REPUBLIC OF UGANDA

MINISTRY OF HEALTH

MANUAL

OF

THE NATIONAL TUBERCULOSIS AND LEPROSY PROGRAMME

2nd EDITION

2010

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FOREWORD

Uganda like most of Sub-Saharan Africa is battling the dual Tuberculosis (TB) and HIV/AIDS epidemic. This dual epidemic has resulted in a fourfold increase in the notification numbers of TB cases in the region. Furthermore TB stands as the number one single killer of HIV/AIDS patients. The clinical presentation of TB among the dually infected persons changed and this has a bearing on the clinical management and design of the public health interventions to effectively respond to the dual epidemic.

This manual has been written to guide professionals at health facilities in the management of TB patients during this HIV era by promoting implementation of integrated services such that the dually infected persons get comprehensive medical attention once they interface with the health system. It provides a timely emphasis on the newly recognized priority interventions of MDR-TB, Childhood TB and TB infection control in health care settings. It helps planners of national and district health services in drawing and monitoring their intervention strategies and plans. The manual is guided by the STOP TB strategy and the Global Plan to STOP TB and incorporates WHO recommendations on TB treatment regimens and monitoring.

Whereas Uganda has already achieved the target of elimination of leprosy as a public health problem, a number of new cases of leprosy continue to be notified annually. Many of these have established disabilities and a significant proportion are children. This manual guides the frontline health worker on how to suspect and diagnose leprosy, the referral mechanisms and the recommended treatment regimens. While focusing on the Ugandan context, it remains well aligned to the Operational guidelines of the WHO Enhanced Global strategy for further reducing the disease burden due to leprosy 2011-2015. It includes a new emphasis on essential activities for integration, prevention of disability and rehabilitation.

The Ministry of Health is strongly committed to the control of TB and Leprosy and this is well illustrated in the Health Sector Strategic Plan. The manual promotes effective implementation of the plan.

I congratulate the authors of this manual on the achievement and strongly recommend it as a guide to health workers in their daily efforts to control TB and leprosy in Uganda.

Dr. Nathan Kenya-Mugisha
Ag. Director General of Health Services.

PREFACE

The revised manual of the National TB and Leprosy Programme, which comprises technical and operational guidelines, is an update of the first edition which was meant for the District Tuberculosis and Leprosy Supervisor. The update was considered necessary in recognition of the following:

- The increased number of stakeholders involved in tuberculosis (TB) and leprosy control activities which now include clinicians, public health workers, trainers and health planners as well as the CSOs
- The interaction between TB and HIV/AIDS which has resulted in increasing numbers of TB and a changed clinical picture which call for a change in the management of these patients. Control of TB will only be achieved through control of HIV/AIDS and vice versa
- The importance of addressing childhood TB in the population
- Addressing the emerging Multi Drug resistant TB (MDR-TB) and the
- Urgent need to institutionalize TB infection control in the health care facilities to avoid nosocomial spread and ensure protection of the health workers
- The need to re-organize leprosy control activities in the post elimination era

This edition is laid out as a quick reference and resource book to facilitate those taking care of patients affected by TB, TB and HIV and leprosy. It will serve as a useful resource for those who design and conduct training and further guide all health workers involved in control activities at district level. The annexes incorporate monitoring and evaluation tools which have been modified to capture TB/HIV data in an integral manner.

I am confident that all health workers will find this a useful manual which, if adhered to, will go a long way towards achieving a coordinated national response to the dual TB/HIV epidemic and sustaining leprosy control activities across the country.

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ABBREVIATIONS

AFB	acid-fast bacilli
AIDS	acquired immune deficiency syndrome
ARI	annual risk of TB infection
ART	antiretroviral treatment
BCG	Bacille Calmette-Guerin
BI	bacteriological index
CB-DOT	community-based DOT
CBR	community-based rehabilitation
CME/CPD	continuing medical education/continuous professional development
CPT	cotrimoxazole preventive therapy
DG	disability grading
DOT	directly observed treatment
DST	drug susceptibility testing
DTLS	District TB Leprosy Supervisor
E	ethambutol
EHF	eye-hand-foot
ENL	erythema nodosum leprosum
EPTB	extrapulmonary tuberculosis
EQA	external quality assurance
FDC	fixed dose combination
FEFO	“first to expire, first out”
H	isoniazid
HIV	human immunodeficiency virus
HSD	Health Sub-District
ILEP	International Federation of Anti-Leprosy Associations
IDP	internally displaced persons
IPT	isoniazid preventive therapy
IRIS	immune reconstitution syndrome
LC I	Local Council I
MB	multibacillary leprosy

MDR	multi-drug resistant
MDR-TB	multidrug-resistant tuberculosis
MDT	multidrug therapy
NTLP	National Tuberculosis and Leprosy Programme
NTRL	National TB Reference Laboratory
PB	paucibacillary leprosy
PHC	primary health care
PLWHA	people living with HIV and AIDS
PPD	purified protein derivative
POD	prevention and management of disability
PTB	pulmonary tuberculosis
PWD	persons with disabilities
R	rifampicin
S	streptomycin
SCC	short-course chemotherapy
SCHW	Sub-county Health Worker
ST	sensory test
STD	sexually transmitted disease
TB	tuberculosis
TST	tuberculin skin test
VHT	village health team
VMT	voluntary muscle test
WHO	World Health Organization
XDR	extensively drug-resistant
XDR-TB	extensively drug-resistant tuberculosis
Z	pyrazinamide
ZTLS	Zonal TB/Leprosy Supervisor

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SECTION ONE

INTRODUCTION AND DESCRIPTION OF THE NTLP

1.1 INTRODUCTION

1.1.1 Geography and Demography

Uganda is a tropical country bordered by Sudan in the north, Kenya in the east, Tanzania and Rwanda in the south and Democratic Republic of Congo in the west. It covers a surface area of 241,038km^2. The capital city is Kampala. The climate of Uganda is a typically tropical one, with two rainy and two dry seasons.

The population of Uganda was estimated to be about 30 million in the year 2009. About 90 percent of the population lives in rural areas while 10 percent live in urban areas. The life expectancy is 52 years for males and 54 years for females. The crude birth rate is 49.6 per 1,000 population, and crude death rate is 14.8 per 1,000 population.

1.1.2 Health Service

Health care services are mainly provided by the Government of Uganda, Ministries of Health and local governments. There are also private health providers who complement the public health services in Uganda. However, the Ministry of Health (MoH) is the sole authority responsible for providing policy and technical guidelines. The Ministry is headed by the Minister of Health. The managerial division of the MoH is headed by a Permanent Secretary, while the technical division is headed by a Director General, under whom are 7 departments headed by commissioners. The National Tuberculosis and Leprosy Programme (NTLP), headed by the Programme Manager belongs to the Department of National Disease Control.

1.1.3 Tuberculosis Morbidity and Mortality

Uganda was ranked 18th out of the 22 tuberculosis (TB) high-burden countries in the world during 2009. The Annual Risk of TB Infection (ARI) for Uganda is estimated at 3 percent. The incidence of TB is 330/100,000 population for all TB cases and 136/100,000 population for sputum smear-positive pulmonary TB. The death rate among sputum smear-positive pulmonary TB patients registered during 2008 was 5.3 percent in 2008.

1.1.4 Leprosy

Uganda has noted consistent decline of new leprosy cases reported over the last two decades. Although Uganda achieved the elimination phase of leprosy in 2004, it is continuing with leprosy control and rehabilitation activities.

In 2008, the new case detection rate was 1.12 per 100,000 of population. About 8 percent of new cases were children under 15 years of age. The proportion of new cases with visible (Grade 2) disabilities at the time of detection was 15 percent.

A Rehabilitation Advisory Committee set up at the NTLP Central Unit in the early 1990s oversees activities aimed at enabling people affected by leprosy to access the mainstream community-based rehabilitation (CBR) services.

1.2 THE NATIONAL TUBERCULOSIS AND LEPROSY PROGRAMME

The NTLP is the programme in the department of National Disease Control in the MoH charged with performing the core functions for providing TB/leprosy control services. The vision, mission and core functions are stated below.

Vision: A Uganda free of tuberculosis and leprosy

Mission: Provide quality diagnosis of TB and leprosy and patient-centred treatment

Core functions:

i) Establish countrywide quality diagnosis and treatment services for TB and leprosy

ii) Coordinate implementation of TB and leprosy control activities

iii) Prevent and manage leprosy-related disabilities

1.2.1 Management, Operational Structure and Function of NTLP

The NTLP management structure consists of central (national), regional (zonal) and district levels. The provision of services is integrated into the general health services.

The NTLP has the following levels of operation:

I. NTLP Central Unit (national level)

The Central Unit is responsible for TB/leprosy control for the whole country. It is headed by a **Programme Manager**, assisted by technical and support staff. There are 9 operational zones. These zones are under the responsibility of **Zonal TB and Leprosy Supervisors (ZTLSs)**. The Central Unit has several operational sections, including logistics management, monitoring and evaluation, and the National TB Reference Laboratory (NTRL).

The Central Unit is responsible for:

i) Formulating/revising policies and guidelines

ii) Planning, monitoring and evaluating NTLP activities

iii) Resource mobilization

iv) Advocacy for and coordination of all TB/leprosy programme activities within the country in collaboration with:

a. District Health Officers (DHO)
b. Other MoH divisions and departments
c. Non-governmental organisations (NGOs)
d. Other government ministries
e. International organizations and health agencies involved in TB/leprosy control in Uganda

v) Advising on appointment of staff at the Central Unit

vi) Advising the DHO on selection of District TB/Leprosy Supervisors (DTLS)

vii) Quantifying and ensuring procurement and steady flow of adequate amounts of drugs, reagents and equipment for the programme, in collaboration with the Procurement Unit of the MoH

viii) Setting standards and quality assurance

ix) Identifying training needs and addressing them

x) Organizing quarterly and annual TB/leprosy review meetings

xi) Compiling and disseminating quarterly and annual reports

xii) Identifying priority areas for research, guiding and conducting operational / applied research, including dissemination/use of results

II. The District Level

At this level, the management of service delivery in the districts is planned and implemented. The **District Health Officer (DHO)** is responsible for TB and leprosy control activities and assigns tasks for the control activities to the **District TB and Leprosy Supervisor (DTLS)**, **District Laboratory Focal Person (DLFP)**, and staff-in-charge of Health Sub-District (HSD**)** and health facilities.

A. The District Health Officer (DHO)

The DHO is the overseer of TB/leprosy control activities in the district. The responsibilities of the DHO in TB/leprosy control activities are:

i) To plan and prioritize TB/leprosy control activities, including advocacy, communication and social mobilization (ACSM) in the district

ii) To ensure TB/leprosy control activities are implemented by the staff of the health facilities as per NTLP guidelines

iii) To promote efforts of health workers in the introduction and expansion of TB/leprosy case-finding and TB/HIV collaborative activities in all health facilities

iv) To identify suitable officers to act as the DTLS and DLFP

v) To support and supervise the DTLS, DLFP and HSD in-charges

vi) To review reports on TB/leprosy control compiled by the DTLS

vii) To keep an up-to-date record of information and provide the most relevant information on the epidemiology of TB/leprosy to the Health Management Information System (HMIS)

viii) To ensure that drugs, laboratory supplies, registers, record cards and forms for the district are requisitioned and received from the NTLP Central Unit and other sources

ix) To identify training needs and resources to address them

B. The District Tuberculosis and Leprosy Supervisor (DTLS)

TB/ Leprosy control activities at district level are carried out under supervision of a DTLS who is answerable to the DHO. The responsibilities of the DTLS are:

i) To supervise implementation of TB and leprosy control activities by the staff of the health facilities as per NTLP guidelines

ii) To assist health workers in the introduction and expansion of TB/leprosy case-finding and TB/HIV collaborative activities in all health facilities

iii) To work with HSD in-charges in the selection of a suitable HSD focal person

iv) To regularly support and supervise the HSD focal person in collaboration with the HSD in-charges

v) To advise the health facility in-charges in the selection and replacement of Sub-county Health Workers (SCHWs)

vi) To participate in supervision of the SCHWs together with the HSD focal person and health facility in-charges

vii) To validate the diagnosis and classification of all leprosy cases in the district

viii) To supervise TB/leprosy patient care throughout the district and especially ensure that:

a. the NTLP recommended regimens are prescribed
b. regimens are adhered to for the recommended period and ensure that a treatment outcome is determined
c. patients under treatment are individually advised by health workers about the diseases and encouraged to take drugs regularly under the supervision of a treatment supporter
d. sputum is examined for AFB at required intervals for TB suspects and patients
e. when necessary, patients are referred for reconsideration of the treatment regimen

ix) To keep the district registers up to date with TB/leprosy information and check that treatment cards and unit registers are properly filled in by health workers in the facilities

x) To be responsible for ensuring that drugs, laboratory supplies, registers patient cards and forms are available in the district. This is done by:

a. ensuring health facilities regularly submit requests to the district on time
b. compiling the district requisitions using the health facility reports
c. submitting the district requisitions with the facilities' reports attached, if necessary to the NTLP central unit through the DHO

xi) To participate in planning and prioritization of TB/leprosy control activities in the district plans, including ACSM

xii) To compile quarterly reports on case-finding of TB/leprosy and results of treatment of TB/leprosy cases and submit to the DHO

xiii) In collaboration with the DLFP to ensure that all TB diagnostic facilities' laboratories participate in External Quality Assurance (EQA)

C. Health Sub-District In-Charges

The HSD in-charges are responsible for TB control in their respective health sub-districts. The responsibilities of HSD in-charges are:

i) To plan and prioritize TB/leprosy control activities, including ACSM and staff retention in the HSD

ii) To ensure TB/leprosy control activities are implemented by the staff of the health facilities as per NTLP guidelines

a. To regularly support and supervise the activities of HSD focal persons

b. To ensure that the DTLS's functions are carried out in his HSD

D. Health Sub-District Focal Persons

These are persons identified from health facility staff who assist the DTLS in the control of TB/leprosy in their respective HSDs. The responsibilities and tasks of the HSD focal persons are:

i) To supervise implementation of TB/leprosy control activities in their own and other health facilities in the HSD as per NTLP guidelines

ii) To assist in establishment of TB/HIV collaborative activities in all health facilities in the HSD

iii) To assist the health facility in-charges in identification and management of leprosy suspects

iv) To supervise TB/leprosy patient care throughout the HSD and especially ensure that:

a. The NTLP recommended regimens are prescribed

b. Regimens are adhered to for the recommended period and ensure that a treatment outcome is determined

c. Patients under treatment are individually advised by health workers about the disease and encouraged to take drugs regularly under the supervision of a treatment supporter

d. Sputum is examined for AFB at required intervals for TB suspects and patients

e. When necessary, patients are referred for reconsideration of treatment regimen

v) To keep up-to-date accurate HSD registers for TB and check that treatment cards and unit registers are properly filled in by health staff in the facilities. To provide the most relevant information on the epidemiology of TB to the health facility in-charges and the DTLS

vi) To work with village health teams to carry out ACSM of TB/leprosy

vii) To visit the health facilities at least once each month to provide support and supervision on unit register maintenance, microscopy services, drug storage, treatment of patients with correct regimens, health education activities, sputum smear examination follow-ups and referral of complicated patients.

E. Health Workers at the Health Facility

All health facilities should be involved in TB/leprosy control activities. Some health facilities diagnose and treat TB/leprosy patients, while others only diagnose TB or treat TB. Diagnostic facilities may receive TB/leprosy suspects referred by non-diagnostic facilities.

The health workers at the facility must closely liaise with the SCHWs, informing them about every new TB case diagnosed from within their jurisdiction. The health workers are responsible, in addition to other day-to-day medical work, for case-finding and treatment, including:

i) Identification of suspects and sputum examination in coordination with the diagnostic facility and referral for leprosy diagnosis
ii) Offering TB/HIV services as recommended
iii) Filling in the TB/leprosy patient card and record in the unit register
iv) Directly observing TB/leprosy patients on facility based DOT, including those admitted
v) Regularly updating TB unit register with information collected from the SCHWs and from the patients' treatment cards during sputum follow-up visits
vi) Managing TB/leprosy patients with side-effects, complications or treatment failure and, when necessary, referring them to the next level
vii) Sharing information through CME/CPD sessions at health facilities
viii) Ordering, receiving, recording and safe custody of drugs and other supplies from the DHO's Office
ix) Providing health education to TB/leprosy patients and to the community
x) Implementing TB infection control measures according to guidelines
XI) Planning and prioritizing TB/leprosy activities for the health facility and including them in the facility plan

F. The Sub-County Health Worker (SCHW)

The SCHW is the key resource person for DOTS implementation at sub-county level. The SCHW should be based at a health facility. It is the responsibility of the health facility in-charge together with the HSD focal person and DTLS to select a suitable SCHW. The broad definition of the title allows for flexibility in identifying the most suitable health worker (nurse, laboratory staff, nursing assistant, health educator, leprosy assistant, and health assistant, etc.) for this role in each area.

SCHWs are the link between the formal health services and the community through the village health teams (VHTs), the Local Council I (LC I) and treatment supporters. They will integrate CB DOTS-related activities and visit local communities, with other routine duties in order to make their field work the most cost-effective.

The following are the responsibilities of the SCHW:

i) Approach the community through VHTs and Local Council I and motivate them to identify and select treatment supporters

ii) Train treatment supporters

iii) Provide regular support supervision of treatment supporters

iv) Conduct ACSM activities

v) Regularly deliver drugs and other supplies to treatment supporters

vi) Liaise with treatment facility at sub-county level to receive notifications of new patients, give feedback on patients' DOT in order to update unit registers, and refer patients with complications

vii) Maintain an updated sub-county health register

viii) Advise VHTs or LC I about compliance of patients and treatment supporters

ix) Identify TB suspects and carrying out contact tracing

Note: Any SCHW who does not perform to expectations should be replaced.

G. Treatment Supporter

Treatment supporters are identified in the village meeting involving VHT, LC1 and community members. They help TB patients adhere to the taking of anti-TB drugs. A treatment supporter should live near enough to the patient being supported to carry out the following tasks and responsibilities:

i) To observe the patient taking the daily dose of anti-TB drugs correctly

ii) To tally the drug intake day by day on the patient's treatment card

iii) To ensure uninterrupted availability of drugs. In the rare event that the SCHW is delayed, the treatment supporter should collect the drugs from the health facility.

iv) To remind the patient to go for sputum follow-up examinations at 2 (3), 5 and 8 months of treatment

v) To encourage the patient to continue taking treatment

vi) To keep the patient's drugs safe

*vii)*To inform the SCHW of any problem related to the health of the patient or to any constraint in administering DOT

The treatment supporter is therefore responsible to the SCHW and the community. It is recommended that the treatment supporter should have the following characteristics:

a) be a resident of the community, such as a neighbor, family member or another relative
b) have a minimum level of literacy (able to read and write)
c) be identified by the community and accepted by the patient
d) understand and accept the role of treatment supporter

Note: A TB/HIV co-infected patient on both ART and anti-TB medication should have the same treatment supporter for both conditions.

1.2.2 NTLP Strategies

NTLP adopted the WHO Stop TB and the WHO leprosy control strategies for implementing TB and leprosy control activities in Uganda.

The **Stop TB Strategy** has 6 components:

1. *Pursue high-quality DOTS expansion and enhancement*
2. *Address TB/HIV, MDR-TB and the needs of poor and vulnerable populations*
3. *Contribute to health system strengthening based on primary health care*
4. *Engage all care providers*
5. *Empower people with TB and communities through partnership*
6. *Enable and promote research*

The **Leprosy Control Strategy** is to further reduce the disease burden due to leprosy.

1.2.3 Implementation of CB-DOTS in a Rural Setting

Community-based DOT implementation is usually linked to a health facility level, which is usually located in a sub-county.

- The SCHW is a key person in the implementation of community-based DOT.
- TB patients who are diagnosed in the health facilities and do not require hospitalization, should be enrolled in community-based DOT.
- The SCHW is informed by the health facility staff about the patient and contacts the VHT or the Local Council (LC) I.
- The VHT or LCI convenes a community meeting to identify a treatment supporter whose role is to supervise the patient's TB treatment in the community.
- The SCHW will brief, orient and supervise the treatment supporters. After training is completed, the SCHW provides the treatment supporter with a 2-week supply of the anti-TB drugs and a patient treatment card for each patient with TB in the community.
- The treatment supporter is responsible for ensuring DOT and recording each dose of anti-TB drugs swallowed on the patient treatment card. The treatment supporter will also be responsible for referring the TB patient to the health facility at end of 2 (3), 5 and 8 months for follow-up sputum checks and to monitor the patient for side-effects.

If the treatment supporter identifies TB suspects (e.g., cough of 2 weeks or more duration) in the community, the treatment supporter should refer them to the health facility for evaluation.

- The SCHW will visit the treatment supporter every 2 weeks during the intensive phase and monthly during the continuation phase to replenish drug supplies, review and record information from the patient treatment card and provide additional training as needed
- The SCHW liaises with both the VHT and LC I to update records and recommend community action.
- The following procedures should be observed for TB patients who opt for a **family member as a treatment supporter:**
    - Upon diagnosis of TB, the health worker in the health facility must observe the swallowing of the first dose, give a 1-week supply of drugs and request the patient to bring the proposed treatment supporter within the 1 week, before the drugs are finished.
    - In the event that the TB patient has someone who can be a treatment supporter, the health worker then trains this person to carry out the responsibilities of a treatment supporter.
    - The health worker should link the treatment supporter to the SCHW.

Note:

TB patients who are too ill to be enrolled on community-based DOT should be admitted or referred to a health facility with admission facilities. The health facility nurse will be responsible for observing the swallowing of drugs and recording the information on the patient treatment card. TB patients who are no longer ill enough to require hospitalization will be referred to the nearest health facility and offered community-based DOT.

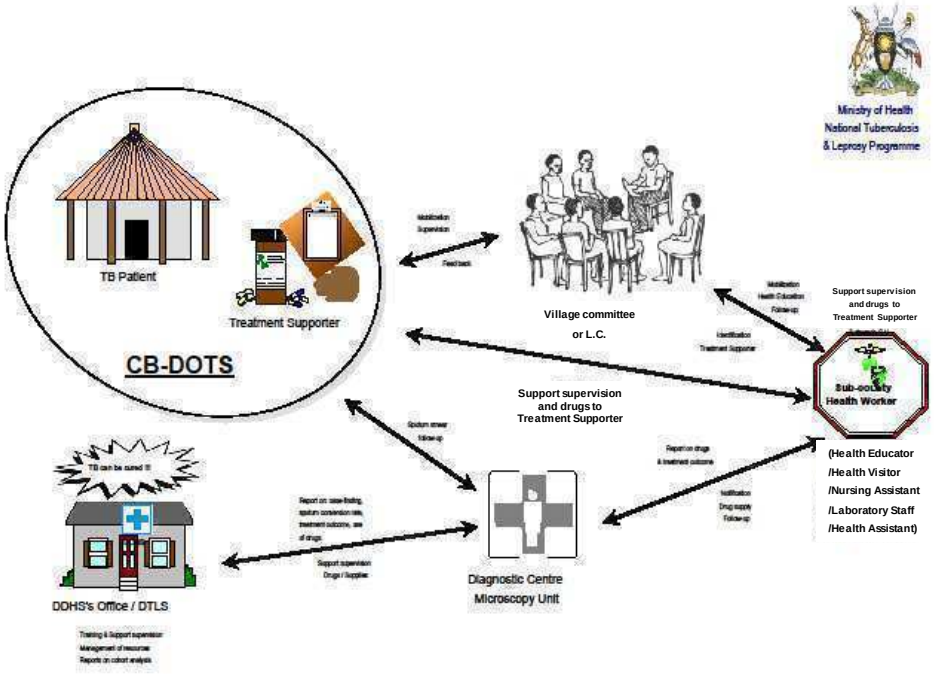

Figure 1.1 Implementation of CB-DOTS referral system in a rural setting

1.2.4 Implementation of CB-DOTS in an Urban Setting

The management of TB patients in large hospitals and health centres located in urban areas poses special challenges. The advantage of shorter distances from the health facilities is unfortunately counteracted by many factors: i) the higher cost of services, ii) the overcrowding of out-patient departments and hospital wards, iii) the de facto lack of coordination between private and public sector and iv) the frequent absence of an extended family who can support the patients and their closest relatives during the time of sickness.

As a result, patients can hardly afford to be admitted even for a few days. Further, the majority of patients stop the treatment because of the unaffordable prices of anti-TB drugs in private pharmacies. This poses extremely serious immediate threats to the health of the patients and their families and increases the transmission of TB in an environment that is obviously more

populated than the rural areas. Despite all these constraints, the anti-TB treatment **must** still be observed, completed and evaluated for the sake of curing the patient and controlling TB.

As the social structure and the organization of the health services in large cities are different from that of rural areas, the implementation of DOT must follow different steps.

