Regimen for Relapses, Failures, RAD and Others: 2SRHZE/RHZE/5RHE

Regimen	Pre-treatment weight			
	> 70 kg	55-70 kg	38-54 kg	30-37 kg
<i>Intensive phase: daily <u>supervised</u> for 3 months</i> Combined tablet of RHZE (150mg + 75mg + 400mg + 275mg) <i>Add in the first two months daily:</i> Streptomycin	5 1 gram	4 1 gram	3 0.75 gram	2 0.5 gram
<i>Continuation phase: daily intake for 5 months, <u>supervised</u></i> Combined tablet of RHE (150mg + 75mg + 275mg)	5	4	3	2

i. Streptomycin should NOT be given to pregnant women.

ii. Patients >45 years should not be given more than 0.75g of streptomycin irrespective of weight

2.7.3.2 CHILDREN (0-14 YEARS)

Category 1 Regimen for New Cases: 2RHZ/4RH

Regimen	Pre-treatment weight			
	21-29 kg	11-20 kg	5-10 kg	< 5 kg
<i>Intensive phase: daily <u>supervised</u> for 2 months</i> Combined tablet of RHZ (60mg+30mg+150mg)	4	3	2	1
<i>Continuation phase: daily for 4 months (monthly collection)</i> Combined tablet of RH (60mg + 30mg)	4	3	2	1

Children with severe forms of TB (TB meningitis, Disseminated TB, TB Spine, TB pericarditis) should have streptomycin added during Intensive Phase for dosage see table below

Category 2 Regimen for Relapses, Failures, RAD and Others for children

Regimen	Pre-treatment weight			
	21-29 kg	11-20 kg	5-10 kg	< 5 kg
<i>Intensive phase: daily <u>supervised</u> for 3 months</i> Combined tablet of RHZ (60mg+30mg+150mg)	4	3	2	1
Tablet Ethambutol (100mg)	3	2	1	
Injection streptomycin	0.5gm	0.5gm	0.25gm	0.25gm

Continuation phase: daily for 4 months (monthly collection)				
Combined tablet of RH (60mg + 30mg)	4	3	2	1

2. Where loose drugs are needed refer to Annex1 for drugs and dosages

Monitoring progress of tuberculosis patients while on treatment is an essential part of the 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 is done through the following methods:

- Sputum microscopy: Looking for AFB in sputum at specified intervals
- Clinical: Regular clinical assessment including weight monitoring
- Drug intake: Through assessment of patient’s records for regularity.

NB: Culture may be used where necessary and available.

2.8.1 Follow-up of Patients using Sputum Microscopy

Two sputum smear examinations (taken as two early morning samples within 2 days) are done at different points during treatment:

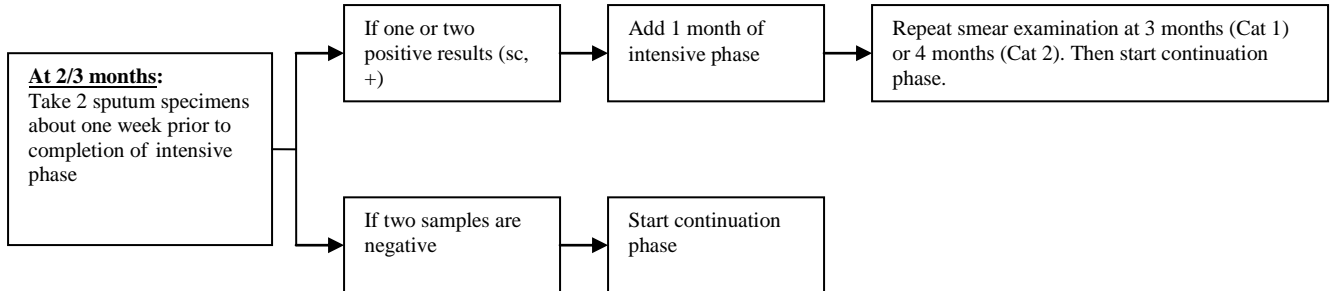
- For smear positive patients, collect and examine sputum at:
end of the 2nd month for new cases or 3rd month for re-treatment cases
end of 5th month
end of 6th months for six months regimen and end of 7th month for eight month regimen
- **For smear negative patients, collect and examine sputum only at the end of the 2nd month.**

All sputum samples are to be collected one week prior to the end of the month specified above.

If a patient no longer produces sputum, but saliva instead, the laboratory should examine these materials for AFB.

The following flow chart should be used for decision making during treatment.

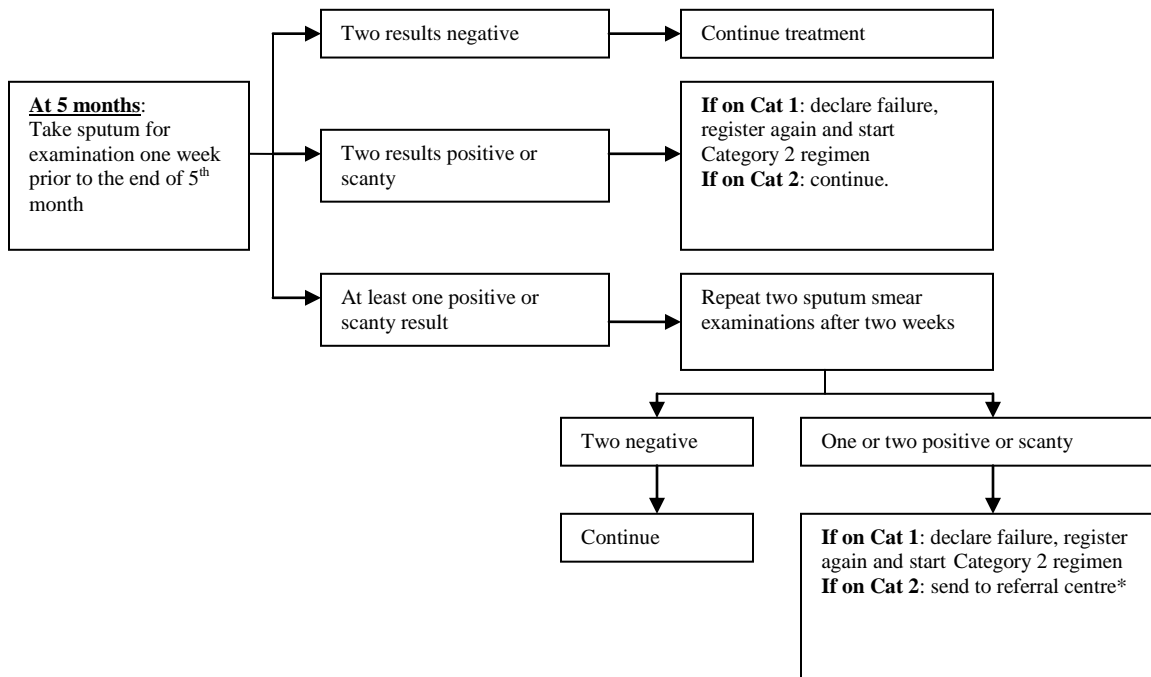
I)



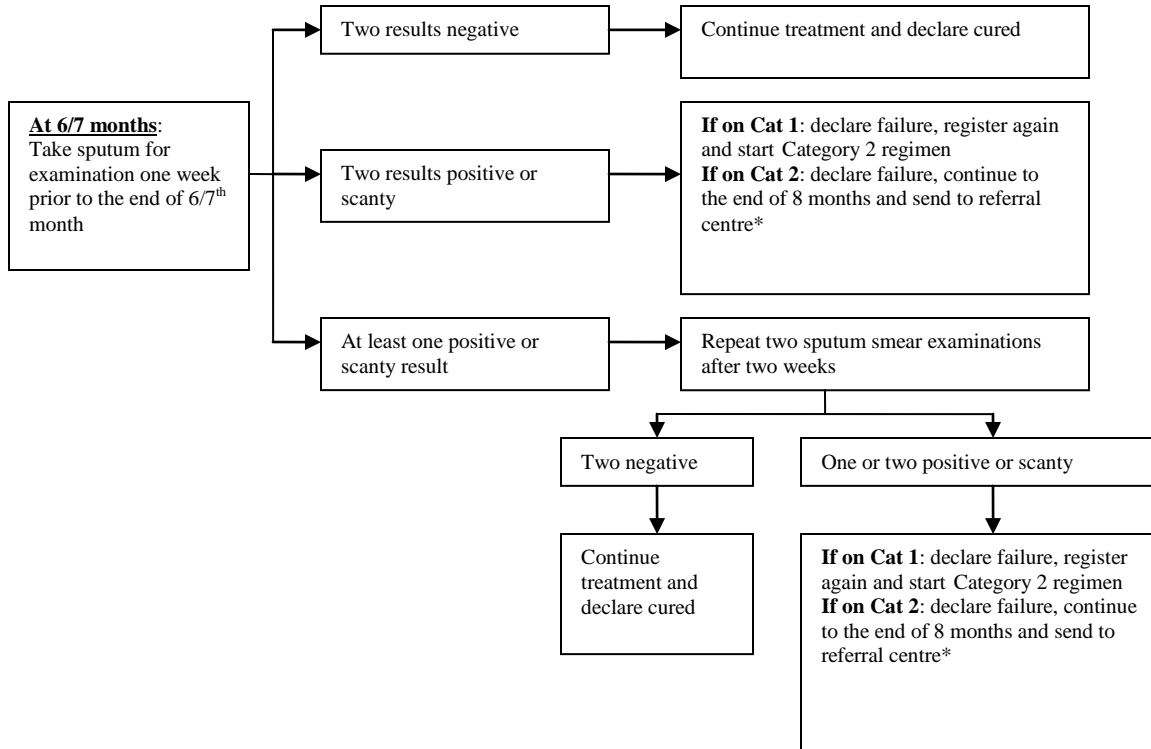
Remark 1: If a patient was smear negative at diagnosis and his sputum becomes positive at 2 months, this patient is NOT a failure case. Intensive phase should be extended by one month as shown in the box above.

Remark 2: All effort should be made to obtain the sputum result before the end of intensive phase. However if this is not possible for certain reasons give drugs for the Intensive phase for seven days. If the results are still not available after 14 days, switch to continuation phase drugs irrespective of the results.

2)



III)



Patients who remain positive after cat 2:

- Continue RHE medication
- Inform LGTBLS/STBLCO
- Refer to medical officer for sputum culture, sensitivity test and appropriate treatment

2.8.2 **Patients who remain positive at 5/6 months on cat 2 should be considered as MDR TB suspect:**

Adequate treatment of each case for the full duration of the prescribed regimen is very important if success in treatment is to be achieved. Any change to the treatment regimen due to side effects must be made only after careful consideration.

Avoid the use of Streptomycin in patients who are pregnant due to risk of damage to the ear of the foetus. Similarly, children below 6 years of age should NOT be given Ethambutol due to risk of eye damage.

2.8.2.1 When To Stop Treatment Without Further Consideration

SIDE EFFECTS	POSSIBLE CAUSE	ACTION
Skin irritation or rash in any patient on	Thiacetazone*	STOP treatment and refer to the medical officer.
General reaction including shock, purpura** and fever	Rifampicin Pyrazinamide Streptomycin	STOP treatment and refer to the medical officer.
Impairment of vision in a patient on	Ethambutol	STOP treatment and refer to the medical officer.
Jaundice (Yellowness of the eye)	Isoniazid Rifampicin Pyrazinamide	

*Thiacetazone is no longer recommended in TB treatment.

**Purpura is a dark patchy discolouration of skin due to bleeding under the skin.

2.8.2.2 Side-Effects/Reactions Not Requiring Interruption of Treatment

SIDE EFFECT	POSSIBLE CAUSE	ACTION
-------------	----------------	--------

Giddiness (staggering / loss of balance)	Streptomycin	Reduce dosage by one quarter, but if it persist for more than one week then stop and refer to the medical officer.
Severe nausea and vomiting.	Rifampicin	Give the Rifampicin after food
Skin rash in a patient not on Thiacetazone	Isoniazid Streptomycin Pyrazinamide	If patient is clinically well (not advanced TB or serious forms such as meningitis or disseminated disease) stop and resume when the reaction has subsided If symptoms recur, refer to Medical Officer
Numbness or tingling sensation on the extremities	Isoniazid	Supplement with tab. Vit. B ₆ At a dose of 100 mg daily
Joint pains	Pyrazinamide	Check the dosage by weight as it is usually caused by over-dosage. Easily alleviated with Aspirin (600 mg tds x 5 days) or Paracetamol (1000mg tds x 5 days)
Red/orange coloured urine	Rifampicin	Reassure patient

2.8.2.3 Severe Drug Reaction

Though rarely, patients may develop hypersensitivity reaction to anti-tuberculosis drugs. **Stop administration of all drugs immediately and refer to appropriate health facility for management.**

Patients experiencing hypersensitivity reactions should be referred/admitted in the hospital for drug challenging procedure. This procedure helps to identify the drug responsible for the hypersensitivity reaction. This procedure should not be begun until the hypersensitivity reaction has disappeared.

DRUGS

CHALLENGING DOSE

	DAY 1	DAY 2
INH (100 mg)	½ Tablet	300 mg
Rifampicin (RH 250 mg,)	½ Tablet	2 Tablets
Pyrazinamide (400 mg)	½ Tablet	2 Tablets
Ethambutol (400mg)	½ Tablet	1 Tablet
Streptomycin (1 g)	150 mg	500 mg

Modified from *Clinical Tuberculosis* by Crofton. J, Home N, Miller F, and

Practical Steps to Drug challenging

- Only start testing after all symptoms have subsided.
- Test one drug at a time.
- If after two challenge doses with a drug and there has been no adverse reaction, continue with this drug in the normal dosage and start testing the next drug.
- If any adverse reaction does occur after a challenge dose of a drug, stop this drug. Wait till reaction subside, and then start testing the next drug.
- Use half of the dosages indicated above if the pre-treatment weight is below 30 kg and quarter of the dosages indicated above if the pre-treatment weight is below 15 kg.
- When using combined tablets for testing, make sure that the correct dosage of the already re-introduced drug is given.

2.8.2.4 Desensitisation procedure

When the drug responsible for the reaction has been identified, one may consider omitting the causative drug. If possible, it is replaced with another drug. If INH or Rifampicin is involved, desensitisation may be attempted since these drugs form the cornerstone of the Short-course Chemotherapy for TB treatment.

Practical steps to desensitisation procedure

- Start with a tenth of the normal dose. If the reaction does not recur, increase by a tenth every day until the patient has a full dose on the tenth day.
- If there is a mild reaction, give the same dose the next day.
- If there is a severe reaction, which is unusual, go back to a lower dose and increase the doses more gradually.
- While desensitizing for one drug, the other drugs can be given in their normal dosages.
- Start with INH (the least likely to cause allergic reaction), then Rifampicin, then Pyrazinamide, Ethambutol and finally Streptomycin

2.9 EXAMINATION OF CONTACTS AND INH-PROPHYLAXIS

2.9.1 Contacts to be Screened

Contacts of all smear-positive PTB patients should be invited to the health facility to be screened for TB. These are:

- All adult contacts who are coughing for 2 weeks or more
- Those with known positive HIV status (with or without cough)
- All children of the household (including children born while on treatment)

Record should be kept of these contact persons in an exercise book.