After the diagnosis of tuberculosis is established:

- If the patient's clinical condition requires admission to a health facility, the nurses start DOT and are responsible for the daily administration of drugs and the daily update of the patient treatment card.
- If the patient's clinical condition allows for immediate referral home, the patient is given the essential information about the disease and its treatment, given the first dose of anti-TB drugs to swallow and is told to return along with a treatment supporter to attend a session of health education and training on how to administer DOT at home.
- Patients may receive enough drugs for a few days if they cannot return the following day. They should be told that the drugs are available free of charge.
- On returning with the treatment supporter for the health education session (ideally organized twice a week at the health facility), the patient will receive a 2-week drug supply during the intensive phase and a 4-week drug supply during the continuation phase.
- Every 2 weeks during the intensive phase, or every 4 weeks during the continuation phase, either the patient or the treatment supporter will return to the health facility to receive a new drug supply, to report any problem/complication of treatment and to allow transposition of information from the patient treatment card to the Unit TB Register. All TB patients admitted for initial treatment will continue DOT at home with the support of a treatment supporter, after their discharge from the hospital.
- The key principles for case management of patients treated in urban setting remain the same as those for patients treated with community-based TB care.

Note:

An essential component of the CB-DOTS model is the **referral system** between Diagnostic Unit ⇒ Sub-county Health Worker ⇒ community at LC1, VHT and ⇒ the treatment supporter living close to the patient. This referral system cannot be reproduced in urban areas because of their different social organization and because the primary healthcare (PHC) system is weaker.

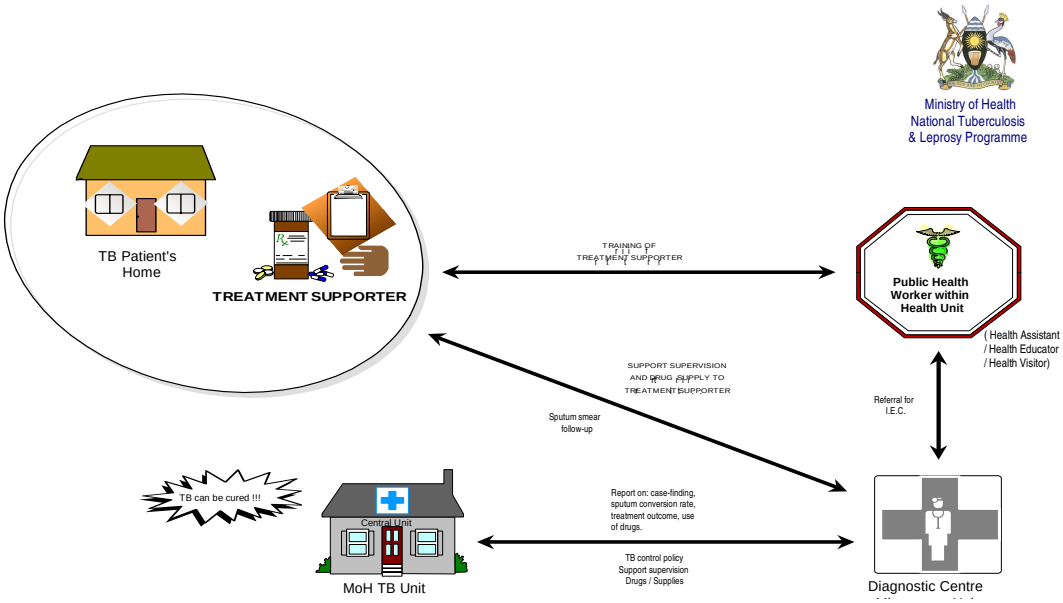

Figure 1.2 Implementation of DOT referral system in an urban setting

1.2.5 Engaging Private Providers in CB-DOTS Implementation

Private providers play a big role in diagnosing and treating TB. Efforts have been made by the NTLP to engage some of the private providers to ensure appropriate delivery of TB services through a coordinated framework. The different categories of private providers who can play a role in managing TB suspects and patients include:

- Private health providers
- Private, not-for-profit hospitals and health centres
- Individual private physicians, nurses, midwives, clinical officers, etc
- Pharmacies and drug shops
- Practitioners of traditional medical systems
- Informal and non-qualified practitioners

The NTLP can engage the private providers in several ways depending on the capacity and operational level of the private provider institution. The public-private mix (PPM) DOTS strategy shall include but not be limited to:

- For large hospitals and clinics, the NTLP can train the health workers in the identification of TB suspects and diagnosis of TB. The health workers in these large hospitals and clinics are also trained to carry out recording and reporting using the NTLP monitoring and evaluation forms. Quarterly reports from such private health providers are submitted to DTLS to be forwarded to ZTLS.
- The NTLP:
    - Conducts training for health workers of the smaller private provider units so that they can recognize and refer TB suspects to diagnostic facilities and keep a record of such referrals
    - Conducts regular training to update private providers on current TB management recommendations
    - Includes the private provider's facilities in its support and supervisory visit schedule. This will ensure that the private providers carry out work according to NTLP recommendations.
    - Provides anti-TB drugs to private health providers

- Ensures the private providers do not charge TB patients for the anti-TB drugs provided.

1.2.6 Facility based DOT

Patients who for some reason can not follow the CB-DOTS options described above should have their anti-TB treatment observed daily by the health worker at the health facility at least during the intensive phase of treatment.

SECTION TWO

TUBERCULOSIS

2.1 CAUSE, TRANSMISSION AND DEVELOPMENT OF TUBERCULOSIS DISEASE

2.1.1 Cause

Tuberculosis (TB) is usually caused by a bacterium, ***Mycobacterium tuberculosis (M. tb) complex (Mycobacterium tuberculosis, Mycobacterium bovis, Mycobacterium africanum and Mycobacterium microti)***. In clinical and laboratory settings, these bacteria are also referred to conventionally as tubercle bacilli (because they cause lesions in tissues called tubercles) or acid-fast bacilli (AFB), because they retain a red dye after washing with alcohol following staining. Clinically there are two types of TB.

i) Pulmonary TB: this is TB that involves the lungs. It is the most common form of TB and accounts for approximately 80 percent of all the patients with TB. These patients, particularly the sputum smear-positive ones can transmit the bacilli to others.

ii) Extrapulmonary TB: This is TB that occurs in organs of the body other than the lungs. These patients are unlikely to transmit the bacilli to other people.

2.1.2 Transmission

Transmission of tubercle bacilli occurs when a patient who suffers from pulmonary TB coughs and produces droplets in the air containing the bacilli. The liquid in the droplets evaporates leaving the droplet nuclei containing the bacilli. The droplet nuclei are small enough to be inhaled into the lungs and deposited into the alveoli. Transmission is easier in a closed environment where ventilation is poor.

Close contact over a prolonged period with a pulmonary TB sputum smear-positive patient who is not yet on treatment increases the chance of becoming infected with *M. tb*. Alternatively, the chance of getting infection is low if the contact is occasional or the patient has extrapulmonary TB.

2.1.3 Infection and Development of TB Disease

When transmission of tubercle bacilli takes place and the person is infected for the first time ever, it is called **primary infection**. Tubercle bacilli multiply in the lungs and lymphatics and causes lymph node enlargement in the chest. The tubercle bacilli also spread from lymphatics through blood to other parts of the body. This process takes 6-8 weeks. At the end of 6-8 weeks, immunity is developed in up to 90 percent of persons who get primary infection. This immunity then controls the further multiplication and spread of the tubercle bacilli, and the person recovers.

However, tubercle bacilli have a special ability to remain dormant for long periods. This is the situation in the 90 percent of these infected persons. Under normal conditions, these infected persons can be recognized by being tuberculin (Mantoux) reactive or positive. However, under conditions of reduced immunity, it may be difficult to detect such infected but not diseased persons.

The immunity of about 10 percent of people, however, may be too low to contain infection at the time of primary infection. These persons develop disease as a direct result of primary infection. Such disease is referred to as **primary disease** because it is a direct progression of primary infection. The diseases could be TB meningitis, miliary TB, pleural effusion or disseminated TB.

Later in life, immunity may start to weaken in a person whose immunity had earlier on controlled the infection (the 90 percent described above). This may occur in conditions like HIV infection, diabetes mellitus, alcoholism, malnutrition and many others. When such a situation arises, the previously dormant tubercle bacilli start to multiply and cause tissue damage (commonly in the lungs) and disease in the affected person. This is called **post-primary disease (or adult disease)**, in contrast to **primary disease,** which is also sometimes referred to as **childhood disease**. The majority of TB patients develop their disease by the post-primary mechanism.

2.2 DIAGNOSIS OF TUBERCULOSIS

The procedure(s) for diagnosing tuberculosis are usually carried out on patients who have symptoms and have reported to the health facility on their own. After the patient's history has been taken and a physical exam has been performed, investigations are carried out. In most cases, sputum specimens (1 spot and 1 early morning) are examined for AFB. If facilities are available, patients can also be investigated by culture for *Mycobacterium tuberculosis*, chest X-ray and tissue histology.

2.2.1 Diagnostic Tests

The investigations and tests useful in the diagnosis of TB are described below:

- ***Ziehl-Neelsen stain:*** Used to examine sputum specimen or gastric aspiration fluid. This is reported as +++, ++, +, scanty or negative.
- ***Fluorescence microscopy stain:*** Another method of identifying the bacilli in the specimen examined.
- ***Chest X-ray:*** Features of chest X-ray consistent with TB disease include miliary picture, pleural effusion and mediastinal lymph gland enlargement with lung infiltration. Although the findings of radiology are nonspecific, abnormalities like any heterogeneous opacities and cavitations, if located in the upper parts of the lung, are more likely to be caused by TB.
- ***Culture for* Mycobacterium tuberculosis:** Although this is the definitive diagnostic test, it is expensive and difficult to carry in the general health service. It will be available only for special situations, such as research and drug-resistant TB.
- ***Aspirated serous fluid:*** Examines pleura peritoneum and pericardium for total protein, cells (total and differential). This test classifies the fluid into exudate and transudate. Exudative fluid is caused most frequently by TB in countries with high prevalence of TB and HIV.
- ***Tissue aspirate***: Ziehl-Neelsen or fluorescence staining of the aspirate, e.g., lymph node aspirate.
- ***Tissue biopsy*:** Histology examination to see if morphologically the inflammation is diagnostic of TB.

After testing, patients may then subsequently be diagnosed as TB patients. The TB patient is then referred to as a case of TB.

2.2.2 Case Definitions

It is important that before TB patients take drugs, they understand the common phrases used in diagnosis of TB. Below are some of these phrases:

i) ***TB suspect*** is any patient who presents with symptoms and signs suggestive of TB, in particular a cough that has lasted 2 or more weeks.

ii) ***Case of TB*** is a patient in whom TB has been bacteriologically confirmed (1 sputum smear positive or culture) or diagnosed by a clinician.

iii) ***Definite case of TB*** is a patient with a positive culture for *Mycobacterium tuberculosis complex*. In the absence of a culture result, a patient with 2 sputum smears positive for acid-fast bacilli (AFB) can be considered a "definite" case.

Note:

For a TB suspect to be treated as a TB patient, s/he must first be declared a TB patient by the use of laboratory tests and decision to treat for TB. A TB patient is what is referred to as a case of TB. However not all TB patients have the same characteristics. It is this process of characterizing the different types of TB patients that is called ***Case definition.***

Why case definitions?

- To ensure proper case registration and case notification
- To evaluate the trend in proportions of new smear-positive cases, smear-positive relapses and other treatment categories
- To allocate the cases to standardized treatment categories in such a way that priority is given to infectious patients

2.2.3 What Determines Case Definition?

Three factors determine the case definition: the site of the disease (body organ involved), the bacteriology (sputum status) and the patient's history of previous treatment

I. Site of the disease

The description below applies to all patients irrespective of HIV status.

A. ***Pulmonary TB***. This is TB involving lung tissue. If TB involves more than one organ including the lung parenchyma, then it is recorded and reported as pulmonary.

i) **Smear-positive pulmonary TB**

- One or more sputum smear examination positive for acid-fast bacilli (AFB)

ii) **Smear-negative pulmonary TB**

- At least 2 sputum specimens negative for AFB **and**
- Radiological abnormalities consistent with active TB disease **and**
- Non-response to a course of broad spectrum antibiotics (excluding fluoroquinolones) for 7 days **and**
- Decision by a clinician to treat as pulmonary TB with a full course of anti-TB drugs

OR

- A patient with AFB smear-negative sputum that is culture-positive for *Mycobacterium tuberculosis*

B. ***Extrapulmonary TB***. This is TB that involves organs of the body other than lung tissue.

- One specimen from an extrapulmonary site culture-positive for *Mycobacterium tuberculosis*, but without evidence of pulmonary disease

OR

- Tissue histology consistent with TB disease or strong clinical evidence consistent with TB disease, **and**
- A decision by a clinician to treat with a full course of anti-TB drugs

OR

- Strong clinical evidence consistent with TB disease **and**
- A decision by a clinician to treat with a full course of anti-TB drugs

II. Bacteriology (sputum status)

Patients are recorded and reported as ***pulmonary TB sputum smear-positive*** or ***pulmonary TB sputum smear-negative***.

III. History of previous treatment

A. ***New case***, A new case is a TB patient who has never had treatment for TB or one who has had treatment for less than 1 month (4 weeks).

B. ***Retreatment case.*** Any TB patient who received anti-TB treatment for more than 1 month and is being treated again is a retreatment case. The various types are:

i) ***Relapse***. A patient who was previously treated for TB and declared cured or treatment completed and who is diagnosed with bacteriologically positive (smear or culture) TB

ii) ***Treatment after failure***. A TB patient who is started on re-treatment regimen after having failed previous TB treatment

iii) ***Treatment after default***. A TB patient who completed a minimum of 1 month of anti-TB treatment, interrupted for 2 or more consecutive months, is sputum smear-positive and is started on retreatment

iv) ***Other.*** If it is too difficult to determine the treatment history accurately enough to define a case, but the patient has definitely swallowed anti-TB drugs, the patient is referred to as "other". This group also includes chronic cases, which are defined as patients who are sputum smear-positive at the end of a directly observed retreatment regimen

In order to finally define a case of TB, the case determinants listed above, plus other laboratory results as shown below, are used:

i) History of TB treatment
ii) Sputum acid-fast bacilli (AFB) smear examination result
iii) Sputum, tissue or body fluid culture for *Mycobacterium tuberculosis* result
iv) Body fluid examination result consistent with active TB
v) Tissue histology, morphologically consistent with active TB
vi) Decision by attending clinician to treat the patient for TB
vii) Site of disease

The diagnosis of each TB patient is derived from the case determinants identified in the patient. TB patients are then diagnosed as:

- New, pulmonary TB sputum smear-positive
- New, pulmonary TB sputum smear-negative
- New, extrapulmonary TB
- Relapse, pulmonary TB sputum smear-positive
- Treatment failure, pulmonary TB sputum smear-positive
- Treatment after default, pulmonary TB sputum smear-positive

2.3 TREATMENT OF TUBERCULOSIS

Treatment is the key to stop the spread of TB. Individuals should start treatment as soon as possible and should be treated according to the NTLP recommended regimens under DOT.
The aims of treatment are to:

- cure the patient
- prevent complications and death from TB disease
- reduce transmission
- prevent development of drug-resistant TB

It is important to achieve these aims in order to reduce transmission, the development of acquired drug resistance and relapse.

2.3.1 Anti-TB Drugs

There are 5 **first-line** anti-TB drugs that are used for the treatment of TB most of the time. There are also anti-TB drugs known as **second-line** drugs that are used for treating drug-resistant TB. This section considers only the first-line anti-TB drugs. The first-line anti-TB drugs, together with their standard abbreviations, are shown below:

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

Table 2.1 First-line anti-tuberculosis drugs and characteristics

Drug	Dose (adult)	Route of admin.	Side-effects	Contraindications	Important drug interactions
Isoniazid	10 mg/kg body wt.-max.300mg	Oral	Hepatitis, peripheral neuropathy	Active liver disease, known hypersensitivity	Stavudine, phenytoin, carbamazepine
Rifampicin	10mg/kg body wt.-max.600mg	Oral	Flu syndrome, dermatitis, hepatitis	Hepatic dysfunction, hypersensitivity to rifamycins	Oral contraceptives, neverapine, warfarin, phenytoin, oral anti-diabetic drugs
Pyrazinamide	25mg/kg body wt.	Oral	Arthralgia, hepatitis	Hepatic impairment known hypersensitivity	None
Ethambutol	15mg/kg body wt.	Oral	Impaired visual acuity and colour vision	Pre-existing optic neuritis, established kidney failure	None
Streptomycin	15mg/kg body wt.	Intramus-cular	Headache, tinnitus, skin itching and rash	Impaired hearing, known hypersensitivity, established kidney failure	Other Aminoglycosides, amphotericin B, cephalosporins, lasix

Anti-TB drugs are given in combinations called ***regimens.*** Anti-TB drug regimens have the following characteristics;

- contains at least 1 of the most effective anti-TB drugs (rifampicin or isoniazid) in both the **initial** and **continuation** phase of treatment
- must be written in abbreviation that clearly identifies the drugs in the **initial** and **continuation** phases of treatment
- defines a specific duration of treatment and frequency of giving the drugs
- written with numbers in prefix and the standard abbreviation for the TB drugs.

The prefix number before the drug abbreviation represents the duration in months for which the drugs that follow should be taken. The stroke (/) separates **initial** from **continuation** phase.

Examples (i) 2RHZE/4RH and (ii) 2RHZE/6EH

Regimen (i) has an initial phase of 2 months consisting of daily rifampicin, isoniazid, pyrazinamide and ethambutol, followed by a 4-month continuation phase of daily rifampicin and isoniazid. Regimen (ii) has an initial phase of 2 months consisting of daily rifampicin, isoniazid, pyrazinamide and ethambutol and 6 months of daily ethambutol and isoniazid.

Do not put patients on a trial of anti-TB treatment. Based on available investigation results and clinical features decide and treat the patient with a full course of anti-TB treatment or carry out further investigations to establish other causes of the symptoms in order to offer appropriate treatment.

2.3.2 Treatment Categorization

Treatment categorization is a system whereby TB patients are grouped according to infectivity and severity of disease and matched to the relevant TB drug regimen to which the patients would respond when treated.

Table 2.2 Anti-TB treatment categorization

Category	**Type of patient**	**Recommended regimen**
Category 1	All new patients older than 12 years	2RHZE/6EH OR 2RHZE/4RH
Category 2	Retreatment cases • Relapses • Treatment failure • Default	2SRHZE/1RHZE/5RHE
Category 3	All patients aged 12 years and younger	2RHZ/4RH
Category 4	Drug-resistant cases • Chronic cases • Suspected drug-resistant TB • MDR-TB	Appropriate regimen available at MDR-TB treatment centre

Use of non anti-TB drugs during TB treatment

Non anti-TB drugs are usually given to accompany anti-TB treatment. There are two such commonly used drugs, namely pyridoxine (Vitamin B6) and prednisolone.

I. **Pyridoxine**: This drug may be given to all TB patients once they start on treatment. This is because one of the anti-TB drugs, isoniazid, interferes with the metabolism of pyridoxine in the body thus leading to its deficiency. Therefore an additional amount of 25 mg daily should be given to all patients if possible.

II. **Prednisolone:** This drug is given because of its high potency as an anti-inflammatory drug. It is therefore useful in TB patients in whom complications of severe fibrosis are anticipated because of severe inflammation. These are patients suffering from TB meningitis and TB pericarditis. Prednisolone is given in a dose of 1-2mg/kg body weight (not more than 60mg/day) as a single dose for 4 weeks, and then tapered off over 2 weeks. It is also used as replacement treatment in patients with TB of the adrenal glands.

Table 2.3 Managing frequent side-effects of anti-TB drugs

Side-effects	**Drug(s) likely to cause**	**Management**
Low appetite, nausea, abdominal pain	Pyrazinamide, rifampicin	Give drugs with small meal or last thing at night
Joint pains	Pyrazinamide	Aspirin or paracetamol
Burning sensation in the feet	Isoniazid	Pyridoxine 100 mg daily
Orange/red urine	Rifampicin	Reassure the patient that it is not harmful
Skin rash	Any anti-TB drug	Stop anti-TB drugs, wait for patient to recover then reintroduce one at a time OR Refer the patient
Deafness (no wax on auroscopy)	Streptomycin	Stop streptomycin. Use ethambutol
Dizziness, vertigo, and nystagmus	Streptomycin	Stop streptomycin. Use ethambutol
Jaundice (other causes excluded)	Pyrazinamide, rifampicin and isoniazid	Stop anti-TB drugs till jaundice clears then restart drugs
Mental confusion	Isoniazid, rifampicin and pyrazinamide	*1. If jaundiced,* suspect liver failure, treat as liver failure. *2. If no jaundice*, suspect isoniazid, increase dose of pyridoxine.
Visual impairment (other causes excluded)	Ethambutol	Stop ethambutol. Use streptomycin

Fixed-dose combinations (FDC)

In the table above, anti-TB drugs are presented as single drugs. However these drugs are now given as fixed-dose combinations. The FDCs are a combination of two or more drugs in a single tablet with known weights (mg) of the drugs in each tablet. There are 2-drug FDC, such as rifampicin+ isoniazid (RH), or 3-drug FDC, such as rifampicin+ isoniazid+ pyrazinamide (RHZ), or even a 4-drug FDC, such as rifampicin+ isoniazid+ pyrazinamide+ ethambutol (RHZE). The combinations of more than one anti-TB drug in 1 tablet have the following advantages:

- Prescription errors are minimized. Dosage recommendations are more accurate and adjustment of the dose according to patient weight is easier.
- The patient has fewer tablets to swallow, which contributes to adherence.

If the treatment is not supervised, patients cannot be selective about which the drugs to swallow.

2.3.3 Recommended Standard Regimens in Uganda

I. New adult cases

Initial phase: The initial phase is the first 2 months of treatment. The combination of 4 drugs used during this phase is isoniazid, rifampicin, pyrazinamide and ethambutol (RHZE). Using these 4 drugs, results in rapid killing of the tubercle bacilli. Patients become non-infectious in about 2 weeks. Symptoms reduce, and the majority of the smear-positive cases become smear-negative within the first 2 months.

Continuation phase: The continuation phase is the second part of treatment, which last 6 months (or 4 months depending on the regimen in use). Fewer drugs are used, either ethambutol + isoniazid (EH), rifampicin+ isoniazid+ ethambutol (RHE) for 6 months or isoniazid + rifampicin (RH) for 4 months.

Currently, Uganda is still using the 8-month regimen.

Table 2.4 Recommended anti-TB drug doses for adult new cases (12 years and older)

Pre-treatment body weight (kg)	**2 months initial phase**	**4 months continuation phase given daily**	**6 months continuation phase, given daily**
	RHZE (150+75+400+275) mg	**RH** (150+75) mg	**EH,(**400+150**)** mg
30-37	2 tablets	2 tablets	2 tablets
38-54	3 tablets	3 tablets	2 tablets
55-70	4 tablets	4 tablets	2 tablets
>70	5 tablets	4 tablets	3 tablets

II. Retreatment cases

Retreatment cases have a high likelihood of being drug-resistant due to prior exposure to and use of anti-TB drugs.

Initial phase: The initial phase is the first 3 months of treatment. The first 2 months consist of streptomycin, rifampicin, isoniazid, pyrazinamide, and ethambutol and (SRHZE), followed by 1 month of isoniazid, rifampicin, pyrazinamide and ethambutol (RHZE).

Continuation phase: The continuation phase lasts for 5 months and requires 3 drugs – rifampicin, isoniazid, and ethambutol (RHE).

Table 2.5 Recommended anti-TB drug doses for previously treated patients (retreatment)

Pre-treatment body weight (kg)	**First 2 months – initial phase**		**3rd month – initial phase**	**5 months – continuation phase**			
	RHZE (150+75+ 400+275) mg	streptomycin, vial 1g	RHZE (150+75+400+ 275) mg	RH (150+75) mg	E (400) mg	RH (300+150) mg	E (400) mg
30-37	2 tablets	0.5 gm	2 tablets	2 tablets	2 tablets		
38-54	3 tablets	0.75 gm	3 tablets	3 tablets	2 tablets		
55-70	4 tablets	1.0 gm	4 tablets	4 tablets	2 tablets	2 tablets	3 tablets
>71	5 tablets	1.0 gm	5 tablets	4 tablets	2 tablets	2 tablets	3 tablets

Box 2.1 Key messages for TB patients

Key Messages for TB Patients

1. TB is a disease caused by a germ (bacteria) that is very strong and difficult to kill by just one drug.

Because of this:

2. The treatment uses a combination of more than one drug, and takes a long time (6-8 months). The treatment is divided into two parts. In the **first part,** lasting 2 **months** you will take more drugs than in the **second part** which lasts **6 or 4 months**.

During the 8 or 6 months of your treatment:

3. You will be requested to give sputum for examination at **2 months, 5 months** and in the **8th month.** This is a continuous check to see how the drugs are working on the germs that caused your disease.

4. Do not stop taking the drugs even if you feel well **because** TB will not be cured if you stop the drugs before the correct time has passed. You have to **be discharged** from treatment when you are confirmed cured.

Should you feel the drugs are giving you problems:

5. Do not stop taking the drugs by yourself or on someone else's advice. Report your problem to the health worker at the facility where you collect your drugs; you will be helped properly.

Remember

6. To bring your family members, particularly children under 5 years of age to be checked for TB; particularly if they are suffering from cough.

7. If you came from a village for treatment in town and would like to go back, (or you wish to change your residence) before the 8 or 6 months of treatment are completed, tell the health worker who gives you your drugs, who will explain how to get drugs from your changed place of residence.

8. When you cough, turn your face away from people. Cover your mouth with a handkerchief or hands.

9. As a TB patient, it is important for you to know your HIV status. You are hereby advised to go for HIV counselling and testing.

2.3.4 Treatment Monitoring

Once a TB patient is started on treatment, it is important to find out if the patient is getting better as a result of the treatment. This is called **treatment monitoring**. The following methods are used for treatment monitoring in order of importance:

i) Sputum microscopy (or culture) – must be used for monitoring all pulmonary TB patients. Where culture facilities are available, it can be used to confirm cure or failure and the sensitivity pattern to the drugs can be determined in failure cases.

ii) Clinical monitoring – is particularly useful for children and extrapulmonary TB cases but can also contribute in pulmonary cases.

iii) Radiological monitoring – is a method that should not be used as the sole monitoring tool. In cases where radiological monitoring is used, sputum and clinical monitoring should accompany the radiological monitoring.

I. New Cases

Sputum smears are performed at the end of the **initial phase** (2 months), at 5 months and in the 8th month of treatment. This should be done for both smear-positive and smear-negative pulmonary TB patients.

If the patient has a sputum smear that is positive at the end of the **initial phase** of treatment, consider the following as possible explanations:

- The treatment was poorly supervised.
- The bacillary load was too high, e.g. in cavitary disease with slow clearance of the bacilli.
- Rarely, the patient could have MDR-TB.

The box below shows the action points to be taken during sputum smear monitoring in a new case.

Box 2.2 Monitoring treatment in new TB cases

Action points during treatment

At the end of the initial 2 months:

- Sputum smear-negative; start continuation phase
- Sputum smear-positive; continue the initial phase for I month and repeat sputum exam

At 3 months:

- Sputum smear-negative; start continuation phase
- Sputum smear-positive; do DST, start standard drug-resistant regiment

At 5 months:

- Sputum smear-negative, continue with continuation treatment
- Sputum smear-positive, diagnose **Treatment Failure** and start on retreatment regimen
- Take sputum for culture and sensitivity

During the 8th month:

- Sputum smear-negative, complete treatment and declare **cured** or **treatment completed**
- Sputum smear-positive, diagnose **treatment failure** and start re-treatment regimen. Take sputum for culture and sensitivity

For patients registered as sputum smear-negative before the anti-TB treatment was started, clinical monitoring is recommended together with sputum monitoring. Sputum examination is important in these patients because:

- An error could have occurred at the time of diagnosis
- The patient may have drug-resistant TB

II. Retreatment cases (also known as *previously treated patients)*

Retreatment cases are patients who have **previously taken anti-TB drugs for at least a month**. Sputum examination is done at the end of **initial phase** (3 months), 5 months and in the last month of treatment. These patients must also have culture monitoring, if it is available.

Box 2.3 Monitoring treatment in TB retreatment cases

Action points in managing retreatment patients

Prescribe retreatment regimen for these patients. At the beginning of the treatment, do culture and drug sensitivity testing

At end of 3 months:

- Sputum smear-negative, proceed to continuation phase
- Sputum smear-positive:
  - If result of DST is diagnostic of MDR- or XDR-TB, treat appropriately
  - If result of DST is not diagnostic of MDR- or XDR-TB, repeat DST and start the patient on standard drug-resistant TB regimen

At 5 months:

- Sputum smear-negative, continue with the continuation phase treatment
- Sputum smear-positive:
  - If result of DST is diagnostic of MDR- or XDR-TB, explain to the patient and treat appropriately
  - If result of DST is not diagnostic of MDR- or XDR-TB, continue with continuation phase

At the 8th month:

- Sputum smear-negative, complete the treatment and declare **cured** or **treatment completed**
- Sputum smear positive:
  - Explain to the patient, and start patient on standard drug-resistant treatment
  - Repeat DST

Treatment monitoring is carried out through clinical observation. A patient's weight gain and reduction in symptoms are useful indicators.

2.3.5 Defining Treatment Outcome

A conclusion should be made regarding the status of every TB patient who has been started on anti-TB treatment. This is called ***treatment outcome***. Below in the box are the types and definitions of treatment outcomes.

Box 2.4 Types and definitions of TB treatment outcomes

a) **Cure:** A TB patient who was smear or culture positive and is sputum smear or culture negative at 1 month prior to completion of anti-TB treatment and at least on 1 previous occasion during treatment.
b) **Treatment completed:** A TB patient who completed anti-TB treatment without proof of cure. No sputum results are available on at least 2 occasions prior to completion of treatment.
c) **Default:** A TB patient who completed more than 1 month of treatment and interrupted it for 2 or more consecutive months.
d) **Transfer out:** A TB patient already registered for anti-TB treatment in 1 district who transfers to a facility in a different district to continue with anti-TB treatment.
e) **Death:** A TB patient who dies from whatever cause while still on anti-TB treatment.
f) **Treatment interrupted:** A patient whose anti-TB treatment was interrupted for less than 2 consecutive months before the end of the treatment period and whose sputum smear is negative.
g) **Treatment failure**: A TB patient who remains/ turns sputum smear or culture positive at 5 or more months of anti-TB treatment.

Table 2.6 Managing anti-TB treatment interruption (1–2 months)

Action	Sputum result	Decision
• Trace the patient • Identify and solve the cause, if possible • Do 2 sputum smears, continue treatment while waiting for results	All sputum smears NEGATIVE or extrapulmonary TB	Continue treatment and prolong it to compensate for missed doses
	One or more sputum smears POSITIVE	1. *Treatment <5months* Continue treatment and prolong it to compensate for missed doses 2. *Treatment >5months* • If Cat 1: start Cat 2 treatment • If Cat 2: refer, as may have drug-resistant TB

Table 2.7 Managing anti-TB treatment interruption (2 or more consecutive months = defaulter)

Action	Sputum result	Decision
• Do 2 sputum smears • Identify and solve cause of interruption, if possible • No treatment while waiting for results	Negative smear or extra-pulmonary	Clinical decision on individual basis whether to restart or continue treatment
	One or more sputum smears positive	1. Cat 1: Start Cat 2 treatment 2. Cat 2: Refer to MDR-TB treatment centre

2.4 PREVENTIVE TREATMENT OF TUBERCULOSIS

Preventive treatment is the use of anti-TB drug(s) to prevent the development of TB disease in an individual who has TB infection or is likely to get TB infection. This form of treatment is best suited for areas of low TB prevalence. In high-prevalence areas it should be used very carefully because, if TB disease is not ruled out, its use may lead to the development of drug resistance to the anti-TB drug(s) being used for this purpose.

Does preventive treatment work?

Research has shown that the use of isoniazid (H) for up to 12 months has a protective efficacy of up to 83 percent, and a combination of rifampicin and isoniazid (RH) for 3 months has protective efficacy of 60 percent. Although the degree of protection varies from study to study. the benefit of preventive treatment cannot be denied. However, for operational purposes, isoniazid preventive treatment (IPT) is recommended.

Latent TB

Definition: Latent TB is where person exposed to TB bacilli becomes infected and develops immunity to TB. It is this immunity that usually can be identified by doing a tuberculin test, thus confirming previous exposure to and infection by TB bacilli.

Diagnosis of latent TB*:* Latent TB is considered present in a person whose Mantoux test reading has a diameter of 5 or more mm in an HIV-positive person and 10 or more mm in an HIV- negative person, no signs and symptoms of TB and a normal chest X-ray.

2.4.1 Isoniazid Preventive Therapy (IPT), HIV/AIDS and Antiretroviral Treatment (ART)

- IPT has been shown to be beneficial to people living with HIV/AIDS. It works for patients who are on ART as well as on patients who are ART naïve.
- Since TB is a major cause of illness and death among persons living with HIV/AIDS, IPT should be part of service provision for this group of patients. IPT will lead to a reduction in illness and death due to TB among HIV/AIDS patients.

- Liver damage is a recognized complication of IPT, particularly in patients over 35 years of age. Caution should therefore be exercised in prescribing IPT for patients with chronic liver disease, who have jaundice and are over 35 years old.
- Adherence to IPT is very important for the person to benefit fully. Poor adherence will reduce its benefit.

Using IPT in Patients with HIV/AIDS and Latent TB

To use IPT in patients with HIV/AIDS and latent TB, the following steps should be taken:

i) **Identify TB infection:** This requires a trained person to do a Mantoux test and read it.

ii) **Identify HIV infection:** This requires pre- and post-test counselling and HIV testing.

iii) **Ensure no active TB disease*:** This will require a) investigating patients who cough for more than 2 weeks with Ziehl-Neelsen staining and b) obtaining a history of past treatment for TB and c) taking a chest X-ray.

Only persons who have HIV and tuberculosis infections AND have been ascertained to be free of TB disease should be considered for and given IPT.*

Other indications for IPT

Newborns and other children who are close contacts of patients with smear-positive pulmonary TB disease may benefit from IPT.

Duration of IPT treatment

Persons on IPT should be treated for 6 months.

Another form of TB prevention

Bacille Calmette-Guerin (BCG) vaccination, which should be given at birth or first contact

2.5 TREATMENT OF TUBERCULOSIS IN SPECIAL SITUATIONS

2.5.1 Pregnancy

After diagnosing TB in a woman, inquire about pregnancy. This is to ensure that she is not given any drug(s) that may be considered unsafe in pregnancy. Fortunately, the first-line anti-TB drugs – rifampicin, isoniazid, pyrazinamide and ethambutol – are safe in pregnancy. Streptomycin, on the other hand, should be avoided, because it is ototoxic to the foetus especially in the first trimester. The NTLP-recommended regimens of **2RHZE/6EH** and **2RHZE/4RH** are safe for use in pregnancy.

2.5.2 Breastfeeding

A breastfeeding woman who has TB should be treated with a full course of a standard regimen recommended by the NTLP. The concern here is to find out if the child already has TB disease or is just a contact likely to be infected by the mother. Concentrations of anti-TB drugs in breast milk are too low to prevent or treat TB in infants. The child should therefore be investigated for TB disease and, if found to have TB disease, must be given full course of anti-TB treatment. If the child does not have TB disease, give isoniazid preventive therapy (10mg/kg body weight) for 6 months. Mother and child should stay together and breastfeeding should continue normally. BCG vaccination of the child should be postponed until the end of isoniazid preventive therapy.

2.5.3 Treatment in Patients with Liver Disease

Suspect liver damage when a patient on anti-TB drugs has developed jaundice. Drug-induced hepatitis can be fatal. Pyrazinamide should not be used in patients with known chronic liver disease. In patients with liver failure, a regimen without rifampicin may be used. Streptomycin and ethambutol may be used if treatment is necessary for patients with severe liver disease. The NTLP-recommended regimens for use in TB patients with liver disease are **2SRHE/6EH** or **2SHE/10EH.**

2.5.4 Treatment of Patients with Renal Failure

Isoniazid, rifampicin and pyrazinamide may be given in normal dosage to patients with renal failure, since these drugs are eliminated almost entirely by biliary excretion or are metabolised into non-toxic compounds. Patients with severe renal failure who are receiving isoniazid should also receive pyridoxine to prevent peripheral neuropathy. Streptomycin and ethambutol, which are excreted in the kidney, should be given in reduced doses even where renal functions can be regularly monitored. Ethambutol can accumulate as a result of reduced excretion and cause optic neuropathy. The use of aminoglycosides and capreomycin should be avoided in patients with renal failure.

Individuals on haemodialysis should receive anti-TB drug treatment by direct observation after dialysis because several of the drugs are eliminated during dialysis. The safe regimen for patients with renal failure is **2HRZ/4HR.**

2.5.5 Use of Contraceptives

Rifampicin interacts with estrogen-containing contraceptive medications and reduces the blood levels of estrogen. This leads to the reduced protective efficacy of the contraceptive medicine and may result in unplanned pregnancy. Therefore contraceptive pills with higher doses of estrogens , such as NewFem or Ovral, are recommended. Avoid use of contraceptive medications with low amount of estrogen (e.g., Lo-femenal, SoftSure). Alternatively, another method of contraception should be used.

2.5.6 Treatment of HIV-Infected Patients

In Uganda, TB is a very common infection among people with HIV/AIDS. Among TB patients, 50-70 percent are HIV positive. In addition to its frequency, TB is also associated with substantial morbidity and mortality (30 percent) among patients with HIV/AIDS. Rifampicin containing short-course regimens should always be used in the treatment of TB in HIV/AIDS patients, given under direct observation.

Despite the difficulties of treating two infections requiring multidrug therapy at the same time, antiretroviral therapy can be lifesaving among patients with tuberculosis and HIV/AIDS disease. Refer to Section 2.8, which covers TB and HIV/AIDS.

2.6 DRUG-RESISTANT TUBERCULOSIS

2.6.1 Magnitude of Drug-Resistant Tuberculosis

Although no national drug-resistance survey has yet been done, several local drug-resistance studies have been carried out. The first drug-resistance study in Uganda was conducted in 1996-1997 as part of a global drug-resistance surveillance programme, but was carried out in only part of Uganda. Among the 374 evaluable isolates from the new patients, defined as patients who had received no more than 1 month of anti-TB therapy in the past, the prevalence of resistance to any drug was 19.8 percent; to isoniazid (H), 6.7 percent; to ethambutol (E), 6.1 percent; to rifampicin (R), 0.8 percent; and to streptomycin (S), 13. 4 percent. The prevalence of MDR-TB was found to be 0.5 percent. A study conducted in Mulago Hospital in 2000 on 215 previously untreated patients revealed a similar MDR prevalence of 0.9 percent, but resistance to rifampicin was found in 1.4 percent of the patients. This means that MDR was identified 13 percent of previously treated TB patients and 2 percent of new TB cases**.** A Kampala study conducted in 2008 showed an MDR prevalence of 1.1 percent among new cases and 11.5 percent in previously treated TB cases.

2.6.2 Risk Factors for Development of Drug-Resistant Tuberculosis

Although several factors can contribute to the development of drug-resistant TB, inadequate anti-TB treatment is probably the most important. Inadequate anti-TB treatment leads to mutation in drug-susceptibility bacilli making them drug resistant. Overgrowth of initially drug-resistant bacilli also occurs when inadequate anti-TB treatment is used. Below are situations of inadequate anti-TB treatment:

- Inadequate drug regimen
- Inadequate duration of treatment
- Drugs not taken regularly by the patient

Factors causing inadequate anti-TB treatment can be grouped into health provider factors, drug factors and patient factors.

Table 2.8 Factors contributing to an inadequate anti-TB regimen

Health care providers: inadequate regimens	**Drugs: Inadequate supply/quality**	**Patients: inadequate intake**
• Inadequate DOT • Non-compliance with guidelines • Absence of guidelines • Poor training • No monitoring of treatment • Poorly organized or under-funded programmes	• Poor quality • Unavailability of certain drugs (stock-outs or delivery disruptions) • Poor storage conditions • Wrong dose or combination	• Poor adherence • Lack of money (no free treatment available) • Lack of transportation • Adverse effects • Social barriers • Malabsorption • Alcohol and substance abuse

Table 2.9 Risk groups for drug-resistant tuberculosis

Risk factors for drug-resistant TB	Comments
Failure of retreatment regimens and chronic TB cases	Chronic TB cases are defined as patients who are sputum smear-positive at the end of retreatment. These patients have perhaps the highest MDR-TB rates of any group, often exceeding 80 percent.
Exposure to a known MDR-TB case	Contacts of MDR-TB patients are more likely to acquire and develop MDR-TB.
Failure of Category 1	Failures of Category 1 are patients who while on treatment are sputum smear-positive at 5 months or later during the course of treatment. Not all patients who fail a regimen have MDR-TB, and the percentage may depend on a number of factors, including whether rifampicin was used in the continuation phase and whether DOT was used throughout treatment.
Failure of anti-TB treatment in the private sector	Anti-TB regimens in the private sector can vary greatly. A detailed history of drugs used is essential. If both isoniazid and rifampicin were used, the chances of MDR-TB may be high. Sometimes second-line anti-TB drugs may have been used, and this is important information for designing the retreatment regimen.
Patients who remain sputum smear-positive at month 2 or 3 of Short-Course Chemotherapy (SCC)	Do culture and DST on patients who remain sputum smear-positive at months 2 and 3, if possible. These patients have a likelihood of having MDR-TB.
Relapse and Return after Default without recent Treatment Failure	Evidence shows that most Relapse and Return after Default cases do not have MDR-TB. However, a history of erratic drug use or early relapse points more strongly to possible MDR-TB.
Exposure in institutions that have MDR-TB out-breaks or a high MDR-TB prevalence	Patients who frequently stay in homeless shelters, prisoners in many countries and health care workers in clinics, laboratories and hospitals can have high rates of MDR-TB.
History of using anti-TB drugs of poor or unknown quality	The percentage of MDR-TB caused by use of poor quality drugs is unknown but considered significant. It is known that poor-quality drugs are prevalent in all countries. All drugs should comply with quality-assured WHO standards.
Treatment in programmes that operate poorly (especially recent and/or frequent drug stock-outs)	These are usually non-DOTS programmes with poor drug management and distribution systems.
Other conditions associated with malabsorption or rapid transit diarrhea	Malabsorption may result in selective low serum drug levels and may occur in either HIV-sero-negative or sero-positive patients.

2.6.3 Diagnosis of Drug-Resistant Tuberculosis

When to suspect drug resistance

Suspect drug-resistant TB under the following circumstances:

- Chronic cases (still sputum smear-positive after completing supervised retreatment regimen)
- Contact with known drug-resistant tuberculosis
- Relapses
- Treatment after failures
- Treatment after defaults
- History of frequent interruption of drug treatment

However, the diagnosis of drug resistance is made microbiologically. It is only arrived at after culture and sensitivity testing has been done in the laboratory. All patients who are drug-resistant TB suspects should therefore have sputum/other specimens taken for culture and drug sensitivity testing (DST) in vivo.

Types of drug-resistant tuberculosis

There are two types of clinically important drug-resistant tuberculosis:

- **Multidrug-resistant tuberculosis (MDR-TB)**
  Tuberculosis in patients whose culture and drug sensitivity test results show resistance to at least rifampicin and isoniazid.
- **Extensively drug-resistant tuberculosis (XDR-TB)**
  Tuberculosis in patients whose culture and drug sensitivity test results show resistance to at least rifampicin and isoniazid, plus resistance to 1 injectable second-line drug (amikacin, capreomycin, kanamycin), plus the fluoroquinolone group of drugs.

Once the diagnosis of MDR-TB or XDR-TB has been made, the patients should be put on appropriate treatment regimen as soon as possible. In a health facility where treatment is not possible, the patients should be referred to a health facility or MDR-TB treatment centre where treatment can be offered.

2.7 TUBERCULOSIS IN CHILDREN

2.7.1 Introduction

In most cases, babies are born free of TB infection and disease. Children usually become infected by adults with sputum smear-positive pulmonary TB, such as a family member or a close associate of the child. Infection may also occur from sputum smear-negative patients although the risk is lower. Children may also be infected by *Mycobacterium bovis* if they drink unpasteurized milk. The risk of infection depends on the extent of exposure. Children can present with tuberculosis disease at any age, but most commonly infection and disease occur between 1 and 4 years. The younger the child, the more severe the disease. Children usually present with extrapulmonary TB.

The majority of children who get TB infection do not develop disease in childhood. They develop specific immunity to TB. This is usually evidenced by a positive tuberculin skin test. The likelihood of developing disease is high soon after infection then gradually declines over time. Immunosuppressive diseases may cause easy progression of infection to disease. Some of the common immunosuppressive diseases are protein-energy malnutrition (e.g. kwashiorkor, marasmus), measles, whooping cough and HIV infection.

The diagnosis of TB in children is usually difficult, particularly in younger ones. This is because most childhood TB is extrapulmonary in type. Yet the “gold” standard for diagnosis of TB is bacteriological. Obtaining specimen material for bacteriological examination is very difficult in many situations. Even in cases where a specimen for bacteriological examination has been obtained, the specimen usually contains few bacilli, making the diagnostic yield low. Consequently the diagnosis of TB in children usually depends on a high index of suspicion and the strength of presenting clinical features, rather than on bacteriological confirmation.

BCG vaccination and tuberculosis

The BCG vaccine is a live attenuated vaccine obtained from *M. bovis*. In Uganda, BCG vaccine is given at birth. It protects against severe forms of TB disease, such as miliary TB and TB meningitis. However, the vaccine is not fully effective against pulmonary TB. Children with malnutrition and severe infections such as HIV, whooping cough and measles may develop severe forms of TB disease irrespective of their vaccination status.

Among symptomatic HIV-positive children, vaccination may result in disseminated BCG disease. In high-burden countries, the benefits of BCG vaccination outweigh the risks of vaccine-related disease. Therefore in Uganda, BCG is only contraindicated in children with symptomatic HIV disease.

Box 2.5 Diagnosis of TB in children

A high index of suspicion is key to the diagnosis of TB in children

Most children with TB will present with symptoms such as prolonged cough lasting 2 weeks or more; fever >2 weeks, often associated with poor weight gain; and loss of weight, energy, activity or appetite. Although fever and weight loss are common in children with extrapulmonary TB, the conspicuous symptoms are usually associated with the site of disease.

2.7.2 Diagnostic Approach

A good history, a thorough physical examination and a high index of suspicion are vital aids to diagnosis. TB diagnosis in children is based on a combination of clinical features, history of exposure to adult patients with TB, the result of a tuberculin (Mantoux) test and radiological findings.

Suspect TB disease in a child under the following conditions:

- History of contact with PTB sputum-smear positive in a child who is 5 years or younger.
- Cough of 2 weeks or more
- Unexplained prolonged fever greater than 38 degrees Celsius after exclusion or failure of treatment for usual diseases such as malaria or pneumonia
- Unexplained loss of weight
- Failure to gain weight
- HIV infection
- Past history of TB treatment
- Non-response to nutritional rehabilitation after at least 2 weeks of proper nutritional care
- Hemoptysis

Box 2.6 Key signs regarding TB during physical examination of children

Signs to look for in a physical examination

- Severe wasting
- Enlarged cervical lymph nodes that may be painful
- Swelling (angulation), also known as gibbus, in the middle of the back
- Pleural effusion
- Progressive deformity of bones or joints

Other signs that may be consistent with TB disease:

- High temperature (>38 degrees Celsius)
- Localized signs in the chest such as crackles or bronchial breathing
- Meningitis that is not responding to antibiotics

The table below shows the practical approach to diagnosing TB in children by site of suspected disease.

Table 2.10 Procedure for diagnosis of TB in children

Site of disease	Diagnostic approach
Lymph node (peripheral)	Needle (G22) aspiration
Miliary	Chest X-ray
TB meningitis	Lumbar puncture
Pleural effusion	Pleural tap
Abdominal TB	Abdominal ultrasound
Pericardial TB	Cardiac ultrasound and tap
Pulmonary TB	Pulmonary secretions (sputum, gastric washout or induced sputum)

Tuberculin skin test

The recommended test is the Mantoux test. Depending on the person's risk factor, an induration (palpable raised firm area of skin) of 5 mm and above to 5 tuberculin units of PPD is considered a positive result indicating TB infection but not necessarily disease. Interpretation of tuberculin skin testing (TST) must always be done with care, taking into consideration the patient's immunological level and BCG vaccination status. Consider TST positive as shown below:

- 5 mm or more is positive if the person is:
    - HIV positive
    - A recent contact of TB case
    - Severe malnutrition
    - Children in other immunosuppressive states
    - Recent measles or whooping cough
- 10 mm or more is positive in all children except the above listed category.

2.7.3 Treatment of TB in Children

The principles and objectives of TB treatment, which have described in section 2.3, are the same in all patients (adults and children). However, effective treatment of TB in children can promote growth and development. The following points must be adhered to when treating TB in children:

- Children receiving anti-TB treatment must be weighed every month.
- Treatment doses must be adjusted as soon as a child changes weight bands.
- Tablet strength must be checked carefully.
- Children weighing more than 30 kg should be treated according to adult treatment guidelines.

Following are tables that show the recommended dosage of the drugs and the regimens for treatment categories in children.