2.9.2 Isoniazid Prophylaxis for Children Below 6 Years

Every child below 6 years of age that is living under the same roof with a smear-positive patient, should be brought to the health facility for examination. For symptoms of TB in children see under 2.5.7 – Diagnosis of TB in Children.

- If symptoms of tuberculosis are present (as listed in 2.4.3) **refer to a Medical Officer** who will confirm the diagnosis. Register the patient and start treatment if diagnosis of TB is confirmed.
- If symptoms of tuberculosis are absent, preventative treatment should be given after certification by the Medical Officer, regardless of whether BCG vaccination has been given in the past. Register the patient in the Isoniazid-prophylaxis Register (NTBLCP/TB9) and fill the Child INH Prophylaxis Card (NTBLCP/TB8) according to the NTBLCP guidelines and staple this card to the treatment card of the smear-positive contact of the child.

Preventative treatment: Isoniazid 5 mg/ kg body weight; daily for 6 months

Dosage table for INH Prophylaxis

Weight	< 13 kg	13-25 kg	>25 kg
No. of tablets of H ₁₀₀ mg	½	1	1 ½
Syrup INH _{10mg/ml}	1 tea spoon	2 tea spoon	3 tea spoon

The child needs to be weighed every month and the dosage administered should be adjusted accordingly.

Possible outcomes for the Isoniazid prophylactic treatment are:

- Completed treatment
- Defaulted
- Transferred out
- Died
- Developed active TB

2.9.3 INH Prophylaxis for PLHIV (refer to CHAPTER 3 - TB/HIV CO-INFECTION)

2.10 ENSURING TREATMENT COMPLIANCE

Health Workers should do all that is humanly possible to ensure that patients complete treatment in the required time.

Treatment compliance of every patient is absolutely essential in order to cure the patient and prevent drug-resistant Tuberculosis.

2.10.1 Treatment Interruption

New cases: Any individual who has not come to receive his/her treatment for **two consecutive days for Rifampicin regimen** or has failed to collect drugs for **two weeks** after the expected date **during the continuation phase for patients on EH** should be regarded as having interrupted treatment and therefore be traced. All effort is taken to bring the patient back on treatment. A report of the defaulter-tracing visit should be attached to the treatment card.

Re-treatment Regimen: Any individual who has not come to receive his/her treatment for **two consecutive days** should be regarded as having interrupted treatment and therefore be traced. All effort must be made to bring the patient back on treatment. A report of the defaulter-tracing visit should be attached to the treatment card.

2.10.2

First action:

- Trace patient
- Solve the reason for interruption of treatment
- A patient must complete all 56 doses of the intensive phase.

Length of interruption	Do a smear?	Result of smear	Duration of treatment	Treatment
< 1 month	No	-	-	Continue Rx and prolong to compensate for missed doses
1-2 months	Yes (3 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	If on Cat 1: Start Cat 2 If on Cat 2: Refer (Suspect MDR TB)
2 or more months	Yes (3 samples)	Negative or EPTB	-	Clinical decision on individual basis whether to restart or continue

				treatment, or no further treatment
		If 1 or more positive	-<1 month >1 month	Re-start cat 1
				If on Cat 1: Start Cat 2
				If on Cat 2: Refer (Suspect MDR TB)

2.10.3 COMPLICATION OF PULMONARY TUBERCULOSIS

1. Coughing blood (Haemoptysis)

ACTION

- Reassure the patient.
- Record volume of blood.
- Refer to the nearest hospital urgently, if frequent or the amount is plenty.
- If facilities are available, determine the blood group.

2. Spontaneous Pneumothroax.

There is sudden shortness of breath, increasing with time.

ACTION

- Refer urgently.

3. Pleural effusion.

There is increased difficulty in breathing

ACTION

- Refer urgently

4. Cor pulmonale.

There is an increased difficulty in breathing, leg-swelling and abdominal swelling.

ACTION

- Refer urgently.

5. Destructive lung disease

Breathlessness on effort despite anti-tuberculosis treatment

ACTION

- Refer urgently.

2.11 TREATMENT OUTCOME

Within the NTBLCP, the outcome of all smear-positive cases (both on Cat. 1 and Cat. 2) is evaluated in the quarterly “Tuberculosis Cohort Report” (TB14A). The LGTBLS has to ensure that she or he obtains the outcome of every patient, including those that were referred to another health facility if possible.

Cured:	A patient who was smear-positive at diagnosis, who completed 6 or 8 months of treatment and who is smear-negative at the end of 6 th or 7 th month of treatment and at least one previous occasion.
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Treatment completed	<ol style="list-style-type: none"> 1. Any patient who was smear-positive at diagnosis and who completed treatment but in whom smear examination results are not available at the end of treatment. 2. <i>All</i> smear-negative and extra-pulmonary patients who completed treatment.
Treatment failure	Any patient who remains or becomes smear positive again at the end of fifth month or later during chemotherapy
Died:	Any patient who dies for any reason during the course of his/her chemotherapy.
Defaulter:	Any patient who has interrupted for 8 consecutive weeks or more after the date of the last attendance during the course of treatment.
Transferred out:	A patient who has been transferred to another treatment centre in another State and whose treatment result is not known. Note: 'transferred out' is not allowed within the same state; rather the patient can be referred to another LGA and his treatment outcome obtained during the quarterly review meeting

2.11.1 Guidelines for Patient Education at the Time of Discharge:

Inform the patient that:

- The laboratory result shows that the disease is cured
- He should come back to report if any of the symptoms or signs of the disease or drug reaction re-appear
- He should inform the people in the community about the signs and symptoms of TB and that it is curable
- He should persuade any suspect to report to the clinic for screening.

CHAPTER 3 TB/HIV CO-INFECTION

3.1 INTRODUCTION:

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). TB is responsible for around 30% of deaths among PLHIV. The recorded HIV prevalence among TB patients rose from 2.2% in 1991 to about 27.4% in 2008.

The objectives of TB/HIV collaborative activities are to establish mechanism for collaboration, reduce the burden of TB among PLHIV and also the burden of HIV among TB patients.

Therefore interventions aimed at controlling TB and HIV will contribute to the decrease in the burden of Tuberculosis in populations affected by both diseases. The services at the different services points are as follows:

3.2 TB service site:

Every TB suspect and patient should be encouraged to know his/her HIV status through provider initiated HIV testing and counselling

3.2.1 TB suspect:

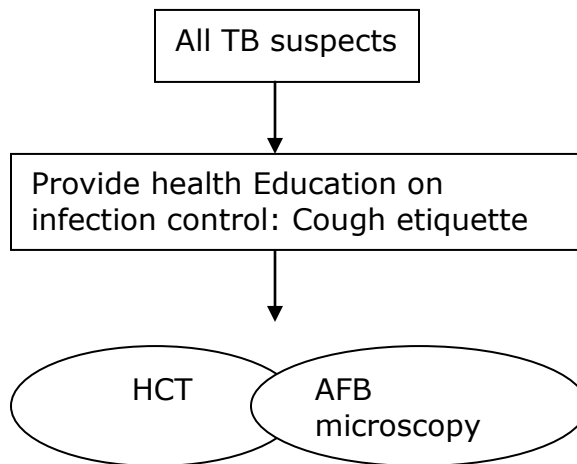
- Provide pre-test information by the health worker includes four main steps:
 1. Provide key information on HIV/AIDS and TB
 2. Explain procedures to safeguard confidentiality
 3. Confirmation of willingness of patient to proceed with test and seek informed consent
 4. Test for HIV and TB according to National Guidelines

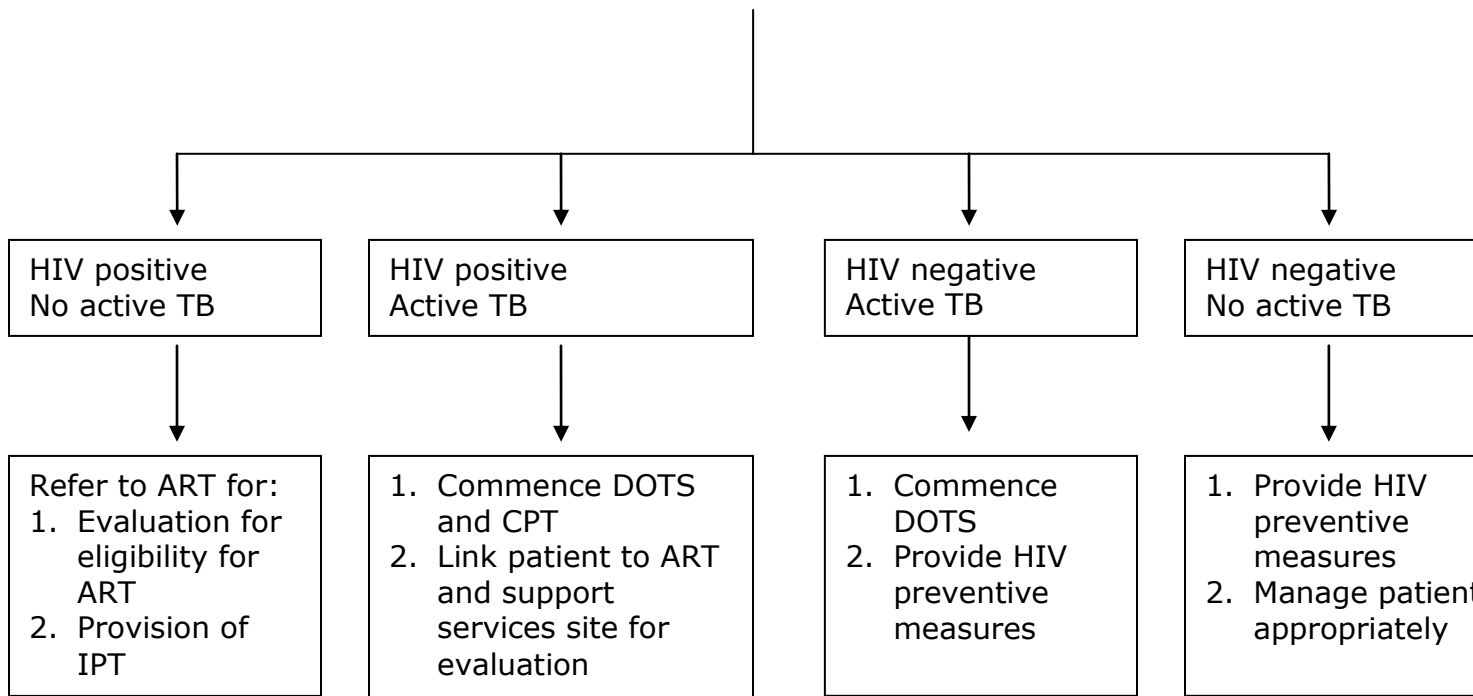
3.2.2 Confirmed TB case:

- **TB patients with HIV status unknown:**
The procedure for this group of patients is as stated in 3.2.1 above.
- **TB patients with HIV positive results (a TB-HIV patient):**

- Commenced anti-TB treatment
- Offer CPT
- Refer to a medical officer who can assess for ARV.
- Refer for care and support
- **TB patient with HIV-negative results**
 - Start anti-tuberculosis treatment
 - Repeat HIV testing 3-6 months later.

Use the chart below as a guide:





A person who has recently been infected may not yet be making antibodies to the virus. The HIV test detects the antibodies to the virus, not the virus itself. In this case, the test would not detect antibodies against HIV in the blood. This time period is often called the window period. This might be 4 - 12 weeks after infection.

All patients with HIV negative results should be encouraged to repeat the test after 3-6 month.

3.3 HIV service sites.

Intensify TB case finding at ART centre by ensuring *all PLHIV are screen for TB disease at all visits/follow-up*

3.3.1 Clients accessing HIV services

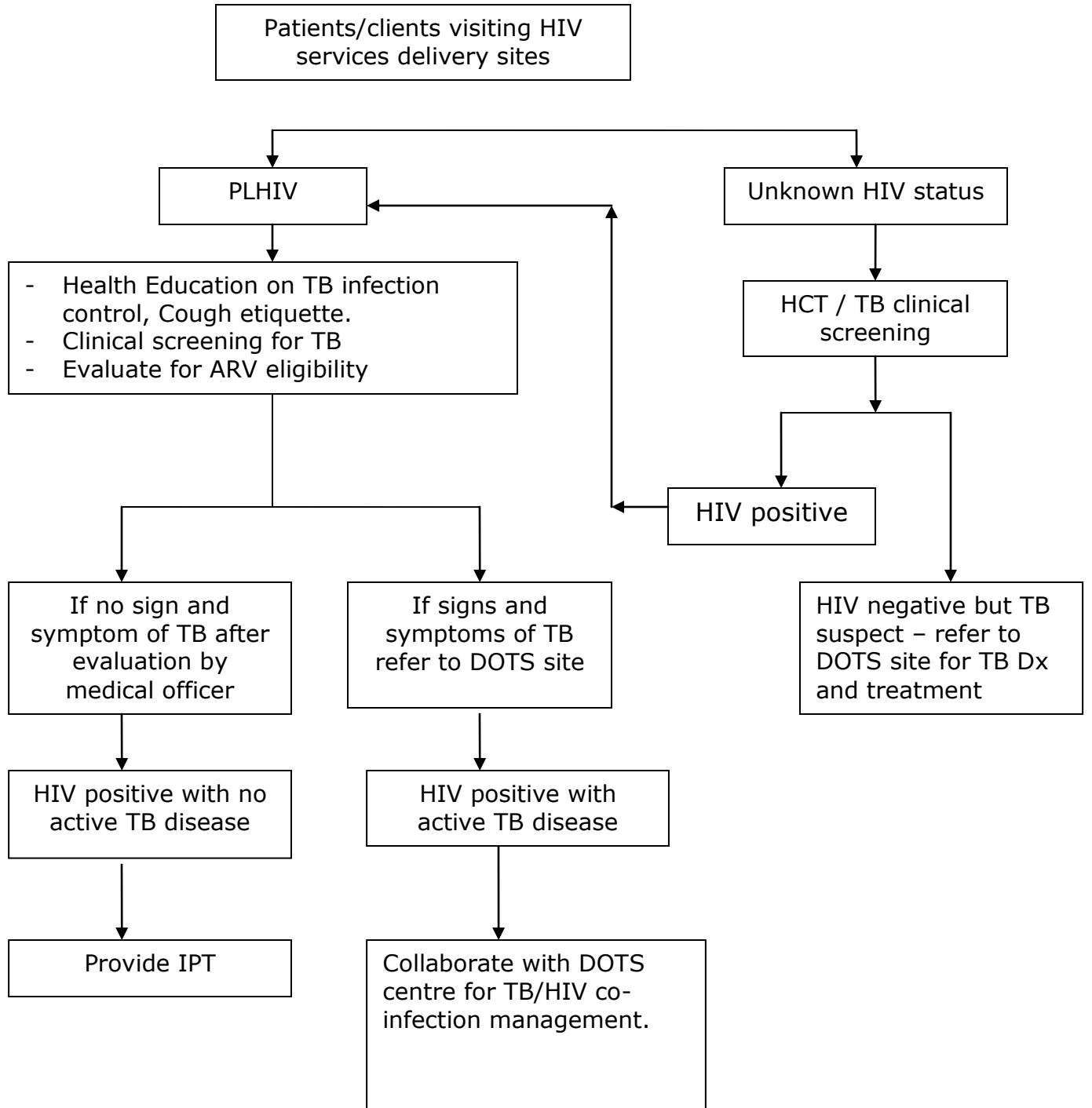
- Provide clinical screening for TB

Use the chart below as a guide:

TB/HIV facility guide

HIV/AIDS Clinic staff





3.3.2 An HIV positive patient who develops active TB

- **Patients already on ART**
Refer to a medical officer who will decide if the current ART regimen should be modified before initiation of anti tuberculosis treatment.
- **Patients not yet on ART**
 - For patients with active TB in whom HIV infection is diagnosed, the first priority is to initiate standard anti-tuberculosis treatment (in accordance with national TB policy and guidelines).
 - Refer to a medical officer who will decide if and when to initiate ART.
 - For information on when to start ART and what regimens, refer to table (See Annex below.