Table 2.11 Recommended dose of first-line anti-TB drugs for children

Drug (*Abbreviation)*	**Daily doses mg /kg/body weight (Range)**	**Maximum daily dose**
Rifampicin (R)	15 (10–20)	600 mg
Isoniazid (H)	10 (10–15)	300 mg
Pyrazinamide (Z)	35 (30–40)	2 g
Ethambutol (E)	20 (15–25)	1.2 g
Streptomycin (S)	15 (12–18)	1 g

Table 2.12 Recommended anti-TB treatment regimen for children in each treatment category

TB treatment category	TB cases	Regimen	
		Intensive phase	**Continuation phase**
3	• New smear-negative pulmonary TB (other than in category 1) • Less severe forms of extrapulmonary TB	2HRZ	4 HR
1	• New smear-positive pulmonary TB • Severe forms of extrapulmonary TB • Severe concomitant HIV disease • New smear-negative pulmonary TB with extensive parenchymal disease	2HRZE	4HR
1	TB meningitis	2RHZS	4RH
2	Previously treated smear-positive pulmonary TB	2HRZES/1HRZE	5HRE
4	Chronic and MDR-TB	Specially designed standardized regimens or individualized regimens (see treatment guidelines for MDR-TB)	

Table 2.13 Dosage of anti-TB drugs for children 0-12 years using FDCs

Patient	**Category 1**			
Weight bands (Kg)	Initial phase–2 months (daily dose)			Continuation phase–4 months (daily dose)
Adjust dosages accordingly	RHZ (60+30+150)mg	RH(60+30) mg	E 400mg	RH (60+30)mg
5-8	1 tab	1 tab	¼ tab	1 tab
9-12	2 tabs	2 tabs	½ tab	2 tabs
13-16	2 tabs	2 tabs	¾ tab	3 tabs
17-20	3 tabs	3 tabs	1 tab	3 tabs
21-24	3 tabs	3 tabs	1 tab	4 tabs
25-29	4 tabs	4 tabs	1 ¼ tab	4 tabs

2.7.4 Contact Tracing

Contact tracing is the process of identifying children who have been in contact with a patient suffering from pulmonary TB. The active process of inquiring about symptoms and carrying out tests to diagnose TB is called *contact screening.* The main aims of contact screening are to:

- Identify children with TB disease (symptomatic children with TB disease) and treat them
- Identify children at risk of getting TB infection (close contacts of sputum smear-positive cases) and provide them with preventive therapy

2.7.4.1 Definitions

Contact: a child who has been together at some point with a TB patient (particularly sputum smear-positive PTB)

Source case: a case of PTB (most likely sputum smear-positive) that results in infection or disease among contacts

Contacts for screening: all children who have been in close contact with a source case should be screened for symptoms of TB and managed appropriately (Fig. 2.1)

Close contact: living in the same household as the source case (e.g., the child's caregiver) or in frequent contact (e.g., teacher) with a source case

"Reverse contact tracing" (source case investigation): screening symptomatic adults who have been in contact with a child diagnosed as a TB case

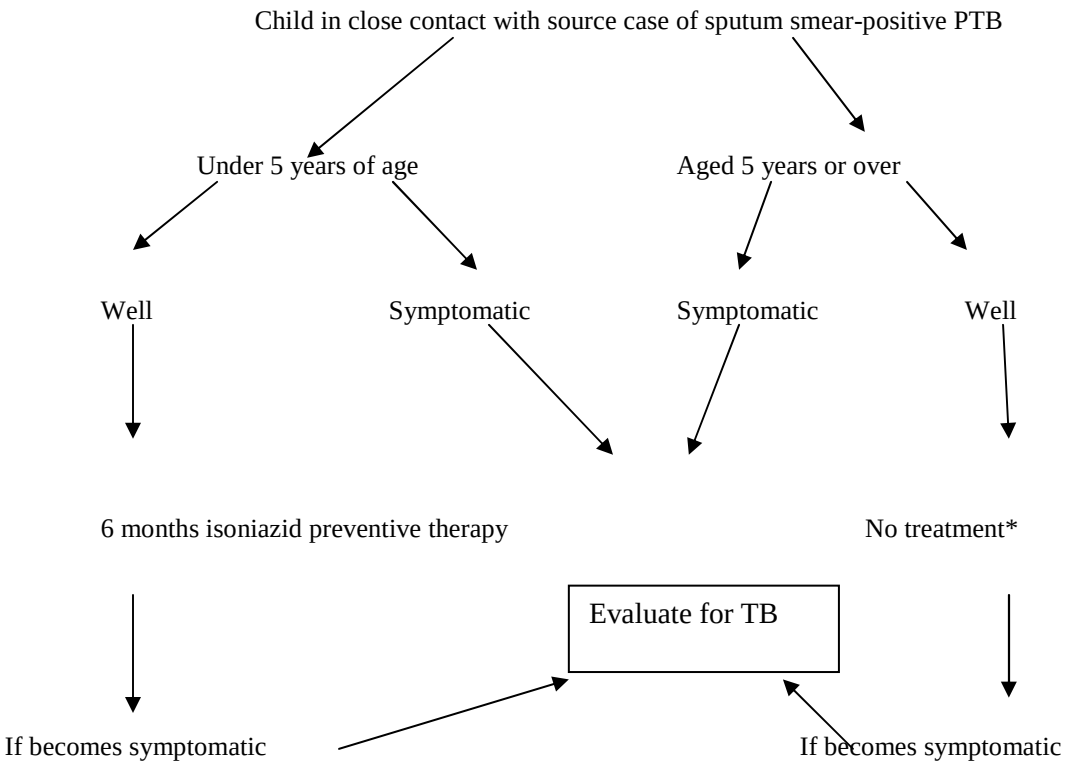

Figure 2.1 Approach to TB contact management

Adapted from *Guidance for national programmes on the management of tuberculosis in children.* World Health Organization, 2006.

*If child is HIV-positive, give 6 months of isoniazid preventive therapy.

2.7.5 Children with TB and HIV

Children with HIV are at very high risk of acquiring TB infection and developing TB disease. Those who develop TB disease have a worse prognosis for severe disease. In most children with a competent immune system, there is no subsequent progression of disease. About 50 percent of HIV sero-positive children with TB infection go on to develop the TB disease. Malnourished HIV sero-positive children have a higher likelihood of TB disease. In some of these cases, there may be no TST response or a very weak one. Primary infections in such children are more likely to progress directly into active disease (primary TB), and often, to death.

In children with HIV, TB commonly presents in a disseminated form.

2.7.5.1 How do you diagnose TB in HIV-infected children?

The most important diagnostic clue for detecting TB in HIV-infected children is a history of contact with an adult who has infectious TB. Since TB may not have yet been diagnosed in this adult, a prompt evaluation for TB in adults who care for the children is a critical part of the evaluation of the children. In the HIV-infected children, consider the following as suggestive of TB:

- History of TB contact
- Feels unwell
- Prolonged cough of 2 weeks or more
- Fever

Box 2.7 Recommendations for HIV-infected child who develops TB

- If a patient is already receiving antiretroviral drugs at the time TB is diagnosed, continue ARVs.
- Consider using anti-TB drugs that have less interaction with ARVs (such as rifabutin instead of rifampicin).
- Adjust doses of neverapine if the child is on rifampicin and has to be maintained on the nevirapine-based regimen.
- The child with TB disease and HIV can also be treated with a triple nucleoside reverse transcriptase enzyme inhibitor (NRTI) regimen for the duration of TB treatment.

Immune Reconstitution Syndrome (IRIS)

This is a temporary clinical deterioration that sometimes occurs after beginning anti-TB therapy. This especially occurs in TB patients who are co-infected with HIV. Management consists of continuing anti-TB treatment, assessing the child for new illness and, in some cases, corticosteroids may be useful.

2.7.6 Follow-up of TB Treatment in Children

Health workers providing TB treatment to children should assess progress:

- at 2 weeks after start of treatment
- at the end of the *initial* phase of treatment and
- monthly thereafter until treatment completion

The child should be assessed for symptoms, treatment adherence, adverse events and weight change. Medication dosage should be adjusted for any weight gain.

For sputum smear-positive children, sputum should be examined at these points:

- end of 2 months
- 5 months
- during the last month of treatment

Chest X-rays are not routinely required for treatment follow-up in children as many children have slow radiological response to treatment, especially those with hilar and mediastinal adenopathy. A child not responding to anti-TB treatment in the first 2 months should be referred for further assessment and management. These children may have drug-resistant TB, unusual complications of pulmonary TB, other causes of lung disease or problems of treatment adherence.

2.8 TB/HIV CO-INFECTION

2.8.1 Introduction

The interaction of TB and HIV is increasing the burden of both diseases. HIV is one of the major risk factors for the development of active TB among individuals infected with *Mycobacterium tuberculosis complex*. At present, an estimated 60 percent of TB patients in Uganda are also infected with HIV. TB is a leading cause of morbidity and mortality for people living with HIV/AIDS (PLWHA) and accounts for 30 percent of all deaths among them. This information demonstrates that HIV prevention and care should be a priority concern of the NTLP while TB care and prevention should also be a concern of the HIV/AIDS Control Programme. There is therefore a need to establish TB/HIV collaborative activities whose goals and objectives are:

1. To establish mechanisms of collaboration between TB and HIV/AIDS programmes
2. To decrease the burden of TB in people living with HIV/AIDS
3. To decrease the burden of HIV in TB patients
4. To provide care and support services for patients in TB and HIV/AIDS programmes who are co-infected

The table below summarizes the recommended TB/HIV collaborative activities.

Box 2.8 TB/HIV collaborative activities

Decrease the burden of tuberculosis in people living with HIV/AIDS

- Establish intensified tuberculosis case-finding
- Provide isoniazid preventive therapy (IPT), where feasible
- Provide TB treatment to those with active TB
- Ensure tuberculosis infection control in health care and congregate settings

Decrease the burden of HIV in tuberculosis patients

- Provide diagnostic HIV counselling and testing
- Provide HIV prevention methods
- Provide cotrimoxazole preventive therapy (CPT)
- Provide HIV/AIDS care and support
- Provide antiretroviral therapy, if eligible

Adapted from *National Policy Guidelines for TB/HIV collaborative activities in Uganda. March 2006*

2.8.2 HIV/AIDS Care and Support in TB Clinics

The provision of HIV/AIDS care in TB clinics is part of a continuum of a comprehensive AIDS care strategy. The strategy includes clinical management with laboratory support (prophylaxis, early diagnosis of TB or HIV/AIDS, rational treatment and follow-up care for non-TB opportunistic infections). Those who have completed their TB treatment should continue with HIV care service or be referred where such service can be offered. TB/HIV collaborative care aims to provide comprehensive care to the TB/HIV co-infected patient. As part of TB/HIV collaborative activities, the following should be planned and carried out in TB clinics:

i) **Diagnostic HIV testing and counselling**

Diagnostic HIV testing and counselling should be offered to all TB patients. Patients should be allowed to opt out if they did not want to be tested. This service offers an entry point for a continuum of prevention, care, support and treatment for HIV/AIDS in addition to TB.

ii) **Cotrimoxazole preventive therapy (CPT)**

All TB patients who are co-infected with HIV should be provided with cotrimoxazole preventive therapy, and it should be provided for life.

iii) **Isoniazid preventive therapy (IPT)**

Isoniazid is given to HIV-positive individuals with latent infection with *Mycobacterium tuberculosis* in order to prevent progression to TB disease. Isoniazid is given daily as self-administered therapy for 6 months. This is described under the section 2.4 on preventive treatment of TB.

iv) **HIV prevention methods in the TB clinics**

All clients attending the TB clinics should be screened for sexually transmitted diseases using recommended approaches. Those with symptoms of sexually transmitted infections should be treated or referred to an STD clinic. A referral linkage should be established within and between TB and HIV service provision points.

Health workers should provide HIV prevention messages to all TB patients. Positive living among those already infected and safe sex practices should be emphasized in order to prevent spread within the community.

v) **Intensified TB case-finding**

Intensified TB case-finding comprises:

- Screening for symptoms and signs of TB suspects in settings where HIV-infected people are concentrated or in congregate settings (e.g., prisons, police, military barracks, Internally Displaced Persons camps, outpatient departments, HIV clinics, inpatient wards, schools).
- laboratory examination of TB suspects
- increasing the awareness and knowledge of interactions between TB and HIV among health care workers
- increasing the awareness and knowledge of interactions of TB/HIV in the population.

vi) **Surveillance of HIV prevalence among TB patients**

Surveillance is essential to inform programme planning and implementation. HIV counselling and testing of tuberculosis patients should therefore be done routinely.

vii) **Provision of antiretroviral treatment**

All TB patients co-infected with HIV should be given antiretroviral drugs. If the drugs cannot be obtained within the TB clinic, the patient should be referred to a place where they can be obtained.

2.8.3 Community Involvement in Collaborative TB/HIV Activities

Through support groups for people living with HIV/AIDS, village health teams (VHTs) and community-based organizations, TB prevention and care can be integrated with HIV/AIDS prevention, care and support. Communities should be effectively mobilized to advocate for resources and opportunities to implement collaborative TB/HIV activities.

Community-based organizations (such as those providing HIV/AIDS home-based care), CB-DOTS treatment supporters and workplace managers or staff associations may also be involved in identifying people with symptoms and signs of TB or HIV/AIDS, referring them to health facilities for diagnosis and treatment and ensuring directly observed treatment. Innovative mechanisms for delivery of ART could be designed along these same lines.

2.8.4 Monitoring and Evaluation of Collaborative TB/HIV Activities

Monitoring and evaluation provide the means to assess quality, effectiveness of delivery and coverage of collaborative TB/HIV activities. Monitoring and evaluation involve collection and analysis of data for indicators of TB/HIV collaborative activities. These data are collected from the level of provision of service. The core NTLP indicators shown in Table 2.19 for monitoring TB/HIV collaborative activities only include those based on information collected from TB care facilities.

2.8.5 Management of a Co-infected TB/HIV Patient

The clinical presentation of TB in early HIV infection is similar to that in HIV-negative persons. However, as HIV infection progresses, CD4+ T lymphocytes will decline in number and

function. These cells play an important role in the body's defence against tubercle bacilli. Thus, the immune system becomes less able to prevent growth and local spread of *Mycobacterium tuberculosis*. Disseminated and extrapulmonary TB diseases become more common.

I. Pulmonary TB in HIV-infected patients

Even in HIV-infected patients, PTB is still the commonest form of TB. The presentation depends on the severity of immunosuppression. The table below shows how the clinical picture, sputum result and chest X-ray appearance often differ in early and late HIV infection.

Table 2.14 Comparison of pulmonary TB in early and late HIV infection

Features of PTB	**Stage of HIV infection**	
	Early	**Late**
Clinical picture	Often resembles post-primary PTB	Often resembles primary PTB
Sputum smear result	Often positive	Often negative
Chest X-ray appearance	Often cavities	Often infiltrates with no cavities

II. Extrapulmonary TB in HIV-infected patients

The usual forms of extrapulmonary TB – pleural effusion, lymph node, pericarditis, miliary, meningitis and disseminated TB (with mycobacteraemia) – can occur in patients who are HIV positive. Occurrence of extrapulmonary TB (except TB lymph node only) implies severe HIV disease (WHO disease classification stage 4).

2.8.6 Diagnosis of TB in HIV-Infected Patients

The follow methods can be used to diagnose TB in HIV patients:

i) **Sputum microscopy**

Sputum microscopy is the main test for the diagnosis of TB in high-prevalence areas such as Uganda. All TB suspects, (whether HIV-positive or negative) should have 2 sputum specimens examined for acid-fast bacilli (AFB).

ii) **Mantoux test**

Although this test may be useful in measuring the prevalence of TB infection in a community, it is not useful for individual adult diagnosis. In late stage HIV infection, the test is likely to be negative even in the presence of TB disease.

iii) **Chest X-ray**

Radiological investigation of the chest can add invaluable evidence(s) in the diagnosis of TB, particularly when the sputum smear is negative. This investigation should be carried out whenever possible.

i*v)* **Culture for *Mycobacterium tuberculosis complex***

This test is the one that provides the definite diagnosis of TB. It is also the test used to diagnose drug-resistant TB. It is useful in those who are HIV- positive.

2.8.7 TB Treatment in PHAs with TB Disease

All patients diagnosed with TB, including PHAs, should be treated with anti-TB drugs according to the NTLP recommendations. All patients on TB treatment should be supported to complete their medications under directly observed treatment (DOT).

Antiretroviral therapy should be offered to all HIV-positive TB patients, according to the National ART and care guidelines for all adults and children. It is a lifelong treatment requiring a high adherence rate to achieve long-term benefits and minimize the development of drug

resistance. Availability of antiretroviral therapy can serve as an incentive for people to be tested for HIV. The table below gives guidance on when to start ART in a TB patient who is HIV infected.

Table 2.15 Guidance on when to start ART in TB patients co-infected with HIV

TB patient clinical status	How to manage—when to start ART or refer to doctor
Smear-positive pulmonary TB only (no other signs of clinical stage 3 or 4) and patient is gaining weight on treatment.	Start TB treatment. Reassess after initial phase of TB treatment to determine when to start ART during TB treatment.
Smear-negative pulmonary TB only (no other signs of clinical stage 3 or 4) and patient is gaining weight on treatment.	Start TB treatment. Reassess after initial phase of TB treatment to determine when to start ART during TB treatment.
Any pulmonary TB and patient has signs of clinical stage 4 or thrush, pyomyositis, recurrent pneumonia, persistent diarrhœa, new prolonged fever or losing weight on treatment or if no clinical improvement.	Start TB treatment. Assess after 2 weeks. If TB treatment tolerated, start ART. OR Reassess at 4 weeks, if TB treatment not tolerated at 2 weeks, and decide on ART.
Extrapulmonary TB	Start TB treatment. Assess after 2 weeks. If TB treatment tolerated, start ART OR Reassess at 4 weeks, if TB treatment not tolerated at 2 weeks, and decide on ART.

**Any HIV-positive patient receiving an anti-TB drug regimen containing isoniazid should also receive pyridoxine 25 mg daily to prevent peripheral neuropathy.*

2.8.8 Common TB-ART Co-Treatment Regimens

A trained staff or medical officer needs to decide when to start ART and the regimen. For patients being considered for, or already on TB-ART co-treatment, the following should be noted by the attending health worker:

- A patient on TB-ART co-treatment will have many tablets to swallow and may experience more side-effects. Educate the patient on how to manage mild to moderate side-effects and report to the health worker immediately for severe ones.
- The patient continues receiving cotrimoxazole.
- There are many tablets and several changes may take place in the regimen during the course of treatment. This requires careful education of the patient and treatment supporter at each change. The TB treatment is not necessarily in the morning.
- The following examples are based on a rifampicin-based regimen during the initial and continuation phases of TB treatment. The patient is put on an efevarenz-based ART regimen if it is started during TB treatment.

Table 2.16 Recommended ARV regimen for patients on anti-TB treatment

Patient group	First-choice regimen	Alternative regimen
Children younger than 3 years or weighing 10 kgs or less	AZT +3TC +ABC	NRTIs +NVP
Adults	AZT +3TC + EFV	AZT or d4T + 3TC + NVP or TDF+3TC+EFV

EFV=efavirenz, NVP = nevirapine, TDF=tenofovir, d4T=stavudine

NRTIs, e.g., zidovudine (AZT), didanosine (ddI), lamivudine (3TC), abacavir (ABC), emtricitabine (FTC), zalcitabine (ddC)

Box: 2.9 Immune reconstitution syndrome (IRIS)

Occasionally a patient's condition becomes worse after starting anti-TB drugs or antiretroviral treatment. The patient develops fever, lymph nodes increase in size worsening radiological signs and increasing pleural effusions. This is called immune reconstitution syndrome (or paradoxical reaction). However, the diagnosis should only be made after thorough investigations have excluded other causes of failure to respond to treatment. The treatment is prednisolone at a dose of 1mg/kg body weight for 2 weeks, then gradually reduced over another 2 weeks.

ART and anti-TB treatment should be continued.

2.9 TUBERCULOSIS INFECTION CONTROL

2.9.1 Introduction

Transmission of TB occurs when an infectious TB patient coughs, sneezes and talks, hence releasing droplets in the air. These droplets can be inhaled by a person close to the patient. The TB patients who are most likely to release infectious droplet nuclei are the ones who are PTB AFB sputum smear-positive, although infectious droplets may also be produced by PTB AFB sputum smear-negative. Pulmonary TB patients are most likely to transmit tuberculosis when they are not yet on anti-TB treatment.

Although inhalation of infectious droplet nuclei is the most common route of acquiring TB infection, infection can also be acquired by drinking unpasteurized milk.

There are three levels of infection control measures listed below in hierarchy of importance:

1st priority: Administrative controls (workplace)

This is the most important level, which attempts to stop/prevent the release of droplet nuclei into the air.

2nd priority: Environmental controls

These actions complement the administrative measures. They reduce the concentration of droplet nuclei in the air.

3rd priority: Personal protective measures

These measures protect individual persons from releasing or inhaling the droplet nuclei.

2.9.2 Administrative TB-IC in General Health Facilities

The staff in the general clinics should take the follow steps to ensure infection control:

i) Develop a “triage” system whereby patients likely to be TB suspects are identified and sent to the laboratory for sputum AFB smear examination immediately or put in a well-ventilated place or helped to see a clinician first. The health workers do this by asking the patients questions such as: Who among you has a cough that has lasted for 2 or more weeks? Is there anyone among you who has ever been treated for TB?

ii) Educate patients about cough hygiene: When you cough, cover your mouth and nose with a handkerchief or paper tissue. If you do not have a handkerchief or paper tissue, turn to

the inside of your arm, and cover your nose and mouth with it (See Fig. 2.2). This figure should hang on the wall in the clinic.

iii) Even if the mouth is covered, tell the patients always to turn away from facing other people when coughing, whether the mouth is covered by a handkerchief, tissue or an arm.

iv) Identify an area of the ward and designate it for diagnosed TB patients and TB suspects. This area should be a well-ventilated area of the ward

v) Develop written instructions on keeping windows and doors open for ample circulation of air. This instruction should clearly indicate time to open windows and doors, and the patients should be informed about this when first admitted and constantly reminded about it.

2.9.3 Administrative TB-IC Measures in Tuberculosis Health Facilities

The staff in the TB clinics should:

i) Regularly educate TB patients about the importance of preventing transmission of TB in the wards and on all outpatient days.

ii) Ask the patients to identify anyone with 2 or more weeks of cough in their family or community so that they can be examined for TB disease.

iii) Educate the patients about cough hygiene (described above) and show the picture hanging on the wall. Sputum produced after coughing should be placed in a handkerchief, tissue or sputum container.

iv) Instruct patients to cover their mouths and noses with a handkerchief. This is to prevent further transmission between themselves (patients), attendants and staff. Explain to them that this is for the benefit of everybody and should not make them feel bad or discriminated against.

v) Identify known or suspected drug-resistant TB patients and separate them from other TB patients.

vi) Develop and hang health education messages on the ward and clinic walls.

vii) Develop written instructions on keeping windows and doors open for free circulation. This instruction should clearly indicate time to open windows and doors, and inpatients should be informed about this when they are first admitted and constantly reminded about it.

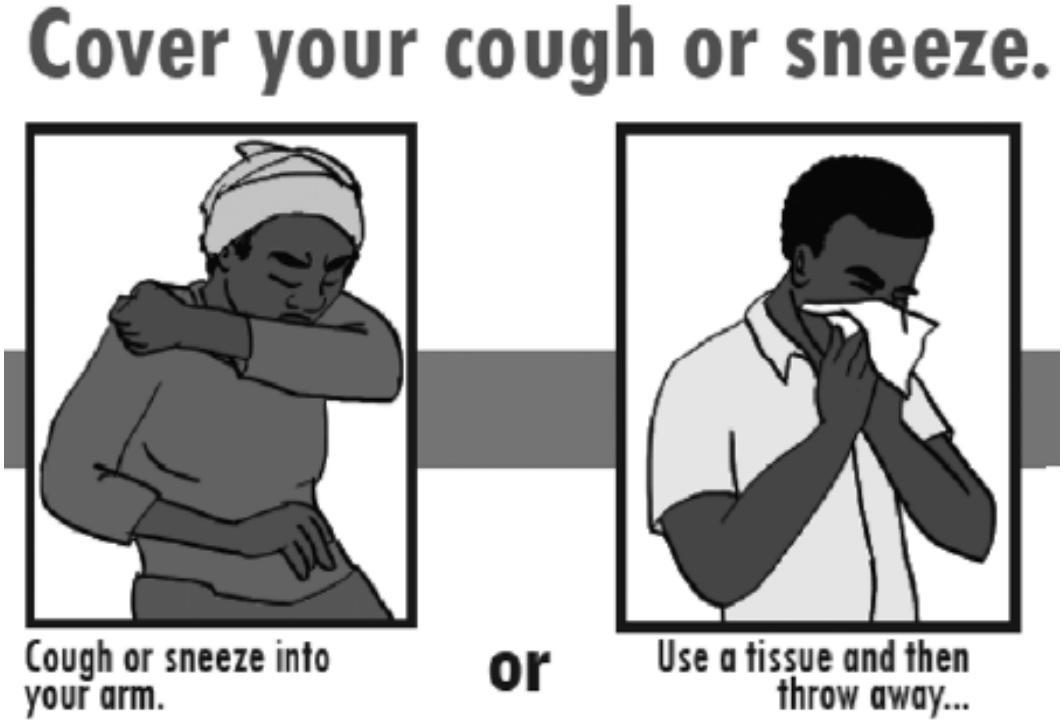

Figure 2.2 Illustration showing cough hygiene

Adapted from WHO

2.9.4 Personal TB-IC Measures for Health Workers

In order to control TB infection among health care workers, they should:

i) Learn the symptoms of TB suspects. Should any health worker have a cough that lasts for 2 or more weeks and is associated with fevers, loss of weight and reduced appetite, such health worker should report for examination to diagnose TB.

ii) Be encouraged to know their HIV status and, if positive, must not be assigned to work in TB wards or clinics.

iii) Whenever possible, health workers should be examined yearly by tuberculin skin testing and chest X-rays. Those found tuberculin skin test negative should be given BCG vaccination.

iv) Wear and N95 mask whenever possible.