Scenario 1: Newly diagnosed TB (Category I) and HIV co-infection	
CD4 count >350/mm ³	<ul style="list-style-type: none"> • Start category I TB treatment immediately • Reassess as per TB review schedule and consider initiation of ART if clinical condition of patient deteriorates while on TB treatment. Patient may be referred to higher level of care • Initiate Co-trimoxazole Preventive Therapy
CD4 count 200-350/mm ³	<ul style="list-style-type: none"> • Start category I TB treatment immediately • Reassess monthly and consider initiation of ART. If clinical condition of patient deteriorates while on TB treatment or refer patient to higher level of care • If patient's condition is stable, commence ART after completion of the intensive phase of TB treatment. • Initiate Co-trimoxazole Preventive Therapy
CD4 count <200/mm ³	<ul style="list-style-type: none"> • Start category I TB treatment immediately • Start ART as soon as TB medications are tolerated (usually within 2-8 weeks), particularly in patients with severe immuno suppression • Initiate Co-trimoxazole Preventive Therapy
Scenario 2: All TB patients (category II) and HIV co-infection	
	<ul style="list-style-type: none"> • Evaluate eligibility for ART as in scenario 1 above • Commence or continue category II TB treatment • Choice of ART regimen should take into account that patients would be on Rifampicin throughout TB treatment • Initiate Co-trimoxazole Preventive Therapy
Scenario 3: PLHIV on ART who develops TB	

Develops TB while on ART within the first six months	<ul style="list-style-type: none"> • Start TB treatment immediately and if ART regimen includes Niverapine, substitute Niverapine with Efavirenz and continue ART • If patient's clinical condition deteriorates, consider immune reconstitution syndrome, refer to higher level of care
Develops TB while on ART after six months of initiation	<ul style="list-style-type: none"> • If the presentation is extra pulmonary TB, this should be considered as indicating ART failure,(although simple lymph node TB or uncomplicated pleural disease may be less significant than disseminated TB). • Start TB therapy in line with National guidelines
Patient on TB treatment is diagnosed HIV-positive	
HIV diagnosed during intensive phase of category I or II TB treatment	<ul style="list-style-type: none"> • Refer to instructions in scenario 1 and 2 above.
HIV diagnosed during the continuation phase of TB treatment	<ul style="list-style-type: none"> • If patient is clinically stable, complete TB treatment and refer patient for assessment of eligibility of initiating ART. • If patient deteriorates refer to instructions in scenario 1 and 2 above. • If ART is required immediately avoid Niverapine in patients on category II TB treatment or category I with abnormal liver function
HIV and TB treatment in pregnancy	
HIV positive pregnant woman on ART develops TB	<ul style="list-style-type: none"> • Re-assess/refer to ART unit for ART regimen review in view of potential drug-drug interaction with anti-tuberculosis drugs or refer to higher level of care • Thereafter commence anti-tuberculosis treatment
Pregnant woman on TB treatment tested positive for HIV	<ul style="list-style-type: none"> • Continue TB treatment • Refer for PMTCT or ART clinic to determine eligibility and choice of ARV regimen • Where possible defer ART until end of TB treatment or start in the second trimester of pregnancy
PLHIV on 2 nd line ARVs and develop TB.	<ul style="list-style-type: none"> • • Start anti -TB treatment using loose drugs • Rifampicin should be replaced with Rifabutin

Important cautions:

- **An EFV-containing regimen is the first-line treatment recommendation for patients with TB and HIV but should not be used during the first trimester of**

pregnancy or in women of childbearing age potential unless effective contraception is ensured.

- If a pregnant woman is in the second or third trimester, an EFV-containing ART regimen can be considered. Effective contraception would have to be assured postpartum if the regimen were continued.
- Drug levels of oral contraceptives may not be enough to guarantee contraception if patient is on NNRTIs particularly Niverapine.
- PLHIV on 2nd line ARVs who developed TB, Rifampicin should be replaced with Rifabutin and patient to be place on loose anti TB drugs.

3.4 IMMUNE RECONSTITUTION INFLAMMATORY SYNDROME (IRIS) IN PATIENTS DIAGNOSED WITH TB WHO START ON ART

The Immune Reconstitution Inflammatory Syndrome (IRIS) may present as a worsening of clinical disease after initial improvement.

- It may occur in up to a third of persons with tuberculosis who initiate ART.
- IRIS typically presents within three months of the initiation of ART but can occur as early as five days.
- TB-associated IRIS most commonly presents with fever and a worsening of pre-existing lymphadenopathy or respiratory disease.

- It is similar to, but more frequent than, the paradoxical reactions seen in immuno competent patients on anti-tuberculosis therapy.
- Reports suggest that IRIS is more common if ART is started early in the course of TB treatment and in patients with low CD4 counts.
- Most cases resolve without any intervention and ART can be safely continued. Serious reactions such as tracheal compression (with noisy breathing-stridor), caused by massive adenopathy, or respiratory difficulty, may occur. Therapy may require the use of corticosteroids: patients should be referred to a medical officer for appropriate management

NB: Any patient with above symptoms of IRIS at primary health care facility should be referred to secondary or tertiary health facility.

3.4 PREVENTING TB AND OTHER OPPORTUNISTIC INFECTIONS IN PLHIV

- Preventing activation of latent TB (Isoniazid Preventive Therapy-IPT)
- Preventing other opportunistic infections (Cotrimoxazole prophylaxis)

3.4.1 Preventing activation of latent TB (Isoniazid Preventive Therapy)

Isoniazid Preventive Therapy (IPT) is the use of Isoniazid in HIV-positive individuals with latent TB infection in order to prevent the development of active TB disease. Available evidence shows that TB is the commonest opportunistic infection and cause of death among PLHIV and also that IPT is effective in preventing it.

IPT is not the treatment for active TB. It is therefore necessary to exclude active TB before commencing a patient on IPT.

3.4.1.1 Eligibility

For a patient to benefit from IPT, he/she must:

- Be an asymptomatic HIV positive patient
- Not having active TB
- Start IPT 3 months after commencement of ARV
- Be motivated to adhere to treatment

3.4.1.2 Steps for IPT

- Verify/Confirm HIV Status.
- Counsel on TB/HIV interactions.
- Exclude active TB.
 - Ask the patient about Cough, Chest Pain, Fever and Night Sweat.
 - Check for Lymph Node enlargement

- Those with above signs and symptoms, do sputum examination. If smear positive, commence anti-tuberculosis treatment or refer to a DOTS centre.
- Those with negative sputum results should be referred to MO for further assessment including Chest X- RAY

If active TB has been ruled out (bacteriology and radiologically) give IPT

Dosage of INH for IPT is 5mg/kg/day to a maximum of 300mg/day for 6 months. Dispense on monthly basis.

- Review after 2 years.
- Counsel patient on:
 - Treatment adherence
 - Side effects of INH
 - Immediate recognition and reporting of signs and symptoms of active TB
- During the monthly visit monitor the patient for:
 - Signs and symptoms of active TB
 - Side-effects. The commonest side effect is peripheral neuropathy (numbness/tingling sensation of extremities). In addition allergic skin eruptions and jaundice can occur.

If patient develops active TB during the course of IPT, discontinue IPT and refer to DOTS clinic.

If numbness/tingling/burning sensation is present give Pyridoxine 100mg daily.

If jaundice develops, discontinue IPT and refer to Medical Doctor for assessment.

- Complete necessary INH Prophylaxis Register and INH Appointment Card (Use NTBLCP INH Register)
- Refer/assess for ART

3.4.2 Preventing other opportunistic infections (Cotrimoxazole Preventive Therapy)

Cotrimoxazole Preventive Therapy (CPT) is use of Cotrimoxazole for the prevention of several secondary bacterial and parasitic infections in HIV infected individuals. It helps to improve the quality of life and reduce the rate of death among HIV infected patients and those that are dually infected. All TB/HIV co-infected patients should be provided with CPT.

3.4.2.1 Eligibility

For a TB patient to benefit from CPT, he/she must be:

- HIV positive
- Be motivated to adhere to treatment

3.4.2.2 Steps for CPT

- Verify HIV status
- Counsel on opportunistic infections in HIV infection
- Treat opportunistic infections, if present
 - Take medical history
 - Conduct physical examination
 - Give appropriate treatment for diagnosed opportunistic infection (Refer to guideline on management of opportunistic infections)
- Screen for contraindications to CPT
 - Known allergy to sulphur-containing drugs (which includes Cotrimoxazole and Sulphadoxine-Pyrimethamine)
 - First trimester Pregnancy
 - Kidney or liver disease. (Refer for specialized medical assessment if in doubt)
 - Seriously ill patients. (Refer for specialized medical care)
- If contraindication to sulphonamides exist, patient should be placed on Azithromycin
- Counsel patient on:
 - Drug adherence
 - Side-effects of Cotrimoxazole
 1. Skin eruptions which may be severe (Stevens Johnson syndrome)
 2. Kidney or Liver Failure.
 3. Anaemia
- Commence CPT
- Monitor patients.
 - Adults should be reviewed monthly initially, and then three monthly thereafter if the medications are tolerated.
 - Laboratory monitoring of adults should take place every six months or when clinically indicated. This should include haemoglobin and white cell count.
 - Children should be reviewed monthly.
 - Replenish patient's drug during review.
- Discontinuation of CPT
 1. Occurrence of side-effects.
 2. Children testing HIV-negative when older than 18 months (in whom CPT was commenced in infancy).
- Complete necessary CPT Prophylaxis Register and Treatment Appointment Card.
- Refer/assess for ART

- After completing the ant-tuberculosis treatment the patient on CPT should be referred to the ART clinic for continuation of CPT

Dose of Cotrimoxazole in CPT.

a. Adults

- Cotrimoxazole 960mg daily (two single strength tablets) for life.
- Stop if on ART with CD4 > 500 cells/mm³.

b. Children

Cotrimoxazole syrup should be given once daily. If syrup is unavailable cotrimoxazole tablets may be crushed.

The recommended dose is 60mg/kg body weight. See table below

Doses of Co-trimoxazole in infants and children living with or exposed to HIV/AIDS.

Recommended daily doses	Suspension (5ml of syrup 200mg/40mg)	Child- tablet (100mg/20mg)	Single strength adult tablet (400mg/80mg)	Double strength adult tablet (800mg/160mg)
<6 months 100mg sulfamethoxazole/20mg trimethoprim	2.5ml	One tablet	¼ tablet possibly mixed with feeding	–
6 months-5 yrs 200mg sulfamethoxazole/40mg trimethoprim	5 mls	Two tablets	Half tablet	–
6-14 yrs 400mg sulfamethoxazole/80mg trimethoprim	10mls	Four tablets	One tablet	Half tablet
>14 yrs 800mg sulfamethoxazole/160mg trimethoprim	–	–	Two tablets	One tablet
Frequency - once daily				

CHAPTER 4 TUBERCULOSIS INFECTION CONTROL IN HEALTH CARE SETTING

4.1 INTRODUCTION

TB IC refers to all actions and policies put in place to reduce the transmission of TB at all levels. Health care workers and other staff are at particularly high risk of infection with TB because of frequent exposure to patients with infectious TB disease. They may also be immune-suppressed due to HIV infection and be at higher risk of developing TB disease once infected.

Persons with HIV-associated immune-suppression may become infected or re-infected with TB if they are exposed to someone with infectious TB disease. They can progress rapidly from TB infection to disease – over a period of months rather than a period of years as is common for persons with a normal immune system.

Long waiting hours as well as overcrowding and poor ventilation of health facilities increase the risk of TB transmission among clients receiving care and portraying danger to health workers delivering care.

Therefore as the NTBLCP scales up MDR-TB, TB, HIV and TB/HIV services it is important to put in place measures that will minimize the risk of TB transmission in health care facilities and other settings where the risk of transmission of TB is high

4.2 INTERVENTIONS TO REDUCE RISK OF INFECTION

There are three ways in which the risk of Tuberculosis infection can be reduced.

- Work practice and administrative control measures
- Environmental control measures
- Use of protective wears (respirators)

4.2.1 Steps for setting up IC measures within the health facilities:

- Set up an IC team and identifying IC focal person
- Develop/adapt an IC plan
- Train all health workers on IC
- Facility improvement where necessary including waste management

4.3 Practical tips on prevention of transmission of TB

4.3.1 Recommended steps at GOPD/other waiting areas

1. Ensure adequate ventilation. Waiting areas should have large windows and must be open at all times.
 2. Educating the TB suspects and TB patients on Dangers of Exposure and Prevention covering the mouth with a clean handkerchief/cloth when coughing/sneezing, and using sputum pots with lids.
 3. Early identification of patients who are coughing, separation and referral to the lab
 4. When examining TB patients or suspects, ask them to turn their head away, to avoid coughing directly at the health worker.
 5. Ensure prompt diagnosis and treatment of patients with confirmed TB
 6. In-patient management of intensive phase TB patients should as much as possible be avoided.
 7. At all service points (wards, outpatient clinics, microbiology laboratories, surgical and autopsy suite), keep the doors closed and the windows open.
 8. Ensuring strict adherence to SOPs at all service points especially the lab
 9. Encouraging staff to know their HIV status and take appropriate actions.
 10. Known HIV positive health workers/lab staff should not work in TB clinics.
 11. Offering HCT to all patients visiting the facility.
 12. Displaying appropriate IEC materials at different service points.
 13. Prohibiting hawking and children visitations
 14. Wet floor before sweeping (bleach should be used rather than disinfectants like Izal, Dettol etc.
- 4.3.2 Recommended steps in the wards
1. Admitting TB and HIV co-infected patients in different wards in the facility.
 2. If there are no facilities to separate PTB suspects from other patients, at least try to keep PTB suspects in a part of the ward away from other patients.
 3. Staff should also encourage PTB suspects to spend daylight hours outside the ward if the weather is good.
 4. Sputum for smear examination should be collected as rapidly as possible.
 5. The laboratory should process and examine sputum smears rapidly and efficiently.
 6. Hospitals should ensure a minimum of delay in delivering smear examination results back to the wards.
 7. Children should be discouraged to accompany infected adults for DOTS follow-up and from entering TB inpatient wards/clinics for social visits

4.4 Practical tips on the prevention of transmission of HIV in health facility settings

- Use one sterile needle and syringe per patient for only one injection!
- Discard all “sharps” (needles and syringes) into a disposable container and burn them every day.
- In the event of a needle-stick injury,
 - Wash well with soap under running water.
 - The affected health worker must see a medical officer immediately for post exposure prophylaxis (PEP).
 -

Assume that all blood and body fluids are potentially infectious

The table below gives some guidance on prevention of transmission to health workers.

EXPOSURE TO RISK	PRECAUTION FOR PREVENTION OF TRANSMISSION OF HIV
Venapuncture	<ul style="list-style-type: none"> • <u>Wear gloves</u> • Use a closed vacuum system if available • Discard needle and syringe into sharp box • Discard gloves and swabs into leak-proof plastic bag for incineration (burning) • Label blood bottle and request form “inoculation risk”
Invasive procedure, Surgery, Delivery of a baby	<ul style="list-style-type: none"> • <u>Wear gloves and apron</u> • Protect your eyes (glasses or protective goggles) • Discard sharps into sharps box
Spilled blood	<u>Clean up as soon as possible using available disinfectant (e.g. Dettol, Purit, Savlon, IZAL)</u>
Resuscitation	<u>Avoid mouth-to-mouth resuscitation (use Ambu-bag)</u>

4.5 GUIDELINES FOR POST-EXPOSURE PROPHYLAXIS (PEP) HIV

Introduction and Rationale of PEP

Information about primary HIV infection indicates that systemic infection does not occur immediately after exposure, leaving a brief window of opportunity during which administration of PEP might prevent viral transmission and replication. Commencement of PEP within 2 hours after exposure might inhibit or prevent systemic infection. After an exposure the following steps should be pursued:

4.5.1 First Aid

Following any occupational exposure, the following are recommended before reporting:

1. Wash percutaneous injuries with soap under running water (tap or stored water) and allow the wound to bleed freely; do not compress to stop bleeding.
2. Use water to flush out nose, mouth or areas of the skin (broken) that have been splashed with blood.
3. Irrigate eyes when exposed with saline or clean water
4. Report and document incident immediately through supervising officer.
5. Index worker and supervisor should consult an expert or the designated persons listed immediately or be immediately referred to an ART treatment centre for PEP.

4.5.2 Evaluate Exposure Risk Assessment

4.5.2.1 Low risk

- Solid needle injury
- Superficial sharps injuries
- Exposure to blood / fluid from asymptomatic HIV patient with low viral load or suppressed viral load on therapy
- Exposure to a small amount of infected blood / fluid
- Splash of blood on intact skin

4.5.2.2 High risk

- Deep injury with hollow especially large bore needle
- Exposure to blood / fluids of patient with AIDS or advanced HIV infection or acute sero-conversion illness
- Extensive and deep sharp injury
- Exposure to large volume of infected blood / fluid
- Splash of blood on broken skin.

4.5.3 Evaluation of Exposure Source

4.5.3.1 Known Source

- Enquire whether patient is known to be infected with HIV.
- Evaluate HIV-infected patient's stage, performance status, CD4 cell count (or lymphocyte counts) and clinical condition.
- If status unknown, test for HBsAg, HCV and HIV antibodies using rapid HIV testing technique with informed consent.[Screening for HIV should not be delayed or deferred to await HBV and HCV screening].
- If source is not infected with any of the above viruses, baseline testing or further follow-up is not necessary (unless strong suspicion or possibility that he / she is in the window period – should especially suspect sexually active individuals).
- If source person refuses testing, consider clinical presentation, diagnosis and history of risk behaviours; consider source infected, if sexually active.

4.5.3.2 Unknown Source

- Evaluate the likelihood of exposure to a source at high risk for infection
- Consider the likelihood of infection among patients in the exposure setting

Following risk evaluation, document in appropriate register and refer appropriately

CHAPTER 5 PREVENTING DRUG-RESISTANT TUBERCULOSIS

5.1 INTRODUCTION

The emergence of resistance to drugs used to treat Tuberculosis and particularly multi-drug resistant TB (MDR-TB) is a significant problem and pose obstacle to effective TB control and both national and global levels. Resistance arises from both service related and patient-related factors in the management of the disease, ranging from poor compliance, inadequate supervision, inadequate dosing, drug combinations, or duration of treatment, poor training of health staff.

There has been no systematic population-based national drug resistance surveillance in Nigeria. However, from isolated and limited studies and anecdotal reports, it is known that the problem of MDR-TB is an emerging public health problem in Nigeria. For instance, WHO estimated MDR-TB among new cases at 1.9% and among previously treated TB cases at 9.3.% (WHO Report 2009 Global TB Control).

The WHO Stop Department estimates that the global incidence of MDR-TB as at 2004 is about 458,000 cases. The prevalence is about two to three times higher than the number of incident cases.

Definitions:

- Drug resistance: A patient is said to have drug resistant TB if only there is a laboratory confirmation of resistance to one or more of the 1st line anti-TB drugs.
- Mono-resistance: TB in patients who have resistant e bacilli to one 1st line anti TB drugs.
- Poly resistance: TB in patients who have resistant bacilli to more than one 1st line anti TB drugs other than RH
- MDR TB: TB patient who have resistant bacilli to both Rifampicin and Isoniazid.
- XDR TB: MDR TB plus resistance to any of the fluoroquinilones (Ofloxacin, Moxifloxacin, Levofloxacin) and one of the second line injectables.

5.2 TYPES OF DRUG RESISTANCE TB

There are two types of drug resistance

Drug resistance among new cases (formerly “*primary drug resistance*”) is the presence of resistant strains of *M .tuberculosis* in a newly diagnosed patient who has never received anti-tuberculosis drugs or has received them for less than one month of treatment.

Drug resistance among previously treated cases (formerly acquired drug resistance)

Is that found in a patient who has previously received at least one month of anti-tuberculosis therapy.

5.3 SUSPECTING DRUG RESISTANT TB

It is important to identify suspects, confirm diagnosis and initiate adequate treatment for DR-TB in a timely manner. Timely identification leads to timely treatment which prevents the spreading of the disease to others.

Health workers should suspect drug resistant TB in the following situation;

- Failure of retreatment (CAT 2) regimen or chronic TB cases
- Symptomatic contacts to a known MDR-TB case
- Failure to cat 1 regimen
-

5.4 MANAGING MDR TB SUSPECTS

Those identified as suspects for DR-TB require urgent intervention to prevent further damage to their lungs and prevent further spread of the disease. The following actions should be taking as soon as suspects are identified:

- Complete appropriate recording and reporting forms.
- Notify the control/medical officer for further actions
- Collect sputum sample and send to designated MDR TB laboratories for confirmation
- Provide health education on possible outcome and infection control.

5.5 PREVENTION OF DRUG RESISTANCE

The current anti-TB drugs are still effective in treating drug susceptible Tuberculosis. Drug resistant TB can therefore be prevented, largely, through effective implementation of basic DOTS. Essential elements to prevent drug resistance are:

- Uninterrupted supply of good quality anti-TB drugs for the full duration of the treatment.
- Free anti-TB services to the patients
- Prescription of anti-TB drugs is consistent with the national guidelines
- Provide adequate patient education throughout the course of treatment to ensure adherence to treatment
- Direct observation of treatment (DOT) is provided especially during the intensive phase of CAT 1 and throughout in the treatment of CAT 2 cases
- Provide DOTS services as close as possible to patients' homes.
- Prompt management of interruption of treatment and default.
- Proper triage of suspects/patients who attend general outpatient departments or DOTS clinics.

Resistance is commonly due to inadequate chemotherapy, it is therefore absolutely essential that patients are provided with adequate chemotherapy with recommended drugs for the entire duration of treatment.

5.6 DIAGNOSIS AND TREATMENT

Diagnosis of drug resistant TB requires specialized facilities for culture, molecular line probe assay and drug susceptibility testing. Sputum samples from suspects should, therefore, be sent to designated centre immediately for early diagnosis. Confirmed cases should be referred to designated treatment centres. . The List of designated centers is available with the State TBL Control Officer.

Treatment for MDR TB patients refer to MDR guideline.

5.7 Role of STBLCO/ LGTBLS in the management of X/MDR-TB

- Should coordinate / facilitate X/MDR-TB suspects to access diagnosis
- Should prepare / link diagnosed cases to specialized treatment centres for clinical management
- Should collaborate with specialized treatment centres in the planning and linking of cases to DOTS clinics/CVs/Treatment supporters for the ambulatory phase of treatment
- Ensure complete documentation of all patients' information.
- Ensure provided basic protective materials are available and in use for infection control
- Organize /facilitate patients access to follow up (required periodic monitoring tests)
- Provide supportive supervision to DOTS clinic/CVs/ TS to ensure effective ambulatory treatment

CHAPTER 6 PUBLIC-PUBLIC, PUBLIC PRIVATE MIX DOTS (PPM-DOTS)

6.1 PURPOSE

Among the important interventions required to reach global and national targets would be a systematic involvement of all relevant health care providers in delivering effective TB services to all segments of the population. Public-Public and Public-Private Mix DOTS (PPM-DOTS), therefore, represent a comprehensive approach to engage wide variety of health care providers currently outside the NTBLCP. The implementation of PPM-DOTS will improve case detection and case management by bringing all patients managed by these diverse health care providers under DOTS.

6.2 TYPES OF COLLABORATION

- Public-private (between NTBLCP and the private sector)
- Public-public (between NTBLCP and other public sector e.g. secondary, tertiary and health facilities in the prison, army barracks and police barracks.)
- Collaboration with professional bodies (Medical dental council, Nursing council, Association of chest physicians)
- Private-private (between an NGO or a private hospital and the neighbourhood private providers).

6.3 SCHEMES FOR COLLABORATION (SCOPE OF PARTICIPATION)

There are different schemes of collaboration by private health providers depending on the identified ability of the hospital and the willingness of the health provider. These are possible schemes:

- Scheme 1: referral of TB suspects for diagnosis
- Scheme 2: provision of direct observation of treatment only
- Scheme 3A: provision of microscopy services only
- Scheme 3B: provision of both microscopy & treatment services

6.4 STEPS/process of PPP-DOTS implementation

The TB programme should:

- Organise a consensus building meeting with relevant stakeholders (Association of General and Private Medical Practitioners, Guild of Medical Directors, association of chest physicians association of paediatrics, association of patent medicine vendors and traditional healers).
- Set up a coordinating mechanism (steering committees) at the national and state levels
- Make a list of all health care providers within the state/LGA
- Determine if they are presently linked to the NTBLCP

- Assess what potential contributions the providers can make and identify inputs required for maximum contribution
- Obtain a signed agreement with the health care facility to offer TB services according to the national guidelines
- Categorise relevant care providers according to schemes and provide relevant training
- Provide anti-TB drugs and other relevant materials (e.g laboratory reagents, recording and reporting materials)
- Provide regular supportive supervision and monitoring
- Ensure regular data collection and provision of feedback
- Evaluate performance and expand as necessary.

For details refer to the national PPM guideline

CHAPTER 7 COMMUNITY TB CARE (CTBC)

7.1 PURPOSE

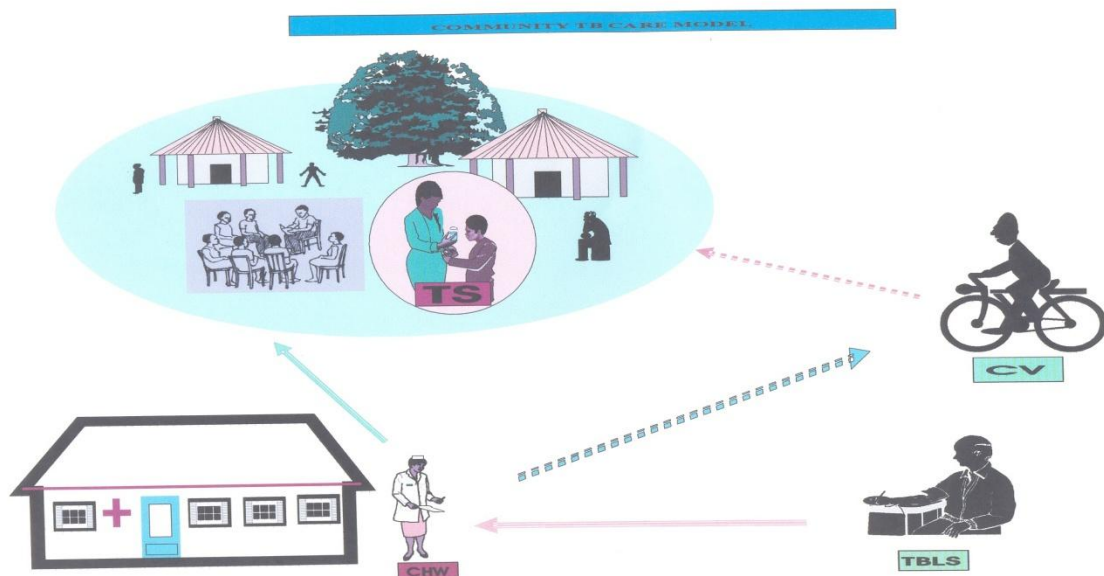
Community TB Care - This is TB Care in a community, by community members who may or may not be health workers, and implemented within the context of the National Programme. The major aim of CTBC is to strengthen TB case finding and case holding in close partnership with the communities through community participation that will encourage ownership and sustainability of TB control activities at the community level

7.2 STRATEGY

The strategies of CTBC include:

- Effective community engagement through situation assessment, advocacy, communication and social mobilisation
- Capacity enhancement through training of community volunteers/treatment supporters for TB care
- Patient empowerment and mobilisation for TB care in the community
- Adopt a patient-centred approach to TB care
- Programme strengthening through establishment and strengthening of the recording and reporting system, supervision, monitoring and evaluation

7.3 THE CTBC GENERIC MODEL



TS = Treatment supporter, CV = Community volunteer, CHW = Community Health worker, TBLs = Tuberculosis and Leprosy Supervisor

A TB suspect should report to the DOTS centre for diagnosis by the DOTS provider. Following diagnosis, a community health worker at the DOTS centre will work in collaboration with the community volunteer to identify an acceptable treatment supporter for the patient. The treatment supporter should support and encourage the patient to commence and complete his/her treatment.

The TBLS is responsible for the programme, especially as it relates to the logistic support to the health facility and will in addition provide training support for the Community Health Worker (CHW), Community Volunteers (CV) and treatment Supporters (TS).