2.9.5 Disinfection and Disposal of Sputum

i) Health workers must ensure that, after instructing the patients how to obtain a sputum specimen, they tell the patient to go and perform the act of producing the specimen away from the laboratory. When a designated area for taking sputum specimen is available, the patient is sent to the area.

ii) Sputum of inpatients is collected in a sputum mug or a plastic screw cap container. This container should have disinfectant liquid poured into it before the sputum material is put in it. Sputum from all the inpatients in a ward should be collected into one big container, further disinfected and then disposed of.

2.9.6 TB-IC in Congregated Populations

A congregated population is a group of people staying close to each other – for example, school children and prisoners. The measures described below are useful for controlling TB infection in such a population:

i) Plan for and develop TB and HIV/AIDS collaborative activities for the institution with a congregated population.

ii) Establish TB diagnostic and treatment services.

iii) Educate population and staff on relationship between TB and HIV infection, so that they can recognize TB suspects.

iv) Advocate for an isolation unit for patients diagnosed with TB.

v) Consider “active screening” of the immediate group members for TB suspects, when a new pulmonary TB sputum smear-positive is diagnosed.

2.10 LABORATORY SERVICES

2.10.1 Diagnostic Methods

All tuberculosis (TB) suspects must be examined according to the standardized procedures of which sputum microscopy is the most accessible and reliable. By rank of importance the diagnostic methods to confirm/exclude TB are:

- Microscopic examination of sputum smears
- AFB culture
- Histopathology

2.10.2 Microscopic Examination of Sputum Smears

Sputum microscopy is the most efficient way of identifying patients with infectious forms of pulmonary TB. Microscopy is currently the primary tool for diagnosing TB in Uganda; it is easy to perform at the peripheral laboratories, cheap and accurate. It can be used for diagnosis, monitoring response to treatment and defining cure. It is a key tool for case detection and monitoring.

Sputum microscopy is kept reliable by the laboratory participating in external quality assurance (EQA). A maximum of 2 sputum specimens should be collected and examined on 2 consecutive days **(spot** and **early morning).**

Note:

PTB+ is confirmed when at least 1 out of the 2 smear results is positive for AFB.

The laboratory should keep all positive and negative slides in the same slide box in sequence to facilitate quality assurance procedures. The sputum specimen collection procedures are provided in the annex.

2.10.3 Culture

The probability of finding AFB in sputum specimens by smear microscopy is directly related to the concentration of bacilli in the sputum. In comparison, mycobacterial culture can detect far lower numbers of TB bacilli. Moreover, the culture makes it possible to identify the mycobacterial species on the basis of biochemical and other properties.

Culture of *M. tb* bacilli is very sensitive and specific, but is expensive, as it is a complex and sophisticated procedure. It requires a specialized laboratory set-up, and culture results are available only after several weeks. Culture with DST takes even longer. If available, culture can be used for diagnosis or confirmation of the diagnosis of TB in patients with PTB and EPTB. Since it is more sensitive than smear, culture may also have a role in the diagnosis of smear-negative, HIV-positive TB suspects who are likely to be paucibacillary.

In addition to its use in surveillance, culture with DST is valuable for diagnosis and management of drug-resistant TB. It is mainly used to screen patients who have a poor response to correct treatment, as well as those that have been previously treated – a group of patients likely to have drug-resistant TB.

2.10.4 Molecular Tests

A molecular test has been developed for rapid detection of resistance against rifampicin and isoniazid. This test, called HAIN (MDR-TB plus), is capable of detecting resistance to the 2 drugs within 1 day in a smear-positive specimen. As in the case for culture, this DST method should be used in patients likely to have drug-resistant TB. It will allow for rapid isolation of multidrug-resistant TB (MDR-TB) patients and fast and appropriate initiation of treatment for both MDR and non-MDR patients among those screened.

2.10.5 Histopathological Examination

Pathology can play a complementary role in confirming the diagnosis of EPTB, such as tuberculous lymphadenitis. Multiplication of tubercle bacilli in any site of the human body causes a specific type of inflammation, with formation of characteristic granuloma that can be found on histological examination. Samples can be taken from the following:

- Fine needle aspiration of the lymph nodes: affected peripheral lymph nodes, particularly cervical nodes, can be aspirated.
- Tissue biopsy: serous membranes (pleura, pericardium and peritoneum), skin, lymph node, endometrium, bronchial mucosa or liver tissue can be taken, with an appropriate instrument or during surgery. Surgical procedures can be useful in getting tissues for biopsy from deep organs.
- Post-mortem: after death from an unknown cause, tissue samples taken at autopsy can be analyzed.

2.10.6 External Quality Assessment (EQA)

To be reliable, laboratories performing microscopy, culture and molecular tests must participate in external quality sssurance (EQA) programmes. The process involves the examination of previously prepared slides to see if:

- Slides were prepared properly
- Slides were examined, and the reported results (positive or negative) are correct
- Recommended laboratory procedures are followed
- Safety measures are adhered to

2.11 TB MONITORING AND EVALUATION

2.11.1 Introduction

Monitoring and evaluation (M&E) plays an important role in the management of the TB programme at all levels. M&E ensures that the resources going into the programme are being utilized; services are being accessed; activities are occurring in a timely manner; and expected results are being achieved. It facilitates the most effective use of human and financial resources for achievement of maximum health benefit for the population served. M&E involves establishment and maintenance of a system to monitor case detection and treatment outcomes through collection and analysis of data.

Monitoring is the careful observation of programme activities to ascertain whether these activities are being accomplished as planned.

Evaluation is the periodic use of data collected in a systematic manner to assess process, outcome and impact of the programmes. However, full description of evaluation is beyond the scope of this manual.

2.11.2 Programme Monitoring

Monitoring requires that there should be “monitoring tools”. The NTLP uses the following forms and registers as tools to monitor programme activities.

- TB Laboratory Form
- Request for Culture and Sensitivity
- TB Laboratory Register
- TB Patient Treatment Card
- TB Unit Register
- Sub-county Health Worker Register
- District TB Register
- TB Referral/Transfer Form
- TB/HIV Referral Form
- Quarterly Report Forms

- Facility Report and Request for Drugs (FRRD)
- Intensified TB Case-finding Form
- TB Suspect Register

Monitoring involves:

- Keeping good records in the above mentioned "monitoring tools"
- Reviewing and updating the collected records regularly
- Compiling data and analyzing key indicators related to TB case detection, treatment and other activities of the TB programme
- Carrying out support supervision

The following measurements are used for monitoring TB programme performance in Uganda:

i) **Case detection:** This is an activity that measures the detection of TB patients in the population. The indicator is:

- Case detection rate

ii) **Case holding:** This is the measurement of how well TB patients adhere to the anti-TB drugs prescribed for them. The indicators used to monitor case holding are:

- Cure rate
- Treatment completion rate
- Default rate
- Death rate
- Treatment failure rate
- Transfer rate
- TB in children

iii) **Programme management:** The indicators used to measure management aspects of the TB programme are:

- Proportion of supervisory visits carried out
- Proportion of TB treatment facilities reporting stock-outs of anti-TB drugs
- Proportion of TB patients on DOT

- Completeness of reporting to NTLP
- Accuracy of reporting to NTLP

iv) **TB/HIV collaborative activities:** The indicators listed under this category cover only TB/HIV collaborative activities that are carried out or can be carried out in a TB treatment health facility:

- Proportion of positive HIV tests among TB patients
- Proportion of HIV testing among TB patients
- Proportion of HIV-positive TB patients who received at least 1 month of CPT
- Proportion of HIV-positive TB patients who are receiving of ART

v) **TB in children:** Here the indicator is:

- Proportion of all TB patient who are children in the programme

vi) **Laboratory services:**

- Proportion of TB microscopy units submitting slides for rechecking
- Proportion of TB suspects who are sputum smear positive
- Proportion of sputum smear-positive PTB registered for treatment
- Proportion of MDR-TB identified out of cultured specimen
- Cumulative number of MDR-TB reported

The indicators, calculation, data source, level and frequency the indicators should be calculated for each of the above categories are shown in the tables that follow.

Table 2.17 Monitoring TB case-finding

Indicator	Calculation	Data Source	Level	Frequency
1) Case detection rate	***Numerator:*** total reported PTB smear-positive ***Denominator:*** calculated expected number PTB sputum smear-positive	Quarterly case-finding reports	Central District	Annually

Table 2.18 Monitoring TB case holding

Indicator	Calculation	Data source	Level	Frequency
1) Cure rate	***Numerator:*** total number of new PTB smear-positive with cure outcome ***Denominator:*** total number of new PTB sputum smear-positive registered in that quarter	Unit TB register Quarterly reports on treatment outcomes	Health facility District Central	Quarterly Annually
2) Treatment completion rate	***Numerator:*** total number of new PTB sputum smear-positive with treatment completed outcome ***Denominator:*** total number of new PTB sputum smear-positive registered in that quarter	Unit TB register Quarterly report on treatment outcomes	Health facility District Central	Quarterly Annually
3) Death rate	***Numerator:*** total number of new PTB smear smear-positive registered in a quarter who died irrespective of cause ***Denominator:*** total number of new PTB sputum smear-positive registered in that quarter	Unit TB register Quarterly report on treatment outcomes	Health facility District Central	Quarterly Annually

Indicator	Calculation	Data source	Level	Frequency
4) Default rate	***Numerator:*** total number of new PTB smear-positive registered in a quarter who defaulted ***Denominator:*** total number of new PTB sputum smear-positive registered in that quarter	Unit TB register Quarterly report on treatment outcomes	Health facility District Central	Quarterly Annually
5) Treatment failure rate	***Numerator:*** total number of new PTB smear-positive registered in a quarter who remained sputum smear-positive 5 months or later after starting treatment ***Denominator:*** total number of new PTB sputum smear-positive registered in that quarter	Unit TB register Quarterly report on treatment outcomes	Health facility District Central	Quarterly Annually

Table 2.19 Monitoring TB programme management

Indicator	Calculation	Data source	Level	Frequency
1) Proportion of support supervision visits	***Numerator:*** total number of supervisory support visits made in a quarter for zone or district ***Denominator*:** total number of planned supervisory support visits for zone or district	Quarterly report on programme management	District Zone Central	Quarterly Annually
2) Proportion of TB treatment health facilities reporting stock-outs	***Numerator:*** total number of TB treatment health facilities that reported stock-outs in a given quarter or year ***Denominator:*** total number of TB treatment health facilities	Reports on support supervision visits	District Zone Central	Quarterly Annually
3) Proportion of TB patients on DOT	***Numerator:*** total number of TB patients receiving treatment under DOT during a given quarter or year ***Denominator:*** total number of TB patients registered in the specified quarter/year	Quarterly reports on case-finding	District Zone District	Quarterly Annually
4) Completeness of reporting to NTLP	***Numerator:*** total number of districts that submitted TB case-finding and treatment outcomes report to NTLP in a given quarter or year ***Denominator:*** number of districts expected to submit TB case-finding and treatment outcomes reports to NTLP in a given quarter or year	Zonal and NTLP reports	Zone Central	Quarterly Annually
5) Accuracy of reporting to NTLP	***Numerator:*** number of TB case-finding and treatment outcome reports submitted that were recorded completely and accurately ***Denominator:*** total number of case-finding and treatment outcome reports examined for completeness and accuracy	Zonal and NTLP reports Unit and district TB registers	District Zone Central	Quarterly Annually

Table 2.20 Monitoring TB/ HIV collaborative activities

Indicator	Calculation	Data source	Level	Frequency
1) Proportion of registered TB patients tested for HIV	***Numerator:*** number of registered TB patients in a given quarter or year tested for HIV during TB treatment ***Denominator:*** total number of registered TB patients in the same quarter or year	TB unit and district registers Quarterly report on case-finding	Health facility District Central	Quarterly Annually
2) Proportion of TB patients who are HIV-positive	***Numerator:*** number of registered TB patients in a given quarter or year who tested HIV-positive ***Denominator*:** total number of TB patients registered in the same quarter and tested for HIV	TB unit and district registers Quarterly report on case-finding	Health facility District Central	Quarterly Annually
3) Proportion of registered TB patients co-infected with HIV who get at least 1 month of CPT during TB treatment	***Numerator*:** number of registered TB patients co-infected with HIV who received at least 1 month of CPT in a given quarter ***Denominator:*** total number of registered TB patients co-infected with HIV over the same quarter	TB and HIV service delivery health facilities Quarterly reports on TB case-finding and treatment outcomes	Health facility District Central	Quarterly Annually
4) Proportion of registered TB patients co-infected with HIV who started or continued ART during TB treatment	***Numerator:*** number of registered TB patients in a given quarter co-infected with HIV who started or continued ART ***Denominator:*** total number of registered TB patients in the same quarter co-infected with HIV	TB unit/district registers Quarterly reports on TB case-finding and treatment outcomes	Health facility District Central	Quarterly Annually

Table 2.21 Monitoring TB in children

Indicator	Calculation	Data Source	Level	Frequency
1) Proportion of all TB patients who are children	***Numerator:*** total number of registered TB patients in a given quarter who are children ***Denominator:*** total number of registered TB cases in the same quarter	Unit and district TB registers Quarterly report on programme management	Health facility District Central	Quarterly Annually

Table 2.22 Monitoring TB laboratory services

Indicator	Calculation	Data source	Level	Frequency
1) Proportion of TB microscopy units submitting slides for rechecking	***Numerator:*** number of TB microscopy units for which slide rechecking results are available during a quarter ***Denominator:*** total number of TB microscopy units performing TB smear during the same specified quarter	NTRL	Central	Quarterly
2) Proportion of TB suspects who are sputum smear positive	***Numerator:*** number of TB suspects found to be smear-positive during a quarter/year ***Denominator:*** the number of TB suspects identified clinically whose sputum microscopy was done in the same quarter/year	Laboratory and/or TB suspect register	Health facility District Central	Quarterly Annually
3) Proportion of sputum smear-positive PTB registered for treatment	***Numerator:*** number of new smear-positive PTB who have initiated treatment during a quarter/year ***Denominator:*** total number of new smear-positive PTB cases detected in same quarter	Laboratory Unit and District TB registers	Health facility District	Quarterly Annually
4) Proportion of MDR-TB identified out of cultured specimen	***Numerator:*** number of MDR-TB cases diagnosed in a quarter/ year ***Denominator:*** number of cultures performed in the same quarter/year	NTRL	Central	Quarterly Annually
5) Cumulative number of MDR-TB reported	Count total number of MDR-TB cases diagnosed in a quarter/year	NTRL	Central	Quarterly Annually
6) Proportion of health facilities with high false negatives AFB smear microscopy	***Numerator:*** number of health units sampled having at least two high false negative AFB smear microscopy results ***Denominator:*** total number of health units sampled	NTRL	Central	Quarterly Annually

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SECTION THREE

LEPROSY

3.1 GENERAL INFORMATION ABOUT LEPROSY

3.1.1 Definition of Leprosy

Leprosy is a chronic infectious disease caused by *Mycobacterium leprae* that affects the skin, peripheral nerves and the mucous membranes. The disease affects people of all races and ages and both sexes.

3.1.2 Source of Infection and Mode of Transmission:

The mode of transmission is uncertain, but it is believed that M. *leprae* is spread from person to person primarily as nasal droplet infection. Untreated leprosy patients discharging bacilli are considered the main source of infection. Persons living in the same household or who otherwise are in frequent contact with an infectious person have the greatest risk of being exposed to the bacilli.

The incubation period is usually long, ranging from 3 to 5 years but it may vary from 6 months to more than 20 years. The peak age of onset is young adulthood, usually 20 to 30 years of age.

Unlike TB, there is no evidence to suggest that an association exists between HIV infection and leprosy.

3.1.3 Natural History

While most individuals exposed to an infectious case of leprosy become infected, only a very small proportion (less than 5 percent) of those infected develop the disease. In the majority of cases, specific immunological defences kill the bacilli.

The different manifestations of leprosy (multibacillary and paucibacillary) are due to differences in the degree of immunological defence of the human body and not due to different kinds of bacilli.

BCG vaccination is known to have some protective effect against leprosy.

3.2 CASE FINDING AND DIAGNOSIS OF LEPROSY

3.2.1 Case definition

A case of leprosy is a person with clinical signs of leprosy who requires chemotherapy.

3.2.2 Case-finding

The NTLP aims at early diagnosis of most cases occurring in the community by:

- Training health workers to recognize symptoms and signs of the disease
- Providing health education to communities aimed at increasing awareness of the disease
- Delivering good treatment services to known leprosy patients, so that other suspects may also have confidence in the good treatment and thus come forward to be examined and treated (self-reporting)
- Establishing a clear referral system to deal with difficult diagnoses
- Through proper examination of all persons presenting themselves at health facilities with different skin conditions
- Encouraging household contacts of new patients to present themselves to health units for examination

3.2.2.1 When to suspect leprosy

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

- Pale or reddish 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; and
- Painless wounds or burns on the hands or feet

If one is not sure of the diagnosis, the suspect should be referred to the next level. The suspect should not be registered as a case.

3.2.2.2 How leprosy is diagnosed

Diagnosis of leprosy must be based on careful **clinical examination** of the patient and, when necessary, backed by bacteriological examination. Leprosy is diagnosed when at least 1 of the following **cardinal signs** is present:

i) Hypopigmented patches with definite loss of sensation in them

ii) Thickened or enlarged peripheral nerves at sites where nerves are often affected (see diagram) with loss of sensation and/or weakness of the muscles supplied by those nerves

iii) The presence of acid-fast bacilli in a slit skin smear

3.2.2.3 Responsibility for diagnosis

Designated facilities

One or more health facilities in the health sub-district will be designated for diagnosing leprosy, and all others will be undesignated health facilities.

The health workers at the **designated diagnostic units** are expected to:

- Carry out a complete physical examination (according to guidelines outlined in this manual)
- Confirm the diagnosis of leprosy
- Explain to the patient what the disease is, what might be expected of treatment and possible complications
- Prescribe the appropriate treatment
- Make a full record of the patient's condition on the leprosy record card, including classification and disability grading
- Enter the patient's particulars in the Unit Leprosy Register
- Write out the patient's Clinic Appointment Card

Confirmation at undesignated centres

At undesignated centres, specific treatment must be given only after the diagnosis has been confirmed by the District TB & Leprosy Supervisor (DTLS). If the DTLS is not expected to visit the health unit soon, the patient should be referred to the unit where the DTLS is based or to the nearest designated leprosy diagnostic unit.

The **DTLS or other designated Focal Person** on visiting undesignated leprosy diagnostic units does the following:

- Carries out complete physical examination on leprosy suspects and patients
- Validates the information recorded by the health facility staff on the Leprosy Record Card and the Unit Leprosy Register
- Organises the taking of skin smears
- Explains to the patient about the disease and its treatment
- Enters patient data in the District Leprosy Register
- Enter the District Registration number in the Unit Leprosy Register, Leprosy Record Card

3.2.2.4 Clinical examination

History taking

The following information must be asked for and recorded on the Leprosy Record Card:

- *General information on the patient:* complete name, sex, place, date of birth, full address distance from home to health unit, occupation
- *Contact information:* other leprosy cases in the household and family
- *Main complaints*: date of onset, sites of the lesions, subsequent changes and development of the disease, treatment received

Physical examination

It is recommended that the physical examination be carried out with:

- adequate light (preferably daylight) available, because it is difficult to see the lesions in poor light
- enough privacy for the person to feel at ease

To ensure that no important sign is missed, the clinical examination should include the entire skin surface, back and front, in the following sequence:

- Head and neck
- Front of chest and abdomen
- Arms
- Back of chest and buttocks
- External genitalia in male patients

- Legs

I. Examination of the skin

The skin should be examined for:

- Presence of skin lesions (patches or nodules)
- Number of skin lesions
- Loss of sensation on the skin lesions (patches)

Box 3.1 Instructions for sensory testing

Test the sensation of skin lesions with a wisp of cotton wool as follows:

- Roll the end of a wisp of cotton wool into a fine point.
- Explain to patients the purpose of the test and what is expected of them.
- After the explanation, conduct a trial test by touching the patients on normal skin with their eyes open so that they can exactly see what is done. Continue until they show that they understand the purpose of the test.
- Then do the testing with the patients' eyes closed. First test on normal skin. When they point correctly, test in the skin patches while touching normal skin now and then. Watch at every touch that the patients keep their eyes closed.
- Touch the skin with this point so that the cotton wool bends.
- Patients should be asked to indicate accurately with the tip of a finger, every spot you have touched with the cotton wool.*
- Failure of the suspect to indicate tested areas accurately implies loss of sensation.

Sometimes patients point accurately to areas of normal skin but point more than 2 cm away from where the skin patch is tested. This is called **misreference, and shows diminished sensation in the patch. If this is consistent during repeated testing of a patch, it is a cardinal sign and thus diagnosis of leprosy is made. For thickened skin areas such as the palms and soles use the tip of a ballpoint pen for testing sensation.*

II. Examination of peripheral nerves

The peripheral nerves are examined for*:*

- Enlargement or thickening
- Tenderness (pain on palpation)
- Nerve function assessment

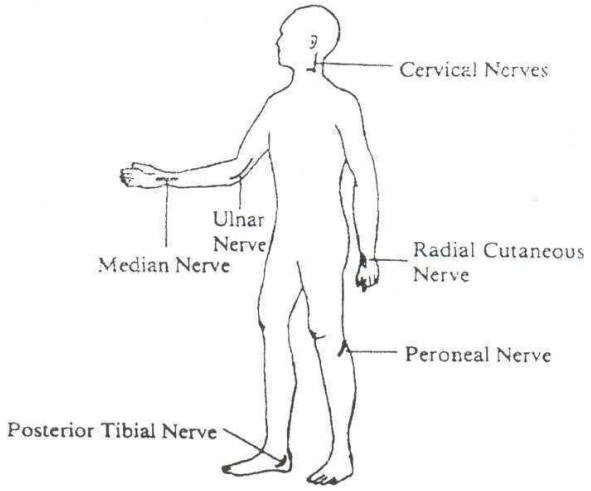


Figure 3.1 Names of superficial nerve trunks and sites where they can be palpated

Box 3.2 Palpation of nerves

Palpation of nerves

- To assess the thickness of a nerve, compare the size of your nerve to that of the leprosy suspect.
- Always compare the patient's left side with the right side nerve(s).
- Palpate the nerve with 2 or 3 fingers by rolling the nerve on the surface of the underlying bone and determine the thickness and tenderness (pain on pressure).
- Finding thick nerves, especially in combination with other signs and symptoms of leprosy, is diagnostic of leprosy.

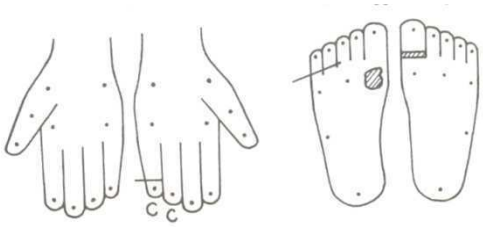
A. Nerve function assessment

Peripheral nerve trunks carry 3 types of nerve fibres – autonomic, sensory and motor. It is recommended to assess each nerve function separately. Any loss of function will indicate possible damage to the relevant nerve fibres.