7.4 Steps for implementation of CTBC.

1. Conduct situation analysis to identify community structure and health services issues
2. Carry out advocacy and community awareness to the identified communities
3. Identify Civil Society Organisation (CSO's) in the communities
4. Selection of community volunteers through active community participation
5. Organise and conduct training for selected community volunteers in collaboration with CSO's
6. Establish linkages with the TB program using appropriate recording and reporting formats.
7. Establish effective drug and logistic management system.
8. Ensure regular supervision.

7.5 Roles of Key Implementers of CTBC

7.5.1 The Treatment Supporter

A TB treatment supporter is a motivated individual *willing and capable* to support a TB patient to commence and complete his/her treatment of TB and follow up sputum examination. The treatment supporter could be a relation or someone close to the patient's home who shall be trained on how to provide support to the patient while on treatment. S/He should:

- be acceptable to the patient
- preferably live close to the patient
- be polite and considerate of the patient's needs at every contact
- be kind to the patient and interested in the patient's welfare
- respect the patient's confidentiality
- be trained by the health services to perform the tasks of a TB treatment supporter
- be a responsible and not a care-free person

The treatment supporter will be required to perform the following tasks:

1. Identification of people who have been coughing for three weeks or more and referral to the DOTS centre for sputum examination, diagnosis and follow up
2. Custody of patient's drugs and Direct Observation of Treatment
3. Ticking of patient's drug in-take in the TB treatment card
4. Recognition of danger signs/side effects and referral of patient to the DOTS centre.
5. Tracking of patients when they interrupt treatment and tracing of contacts of TB patients

6. Provision of support and care to the patient

7.5.2 The Community Volunteer

A community volunteer (CV) refers to a member of the community who:

- Is identified and recommended by the community
- Expresses willingness and commitment to participate in CTBC
- Is resident in the community
- Is able to speak the local language fluently
- May be a volunteer in other health programs in the community

The CV will be responsible for health promotion to the community with emphasis on signs and symptoms of TB and inform community members where services are available and can be accessed. The CV should carry out the following roles in the community:

7.5.3 Role of CSO's

- Help to facilitate community entrance
- Carry out community mobilization
- Facilitate the selection of community volunteers
- Help lobby for government support for TB programme
- Ensure accountability of the health staff to the community
- Facilitate feedback to the community on TB activities

7.6 CRITERIA FOR SELECTION OF COMMUNITIES FOR CTBC

Participating communities should:

- Have a linkage to TB diagnostic and treatment services
- Express willingness and political commitment to be part of CTBC
- Identify willing and acceptable community volunteers and leaders for CTBC
- Support the functioning of community volunteers in line with agreed guidelines
- Be given priority where such communities have poor treatment outcome and/or high defaulter rate
- Be given priority where such communities have high prevalence of TB and HIV/AIDS
- Be given priority where such communities have difficult geographical access
- Be given priority where such communities have existing CBOs and CDC

7.7 CRITERIA FOR SELECTION OF COMMUNITIES VOLUNTEER.

- Identified and recommended by the community
- Express willingness and commitment to participate in CTBC
- Is resident within the community
- Is able to speak local language
- May be a volunteer in other health programme

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For details refer to the national CTBC guideline

CHAPTER 8 LABORATORY SERVICES FOR TUBERCULOSIS CONTROL

8.1 INTRODUCTION

To effectively control TB, there is need for quality assured laboratory services that can detect new TB cases using sputum microscopy to diagnose and follow-up the bacteriological progress of patients during treatment. Microscopy errors will lead to either false positive or false negative result of sputum smear microscopy and thus affect the levels and quality of case detection and treatment outcome of TB control activities. A good Quality Assurance system is therefore essential to ensure the reliability and efficiency of the laboratory component of national TB control programme. For improved quality of AFB smear microscopy, culture, Drug Susceptibility Testing (DST) and Molecular line probe assay, attention must be given to critical areas of sputum collection, smearing, staining, reading and storage to be done professionally in accordance with Standard Operating Procedures (SOP), as well as accurate recording and reporting of results.

8.2 ORGANISATION OF THE LABORATORY

The NTBLCP laboratory network is organized in a pyramidal fashion consisting of four levels as follows:

- **Level 1:** a large number of peripheral laboratories providing AFB services and is readily accessible to all TB suspects and patients at the LGA. The NTBLCP will strive to ensure that a peripheral laboratory serves a population of at least 80,000 – 100,000 population
- **Level 2:** one laboratory for each state of the country, including the Federal Capital Territory. NTLCP will ensure that 37 of such laboratories are in place.
- **Level 3:** 6 zonal reference laboratories to be located in tertiary health facilities in each of the zones.
- **Level 4:** two national reference laboratories, located at Nigerian Institute of Medical Research (NIMR) to serve the southern part of the country and the National TB and Leprosy Training Centre (NTBLTB), Zaria to serve the Northern part of the country.

The NRL will be linked to a Supra-National Laboratory for purpose of technical support and external quality assurance.

NB: The National TB Laboratory Working Group should support FMOH in coordinating all laboratory activities.

8.3. FUNCTIONS AND RESPONSIBILITIES OF THE VARIOUS LEVELS

8.3.1. Level 1: Peripheral Laboratory

a. Technical

- Preparation and staining of smears
- ZN microscopy and recording of results
- Internal quality control

b. Administrative

- Receipt of specimens and dispatch of results
- Cleaning and maintenance of equipment
- Maintenance of laboratory register
- Management of reagents and laboratory supplies

8.3.2. Level 2: State Reference Laboratory: will perform all the functions of Level 1 laboratories in addition to the supervision and monitoring of activities, including quality-assurance functions and report to the Zonal Laboratories.

8.3.3. Level 3: Zonal Reference Laboratory

All the functions of the peripheral level, plus:

a. Technical

- Florescence microscopy (optional)
- Digestion and decontamination of specimens
- Culture and identification of *M. tuberculosis* complex and DST
- Preparation and distribution of reagents for microscopy in peripheral laboratories
- Regular maintenance of equipment
- Oversight functions of state laboratories
- Operational research

b. Managerial

- Training of microscopists
- Support to and supervision of peripheral staff with respect to microscopy
- Quality improvement and proficiency testing of microscopy at lower laboratories.
- All the functions of the levels 2 laboratory, plus:

8.3.4. Level 4: National Reference Laboratory:

All the functions of the intermediate level, plus:

a. Technical

- Drug susceptibility testing of *M. tuberculosis* isolates
- Identification of mycobacterium other than *M. tuberculosis*
- Molecular epidemiology studies

- QAS for state and zonal
- Proficiency testing between the NRL and SNRL
- Operational research

b. Administrative

- Technical control of and repair services for laboratory equipment
- Updating and dissemination of manuals on bacteriological methods for diagnosing tuberculosis
- Development and dissemination of guidelines on care and maintenance of microscopes and other equipment used in tuberculosis bacteriology.
- Development and dissemination of guidelines on tuberculosis laboratory supervision and quality assurance.
- Collaboration with the central level of the NTBLCP in defining technical specifications for equipment, reagents and other materials used in bacteriological investigations, and in estimating laboratory materials and equipment requirements for the Programme budget.

c. Managerial

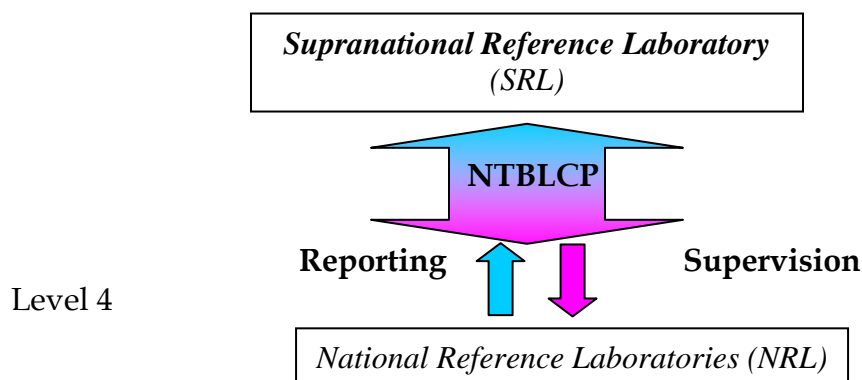
- Training of level 2 and 3 laboratory staff in bacteriological techniques and support activities, i.e. training, supervision, quality assurance, safety measures and equipment maintenance.
- Supervision of levels 2 and 3 laboratories regarding bacteriological methods and their support (particularly training and supervision) to the peripheral laboratories.

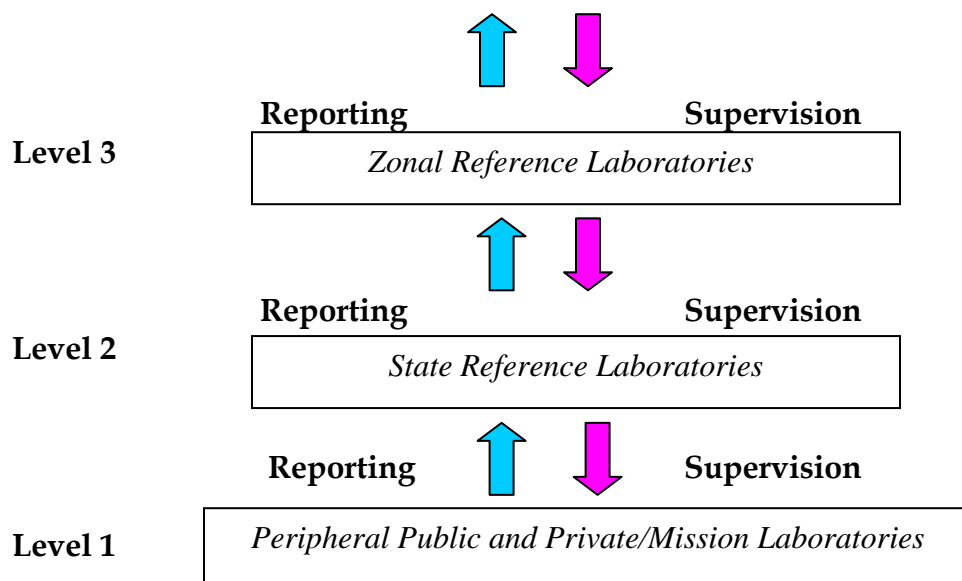
d. Research and surveillance

- Organization of surveillance of primary and acquired mycobacterium drug resistance.
- Operational and applied research relating to the laboratory network, coordinated with the requirements and needs of NTBLCP.

8.3.5 STRUCTURE OF THE LABORATORY

The structure of TB laboratory network is depicted below.





8.4 QUALITY ASSURANCE (QA) IN TB MICROSCOPY

8.4.1 Quality Assurance

Quality Assurance is a system designed to continuously improve the reliability, efficiency and use of laboratory service. In order to achieve the required technical quality in laboratory diagnosis, a continuous system of quality assurance needs to be established.

8.4.2 Components of Quality Assurance (QA) in TB Smear Microscopy

The three components of QA in TB smear microscopy are:

- Internal Quality Assessment or Quality Control (IQA or QC)
- External Quality Assessment (EQA)
- Quality Improvement (QI)

8.4.2.1 Internal Quality Assessment or Quality Control (QC)

This involves systematic internal monitoring of working practices, technical procedures, equipment and materials.

Performance:

- Proper and adequate sputum collection and immediate processing
- Label slides according to guidelines
- Proper slide preparation (correct size, thickness and consistency)
- Ensure air-drying before fixing
- Ensure use of filtered reagents

- Avoid overheating of slides
- Read standard number of fields before reporting
- Avoid recycling slides and containers
- All laboratory effluents should be destroyed by incineration
- All slides be stored for a period of 3 months for EQA
- Wet, sweep and mop the floor.

8.4.2.2 External Quality Assessment (EQA)

EQA is a process of assessing laboratory performance. It allows participating laboratories to assess their capabilities by comparing their results with those obtained in the laboratory network through Panel testing and rechecking.

The three ways that can be combined to evaluate laboratory performance include:

- On-site evaluation
- Panel testing
- Blinded rechecking

8.4.2.2.1 On-site Evaluation:

A visit to the peripheral sites (laboratories,) shall be carried out by trained laboratory personnel from the supervising laboratory periodically, to observe laboratory workers' performance under actual working conditions, and to assess laboratory equipment, supplies, and to assess internal quality control using a checklist attached.

8.4.2.2.2 Panel Testing

This is a nationwide system of sending stained and unstained slides (of negatives and positives) from the National reference Laboratory to the peripheral laboratories/sites for reading and interpretations. It measures the ability of a microscopist to stain and/or read smears. It is also an opportunity to compare performance of one laboratory with the others.

8.4.2.2.3 Blinded Rechecking:

About 10% of the slides at each laboratory in the network will be re-read per quarter by another microscopist other than the laboratory's microscopist, blinded. The slides collected should be representative of the laboratory work load and will include all slides as serially arranged in the slide box.

8.4.3 Quality Improvement (QI)

This is mainly the continuous monitoring of laboratory performance through data collection, data analysis and creative problems solving. It involves continued

monitoring of results by checking any sharp difference from the norm followed by remedial action including retraining when necessary, to prevent recurrence of problems. QI often relies on effective on-site evaluation visits.