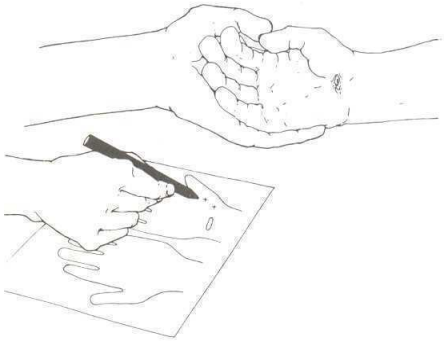
- **Autonomic nerve function** is assessed by looking for dry skin especially on the palms of the hands or the soles of the feet. Finding dry palms and soles of feet implies loss of autonomic nerve function.
- **Sensory nerve function** is assessed by carrying out **sensory testing (ST)** of the eyes, hands and feet as follows:
  - **Eyes**: Observe the eyelids for blinking. If the patient is blinking, assume that the corneal sensation is normal. If the patient does not blink, record "spontaneous blink absent" and refer the patient to the eye clinic.
  - **Hands and feet:** Sensory testing on palms and soles should be done with a ballpoint pen on 10 standard points as indicated on the Leprosy Record Card.
  - **Motor nerve function:** The motor function of peripheral nerves is assessed through **voluntary muscle testing (VMT)**. All muscle movements should be assessed for **range** and the **strength** against the resistance of your hand. Muscle strength should be graded as Strong (S), Weak (W) or Paralysed (P). Test the muscle strength of eyes, hands and feet as follows:

Figure 3.2 Procedure for sensory testing (ST) of hands and feet

1. Mark any wounds, open cracks, clawing of digits and bone loss or absorption on the Leprosy Record Card.



2. Support the patient's hand or foot to prevent any joint movements in fingers/toes during the test.



3. Then touch the skin very gently denting it as little as possible, about 1 mm. The dots on the hand and foot maps on the Leprosy Record Card show you where to touch.
First test while patients are watching and ask them to point with 1 finger wherever they feel a touch, to the exact place touched.
When patients understand the test well and are pointing clearly, ask someone to screen off their eyes or ask them to close their eyes and turn away.

Each time that you dent the skin **record on the hand or foot map** on the Patient Record Card. Record √ **(tick)** at the place if the patients feel and point within 3 cm and **X** if they do not feel anything or point somewhere else

B. Voluntary muscle testing (VMT) of eye

Eye closure: [Facial nerve function]

Ask patients to close their eyes lightly as in sleep. Observe whether or not the closure is complete. Inability to fully close the eye is termed **lagophthalmos**. If there is lagophthalmos, measure the lid gap. The lid gap is recorded in millimetres. A lid gap of more than 5 mm necessitates immediate action to prevent damage. If closure is normal, record "0 mm". Then ask patients to close their eyes firmly while you gently check for strength. Is the closure S, W or P?

C. VMT of hands and feet

Little finger out: [Ulnar nerve function]

Ask patients to move their little finger all the way in (touching the side of the ring finger) and all the way out. Is the movement full?

If the movement is full, ask patients to hold their **little finger out** fully while you apply resistance to the outward movement at the base of the finger by pushing it in. Record the findings as S, W or P.

Thumb up*:* [Median nerve function]

Ask patients to bring the **thumb up and** in front of the index finger but as far away from it as possible. Focus attention on the movements at the base of the thumb rather than the tip. Can they achieve this testing position? Is the movement full?

To test the strength of this movement, instruct patients to maintain the starting position while you push downwards towards the index finger. Record the findings as S, W or P

Foot up; [Peroneal nerve function]

Ask patients to fully lift their foot up towards the shin (dorsiflexion). Check if the movement is full (no more movement possible at the ankle joint).

To test the strength in the testing position, apply resistance to the top of the foot by pushing down. Record the findings as S, W or P.

D. Examination of other organs

Examination of other organs is important in cases of MB leprosy.

i) Examination of the eye

The eyes should be examined carefully under good light, preferably daylight. Besides the changes examined under VMT above, other aspects to be checked include:

- Loss of eyebrows
- Corneas for clearness, ulcers or scars
- Conjunctiva for redness indicating infection, such as conjunctivitis (peripheral redness) or iridocyclitis (redness around the cornea)
- Pupils for regular and round shape. Also check reaction to light and look for signs of cataracts
- Eyeball pressure for glaucoma
- Vision by asking the patient to count fingers

ii) Examination of the nose, tongue and gums, throat, breasts and testes

These organs can also be affected. They should be examined and, in case of doubt, the patients should be referred to leprosy referral centres.

Figure 3.3 Vision testing

Stand 6 metres from the patient.

The vision of each eye is tested separately.

Ask the patient to **cover** one eye. **Raise your hand** against a light background and show the patient 4 times, different numbers of fingers and **ask the patient to count** aloud.

If he can count fingers at 6 metres, record 6/60 for that eye.

Then test the other eye.

A patient who cannot count fingers at 6 metres has severe visual impairment.

IV. Examination of the skin smear

A skin smear is a test in which a sample of material is collected from a tiny cut in the skin and stained for *Mycobacterium leprae.*

The purpose of taking a skin smear is usually to:

- Confirm the diagnosis of skin smear-positive MB leprosy in a suspect
- Help to diagnose MB relapse in a patient who has been previously treated
- Help with the classification of new patients

Only 1 slide, with smears taken from 2 sites must be collected and examined. The basic field guidelines for selection of skin smear sites and steps for taking skin smears are included in Annex 10. The technique for collecting and examining skin smears is described in the ILEP Learning Guide Three: How to do a skin smear for leprosy. Skin smear services are available in the National TB Reference Laboratory (NTRL) and Buluba, Kagando, Kuluva and Kumi hospitals. One positive smear result is diagnostic for MB leprosy.

V. Conclusion of the examination

When the diagnosis of leprosy is certain*:*

- Carefully record all information on skin, nerves, hands, feet and other organs on the Leprosy Record Card.
- Fill in all of the information asked for at the start of treatment as baseline information.
- After each review examination, record every change in findings on the same card.

If leprosy is suspected, but the diagnosis is not certain:

- Patients should be labeled as **leprosy suspects.**
- Educate them about symptoms and signs of leprosy and either:
    - Referral to the next level or
    - Consider the possibility of another skin disease and treat appropriately or
    - Wait 3 months and review the skin lesions again. If it is leprosy, loss of sensation may now be observed. If there is no loss of sensation in the skin lesions and no enlarged nerves, but there are suspicious signs, such as nodules or swellings on the face or earlobes, or infiltration of the skin, it is important to try and get a **skin smear** examination done. A positive skin smear confirms the diagnosis of leprosy

while a negative result (in the absence of other cardinal sign) would rule out leprosy.

3.2.2.5 Differential diagnosis of leprosy

Without careful examination, leprosy can be easily mistaken for a number of skin diseases. Likewise, some skin diseases can be mistaken for leprosy. If patients are examined carefully, mistakes in diagnosis should not occur as none of the cardinal signs of leprosy are found in the common skin diseases such as:

- **Birthmarks:** Lightly or deeply pigmented areas of different sizes that have been present since birth or soon after birth and do not change.
- **Tinea versicolor:** These Lesions often itch. They are hypopigmented, but with no loss of sensation. Usually they clear up within 6 weeks with application of antifungal ointment or cream.
- **Tinea corporis (Ringworm):** Lesions are well-defined areas of hypopigmentation with white scales and without loss of sensation. Usually, they clear within 6 weeks of application of antifungal ointment.
- **Vitiligo:** Completely white areas of skin with a clear flat edge.
- **Pityriasis alba:** Present most commonly on the face, but the upper trunk may be affected. Hypopigmented rounded or oval patches, variable in size and with the margin sharply demarcated, covered with fine adherent scales. Often patients only present with the final hypopigmentation.
- **Psoriasis:** Raised areas with white fatty scales that bleed easily on scratching (test for pin point bleeding)
- **Molluscum contagiosum:** Nodular lesions with a depression in the centre. Firm squeezing results in the appearance of a creamy substance.
- **Onchocerciasis (in endemic areas):** Previous complaints of intense itching. There are itchy nodules and scratch marks. Hypopigmented macules may be one of the manifestations. There is loss of sensation. In a later stage, there are mottled lesions particularly on the loins and shins. Skin smears are negative for AFB.
- **Neurofibromatosis:** Multiple deeply pigmented soft nodules that do not itch and usually appear in adulthood. Skin smears are negative for AFB.

- **Syphilis:** Secondary syphilis presents with a considerable variety of lesions, e.g., papular and nodular lesions. Skin smears are negative for AFB. Serological tests for syphilis will be positive.
- **Kaposi sarcoma:** In HIV-positive patients, Kaposi's sarcoma often presents with nodules on the face and ear lobes. There are often lesions within the mouth and the throat, which may bleed. Skin smears are negative for AFB.

3.2.3 Classification of Leprosy

It is important to classify the type of leprosy the patient has because it determines the treatment regimen and the appropriate messages to give to the patient before administration of treatment.

In relation to this, there are two treatment groups:

I. Paucibillary (PB) leprosy

These are patients who have up to 5 skin lesions in total. These patients should also be skin smear-negative. This group of patients is likely to have high body resistance to leprosy bacilli.

II. Multibacillary (MB) leprosy

These patients have 6 or more skin lesions. All leprosy patients with a positive skin smear must be classified as **MB,** irrespective of the number of skin lesions. The bacilli infecting an individual with very low body resistance will multiply freely in the body, and the person will develop the more severe form of the disease i.e., MB leprosy.

Note:

If there is doubt about the classification, the patient should be classified and treated as MB leprosy.

Box 3.3 Key messages for newly diagnosed leprosy patients

When patients are newly diagnosed with leprosy, they should receive help and counselling so that the disease can be treated quickly and in the best possible way. The following categories of messages should be given to patients (not necessarily at the same sitting):

- General information
  - Patients affected by leprosy should continue to live a normal life.
  - Leprosy is caused by a germ and is curable,
  - Explain where to get answers to any questions regarding leprosy.
  - Consultation and treatment are free of charge; discuss how frequently the person should attend the clinic.
  - Persons who have been in in close contact with patients have been infected and hence should be brought in for examination at the earliest opportunity.
- Information about treatment
  - Leprosy is curable.
  - Leprosy is no longer infectious once treatment has begun.
  - The treatment lasts 6 to 12 months depending on the leprosy type.
  - Tablets must be taken every day at home.
  - A new blister pack is needed every 28 days.
  - Common side-effects include reddening of the urine and darkening of the skin.
  - The skin patches may take time to disappear.
- Complications called "reactions" may occur and can be treated. These can present as follows:
  - Patches can suddenly become red, swollen and more clearly visible again
  - There may be:
    - pain or numbness in the limbs
    - weakness of the hands or feet
    - swelling of hands and feet
    - eye problems such as redness, pain or impairment of vision
- Disabilities
  - New disability can occur at any time, but it can be managed.
  - Existing disability may or may not improve with treatment.
  - When problems occur, treatment may be available locally, or the patient may have to be referred to another clinic for specialist care.
  - Various new skills will have to be learnt to prevent and manage disability.

3.3 TREATMENT OF LEPROSY

3.3.1 Multidrug Therapy (MDT)

Multidrug therapy or MDT is a combination of drugs that is very safe and effective in treating leprosy to prevent the emergence of drug resistance; leprosy patients should never be treated with a single drug.

Other important information:

- MDT is distributed free of charge to all those who need it.
- The drugs are all taken orally; the daily drugs should be taken in a single dose on an empty stomach.
- The drugs are given out in blister packs that provide 4 weeks of treatment (1 month).
- There are different packs with the same drugs but in smaller doses for children.
- MDT is safe for women and their babies during pregnancy and breastfeeding.
- MDT can be given to HIV-positive patients, those on antiretroviral treatment and to patients on treatment for TB. If a leprosy patient is on treatment for TB, the MDT regimen should omit rifampicin as long as the TB regimen contains rifampicin.

3.3.2 MDT Regimens

PB patients are given 2 drugs for 6 months, while **MB** patients are given 3 drugs for 12 months. Every effort must be taken to ensure regularity of drug intake, so that PB patients complete their treatment in 5 months and MB cases in 12 months.

Specific blister packs are available for MB and PB leprosy, as well as for adults and children.

The health worker or other accompanying person (if the health worker is not available) should see the patient take the monthly dose of treatment. This helps to guarantee that the treatment is taken properly as a measure to prevent drug resistance. It also gives the health worker an opportunity to check the patient for any complications of leprosy.

3.3.3 MDT for Children Below 10 Years of Age

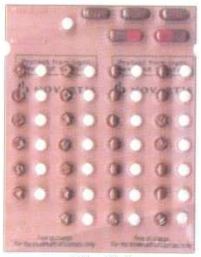
The appropriate dose for children under 10 years of age can be decided on the basis of body weight. [rifampicin: 10mg /kg body weight; clofazimine: 1 mg/kg body weight daily and 6 mg/kg body weight monthly; dapsone: 2mg/kg body weight daily]. The standard child blister pack may be broken up so that the appropriate dose is given to children under 10 years of age. Clofazimine can be spaced out as required.

3.3.4 MDT for MB Patients with a Very High Bacterial Index (BI)

Rarely, it may be considered advisable to treat a patient with a high bacterial index (BI) for more than 12 months. This decision may only be taken by the Zonal TB/Leprosy Supervisor or specialists at referral units, after careful consideration of the clinical and bacteriological evidence.

Table 3.1 Summary of MDT regimens

The standard **adult** treatment regimen for **MB** leprosy is:



MB - Adult

Rifampicin: 600 mg once a month

Clofazimine 300 mg once a month and 50 mg daily

Dapsone: 100 mg daily.

Duration: 12 months (12 blister packs)

The standard **adult** treatment regimen for **PB** leprosy is:

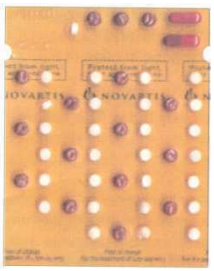
PB - Adult

Rifampicin: 600 mg once a month

Dapsone: 100 mg daily

Duration: 6 months (6 blister packs)

The standard **child** (10–14years old) treatment regimen for **MB** leprosy is:



MB - Child

Rifampicin: 450 mg once a month

Clofazimine: 150 mg once a month and 50 mg every other day

Dapsone: 50 mg daily

Duration 12 months (12 blister packs)

The standard **child** (10–14 years old) treatment regimen for **PB** leprosy is:

PB - Child

Rifampicin: 450 mg once a month

Dapsone: 50 mg daily

Duration: 6 months (6 blister packs)

3.3.5 Procedure for Giving MDT

For patients to be treated with MDT, carry out the following steps:

- Determine which type of MDT is required – PB or MB
- Fill in the Patient Record Card, the Leprosy Unit Register and the Patient's Identity Card
- Counsel the patient (and the parents, if it is a child)
- Give the first dose of treatment and explain how to continue the treatment at home

The drugs administered once a month should be directly observed; the health worker should make sure that the drugs have actually been swallowed. The taking of the supervised dose is most conveniently arranged by having the patient attend the clinic each month. This monthly visit is also useful for monitoring the regularity of treatment and for identifying complications at an early stage. The other drugs are taken at home.

Table 3.2 Side-effects of MDT drugs and their management

MDT is safe, and serious side-effects are very rare. Some of the usual ones are summarized in the table below.

Side-effects of MDT	Drug responsible	Management
i. Red urine	Rifampicin	Reassurance
ii. Darkening of the skin	Clofazimine	Counselling
iii. Gastrointestinal irritation e.g., abdominal pain, diarrhoea, nausea	All 3 drugs. Increased with high-dose clofazimine	Give drugs with food
iv. Anaemia	Dapsone	Give iron and folic acid
v. Itchy skin rash	Dapsone	Stop dapsone and refer
vi. Allergy, urticaria	Dapsone or rifampicin	Stop both and refer
vii. Jaundice	Rifampicin	Stop rifampicin and refer
viii. Shock, purpura, renal failure	Rifampicin	Stop rifampicin and refer

*Other drugs are available for use, if one or more of the standard drugs have been stopped, but they are also associated with serious adverse effects and must be managed by specialists.

3.3.6 How to Ensure that Treatment Is Taken Regularly

- Patients should be treated with respect.
- Take time to explain the illness and its treatment to each patient.
- Make sure patients understand how to take the treatment and the date of their next clinic visit.
- Make sure there is a good supply of medicines ready for your patients to take.
- Listen to patients' concerns and answer their questions.
- Record the treatment given on the Patient's Identity Card, the Leprosy Record Card and the Unit Leprosy Register.
- The DTLS should check those documents regularly to make sure that all patients are taking their treatment regularly.

3.3.7 Management of Patients Who Do Not Regularly Attend the Clinic for Treatment

Common reasons for patients not to attend regularly for treatment include:

- Poor accessibility of the clinic (long distance, difficult terrain or inconvenient timing)
- Difficulty in getting time off at work
- Nomadic life style
- Lack of understanding of the disease and the need for regular treatment
- Stigma
- A poor relationship with the health worker

As soon as patients miss an MDT appointment, action should be taken to find out the reason and to remind them to attend the clinic regularly. This is facilitated by recording mobile telephone contacts for patients at the start of treatment.

If this proves insufficient, a home visit by a local community worker should be arranged (preferably within the first month following the date of the missed visit).

If patients have difficulty attending the clinic, it is possible to give them 2 blister packs at once, but in such cases a treatment supporter (community volunteer, family member or neighbour)

should be involved in helping the patients to continue the treatment at home and reporting to the clinic in case of any proble

3.3.8 How to Care for Patients During Treatment

Every time patients come to take their drugs they should be asked:

- If there have been any problems since the last visit

The main problems anticipated include:

- Side-effects of the drugs
- Signs of new nerve damage or reaction
- New social problems related to leprosy, for example, loss of employment

3.3.9 Management of Patients Who Have Completed MDT

When the patient has taken 6 months of treatment for PB leprosy or 12 months for MB leprosy, issue the NTLP certificate for treatment completion and record in the unit register that the patient has **completed the treatment** under the heading "Treatment Outcome".

Although patients who have completed MDT are cured (the leprosy bacilli have been killed), some signs of leprosy may remain:

- Skin patches caused by leprosy may not disappear immediately or may remain permanently
- Loss of feeling, muscle weakness and other nerve damage may also remain

These residual signs should be recorded on the Leprosy Record Card at the time of stopping MDT.

The patient should be counselled regarding the following:

- significance of the remaining patches
- essential actions to take in order to prevent further damage
- signs and symptoms of reactions that can occur after MDT
- need to return to the clinic should any of the previous symptoms recur

When patients return with a leprosy reaction after completing a full dose of MDT, only the reaction should be treated. This is not a reason to re-start MDT.

3.3.10 Defaulting

Every effort must be made to ensure that PB patients complete their treatment in 6 months and MB patients in 12 months. When that is not possible, the treatment regimen for PB leprosy must be completed within a **maximum** period of 9 months. The treatment regimen for MB leprosy must be completed within a **maximum** period of 18 months.

A defaulter is an individual who fails to complete treatment within the maximum allowed timeframe.

Whenever a PB patient has missed more than 3 months of treatment or an MB patient more than 6 months, it is not possible for them to complete the regimen in the maximum time allowed, and they should be declared **defaulters.** This should be indicated in the Unit Leprosy Register under the heading "Treatment Outcome".

Patients returning after defaulting should be examined and the findings recorded in the same way as for new cases. Returning patients should be managed as follows:

- Count the number of lesions to confirm the original classification.
- Reclassify as PB or MB according to the number of lesions, register the patient under category Treatment after Default and treat with a full course of MDT.
- If there are signs of reaction, manage appropriately.
- Remember that a reaction can be mistaken for a return of the disease.

A defaulter who either remains very irregular on treatment or repeatedly defaults should be referred to a designated health facility n the district.

3.3.11 Relapse

Relapse in leprosy is defined as the re-occurrence of the disease at any time after the completion of a full course of treatment with WHO-recommended MDT. Relapse after MDT is rare. It is important to continue vigilance because some sporadic cases of relapse due to drug resistance have been reported.

Signs of a relapse

- The appearance of definite new lesions
- An increase in the skin smear bacterial index (BI) of 2 or more units at any single site compared to BI taken from the same site at the previous examination. Care should be taken to exclude patients suffering from leprosy reactions.
- MB patients who start treatment with a high BI are more likely to suffer a relapse later; most relapses occur long after the treatment was given (sometimes more than 10 years later).

It can be difficult to distinguish relapses from reactions. Some guidelines for distinguishing them have been summarized in the table below.

Table 3.3 Differentiating a leprosy relapse from a reaction

The following criteria may be useful in distinguishing a relapse from a reaction

Criteria	Relapse	Reaction
Time since completion of treatment	More than 3 years	Less than 3 years
Progression of symptoms and signs	Slow	Fast
Site of skin lesions	In new places	Over old patches
Pain, tenderness or swelling	No	Yes, skin and nerves
Damage	Occurs slowly	Sudden onset
General condition	Not affected	Inflammation

Investigation of suspected relapse

The options for investigating a suspected relapse include:

- Skin smears, at regional referral centres
- Skin biopsy for histopathological examination, not routinely available outside teaching hospitals
- Drug sensitivity testing using recently standardized molecular (DNA sequencing) techniques, though these are not yet available for Uganda

Management of relapse cases

Suspected relapse cases should be referred. Skin smear examinations should be performed on ALL such cases. Relapse cases should be retreated with the same MDT regimen.

3.4 COMPLICATIONS OF LEPROSY AND THEIR MANAGEMENT

Complications of leprosy may be divided into the following categories:

- Leprosy reactions
- Effects of nerve damage – covered under diagnosis and prevention of disability
- Complications of advanced disease
- Psychosocial problems

3.4.1 Leprosy Reactions

A reaction is the sudden appearance of symptoms and signs of inflammation in the skin lesions and /or nerves of a person with leprosy. There is pain, redness, swelling and sometimes tenderness of the skin lesions. New skin lesions may appear. There may also be swelling, pain and tenderness of nerves often accompanied by loss of function.

Please note:

Sometimes impairment of nerve function occurs without other signs of inflammation, making it less obvious; this is called “silent neuritis”.

Any type of leprosy may show reaction but the nature of the reaction differs according to the leprosy type. Reactions can occur before, during or after completion of MDT.

There are two types of reaction:

- Reversal reaction (or Type 1 reaction)
- Erythema Nodosum Leprosum (ENL or Type 2 reaction)

Apart from PB patients with single lesions, most other patients have some risk of getting reversal reactions. Only a small group of MB patients with a high load of bacilli are at risk of developing ENL reaction.

Both types can be divided into mild or severe; severe reactions require treatment with corticosteroids.

Table 3.4a Signs of severe reversal reaction

If any of the following signs is found, the reaction should be treated as severe:

- Loss of nerve function, that is, loss of sensation or muscle weakness
- Pain or tenderness in one or more nerves
- Silent neuritis
- A red, swollen skin patch on the face, or overlying another major nerve trunk
- A skin lesion anywhere that becomes ulcerated
- Marked edema of the hands, feet or face

Table 3.4b Signs of severe ENL reaction

If any of the following signs is found, the reaction should be treated as severe:

- Pain or tenderness in one or more nerves, with or without loss of function
- Ulceration of ENL nodules
- Pain and or redness of the eyes, with or without loss of visual acuity
- Painful swelling of the testes (orchitis) or of the fingers (dactylitis)
- Marked arthritis or lymphadenitis

3.4.2 Management of Reactions

All patients who develop reactions while on MDT should have the MDT continued without alteration of dosage.

Both types of reactions can be precipitated or their response to treatment adversely affected by other concurrent conditions, e.g., malaria, intestinal worms, or tuberculosis. Patients should be carefully screened for these and appropriate treatment given.

Mild reactions

Patients not showing any of the signs of severity listed above may be managed in the treatment centre symptomatically with aspirin. If, after 1 week's treatment, there is no apparent improvement, the patients should be managed as having severe reaction.

Severe reactions

Patients with severe reactions must be referred to the regional referral level where they can be treated and monitored effectively. Recent (within the last 6 months) loss of function in one or more peripheral nerves is the main reason for steroids to be prescribed in leprosy. Nerve function should be monitored on a regular basis following the recommendations in section 3.2.2.4.

Severe reversal reactions

Those should be treated with a course of prednisolone usually lasting 12 to 24 weeks. Prednisolone should be prescribed by a person properly trained in using it.

Table 3.5a Recommended prednisolone regimen for severe reversal reactions in PB patients

Weeks of prednisolone treatment	**Daily dose of prednisolone**
1st to 2nd	40 mg
3rd to 4th	30 mg
5th to 6th	20 mg
7th to 8th	15 mg
9th to10th	10 mg
11th to 12th	5 mg

Table 3.5b Recommended prednisolone regimen for severe reversal reactions in MB patients

Weeks of prednisolone treatment	Daily dose of prednisolone
1st to 4th	40 mg *
5th to 8th	30 mg
9th to 12th	20 mg
13th to 16th	15 mg
17th to 20th	10 mg
21st to 24th	5 mg

* Up to 60 mg of prednisolone may be prescribed at the start, depending on the decision of the clinician.

Because of the prolonged treatment with the prednisolone, patients must be monitored for potential side-effects such as peptic ulceration, osteoporosis, diabetes mellitus, cataracts and exacerbation of latent infections like TB.