8.5 BIO-SAFETY PRACTICES

Safety practices to be observed in the laboratory include:

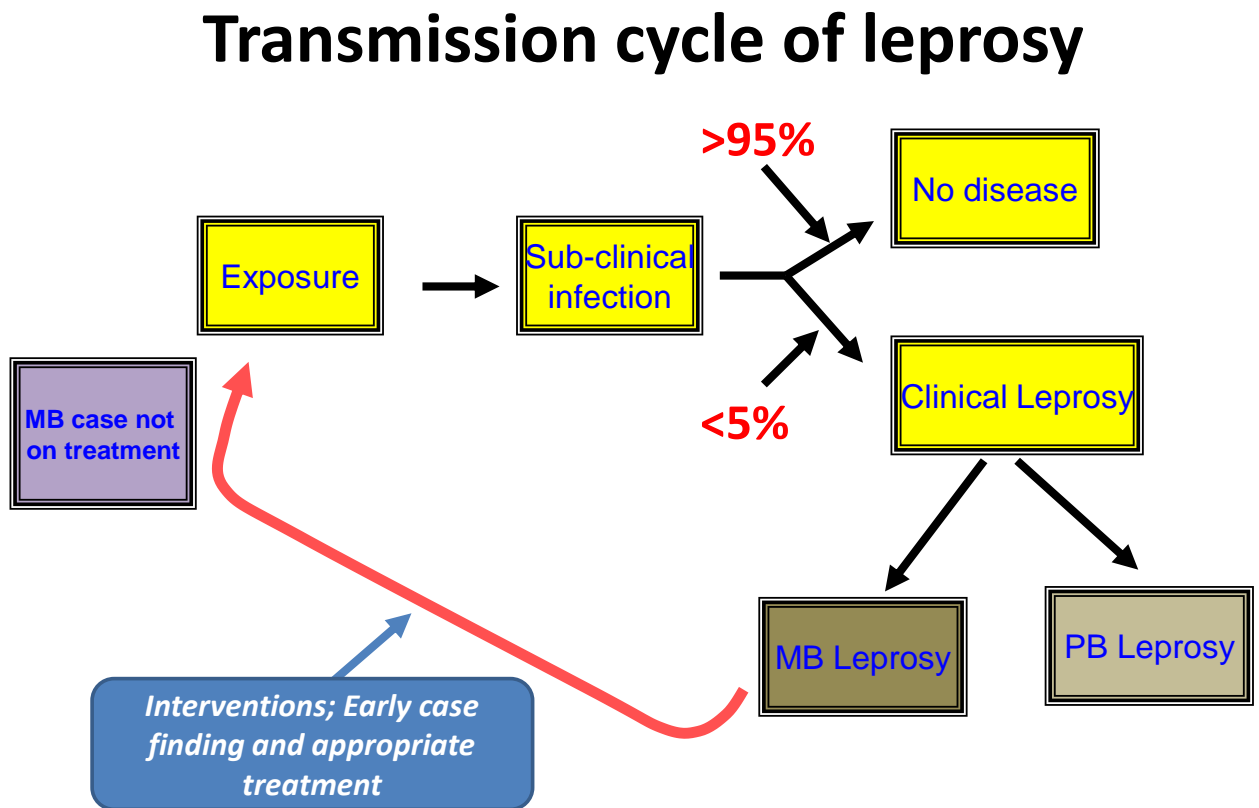
- Closing laboratory doors when experiments are in progress
- Control of access to the laboratory unit by the laboratory head/director
- Establishing policies and procedures for laboratory entry and exit
- Placing hazard warning signs or biohazard symbols on laboratory access doors
- Giving appropriate immunization to personnel or testing workers for the presence of the microbial agents handled or potentially present in the laboratory
- Developing and adopting laboratory manual specific to the laboratory bio-safety measures of the standard operative procedures
- Giving appropriate training to the laboratory personnel on potential hazards associated with the work involved
- Observing high precautionary measures when handling sharp materials
- Conducting manipulations involving infectious materials(e.g. cultural practices and centrifugation) in a bio-safety cabinet
- Routine decontamination of laboratory wastes, equipment and work places with effective disinfectant
- Placing culture, body fluids, wastes, tissues in containers that prevent leakages during collection, handling, processing, storage, transportation or shipping
- Reporting immediately all accidents and spillages resulting in overt or potential exposures to infectious materials
- Wearing protective laboratory clothing and wears
- Centrifugation of infectious materials and performing cultural practices in a class II or class III bio-safety cabinet

CHAPTER 9 LEPROSY COMPONENT

9.1 INTRODUCTION

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 through droplets (coughing and sneezing). The most important route of exit is through the nasal discharges. The average incubation period (that is the period between infection and the appearance of disease) is between 2 and 5 years.

Transmission cycle of leprosy



9.2. GOAL FOR LEPROSY CONTROL

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

9.2.1 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 provide comprehensive care such that < 5% of patients develops disability while on treatment.
3. To provide health education and counseling to ensure >95% and >85% treatment completion rate among PB and MB patients respectively.
4. To ensure 100% MDT coverage for all patients in need of MDT.
5. To develop a comprehensive rehabilitation services in all States.

9.3 LEPROSY CONTROL STRATEGY

1. Expanding opportunities to reduce the disease burden further by means of timely case-finding and treatment, BCG vaccination and improved socioeconomic conditions.
2. Closely monitoring progress of trend of new cases with grade- 2 disabilities in the population.
3. Strengthening leprosy control activities in areas where a high proportion of new cases with grade-2 disabilities are being detected.
4. Promoting the use of community-based rehabilitation to improve the quality of life of persons and families affected by leprosy.
5. Conscious efforts to integrate Leprosy control into the General Health care services.
6. Increase surveillance for resistant strains of *M. leprae*.
7. Applying cost-effective methods to improve community awareness, acceptance and involvement to combat stigma and discrimination against persons and families affected by leprosy.

Leprosy is curable with drugs available and free through the NTBLCP.

9.4 Case detection

Leprosy case detection is based on both passive and active case finding. The following actions are necessary for improvement in case detection.

9.4 How is leprosy diagnosed?

The diagnosis of leprosy requires:

- A good history taking,
- Physical examination of the patients (general, skin, and nerves assessment) and
- Minimal involvement of the laboratory for difficult cases.

9.4.1 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.

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

- Light (Hypo-pigmented) patches on the skin (the most common sign of leprosy)
- Loss, or decrease, of feeling in the skin patch, numbness or tingling of the hands or feet
- Weakness of the hands, feet or eyelids, painful or tender nerves
- Swellings or lumps in the face or earlobes
- Painless wounds or burns on the hands or feet

9.4.2 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)

9.4.2.1 Talk to the Person (History Taking)

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.

How long has the skin patch been there? How did it start? Has it changed?

Leprosy patches usually appear slowly

Do the patches itch? Is there pain?

Leprosy patches do not itch and are usually not painful unless complicated (Leprosy reaction)

Does the person have unusual sensations in his hands or feet, such as numbness, tingling or a burning feeling?

Unusual sensations in the hands or feet can be a sign of leprosy

Does the person think that his hands or feet have become weaker? Does he have problems with holding or lifting things and with moving his hands and feet?

Losing strength of the muscles of eyes, hands or feet can be a sign of leprosy

Has the person experienced any social problems?

This may be more likely if the person already has some deformity due to leprosy

9.4.2.2 Examine the Skin

Conditions for proper skin examination:

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

Look for loss of sensation in the skin patches

Leprosy patches usually have 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 patient with his eyes open
- Ask patient to close his/her eyes or be blindfolded while carrying out the procedure

- Touch a normal skin above the patch, then touch the centre of the skin patch then touch a 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, then, it becomes a cardinal sign of leprosy

Note: Skin lesions on the face may not demonstrate loss of sensation, due to the complexity of nerve supply in the face. Also, non-leprosy scaly lesions may be insensitive to cotton wool test.

Record findings on the leprosy record card (NTBLCP/Lep1)

A person showing a hypo-pigmented or reddish skin lesion with definite loss of sensation is a case of leprosy

9.4.2.3 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 examination of a person affected with leprosy, but requires experience and should be done only by those staff specifically trained to do it.

Nerves which are commonly enlarged are:

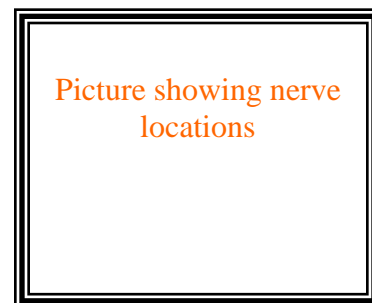
Great Auricular nerve on the side of the neck, below the ear, is sometimes visibly enlarged: gently feel it to make sure it is the nerve (solid) and not one of the veins in the neck (full of fluid).

Ulna nerve at the elbow,

Radial Cutaneous nerve at the wrist

Common Peroneal nerve at back of the knee

Posterior Tibial nerve at inner side of the ankle,



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 pulps of two or three fingers
- Roll nerves gently over underlying surface to get an impression on 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, is diagnostic of leprosy

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

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

9.4.2.4 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

9.4.2.5 Check for sensation in hands and feet

- Check the sensation in 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

Insert hands with four points

- 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 ✓

NB: 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**.

9.4.2.6 Check for muscle function in the Hands and Feet

Hands(1) 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

Demonstration
picture

(2) 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

Demonstration
picture

Feet:

(3) 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

Demonstration
picture

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

9.4.2.7 Slit Skin Smear Examination

Slit skin smear is recommended for difficult and ambiguous leprosy suspect and such suspect 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.

9.5 LEPROSY DIAGNOSIS

9.5.1 Case of leprosy

If leprosy is recognised in its early stages, it can easily be treated and it will not cause the disabilities that most people think of whenever 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).

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

9.5.2 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 hypopigmented but without loss of sensation and often itch. Give an anti-fungal ointment for 6 weeks

Ringworm (Tinea): 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 (Leucoderma): Completely depigmented areas of skin with clear, flat edges without loss of sensation, 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 hypo-pigmented, fine papular ring, with central de-pigmentation, without loss of sensation.

Onchocerciasis (River Blindness): Thickened skin, very itchy nodules, areas of scratch marks, and hypo-pigmentation. 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.

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, hypo-pigmented rounded or oval patches variable in size with the margins sharply demarcated covered with fine

adherent scales. Sometimes the patches are erythematous 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)

9.5.3 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
- **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

9.5.4 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

9.6 CLASSIFICATION OF LEPROSY

9.6.1 Functional/clinical Classification

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

	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 and muscle weakness)	Only 1 nerve involved	Two or more nerves involved

NB:

1. Where SSS was done, if positive patient is classified as MB
2. If there is doubt about the classification, the patient should be classified as MB and treated with MB- MDT
3. Any patient with more than one nerve involvement but less than 5 five skin patches should be classified as MB.

9.6.2 Case Categorisation 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

9.7 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.

9.7.1 WHO RECOMMENDED MDT REGIMENS

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.

- **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

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.

9.7.2 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.

9.7.3 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 treatment.

Guidelines for patient education at the time of discharge:

Inform patient that:

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

9.7.4 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

The table below outlines the common side-effects and actions to take if they occur.

Side-effects of the drugs

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

SIDE EFFECTS/COMPLAINTS	POSSIBLE CAUSE	ACTION
The urine may stain slightly reddish for a few hours after taking the supervised dose.	Rifampicin	This is harmless and should be explained to the patient at the start of MDT.
The skin may in the course of months gradually turn brownish-black and show dryness.	Daily Clofazimine for (MB patient)	It will disappear within a few months after completing MDT, but the patient should be informed when starting 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.	The patient should <u>stop</u> 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.
Jamndice often accompanied by lack of appetite, nausea and vomiting.	Either Rifampicin or Dapsone	<u>Stop</u> 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.
Exceptionally a patient may become very excited or frightened, even psychotic.	Dapsone	Stop the drug and refer to the TBL referral hospital.

9.7.5 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 drug regularly.
- Provide accessible places of 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 VMT/ST 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 guideline.
- Offer comprehensive medical care for the treatment of concurrent ailments

FLEXIBLE MDT DELIVERY

Services must be organised 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 supply 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.

9.7.6 Defaulter Retrieval

9.7.6.1 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.**

9.7.6.2 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

9.8 PREVENTION OF IMPAIRMENTS AND DISABILITIES (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.

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, sexes and culture (activity limitation) e.g. difficulty in reading a book, inability to hold a hoe tightly because of mobile claw etc.

The aims of POD are as follows:

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

9.8.1 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.

9.8.1.1 World Health Organisation (WHO) Impairment Grading

The most widely used grading system (WHO Impairment Grade) is in the following table.

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 (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:

	Eye	Hand	Foot
	E	H	F
Right	2	0	2
Left	0	1	2

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:	Grade at end of treatment
(RFT)	

	E	H	F
Right	2	0	1
Left	0	0	1

WHO grade = 2

E	H	F
2	0	2
0	1	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.

9.8.1.2 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
R	2	0	1
L	0	0	1

EHF score = 4

E	H	F
2	0	2
0	1	2

EHF score = 7

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

The patient has deteriorated between registration and release from treatment

9.8.2 Preventing impairments and disabilities

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

9.8.2.1 Early Case Detection and Effective Treatment with MDT

This topic has been discussed extensively in 9.4 to 9.7 above.

9.8.2.2 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).

9.8.2.3 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.

Leprosy reactions can happen at any time during the illness: before, during or even after release from treatment.

9.8.2.3.1 Recognising Lepra-reaction

Lepra-reaction is an acute inflammatory process, therefore, look for the following signs:

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

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.

Type 1 leprosy reaction:

Body part affected	Mild	Severe
Skin	<i>Red, raised and tender skin lesions (except on the face)</i>	Ulcerating skin lesions <i>Red, raised facial lesion</i>
NERVES	No nerve tenderness	<i>Painful or tender</i> and enlarged nerves on palpation <i>Red, raised patch on or around any peripheral nerve</i>
VMT	No change	<i>Recent change in VMT</i> (less than 6 months duration) Muscle weakness in eyes, hands, feet
ST	No change	<i>Recent change in ST</i> (less than 6 months duration) Change in sensation in one or more points in any one hand or foot
Eyes	Not affected	<i>Sudden lagophthalmos (inability to close the eye)</i> <i>Sudden loss of corneal sensation</i> (loss of automatic blink)
General body condition	Good general condition	fever and malaise can occur in the acute phase only
SYSTEMIC EFFECTS	No effect	<i>joint pain due to enlarged nerves.</i>

Type 2 reaction:

Body Part Affected	Mild	Severe
SKIN	Appearance of red, raised sub-cutaneous nodules (and patches) Few crops of nodules	Ulcerating sub-cutaneous nodules
	No nerve tenderness	<i>Painful or tender</i> and enlarged nerves on palpation

VMT	No change	<i>Recent change in VMT</i> (less than 6 months duration) Muscle weakness in eyes, hands, feet
SENSORY TEST (ST)	No change	<i>Recent change in ST</i> (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	<i>Fever and malaise</i> common and prolonged
SYSTEMIC EFFECTS	No effect	<i>Orchitis</i> - painful, testicular swelling <i>Dactylitis</i> - painful, swollen joints, hands and feet. Renal involvement (blood in the urine)

9.8.2.3.2 Treating Reactions

I 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.

II Treatment of Severe Type I Reaction

Treatment of severe type 1 reaction without conditions for referral should be by general health care workers in the field, however diagnosis and monitoring should be supported by TBLS. Any person with severe type I reaction, without any of the criteria needing referral (see page 74) can be treated in the field 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 finalised before the start of treatment with Prednisolone

Condition	Treatment
Worm infestation	Mebendazole 100mg BD x 3 days
Diarrhoea with blood / mucus suggestive of dysentery	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.

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

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	Total 24 weeks

Patients who do not improve within 4 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.

III Treatment of Severe Type II Reaction

All cases of severe type II reaction are to be treated in the hospital.

SEVERE TYPE II REACTION MUST NOT BE TREATED IN THE FIELD, IT CAN BE LIFE-THREATENING AND DISABLING

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

ANY PERSON IN REACTION WITH ANY OF THE FOLLOWING CONDITIONS SHOULD BE REFERRED TO HOSPITAL:

- Severe type II reaction
- 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 2 years or more after release from MDT
- Younger than 12 years of age
- Recent history of stomach ulcer
- History of diabetes
- General illness and / or fever
- Complications of Prednisolone
- Severe type 1 reaction not responding to standard regimen of Prednisolone
- Hypertension

9.8.2.4 PRESERVATION OF VISION

Eye examination

Tools needed:

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

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

E – Chart to be placed here

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.

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.

Recording the result

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

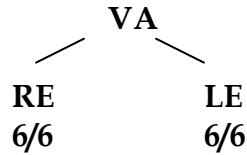
- The top number is the distance from the E chart – that is 6 metres
- The bottom number is the number written underneath the last line read clearly – that is 60 (the very top line)

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

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.