As soon as nerve tenderness decreases, patients with muscle weakness or paralysis should be taught exercises to strengthen the affected muscles and prevent joint stiffness.

Management of severe ENL reactions

ENL reactions are complex medical problems requiring careful management by experienced clinicians. Short courses of prednisolone are often used.

The patients should be treated with prednisolone starting with 60 mg as a single daily dose. After a few days the dose can be lowered and, in general, the prednisolone can be stopped after a period not exceeding 4 weeks. The patient's condition should be assessed before the dose of prednisolone is decreased.

In patients with recurrent attacks of ENL or those on prolonged treatment of corticosteroids, clofazimine should be started and prednisolone gradually withdrawn. It is important to ensure that the patient has no worm infestation, especially strongyloides, before giving high doses of prednisolone. Immune suppression can cause dissemination of strongyloides.

3.4.3 Complications of Advanced Disease

3.4.3.1 Eye complications

Leprosy can lead to blindness following damage to the cornea or due to damage to the internal structures of the eye. Patients who report decreased vision or who have red or painful eyes should be referred to the Ophthalmology Clinical Officer or other eye specialist.

- **Lagophthalmos**

  Patients with blink inefficiency should:

  - Inspect their eyes daily for redness and foreign bodies by looking through a mirror or asking a neighbor to look
  - Learn to blink with effort so that their eyeballs roll up, even if their lids do not close
  - If possible, use sunglasses to help to protect them from dust
  - Apply artificial tears or ointment without injuring the eye
  - Keep dirty fingers and flies away

  In cases of severe lagophthalmos, where part of the cornea remains exposed even on forced closure, patients need surgical treatment and should be referred to the nearest unit where such services are available.

- **Eye infections and corneal ulcer**

  These should be treated with antibiotic eye drops or ointment (e.g., chloramphenicol or tetracycline) to be applied 4 times a day. Those with corneal ulcer should be referred to hospital.

- **Iridocyclitis (Uveitis)**

  Signs of iridocyclitis include red painful eyes, photophobia, diminished vision and flood of tears. Patients with these symptoms should be referred to hospital immediately.

  Chronic iridocyclitis is identified from an irregular pupil that does not dilate fully. This can lead to secondary glaucoma and blindness. These patients should also be referred to hospital.

3.4.3.2 Facial and other deformities

The sunken nose, loss of eyebrows (madarosis) and the so called “leonine” face which used to be characteristic of untreated MB leprosy are disfigurements that can be associated with severe stigma and discrimination. These instances are now rare. They can be corrected with plastic surgery.

3.4.3.3 Other medical problems

Longstanding untreated leprosy and chronic ENL reactions lead to medical complications. These patients should be referred to appropriate specialists.

3.4.3.4 Psychosocial problems

Disabilities, as well as beliefs and prejudices concerning leprosy and its causes, are the main sources of psychosocial problems in leprosy patients. People with leprosy often develop low self-esteem and depression as a result of the negative attitudes of their family and community. Such negative attitudes are also observed among health service providers, including doctors. People suffering from psychosocial problems may need to be referred for counselling or other help.

3.5 PREVENTION OF DISABILITY (POD) AND SELF-CARE

3.5.1 Patients at Greater Risk of Nerve Damage

a) Patients with long delays between the appearance of the first symptoms of leprosy and the start of treatment. The early diagnosis and treatment of leprosy prevents the occurrence of long-term complications.

b) MB patients with impaired nerve function at diagnosis. Such patients should be monitored more closely. Nerve damage can occur during MDT and after the patient has completed MDT; the risk declines steadily during the following 3 years.

3.5.2 The Effects of Nerve Damage in Leprosy

Recent nerve damage (present for less than 6 months) can usually be reversed by steroids. Many patients present with nerve damage of very long duration, from which no further recovery is expected.

The physical problems resulting from nerve damage that affect everyday life of people affected by leprosy can be grouped as follows (see table below).

Table 3.6 Common physical problems and aims of appropriate POD action

Problem	Signs	Secondary effects	Aims of POD action
Weakness of eye closure	Dryness ulceration of cornea, scaring	Impairment of vision Blindness	Preservation of sight
Loss of sensation in the hand	Dryness, cracking and ulceration	Loss of tissue, joint stiffness	Keeping the skin in good condition and avoiding injury
Weakness and deformity of the hand	Visible deformity	Contracture and fixed deformities	Preservation of muscle strengthen and prevention of contractures and deformities
Loss of sensation and ulceration of the foot	Dryness, cracking and ulceration	Chronic infection	Keeping the skin in good condition Provision of protective footwear Prevention of injury
Weakness and deformity of the foot	Foot drop	Ulceration and permanent deformity	Preservation of muscle strength and prevention of contractures and

			deformity

3.5.3 Assessment and Recording of Disabilities

Disability is a broad term covering any impairment, activity limitation or participation restriction affecting a person.

3.5.3.1 Disability grading in leprosy

Every new case of leprosy must be assigned a "Disability Grade" that depicts the condition of the patient at diagnosis. The grade is on a scale of 0, 1 or 2. Each eye, hand and foot is given its own grade, so the patient actually has 6 grades, but the highest grade is used as the disability grade of that patient.

Grade 0 means **no disability** found.

Grade 1 means that **loss of sensation** has been noted in the hand or foot.

This should not be confused with the loss of sensation in a skin patch, which is caused by local damage to the small nerves in the skin, and not to the main nerve trunks. (Note: The eyes are not given a grade of 1.)

Measuring and recording Grade 1 disability is an essential step in preventing damage to the hands and feet of people affected by leprosy. It is therefore a key component of the quality of leprosy services.

Grade 2 means that **visible damage or disability** is noted.

For eyes, this includes the inability to close the eye fully or obvious redness of the eye. (In leprosy, this is typically caused by either a corneal ulcer or by iridocyclitis). Visual impairment or blindness also gives a disability grade of 2.

For the hands and feet, visible damage includes wounds, ulcers, shortening of fingers and/or toes, as well as deformity due to muscle weakness, such as a foot drop or a claw hand.

The EHF (Eye-Hand-Foot) score

The EHF score is the sum of all the individual disability grades for eyes, hands and feet. Since the disability grade can be scored as 0, 1 or 2, it follows that the EHF score ranges from 0 to 12. A score of 12 would indicate Grade 2 disability of both eyes, both hands and both feet.

Health workers at the health facility should be able to:

- Determine at least Grade 1 disability by asking patients about loss of sensation in their hands and feet
- Look for signs of visible disability (Grade 2), e.g., wounds or ulcers on the hands or feet, redness of the eye
- Record the visible disability
- Refer patients to the facility where prevention of disability (POD) services are provided

Health workers at the referral level should be able to:

- Re-examine the disability status more accurately (refer back to guidelines for nerve function assessment)
- Record the findings accurately in the Leprosy Record Card
- Institute appropriate POD action (**Table 3.6**)

3.5.3.2 Care for people with disabilities due to leprosy

Interventions for disabilities are carried out at the following levels:

- Home-based care, including those activities that can be done by the person at home
- Local health facility
- Referral services (requiring the input of specialists)

3.5.3.3 Home-based care for patients

Patients should be shown how to carry out these self-care activities.

a) Problems with eye closure

- Inspect the eye in a mirror to check for redness. (If no mirror, ask a neighbor to check.)
- Learn to blink frequently to keep the eyes moist and exercise the lids.
- Wear a hat with a large brim and/or sunglasses to prevent dust from getting into the eyes.
- Use a sheet or mosquito net to cover the head at night.

b) Problems with hands and/or feet

- Inspect daily for signs of injury.
- Soak the hand/foot in water for about 30 minutes every day.
- Use a rough stone to smoothen the dead skin.
- Apply oil or petroleum jelly when the skin is still wet to prevent the skin from drying out.
- Use a clean cloth to cover any open wound.
- Walk as little as possible, and walk slowly. Take frequent rests (foot care).
- If foot ulcers are present, rest is essential.
- If there is any muscle weakness, such as foot drop, passive stretching and active exercises help to prevent contracture and may lead to some strengthening.
- Use protective foot wear (microcellular rubber or MCR sandals) all the time for insensitive feet and protective appliances (e.g. gloves) for insensitive hands.

3.5.3.4 Local health facility interventions

The next level of interventions can be carried out in a Health Centre III or IV. The health workers at the facility should**:**

- Discuss the management of their patients' disability problems with the District Supervisor, but eventually take over the responsibility for implementing the interventions.
- Instruct and assist the patient in carrying out the relevant home-care activities described above.

a) Problems with eye closure

- Provide artificial tears or any eye ointment (not containing steroids), if the eyes are very dry.
- Treat conjunctivitis with antibiotics.
- Refer more serious eye problems to an Ophthalmology Clinical Officer or the nearest eye clinic.

b) Problems with the hand

- Review to assess the implementation of expected home-care activities and advise as necessary.
- Refer, if required.

c) Problem with the foot

- Review to assess the implementation of expected home-care activities and advise as necessary.
- Take foot maps for protective footwear or arrange for these to be taken by the DTLS or trained community-based rehabilitation (CBR) worker.
- Refer, if required.

3.5.4 Interventions Usually Only Done at a Regional Level Referral Centre

a) Problems with the eyes

- Management of acute eye problems at eye clinic
- Corrective surgery in severe cases of lagophthalmos (with cornea exposed)
- Cataract surgery (Leprosy is not a contraindication to cataract surgery.)

b) Problems with the hand

- Instruction and assistance with adaptating tools to avoid injury to insensitive hands
- Removal of thick callus and trim ulcers with a scalpel blade
- Splinting of joints in the presence of weakness or contractures
- Management of infection of ulcers
- Reconstructive surgery to correct some cases of weakness or claw-hand (as long as the joints remain mobile)

c) Problems of the foot

- Removal of thick calluses and trimming of ulcers with a scalpel blade
- Management of severe infections of foot ulcers
- Surgical management of chronic ulcers
- Provision of orthopaedic appliances, including those for foot drop
- Surgical correction of foot drop

3.5.4.1 Encouraging people to practice self-care at home

It is important that individual patients be given self-care instructions that are relevant to their particular situation and that they are supported to practice self-care at home.

Such support may be provided by:

- Health workers
- Family members
- Other people affected by leprosy or living with disabilities from other causes. Self-care groups offer a good opportunity for people with self-care needs to meet together regularly to discuss the practicalities of self-care.

3.5.4.2 The value of appropriate footwear for people affected by leprosy

The use of appropriate footwear is important for preventing ulceration among people with loss of feeling in their feet. The shoes should be locally available**, s**ocially acceptable and used whenever patients are on their feet and walking.

The NTLP-recommended footwear for people with loss of sensation in their feet is microcellular rubber (MCR) sandals, with a firm under-sole, a soft insole and heel straps. Velcro straps are preferred to other kinds of fastenings. Other shoes meeting the basic criteria can be used.

3.6 REHABILITATION

3.6.1 What Is Rehabilitation?

"Rehabilitation includes all measures aimed at reducing the impact of disability on an individual, enabling him or her to achieve independence, social integration, a better quality of life and self-actualization." UN Standard Rules for Equalization of Opportunities for Persons with Disabilities (PWD).

3.6.2 The Role of Health Workers in Rehabilitation

Whereas health workers and some District Supervisors may not have the time or expertise to be involved in rehabilitation activities, they are expected to:

- Be able to identify physical, functional or socio-economic problems resulting from disability among patients under their care
- Know about available services for rehabilitation
- Know how to refer people to make use of those services
- Play an advocacy role in ensuring that people affected by leprosy have access to health care and rehabilitation services in the same way as other people

Table 3.7 Examples of services to which people with disability can be referred

Problem	**Rehabilitation service required**
Deformity of the hand	Reconstructive surgery
Foot drop	Ankle-foot appliance, reconstructive surgery
Amputee	Artificial limb
Depressed	Counselling
Mobility limitation	Crutches, wheelchair
Stigma in the family	Counselling
Exclusion from community activities	Education and advocacy
Poverty	Microcredit for self-employment

3.6.3 Community-Based Rehabilitation (CBR)

Community-based rehabilitation (CBR) is defined as **a strategy within general community development for the rehabilitation, equalization of opportunities and social inclusion of all people with disabilities.**

Leprosy may lead to variety of physical, functional and social and/or economic problems needing different types of physical and social economic rehabilitation. To address these, comprehensive approaches that maximize benefits for the individual, family and society at large are needed.

CBR is one such approach. It emphasizes community participation and empowerment of the individuals involved. CBR requires the full participation of **the clients, their families and the communities** in the rehabilitation process.

Whereas people with disabilities may need temporary referral to specialized services, e.g., for provision of assistive devices or appliances, the specialized services should be linked to CBR programmes.

Organizations of people with disability need to be involved in the planning and management of rehabilitation services.

Persons affected by leprosy who are in need of rehabilitation should have access to any existing general rehabilitation services. Similarly any existing leprosy-specific rehabilitation services should be extended to people with other disabilities.

3.6.4 Promoting Inclusion of Persons Affected by Leprosy in CBR

The following actions may assist in formulating a CBR strategy at district level:

- Develop a district plan for community-based rehabilitation that conforms to the national policy and plan.
- Prepare guidelines for mobilizing local resources and providing special services from government and non-governmental organizations.
- Establish a network of services.
- Develop the capacity of service providers.
- Promote a team approach for providing service.
- Introduce locally specific techniques to train and develop skills and knowledge of people with disabilities and their families.
- Promote opportunities for educational, functional and vocational training and job-placements.
- Involve people with disabilities and their families in the decision-making process.

3.7 MONITORING OF LEPROSY CONTROL

3.7.1 Leprosy Control Indicators

Leprosy control indicators include the following categories:

- Those for monitoring progress in leprosy control
- Those for assessing quality of leprosy services

3.7.1.1 Indicators for measuring progress in leprosy control

Indicators for measuring progress include general (core) indicators and those intended for evaluating case-finding activities in particular. They are summarized in Table 3.8:

- The number of new cases in the district is used to estimate the amount of MDT required for that district during the following year. Depending on the methods used for case detection, the annual figures over a period of several years will show if there is an increase or decrease, which in turn indicates whether leprosy control activities are effective. Calculating the case detection rate makes it possible to compare one area with another.

- The number of cases with Grade 2 disabilities detected in a population gives an indication of under-detection. The proportion of new patients who complete their treatment on time is an indication of how well the leprosy patients are being served by the health services. The rate is calculated separately for PB and MB patients in a cohort analysis. A cohort is a group of patients who all started treatment in the same batch (in the same quarter). The total of the figures from the 4 quarters in a year will give the annual report.

Box 3.4 How to calculate leprosy treatment (MDT) completion rate

How to calculate the MDT completion rate

For PB completion rate, the cohort will be from the same quarter **1 (ONE)** year ago:

- Identify all the PB patients who are new cases in the district register and who started MDT in the reporting quarter **1 (ONE)** year back. Note this number.
- From this cohort, count the number who completed treatment within 9 months of registration.
- The PB treatment completion rate is calculated as follows:

  Number of new PB cases who completed MDT
  ---------- x 100
  Number of new PB cases who started MDT

For MB completion rate, the cohort will be from the same quarter **2** (**TWO)** years ago:

- Identify all the MB patients who are new cases in the register and who started MDT in the reporting quarter **2** (**TWO)** years back. Note this number.
- From this cohort, count the number who completed treatment within 18 months of registration.
- The MB treatment completion rate is calculated as follows:

  Number of new MB cases who completed MDT
  ---------- x 100
  Number of new MB cases who started MDT

- The proportion of new cases with Grade 2 disabilities among all new cases detected during the year is used to assess the delay in diagnosis as an indicator for quality of case detection activities.
- If transmission of leprosy is being reduced in an area, it is expected that the number of child leprosy cases will decrease. This trend should be monitored over several years. It is also used for estimating the required stock of child MDT blister packs.
- Some districts diagnose leprosy more frequently in men than women, but there is concern that women may have less access to health care in some districts. If a male-to-female ratio of higher than 2 is observed, steps should be taken to ensure that women have adequate access to diagnostic services.
- The number and proportion of MB cases among new cases is a useful guide to the cases at risk of complications and is used for estimating the required quantities of MDT drugs.

Table 3.8 Indicators for measuring progress in leprosy control

Indicator	Calculation	Source of data	Level	Frequency
1) Number of new leprosy cases	Count absolute number	Leprosy Registers	District National	Quarterly Annually
2) Case detection rate	Number of new leprosy cases ---------- x 100,000 Total population	District Quarterly Reports on leprosy control	National	Annually
3) Number of new cases with Grade 2 disability	Count absolute number of new cases with Grade 2 disability	District Quarterly Reports on leprosy control	District National	Quarterly Annually
4) Proportion of new cases with Grade 2 disability	Number of new cases with Grade 2 disability ---------- x 100 Total number of new cases	District Quarterly Reports on case-finding	District National	Annually
5) Proportion of new PB cases who complete MDT *	Number of new PB cases who complete MDT ---------- x 100 Total number of new PB cases who started MDT 1 year ago	District Quarterly Reports on treatment outcomes	District National	Annually
6) Proportion of new MB cases who complete MDT*	Number of new MB cases who complete MDT ---------- x 100 Total number of MB cases who started MDT 2 years ago	District Quarterly Reports on treatment outcomes	District National	Annually

Indicator	Calculation	Source of data	Level	Frequency
7) Proportion of new child cases	Total number of new child cases ---------- x 100 Total number of new cases	Leprosy Registers and District Quarterly Reports	District National	Annually
8) Proportion of new female cases	Total number of new female cases ---------- x 100 Total number of new cases (Male + Female)	Registers and Quarterly Reports	National	Annually
9) Proportion MB cases	Total number of new MB cases ---------- x 100 Total number of new cases (PB + MB)	Registers and Quarterly Reports on case-finding	National	Annually

***S**ee box 3.4 How to calculate MDT completion rates

3.7.1.2 Indicators for assessing the quality of leprosy services

The indicators for quality of leprosy services, summarized in the table below, will be collected at Zonal Level:

- The ZTLS will validate the diagnosis of at least 40 percent of the new cases reported in the zone or make arrangements with a suitable other person to do so. **In zones with less than 10 new cases, all new cases should be validated.** Validation should be performed within 3 months of starting the patient on MDT.
  This exercise will help to identify areas where additional training and/ or supervision is required.
- The NTLP Central Unit will be responsible for organizing confirmation of reported suspected relapse cases and their management.
- The proportion of patients who develop new or additional disability during MDT is an indicator to measure how well new nerve damage is detected and treated. Information for calculating this indicator will be collected using the EHF (eye-hand-foot) score. In order to use the EHF score for measuring the development of new or additional disability during MDT, it should be calculated and recorded at diagnosis and then repeated at the time when treatment is completed.

Table 3.9 Indicators for quality of leprosy services

Indicator	Calculation	Source of data	Level	Frequency
1) Proportion of new cases correctly diagnosed	Number of new cases validated as correctly diagnosed (within 3 months of registration) ---------- x 100 Total number of new cases validated	ZTLS activity reports	Zonal National	Quarterly Annually
2) Proportion of treatment defaulters	Number of cases declared defaulters ---------- x 100 Total number of cases started on MDT 1 or 2 years earlier	Leprosy Registers and District Quarterly Reports on treatment outcomes	Zonal national	Quarterly Annually
3) Number of relapses	Record absolute number of relapses after MDT	Leprosy Registers and District Quarterly Reports on leprosy control	National	Quarterly Annually
4) Proportion of patients who develop new or additional impairments/ disabilities during MDT	Number of cases with increased EHF score ---------- x 100 Total number of cases started on MDT 1 or 2 years earlier	District Leprosy Register	Zonal National	Quarterly Annually

3.7.2 Monitoring Tools

The following monitoring tools are used for recording and collecting information about leprosy cases:

- LEPROSY RECORD CARD

  Individual patients' details are recorded on these cards. They are kept in the treatment unit.
- UNIT LEPROSY REGISTER

  This is where data about new leprosy patients in each treatment unit are recorded. The data are useful for planning and for calculation of indicators. Instructions for completing the register are printed in the inside covers of the register. The DTLS is responsible for ensuring that the register is properly completed and for entering the District Leprosy Numbers of all cases put on MDT. One unit leprosy register may be used for several years.
- PATIENT'S CLINIC APPOINTMENT CARD

  Kept by every patient on MDT, this card indicates the treatment category, the MDT doses received and the date of the next supervised MDT dose.
- DISTRICT LEPROSY REGISTER

  The register lists every patient receiving MDT in the district. For each patient it contains a summary of the information in the Unit Leprosy Register apart from details of the monthly clinic attendance. The information in this register forms the basis for compiling the quarterly reports on case-finding and the outcome of leprosy treatment.
- DISTRICT DISABILITY REGISTER

  Maintained by the DTLS, this register is a summary of individual information about people living with disabilities during and after MDT.
- QUARTERLY REPORT ON LEPROSY CONTROL

  Completed quarterly by the DTLS, this report is a summary of information in the District Leprosy Register.
- QUARTERLY REPORT ON TREATMENT OUTCOMES

  Completed by the DTLS, this report summarizes treatment outcomes of patients started on MDT 12 and 24 months earlier for PB and MB cohorts respectively.
- CERTIFICATE OF MDT COMPLETION

Kept by the patient, this certificate indicates the date when MDT was completed. It is useful for making decisions regarding relapse or other complications occurring after MDT.

3.8 ORGANIZATIONAL ISSUES FOR THE DISTRICT MANAGER

3.8.1 Quality Leprosy Services

Quality is based on:

- Appropriate training of staff at every level
- Regular technical support supervision
- Monitoring of key indicators (see under Table 3.8 above)

Characteristics of quality leprosy services

- Accessible to all who need them.
  - MDT can be provided at the nearest health unit.
  - There are no geographical, economic or gender barriers
- Patient-centred and observe patients' rights, including the rights to timely and appropriate treatment and to privacy and confidentiality
- Address each aspect of case management based on solid scientific evidence, as described in this manual, regarding:
  - Diagnosis (timely and accurate with supportive counselling)
  - Treatment with MDT (available free of charge and user-friendly)
  - Prevention of disability
  - Referral for complications
  - Maintenance of records

3.8.2 Content of Training for General Health Workers (Health Facility Staff)

Leprosy should be included in the core curriculum of all institutions training health workers in Uganda. Training of general health workers should aim at enabling them to:

- Suspect leprosy and refer to a facility where diagnosis can be made.
- Correctly diagnose and classify a case of leprosy (clinical staff).

- Treat a leprosy patient with the appropriate MDT regimen.
- Manage or refer cases with complications.
- Maintain a patient's Leprosy Record Card and Unit Leprosy Register.
- Keep adequate stocks of drugs for MDT.
- Provide appropriate information about leprosy to the patients, their families and other community members.
- Recognise patients in need of rehabilitation and refer them to appropriate services.

3.8.3 Organization of Support Supervision

The aim of support supervision is to ensure that:

- Technical skills required for leprosy control activities are present.
- Any obstacles faced by the health facility staff are identified and removed.
- Plans for future work and improved performance are made.
- Health workers are supported and motivated in their work.
- Additional information not available under the routine reporting system is collected and analyzed.

RECOMMENDED FURTHER READING

The following resources are available online at no charge.