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

EYE COMPLICATION	REDNESS	PAIN	BLURRED	PUPIL
------------------	---------	------	---------	-------

			VISION	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

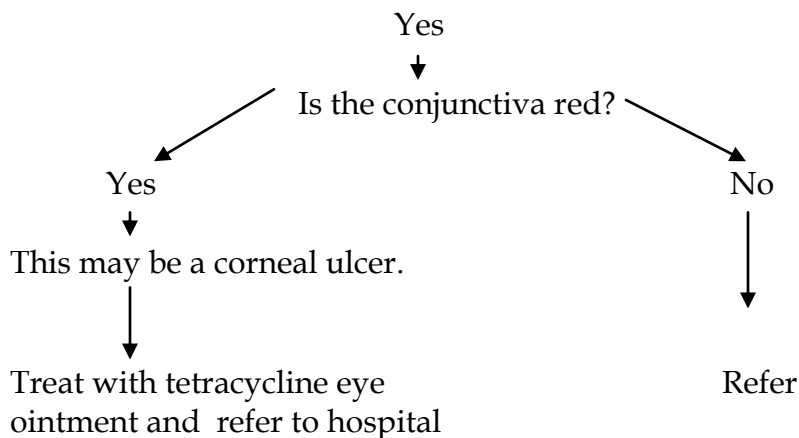
IV Cornea

- 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?
an eye clinic

If no, refer to

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	ACTION TO TAKE
Lagophthalmos less than six months	Protective glasses TCN eye ointment <i>systemic steroids immediately</i>
Lagophthalmos more than six months <5mm If the eye can close fully when closed forcefully If the eye cannot be closed fully when forcefully closed	Protective Glasses Tetracycline eye ointment Artificial Tears (if available) Cover eye when sleeping at night Regular inspection of the eye Self-care training Exercise: Forced eye closure at least 3 times a day for 5 seconds x 20 repetitions Exercise: Passive eye closure ay least 3 times a day x 5 seconds x 20 repetitions
Lagophthalmos more than six months >5mm	Refer for surgery
Tiny pupil	Dilate with atropine and refer to an eye clinic
Acute iritis: Redness around the cornea	Dilate with atropine Glasses (sunshades) Refer immediately to TBL Referral Centre for steroids
Loss of corneal sensation (no blink) – less than six months	Protective glasses Tetracycline eye ointment Prednisolone Self-care training <i>If associated with facial patch then refer to TBL Referral Centre</i>

Loss of corneal sensation (no blink) – more than six months	Protective glasses Tetracycline eye ointment Self-care training BLINK EXERCISES
Conjunctivitis	Wash face and clean with water carefully 3 times daily Tetracycline eye ointment Refer if no improvement in 2 days
Acute keratitis (white / hazy cornea with red conjunctiva)	Tetracycline eye ointment Refer to eye clinic immediately
Corneal ulcer white spot on cornea with red conjunctiva – may have a discharge. Pain. Diminished vision	Tetracycline eye ointment Dilate with atropine Refer to eye clinic immediately Note Do not give steroid (Prednisolone)
Trichiasis Lashes rubbing the eyeball – less than 5 lashes	Remove with forceps Tetracycline eye ointment
Trichiasis Lashes rubbing the eyeball – more than 5 lashes	Tetracycline eye ointment Refer to eye nurse or referral hospital

9.8.2.5

SELF-CARE

Patients should be trained and empowered to take care of the simple problems at home and encourage to form self-care groups.

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 wound

6. Practice simple hand exercise 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 wound
5. Ensure adequate rest of foot with an ulcer- e.g use crutches
6. Practice simple exercise 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 to go to school
5. Support women and children to access general health care services

See the pictures on the following five pages:

CARE OF EYES WITH BLINK PROBLEMS

I AVOID INJURY THROUGHOUT THE DAY

- a) Blink consciously
Try to close with effort regularly



- b) Think when the dust blows
or when rinsing
Make 'think-and-blink'
a habit



- c) Protect your eyes
from wind/dirty air
sun and heat



- d) Keep your eyes clean and free from dirt



- e) Cover your eyes at night

II FOLLOW THIS DAILY ROUTINE

- a) Inspect eyes at least daily for dirt
and redness:
• using a mirror
• ask someone (relative) to inspect

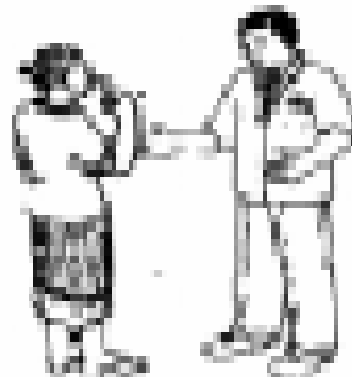


- b) Remove foreign bodies by
repeated 'think-and-blink' or
very gently with a clean cloth

III HEAL WOUNDS QUICKLY

In case of irritation,
vision change or/for injury:

- a) Report to a health visitor



- b) Apply any prescribed
medicines without
touching the eye with
the tube

CARE OF HANDS WITHOUT FEELING

I AVOID INJURY THROUGHOUT THE DAY



Be aware of where feeling is protected best

RECOGNISE DANGER	AVOID		
<p>a) Beware of hot objects</p> 	<p style="text-align: center;">Insulate</p>  <p style="text-align: center;">Allow to cool</p>  <p style="text-align: center;">Keep distance</p> 		
<p>b) Beware of pressure build-up</p> 	<p>Change jobs often</p> 	<p>Cushion tool handles</p> 	<p>Stop for rests</p> 
<p>c) Beware of sharp or rough objects</p> 	<p>Smooth them</p> 	<p>Keep distance</p> 	<p>Use tough gloves</p> 

2 FOLLOW THIS DAILY ROUTINE

- a) Inspect for:
- signs of injury
- hard skin



- b) Rest



- c) Exercise



- d) Rub off hard skin on:
- crack edges
- old wound sites



- e) Oil well



3 HEAL WOUNDS QUICKLY - AVOID RECURRENCE

- a) Work out the wound cause



- b) Check for healing



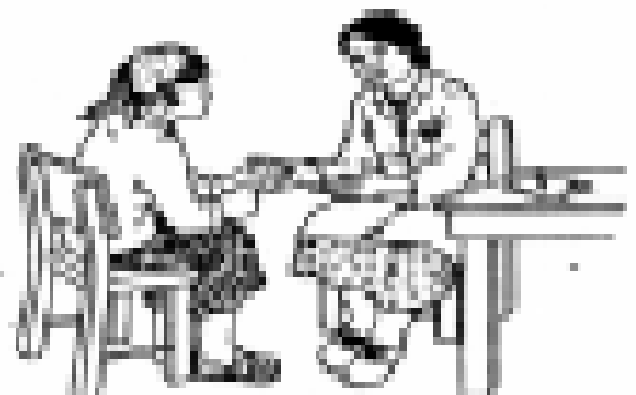
- b) Plan how to avoid recurrence



- c) If no improvement, report care and report to health staff

- c) Clean
Cover
Rest

the wound



CARE OF FEET WITHOUT FEELING

FEET CONTINUED

9.8.2.6 PROVISION OF PROTECTIVE WEARS

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.

9.8.2.7 Proper Management of Ulcers Of Hands And Feet

I Causes:

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 un-noticed
- Burns going un-noticed
- Neglect of small injuries which leads to further damage and larger wounds

II 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 to the wound look like? (colour, swelling, clean,

	<p>blisters)</p> <p>What footwear is the patient wearing? (hard, soft, covered shoe, slippers, sandals in good condition, well-fitting)</p>
TOUCH	<p>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</p> <p>Is the hand or foot swollen? Is there pitting oedema? If yes, these are signs of infection</p> <p>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</p> <p>Is there tenderness? This could indicate a localised infection</p> <p>Check the position and mobility of joints - the fingers, the toes, the ankle and knee, the wrist and elbow.</p>

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

III 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 principals apply, but obviously aseptic techniques are used.

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

Preventative 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

IV 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 the 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 every day

The most important ulcer to prevent is the first one. Once there is an ulcer, there is higher probability of recurrence of that ulcer because the scar formed after healing is fragile and can break down with slight pressure

IT IS IMPORTANT TO REALISE THAT WOUNDS ARE NOT ALWAYS CAUSED BY NEGLIGENCE. 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

CHAPTER 10 IMPLEMENTING BURULI ULCER DISEASE CONTROL COMPONENT

10.1 INTRODUCTION

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.

10.2 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.

10.3 GOAL AND OBJECTIVES OF BURULI ULCER CONTROL

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

The specific objectives

1. To detect and treat early active cases of BU
2. To provide appropriate care (antibiotics, surgery and prevention of disabilities) including
referrals according to standardised guidelines.
3. To ensure BU patients with disabilities receive appropriate rehabilitative care
4. To include BU as part of the integrated disease surveillance system
5. To promote relevant research on the epidemiology, diagnosis, treatment and

prevention of BU

6. To advocate and mobilise resources for the programme

10.4 STRATEGIES (ADOPTED FROM THE GLOBAL BURULI ULCER INITIATIVE (GBUI))

1. Advocacy, social mobilisation and partnership
2. Staff training on early identification and diagnosis
3. Early and community-based case detection
4. Confirmation of cases
5. Case management (antibiotics, surgery and prevention of disabilities)
6. Strengthening health structures
7. Supervision, monitoring and evaluation

10.5 IDENTIFYING THE 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. Identification of Buruli ulcer cases 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 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.

10.6 CASE DIAGNOSIS

10.6.1 General principles

- 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.

10.6.2 Diagnostic means

10.6.2.1 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**

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 hypo-pigmented (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 hypo-pigmented.
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.

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.

10.6.2.2 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 exam, 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 exams, 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.

10.6.3 Confirmed Case of BU

A confirmed case of BU is a 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.

10.7 COMPLICATED BU CASES

If any of the forms of BU described in 10.5.2.1 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.

10.8 CASE MANAGEMENT

10.8.1 General principles:

- 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

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

10.8.2 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 (debridment, excision, skin grafting)
4. Prevention of disability (POD)

10.8.3 Procedures to Be Applied in Case Management

10.8.3.1 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

10.8.3.2 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.

10.8.3.3 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.)

10.8.3.4 Monitoring during the treatment:

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

10.8.3.5 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	Clinical diagnosis of the cases

Medical Officer	Dressing all wounds Combined antibiotics (rifampicin-aminoglycoside) Appropriate referral of BU cases
Health centres with a Medical Officer	<i>Above-mentioned activities of health centre without a doctor</i> 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	<i>Above mentioned activities of intermediate hospital plus</i> Management of complicated cases Reconstructive surgery of complications Physiotherapy Culture, PCR and histopathology

10.9 PREVENTION OF DISABILITY (POD)

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
- **The essentials:**
 - 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

10.10 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.

CHAPTER 11: MANAGEMENT OF DRUGS AND OTHER SUPPLIES

11.1 Introduction

The success of the TBL programme rests mainly in the provision of essential drugs and supplies. A reliable system of logistics (drugs and supplies) support is therefore a necessity for effective programme implementation. The NTBLCP provides all drugs and supplies free of charge to all TBL patients.

11.2 Essential drugs and other supplies for detecting and treating TB and Leprosy in a health facility include:

- Drugs for TB treatment (sufficient quantities of oral drugs for complete regimens, plus streptomycin and additional tablets)
- Treatment-related supplies, such as syringes, needles and sterile water for injection
- sputum containers
- TB forms and Registers.
- Drugs for Leprosy treatment (sufficient quantities of MB and PB MDT blister sheets, Prednisolone)
- Leprosy forms and Registers

Maintaining an adequate drug supply depends on accurate estimates of drug needs. Distribution of drugs and other supplies are done on quarterly basis.

11.3 Presentations and packaging of anti-TB drugs

The drugs currently used in standard regimens for treatment of tuberculosis (with their standard abbreviations) are:

- isoniazid (H)
- rifampicin (R)
- pyrazinamide (Z)
- ethambutol (E)
- streptomycin (S)

Most anti-TB drugs are now manufactured in **fixed-dose combinations** (FDCs) . Fixed-dose combinations are drugs combined in tablet or capsule form, in specific dosages, to facilitate correct drug intake. The following FDCs are becoming widely available:

- Isoniazid-rifampicin-pyrazinamide-ethambutol (HRZE) - **4 fixed-dose combination.**
- Isoniazid-rifampicin-pyrazinamide (HRZ) - **3 fixed-dose combination.**
- Isoniazid-rifampicin (HR) **2 fixed-dose combination.**
- Isoniazid-ethambutol (HE) **2 fixed-dose combination.**

11.3.1 Organizing individual patient kit

One of the challenges in TB treatment is ensuring the availability of drugs through out the duration of treatment to ensure cure and to prevent the possible emergence of MDR TB. A way to ensure a patient's drugs are assured once treatment is commenced is by organizing the drugs into individual patient kits. The NTBLCP has commenced the gradual introduction of patient kits, but all other facilities should commence organizing their drug supplies into individual patient kits pending when supplier-made kits will be made available to all patients.

All facility focal persons should follow these steps to organize kits for their patients:

1. Weigh the patient and record the patients name and weight on a card
2. Check the number of tablets for both intensive and continuation phase to be administered according to the patient weight using the appropriate drug table
3. Write the number of tablets to give to the patient for each dose on a label (card)
4. Calculate and take the number of blister sheets of each treatment phase needed by the patient for a full course of treatment
5. Bind the blister sheets up with a rubber band and attach the labeled card with the patients name, weight and number of tablets per dose
6. Confirm and administer correct numbers of tablets from the patient kit each time the patient visits the facility until treatment is completed
7. Any blister sheets remaining in the patient kits from patients who defaulted, died or were transferred out should be returned to the original blister packet for repackaging for another patient .

11.4 Presentation of anti-leprosy drugs

The drugs currently used in standard treatment of Leprosy are:

- Rifampicin
- Dapsone
- Clofazimine

These drugs are available in blister sheets and according to the classification of patients i.e. PB-MDT and MB-MDT blister sheets.

11.5 Ordering at the Health Facility Level

At the health facility level, the focal person is responsible for:

- Checking the drug regimens being used for the treatment of the different categories of TBL patients.
- Checking that record of drug administration to patients are made as and when due.

- Making request for the facility drugs/supplies based on consumption and the quarterly statistics
- Transfer to supervision
- Carrying out periodic stock control (store inventory) in the facility store where applicable

11.6 Ordering at the LGA/State levels

At these levels, the LGTBLS/STBLCO is/are responsible for:

- Coordinating the logistics support system in the LGA(s)
- Checking the quarterly statistics handed in by the health facilities in the LGA(s) so as to determine the number of TB and Leprosy patients on treatment
- Checking the drug regimens being used for the treatment of the different categories of TBL patients
- Checking the drug/supplies' ordered versus the supply for each quarter
- Checking that the closing stock of the last quarter is the opening stock of the next quarter.
- Comparing the drugs issued last quarter with the number of patients reported.
- Determining the quantities of drugs/supplies to be issued to health facilities.
- Authorizing the quantities of drugs/supplies to be issued by the State Storekeeper or to be supplied to health facilities/LGA(s).
- Carrying out periodic stock control (store inventory) in all TBL stores in the LGA(s)

11.7 Determining Quantities of TB and Leprosy Drugs needed for each Quarter

It is important to ensure that enough drugs are in stock for all TB and Leprosy cases expected to start treatment during the next quarter (all categories of treatment). It is assumed that the number of new patients in each treatment category next quarter and the consumption pattern will be the same, or approximately the same, as it was in the previous quarter.

At the beginning of each quarter, the TBL Supervisor will determine these numbers from records of cases registered in the previous quarter/consumption records of the previous quarter, and will order drugs according to the steps below (ref annex 4 page 206):

- Establish the number of TB or leprosy patients treated last quarter for each treatment category.
- Make a physical inventory of all items in store on the last day of the quarter
- Write the total quantity issued/dispensed in the last quarter
- Divide the total by 3 to determine the average monthly consumption
- At the facility and LGA level, multiply the average monthly consumption by 5 to get the maximum stock level for a quarter
- At state/zonal level, multiply the average monthly consumption by 6 to get the maximum stock level for a quarter

- Determine the quantity to order by subtracting the physical inventory from the maximum stock level, and fill into the LMIS form



11.8 Good Storage and Management Procedures for Drugs and Supplies

Health facility drugs and supplies are kept in the health facility's drug store, which should be well kept and managed by a designated responsible staff member. Good storage and management procedures are important for all drugs and supplies kept in the store or cabinet.

It is important to:

11.8.1 Keep drugs and other supplies safe

- Ensure that store rooms and cabinets are locked when not in use
- Ensure that fire prevention measures are implemented.

11.8.2 Keep the store in good condition

- Keep the temperature, light and humidity in the main storeroom moderate. A drug storeroom should not have excessive heat, light or humidity, as these can cause some drugs to spoil.
- Storage conditions can be improved by some simple measures. Temperature can be controlled by using fans, air vents or windows to increase ventilation, and by using insulating materials for the roof and ceiling. Direct light can be prevented from entering the room by hanging curtains or painting the window glass. Humidity can be controlled by increasing ventilation, creating drainage areas, and repairing any roof leaks quickly.
- No one should eat, drink or smoke in the storeroom. Do not keep food or drink in the store. This will help to keep the storeroom clean and free of pests.

11.8.3 Organize drugs and supplies

- Stocks of anti-TB drugs in the store (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.
- For all drugs and commodities expiring within six months and which may not be consumed within the same period, programme managers should be informed for **re-distribution**.

- When taking drugs off the shelf, use those in front first. These procedures follow the FEFO rule (meaning First to expire, First Out). The oldest drugs are used first. Return expired drugs to the TBL Supervisor.
- Items without expiry date should follow the FIFO rule (meaning First In, First Out), so that oldest items are used first.
- Maintain a stock card for each drug, each drug strength and other supplies
- Keep all stock cards on the shelf.

CHAPTER 12 EVALUATION

SUPERVISION, MONITORING AND

12.1 INTRODUCTION

The Federal Ministry of Health has a Health Management Information System (HMIS) unit under the Department of Planning, Research and Statistics (DPRS). This unit is responsible for the collation and analysis of health data for the entire country.

12.2 THE HMIS CONSISTS:

- Monthly Disease Surveillance and Notification Reports on 40 notifiable diseases;
- Immediate Disease Notification reports on epidemic diseases e.g. CSM, Cholera etc.
- Integrated Disease Surveillance and Response (IDSR)

Tuberculosis is among the 40 Monthly notifiable diseases under surveillance by the Federal Ministry of Health. However, since the establishment of the National Tuberculosis and Leprosy Control Programme (NTBLCP) in 1991, a separate system of monitoring and evaluation based on WHO and IUATLD recommendations was adopted by the programme to track progress in TBL control.

12.3 TB & LEPROSY CONTROL TRACKING BY THE M&E SYSTEM

The following constitute main aspects of TB & Leprosy Control:

- Accessibility of TBL services
- Performance of laboratories with respect to AFB smear microscopy
- TBL case finding
- TBL treatment outcome
- Drug utilization
- HIV & TB related activities

12.4 INFORMATION FLOW FOR EPIDEMIOLOGICAL MONITORING

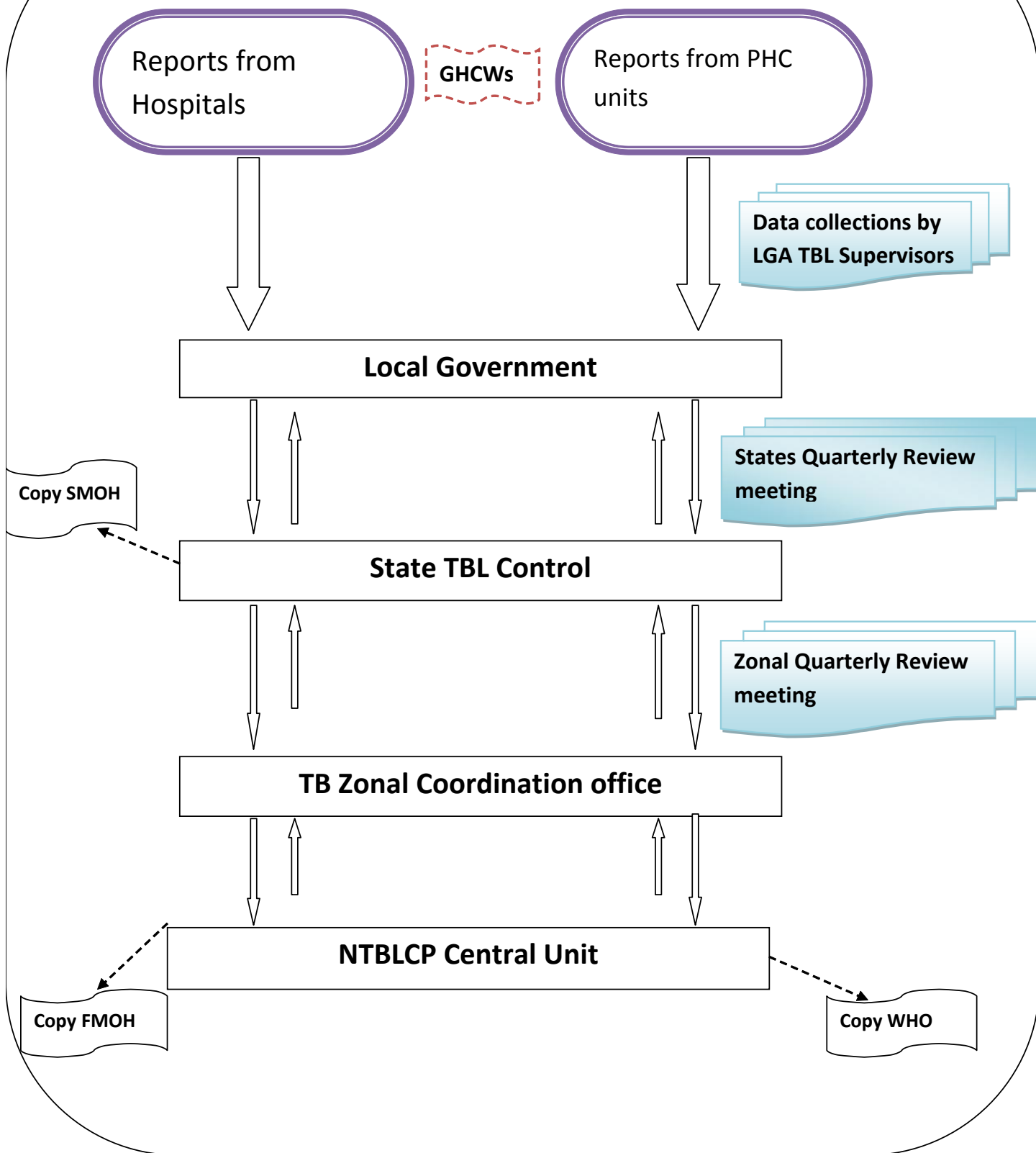
The NTBLCP M&E system starts from the health facility level to the Central Unit of the programme. The M&E responsibilities at the various levels are:

1. At the Health facility level, Health staff records suspects and patients information on the TB clinic sputum register, Sputum request forms, patient treatment cards and LGA/Facility register
2. At LGA level, the LGA TBL Supervisor collects and compile all health facility data into the LGA central Register and quarterly reporting formats;

3. State TBL Control Office collates all LGA TB data into the quarterly reporting formats;
4. At the Zonal level, data is collated quarterly by the Zonal NPOs and NTBLCP M&E officer on a Zonal basis.
5. At the National level, the NTBLCP Central Unit collates all state TBL data on quarterly basis.

The NTBLCP M&E system has an inherent mechanism for validation of data quality at various levels through review meetings at the State and Zonal levels. This focuses on the data consistency and completeness.

Information Flow for Epidemiological monitoring



12.5 SUPERVISION

Supportive supervision is a way of ensuring staff competence and effectiveness through observation, discussion, support and on-the-job training.

The aim is to ensure that:

- a. The technical skills required for TB and Leprosy control activities are present;
- b. Any obstacles faced by the peripheral health worker are identified and removed;
- c. Plans for future work and improved performance are made;
- d. Health workers are supported and motivated in their work; and
- e. Additional information, not available under the routine reporting system, is collected and analyzed.

12.5.1 Essential tools for effective supervision at all levels:

- Supervisory itinerary
- Task based supervision checklist
- Previous supervision reports
- Other documents including statistical data
- Adequate logistics (transport, drugs, recording/reporting/IEC materials, etc).

12.5.2 Responsibilities of the Supervisors (STBLCO, LGTBLS & Laboratory)

1. Arrange for dates of visit together with the health worker
2. Review all available documents and previous report to the facility/state
3. Get appropriate checklist
4. Carry supplies and logistic along
5. Ensure correct identification of TBL cases and administration of correct treatment.
6. Observe facility staff performing specific tasks
7. Check facility-based records to ensure correctness and completeness
8. Interview patients and facility staff with the aid of a checklist.
9. Check drug and supplies stock level and filling of store cards for correctness
10. Check drugs/ other commodities for expiry date and those expiring within the next **six months** should be re-distributed if it cannot be consumed.
11. Provide on-the-job training based on identified area of gaps.
12. Discuss finding (feedback) and agree on recommendations with health workers
13. Write and circulate reports
14. Follow up on the implementation of the recommendations(including visits and phone calls)

12.5.3 Levels of Supervision

Who	Where to supervise	How often
LGTBLS	Health facility	Once a month
STBLCO	Local government/health facility	Once a quarter
Zonal/Partners	State/health facility	At least twice in a year
National	State/health facility	Twice a year

NB: Feedback should be provided to the supervisee and other stakeholders.

12.6 MONITORING

12.6.1 State Quarterly TBL meetings

This meeting takes place on quarterly basis (about 1 week after expiration of the previous quarter) in all states of Nigeria. The participants of the meeting include the State TBL team members, all the LGA TBL supervisors, SAPC and supporting partners. The STBLCO should organise this meeting.

Objectives:

- Review activities of the previous quarter,
- Data collation, validation, analysis and feedback
- Address operational problems and review of annual plan.
- Provide an opportunity for training and retraining.

12.6.2 State Quarterly Quality Assurance meetings

This meeting takes place on quarterly basis (about 1 week after expiration of the previous quarter) in all states of Nigeria. The participants of the meeting include the

State QA lab focal person, first level reader, laboratory scientist/microscopists from diagnostic centres. The State QA officer should organise this meeting.

Objectives:

- Collate laboratory data
- Review TBL laboratory services
- Provide, review and give feedback on QA report
- Provide a QA report
- Address operational problems and review of next quarter plan.
- Discuss new techniques and ideas on TBL bacteriology
- Provide an opportunity for training and retraining.

12.6.3 Zonal Laboratory Quality Assurance Meeting

- The NTBLCP central unit should organise a quarterly laboratory QA meeting at zonal level. The participants should include Medical Laboratory Scientists from Central Unit of NTBLCP and NTBLTC Zaria, State and Zonal QA officers, NIMR and implementing partners.

Objectives:

- Collate, analyse and provide feedback on laboratory data and QA reports
- Review TBL laboratory services
- Address operational problems and review of next quarter plan.
- Discuss new techniques and ideas on TBL bacteriology

12.6.3 Zonal TBL Review Meetings

The meeting takes place about two weeks after the expiration of a quarter (which is usually after the state quarterly meetings). Participants to each zonal meeting should include State TBL programme managers in the zone, NTBLCP Central Unit staff, zonal Lab Quality Assurance officer, SAPCs, Medical Advisors of ILEP partners supporting the programme in the zone, WHO as well as other stakeholders. The NTBLCP Central unit should organise this meeting.

Objectives:

- Improve the timeliness of reporting to the national programme.
- Collect and validate State data.
- Analyse and interpret collated data
- Review of activities of the previous quarter,
- Address operational problems and review of next quarter plan.
- Means of advocacy to the states

12.6.4 Central Coordination meeting

The National programme and stakeholders meet quarterly to collate zonal data into a national profile for the quarter. The NTBLCP should organise this meeting.

12.6.5 Planning Cell Meetings:

These are quarterly meetings between the central unit, zonal coordinators and medical advisers of ILEP/Development partners to review progress made on implementation of planned activities and plan for the next quarter. The NTBLCP central unit should organise this meeting

12.6.5 Insert STOP TB Partnership (membership and TORs)

12.6.6 ANNUAL NTBLCP REVIEW/ COORDINATION MEETING

STBLCOs from all States, Zonal Pharmacists, Zonal Lab quality assurance officers shall meet once in a year with the NTBLCP central unit, representative of Medical Lab Science Council, medical advisers of donor agencies/Development partners supporting the TBL control programme. The NTBLCP central unit should organise this meeting.

Objectives of the annual review/coordination meeting:

- Review of the activities of the NTBLCP
- Review managerial and technical problems and proffer solutions
- Development of recommendations to the federal government on matters relating to TBL control in the state
- Discuss problems relating to TBL control activities common to states and advise accordingly
- Exchange knowledge and ideas on practical aspect of the programme
- Identify areas and topics for operational research
- Share results of operational research and best practices

12.6.7 STOP TB Partnership

The Civil society organisations, Donor agencies/ development partners, Rep of SMOH, NASCP coordinator, Rep of NIMR, Persons affected, Religious organisations(CAN, NSCIA) shall meet quarterly . The NTBLCP through the STOP TB Parnership secretariat (WHO) shall organise this meeting

Objectives of the Stop Tb Partnership meeting

- Secure political commitment for TB control
- Platform for stakeholders to contribute to the fight against TB
- Raise additional resources for TB control (human resource, expertise, financial resources, and in-kind contributions) in the country.

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12.7EVALUATION

The annual plans at all levels will be evaluated on a yearly basis whereas mid term and end term evaluation of the strategic plans will be carried out. Reports of such evaluations will be disseminated to governments at all levels and all stakeholders involved. Such report will be used for future planning. Periodic evaluation will be carried out as may be required by the authorities.

12.8 ESSENTIAL PROGRAMME INDICATORS

See Annex 5 for indicators of the goals and objectives of the NTBLCP