- Common Skin Diseases in Africa. An illustrated guide. Colette van Hees and Ben Naafs, 2001.
- How to Diagnose and Treat Leprosy (ILEP Learning Guide One, 2001)
- How to Recognise and Manage Leprosy Reactions (ILEP Learning Guide Two, 2002)
- How to do a Skin smear Examination (ILEP Learning Guide Three, 2003)
- How to Prevent Disability in Leprosy (ILEP Learning Guide Four, 2006)
- WHO/ILEP technical guide on community-based rehabilitation and leprosy (WHO/ILEP, 2009)
- Enhanced Global Strategy for Further Reducing the Disease Burden due to Leprosy (2011–2015). Operational Guidelines (updated). (WHO, 2009)

GLOSSARY

Acid-fast bacilli	Bacilli that hold colour even after washing with acid. Tubercle bacilli are acid-fast bacilli.
Bacilli	Rod-shaped bacteria
CD4	Specific lymphocytes that are destroyed by HIV. The number of CD4 lymphocytes is reduced in severe HIV infection.
Chronic case	A TB patient who is sputum smear-positive after a retreatment regimen
Continuation phase	The phase of TB treatment after initial phase. The continuation phase lasts 4-6 months during which the patient takes fewer drugs it is meant to eliminate remaining bacilli and prevent relapse.
Contact/household contact	Someone who lives in the same dwelling with the TB patient (sleeps and eats at least 1 meal a day there).
Convert	To change from sputum smear-positive to sputum smear-negative
Conversion	Changing from sputum smear-positive to sputum smear-negative. It is the best indicator that the initial phase TB treatment has been effective.
Conversion rate	The proportion of new sputum smear-positive cases that are sputum smear-negative at the end of 2 or 3 months of treatment.
Culture	A method of diagnosis involving growing bacteria in a special medium that promotes their growth.
Denominator	In a fraction, th**e** number below the line
Diagnostic sputum smear examination	Sputum smear examination is done using a microscope to identify tubercle bacilli and thus diagnose pulmonary TB,
Directly observed treatment (DOT)	Treatment in which a health worker watches the TB patient swallow the anti- TB drugs.
Disability	A broad term covering any impairment, activity limitation or participation restriction affecting a person.
Drug resistance	Failure of drugs to kill microorganisms

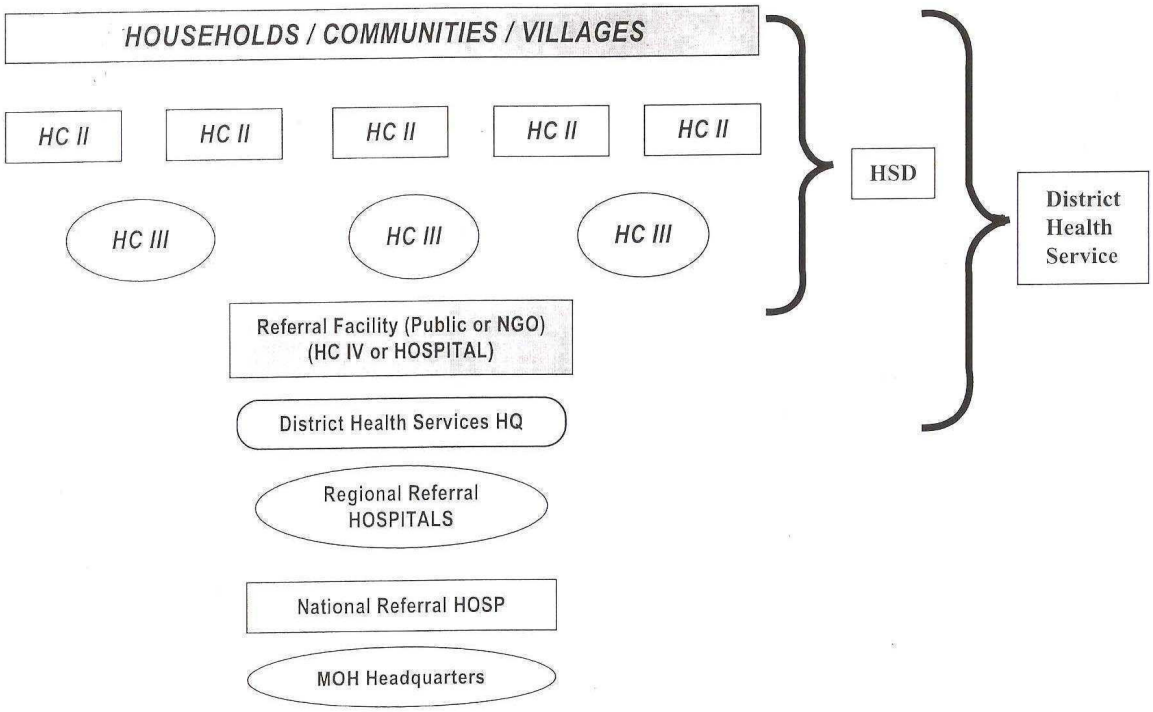
Expired drugs	Drugs in stock past the date recommended for use. The safety and effectiveness of such drugs may be reduced.
Expiry date	The date on which a drug expires, or becomes possibly less safe and effective.
Focal person	A health worker assigned specific responsibilities for a specific disease.
Follow-up sputum smear examination	Sputum smear examination done by microscope to assess the progress of TB treatment or prove cure.
Health facility	The unit where sputum microscopy for diagnosis is done and treatment started.
Incidence	The number of new cases of a disease occurring in a defined population during a given time period.
Indicator	A measureable number, proportion, percentage or rate that suggests or indicates the extent of a programme's achievement or the level of some condition among the population.
Initial phase	The first phase of TB treatment, usually lasting 2 (3) months during which the patient takes an intensive drug regimen (4–5 drugs). Sputum conversion occurs, and the patient gets better.
Jaundice	Yellow coloration of the eyes or tongue
MDR-TB	TB disease with bacilli resistant to at least rifampicin and isoniazid
Microscopy	Examination by means of a microscope
Monitor	To watch closely or check on a routine basis
Mucopurulent	Containing both mucus and pus
Multibacillary (MB) leprosy	Diagnosis for a leprosy patient with 6 or more skin patches
Numerator.	In a fraction, the number above the line
Paucibacillary (PB) leprosy	Diagnosis for a leprosy patient with up to 5 skin patches
Pleura	The membrane covering the lung and the wall of the chest cavity containing the lungs

Prevalence	The number of all cases of a disease (new and old) existing in a defined population at a specific point in time or during a given time period
Proportion	The relationship of a part to a whole, often written as a decimal fraction (0.5) or percentage (50 percent)
Radiographic abnormalities	Abnormalities seen on chest X-rays
Referral	Sending a patient to another health facility or clinician. Patients may be referred for diagnosis, specialized treatment, or admission
Reserve stock	Extra stock kept by the health facility to ensure adequate supplies even if there is increased use or a delay in drug delivery.
Scanty	Result of examination of a sputum sample when fewer than 10 acid-fast bacilli are observed
Side-effect	A secondary and usually discomforting or harmful effect of a treatment or drug
Specimen	Sample or a small amount to be tested (e.g., stool, urine, sputum)
Sputum	Matter ejected from the lungs through the mouth
Sputum smear microscopy	Examination of sputum with a microscope to determine whether acid-fast bacilli are present.
Sputum smear-negative	Sputum smear microscopy result in which AFB bacilli were absent
Sputum smear-positive	Sputum smear microscopy result that showed AFB bacilli present
Transfer	Changing a TB patient's treatment facility when that patient moves
Transfer in	A TB patient who has been transferred to another TB register to continue treatment
Transferred out	A TB patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is not known
Treatment success	An indicator calculated by adding the number or proportion of patients cured to those who completed treatment
Treatment supporter	A person who observes (watches) as a TB patient swallows anti-TB drugs and records that the patient has taken the drugs. This

	person may be a trained community member, family member or a health worker.
Tuberculin test	Intradermal injection of 0.1ml of PPD/ tuberculin (protein extracted from TB bacilli). The test indicates TB infection, not disease. In a person infected with TB, a hardening of the skin can be observed at the injection site in 48–72 hours.

ANNEXES

Annex 1: Organizational Structure of Ministry of Health



Annex 2: Technique for Collecting Sputum

General Principles

- ✓ Sputum specimen collected under instruction of a trained medical worker is likely to be of a better quality.
- ✓ Sputum collection should be collected in an open air space. If not, the collection should be done in a well-ventilated designated sputum collection room. Patients are more likely to collaborate and cooperate if they are out of sight of other patients.
- ✓ Patients who have been chewing food shortly before the sputum collection should rinse their mouths with water before collecting the sputum.
- ✓ For an early morning specimen, the patients should collect the sputum before brushing their teeth.

Before instructing patients to collect sputum specimen, the health worker should

- ✓ Fill in the *Sputum Request Form* for each patient with all of the their identification features, as shown in the form.
- ✓ Enter the patient's record in the *Laboratory Register*.
- ✓ Write on the side of the sputum container the same number as is written on the forms.
- ✓ Give the patient the specimen bottle.

Instructing patients to collect sputum specimen

- ✓ Explain to patients the reasons for sputum collection and demonstrate how to open and close the sputum container.
- ✓ Tell patients that no one should be standing in front of them while they are producing sputum.
- ✓ The patient opens the sputum collection container.
- ✓ Before collecting sputum, the patient should breathe in deeply and rapidly. This starts the coughing.
- ✓ The patient then carefully puts the coughed out material (sputum) into the sputum container without contaminating the outside of the container. The amount of sputum specimen put in the sputum container should be about 5 mls. *If the outside of the sputum*

container is contaminated, the container should be discarded and collection repeated with a fresh container

- ✓ The patient closes the sputum container and returns it to the laboratory.

Schedule for collecting 2 sputum samples

Day 1:

- Collect the "on the spot" sample as described above
- Instruct the patient how to collect early morning sample (first sputum after waking)

Day 2:

- Receive early morning sample from the TB suspect

Instructions for handling sputum samples in the health facility

The health worker:

- ✓ Receives the sputum specimen and examines it in the laboratory OR
- ✓ Isolates each sputum container in a plastic bag and stores it in a cool place, ready for transportation to where it can be examined
- ✓ Washes hands
- ✓ Ensures that the duration of time between sputum collection and examination in the laboratory does not exceed 4 days

Annex 3: Logistics

Estimating anti-TB drug quantity

The quantity of anti-TB drugs required for a health facility, district or region needs to be calculated accurately. This will ensure that the patients receive their drugs without interruption.

Regarding anti-TB drugs, the following terms are important:

> ***Shelf Life:*** Shelf life is the length of time anti-TB drugs may be stored in adequate conditions without affecting their usability, safety, purity or potency.

Pipeline: Pipeline is defined as the entire chain of transportation links through which supplies move from manufacturer to consumer.

Table: Shelf life of anti-TB drugs

Product	**Shelf Life**
(RHZ) + E blister strip 225 mg/150 mg/750 mg + 800 mg	3 years
RHZE blister strip 75 mg/150 mg/275 mg/400 mg	3 years
HE blister strip 400 mg/150 mg	5 years
RH (Adult) tablet 150 mg/100 mg	4 years
RH (Pediatric) tablet 60 mg/30 mg	2 years
Ethambutol tablet 400 mg	5 years
Ethambutol blister strip 400 mg	3 years
Pyrazinamide (Pediatric) tablet 150 mg	3 years
Streptomycin vial 1 mg	3 years

Storage conditions

Storage conditions are important in order to maintain the potency of the drugs. The following conditions should be adhered to:

- Store space/room should be clean, well lit, ventilated and free of insects and rodents.
- Store should be protected from floods, pools of water or damp conditions.
- Keep fire extinguisher at the main entrance of the store, and train staff to use it in order to protect the store from fire.
- Maintain cold storage or cold chain, where applicable for TB supplies.
- Limit access of control area to store staff only.
- Arrange cartons at least10 cm. (4 in.) off the floor with identification labels visible.
- Cartons marked (↑) should be stored likewise.
- Separate and remove expired drugs from usable stock.
- Arrange drugs to facilitate "first-to-expire, first-out" (FEFO).

Dispensing

Anti-TB drugs should be dispensed according to the regimen shown on the patient treatment card. After dispensing anti-TB drugs, the quantity of drugs dispensed is recorded on the **TB Drug Dispensing Log Form.**

At the end of the month, the quantity of the drugs dispensed by the unit, for each day of the month is added up to give the quantity dispensed for the whole month – in blister strips, tablets or vials.

Stock-taking

Stock-taking is the process of preparing a balance sheet for drug consumption for a specific period. This process requires the following steps:

- **Stock card review:** In this step the stock balance is counted and quantified by writing down the quantity of drugs received, issued and lost during the period of stock-taking.
- **Physical count:** Next a physical count of all the anti-TB drugs available in the store is carried out. A date is set for this purpose, and the exercise is conducted by a physical count team. After setting the date for the physical count:

  - ✓ Update stock cards and ledgers

- ✓ Prepare the store by arranging expiry dates, damages/losses
- ✓ Suspend issuing drugs during the time of the physical count
- ✓ Include receipts of drugs issued that day

Compiling facility report and request for anti-TB drug supply

i) Facility Reports

To complete the Facility Report, the following parameters need to be filled in:

- Beginning balance (A)
- Received during review period (B)
- Dispensed (C)
- Losses/adjustments (D)
- Ending balance from physical count (E)

Calculated balance (E) =A+B–C+ (–D). This equation should balance.

ii) Request for anti-TB drug supply

Request anti-TB drug supply for 4 months, by adding the quantity consumed over the previous 4 months (total quantity dispensed in this report plus previous report) subtracted from Ending Balance from physical count (E),

4 months' consumption (F)

Quantity needed = (F–E)

iii) Patient statistics

Count the number and type of patients treated and recorded in the register and write it in the section in the form for this.

No. of New Cases_____

No. of Retreatment Cases_____

No. of Transfer in Cases_____

The facility report and request for drugs should be submitted to the NTLP Central Unit within 7 days following the end of the reporting period.

Distribution/Storage

An efficient system for distributing anti-TB drugs must be put in place to ensure that the drugs reach the health facilities and thus the patients. This requires a reliable transport system, preferably managed by the NTLP Central Unit. The anti-TB drugs must be stored in a safe place. The criteria for a good storage place are:

- Accessible by road throughout the year
- Has water and electricity
- Has telephone or radio call communication
- Safe from flooding
- Security protection

Annex 4: Support Supervision

Supervision is helping people improve their own work performance. Supervisory visits are an opportunity to provide feedback on the reports received on the indicators of monitoring and evaluation. Acknowledge areas of good performance and thank the health workers for a job well done. Areas where performance is lacking should be pointed out and discussed freely with the health workers at the facility. In particular, the focus of discussion should be directed towards learning why the undesirable events occurred and finding solutions.

Schedule of supervisory visits

The NTLP Manager should supervise Zonal supervisors in their respective zones at least once a year.

The ZTLS should make supervisory visits to districts within their zones at least twice a year.

DTLS should visit hospitals and health centre IVs at least monthly and lower level facilities at least once a quarter.

Ways of collecting information during a supervisory visit

- Interview health workers
- Observe interactions between patients and health workers
- Interview TB/leprosy patients
- Review TB/leprosy treatment cards and registers
- Visit the laboratory and check working condition of microscopes and availability of supplies
- Check the drug store; inventory, storage and records of TB/leprosy drugs and supplies

Preparation for supervisory visit

I. Review the quarterly recording and reporting forms submitted. Note which of the monitoring and evaluation indicators have insufficiencies (refer to indicators for monitoring and evaluation).

II. Prioritize the insufficiencies in order of importance.

III. Arrange and obtain requirements– transport, accommodation, meals, per diem, stationery and schedule date and health facility for the supervisory visit.

IV. Usual items to check in supervisory visits:

- The quality and completeness of data on quarterly reports
- The completeness of smear conversion rates at 2 (3) months
- The reported incidence rate and case detection rate for smear-positive cases in the health facility, district or region
- The proportion of PTB sputum smear-positive out of all the PTB patients registered in the health facility, district or region
- The proportion of PTB sputum smear-positive, PTB sputum smear-negative and extrapulmonary TB out of all TB patients registered in the health facility, district or region
- Treatment outcome for new and retreatment PTB sputum smear-positive cases in health facility, district or region
- Any scheduled training in TB for health facility and laboratory staff of district or region
- Supervisory visits to the health facilities by DTLS
- Record of referral between diagnostic units and treatment units – whether the referred patients reached the laboratory, their sputum specimens were examined and results recorded.
- Anti-TB and leprosy drugs – quantity, expiry dates, stock cards, dispensing logs, Facility Report and Request for Drugs and buffer stock for health facility, district or region.
- Check laboratory for reagents, staff and safety for doing TB microscopy
- Enquire about the working linkage of SCHW, treatment supporters and health workers in the facility
- Check TB Unit Registers, TB Laboratory Registers and District TB Registers for numerical counting, patient classification and overall completeness

Conducting supervisory visits

Using the list of insufficiencies prepared when planning the supervisory visit, discuss these issues with the health workers at the facility and the DTLS in order to find the cause of and solution for the insufficiencies. The following areas are important:

- Is someone responsible for carrying out a particular task?

- Is the person's knowledge and skill sufficient for the task?
- Has training been provided in this area?
- Are the staff motivated to perform their work?
- Are there barriers to performing work correctly?

At the end of the supervisory visits, present and discuss a summary of the main findings with the health workers at the appropriate level and agree on next steps. A copy of the written supervision report should be sent to the relevant officers.

Annex 5: Treatment Supporter

The treatment supporter is identified in the village meeting involving the VHT, LC1 and community members. The role of the treatment supporter is to help the TB patient adhere to the taking of anti-TB drugs. It is recommended that the treatment supporter should have the following characteristics:

a) be a resident of the community, perhaps a neighbor, family member or other relative
b) have a minimum level of literacy (able to read and write)
c) be identified by the community and accepted by the patient
d) understand and accept the role

Note: A TB/HIV co-infected patient who is on both ART and anti-TB medication should have the same treatment supporter for both conditions.

The treatment supporter should live near enough to the patient to carry out the following tasks and responsibilities:

- ✓ To observe the patient taking the daily dose of anti-TB drugs correctly
- ✓ To tally the drug intake day by day on the patient's treatment card
- ✓ To ensure uninterrupted availability of drugs. In the rare event that the SCHW is delayed, the treatment supporter should collect the drugs from the health facility.
- ✓ To remind the patient to go for sputum follow-up examinations at 2 (3), 5, and 8 months of treatment
- ✓ To encourage the patient to continue taking treatment
- ✓ To keep the patient's drugs safe
- ✓ To inform the SCHW of any problem related to the health of the patient or to any constraint in administering DOT.

The treatment supporter is therefore responsible to the SCHW and the community.

Basic facts about TB for the treatment supporter

- ✓ TB is caused by a germ that commonly affects the lungs.
- ✓ TB spreads to others when a TB patient coughs or sneezes.
- ✓ TB can be stopped from spreading by treating and curing the patient.
- ✓ The main symptom of TB is a cough lasting 2 or more weeks.
- ✓ TB can be cured if the patient takes anti-TB drugs daily for the recommended duration of treatment,
- ✓ If TB drugs are not taken for the recommended period, the disease may not be cured.
- ✓ Spread of TB can be prevented by *(i) patients covering their mouths or noses when coughing or sneezing and (ii) opening windows and doors to allow fresh air to flow through the house.*

Annex 6: Tuberculin Skin Testing

The tuberculin skin test (TST) is an intradermal injection of mycobacterial antigens that elicit an immune response (delayed-type hypersensitivity). This is shown by an induration that is measured in millimeters. The TST using Mantoux method is the standard method for identifying people infected with *Mycobacterium tuberculosis*.

Administration

I. The forearm is placed palm-side up. The injection site is 5-10 cm below the elbow. Select an area free of scars and sores, and clean the area with an alcohol swab.

II. Check vial of Purified Protein Derivative-S for content (5 TU per 0.1 ml) and expiry date. Get single-dose tuberculin syringe with a short (1/4–1/2-inch) 27 gauge needle. Fill the needle with 0.1 ml of tuberculin.

III. Insert the needle with its bevel up, at an angle of 5–15 degrees to the skin surface. Inject the tuberculin at the chosen site. Check for a raised swollen area at the injection site. If no swelling, repeat the injection at another site.

IV. Record patient identification, name of health facility, date and time TST was performed and the lot number of tuberculin.

V. Inform the patient when to return for the test reading (Indicate the date and time 48 to 72 hours later).

Reading

I. Inspect the site and palpate for induration (raised firm area of skin) using fingertips. Using a pen, mark the circular margins of the induration.

II. Measure diameter of the induration using a clear ruler by placing the “0” of the ruler on the left-hand edge of the induration and reading the millimeters by noting the ruler line on the right-hand side.

III. Record measurement in millimeters. If no induration, record 0.

Interpretation

I. Diameter of induration 5 or more mm is considered positive in:
   - HIV-infected children and adults
   - Severely malnourished children

II. Diameter of induration 10 mm or more is considered positive in:

- HIV sero-negative children , BCG or not BCG-vaccinated
- HIV sero-negative adults

Annex 7: Field Guidelines for Taking Skin Smears for Leprosy

Selection of sites

- ✓ Only two sites are smeared: i) from the centre of the most obvious, active skin lesion (usually nodule) in MB cases, and from the edge of the most active patch in PB cases; ii) from an ear lobe.
- ✓ If there is no suitable skin lesion, take the second smear from the other ear lobe or from sites where lesions were originally recorded.

Steps for taking the skin smears

- ✓ Explain the procedure to the patient (and attendant).
- ✓ Wash your hands and put on gloves.
- ✓ Take a clean slide and mark it using a slide marker with laboratory number and date.
- ✓ Clean the slide with methylated spirit.
- ✓ Make a skin fold and squeeze it between thumb and index finger to make it bloodless.
- ✓ Make a cut of 5 millimetres long and 3 mm deep with a sterile disposable scalpel blade, meanwhile maintaining the pressure on the skin fold with the fingers.
- ✓ If any blood or tissue fluid discharges, wipe it off with a sterile cotton wool swab.
- ✓ Firmly scrape the cut edge and bottom of the wound with the tip of the blade turned to 90 degrees.
- ✓ Gently and equally smear the tissue fluid and pulp on the slide in a circular shape with a diameter of 5–7 mm.
- ✓ Collect the smears of the two sites on one slide.
- ✓ Dress the small wound.
- ✓ Use a new disposable blade for the next patient.

Note: This is a skin piercing procedure with the potential risk of transmitting HIV. The procedure should be performed taking all necessary precautions.

- ✓ Details of the procedures for taking, fixing, staining and reading skin smears are included in *How to do a skin smear examination for leprosy* (ILEP Learning Guide Four, 2006). Copies can be accessed at the NTLP Central Unit, the Leprosy Referral Centres, and online at the ILEP website http://www.ilep.org.uk

Annex 8: TB Forms and Registers

8.1 Request for Sputum Examination

8.2 Patient Treatment Card

8.3 Referral and Transfer Form

8.4 Laboratory Register

8.5 Unit TB Register (part 1 and 2)

8.6 District TB Register

8.7 Sub-county Health Worker Register

8.8 Quarterly Case-finding Form (part 1 and 2)

8.9 Quarterly Treatment Outcome Form

8.10 Request for Culture and Sensitivity

8.11 Intensified TB Case-finding Form

8.12 TB/HIV Referral Form

8.13 TB Suspect Register

8.14 Stock Card

8.15 Dispensing Log

8.16 Facility Report and Request for Drugs

8.17 District Report and Request for Drugs

Annex 9: Leprosy Records and Registers

9.1 Leprosy Record Card (faces 1, 2, 3 and 4)

9.2 Unit Leprosy Register (Right and Left side)

9.3 District Leprosy Register (1 and 2)

9.4 Clinic Appointment Card

9.5 Quarterly Disability Reporting Form

9.6 Quarterly Report on Leprosy Control (1and 2)

9.7 Quarterly Report on Leprosy Treatment Outcomes

Annex 10: Discharge Form

Annex 8.1

(FRONT VIEW)

UGANDA NATIONAL TUBERCULOSIS/LEPROSY PROGRAMME

REQUEST FORM FOR SPUTUM EXAMINATION

Name of Treatment Unit: _____OPD/Ward_____ Date: _____

Name of Patient: _____ Age: _____ Sex | M | F |

Address of Patient: County _____ Sub-County_____

Parish _____ Village (LC 1) _____Tel. No. _____

Reason for Examination: Suspect ☐ Follow –up of **A. 2months B. 5 months C.8 months** Treatment

Specimen Identification No: _____ District TB. No: _____

Date of Sputum collection:_____ Suspect/ Unit TB No: _____

Signature and Name of person who requests Examination:

(BACK VIEW)

RESULT (To be completed at Laboratory)

Specimen Lab. No.:

Aspect of specimen on inspection:

Write the specimen number in the box

Muco – purulent ☐ Bloodstained Saliva ☐ Muco – Salivary ☐ Saliva ☐

Microscopy:

Date	Specimen number	Results *	Positive grading			
			+++	++	+	scanty (1-9)
	1		☐	☐	☐	☐
	2		☐	☐	☐	☐

* Indicate Neg. or Pos.

Date: _____ Examination carried out by (signature) _____

The completed form (with results) should be sent to the treatment centre that requested it.

Month	Date Due	Sputum examination		
		Date done	Smear	Lab No
0a				
0b				
2(3)				
5				
8				

Date when drugs are delivered	Date of next drug delivery

Remarks

Treatment outcome	Record Date
Cured	
Treatment completed	
Treatment failure	
Default	
Transferred out	

NATIONAL TUBERCULOSIS/LEPROSY PROGRAMME
TUBERCULOSIS TREATMENT CARD

District TB No. _____ **Unit TB No.** _____

Name: _____
Address: County: _____Sub-county: _____
Parish: _____Village/LC1: _____
Health Unit: _____
Sex: M ☐ F ☐ Age:_____ Weight:_____
Name of treatment supporter:_____

Disease classification: Pulmonary ☐ **Positive** ☐ **Negative** ☐
Extra pulmonary ☐ **Site** _____

Type of patient

New ☐ Relapse ☐ Return after default ☐ Failure ☐
Other specify _____

TB/HIV

Intervention	**Date**
CT status; *circle one* CT1, CT2 CT3*	
Started ARV *circle one* Yes No	
On CPT *circle one* Yes No	
IEC message given	**Date**
TB/HIV relationship	
TB transmission	
TB Prevention	
Treatment and Importance of Adherence	
Importance of DOT	

** CT3 not yet tested*

INITIAL PHASE – prescribed regimen and dosages: Put an X in the box for the appropriate category. Write the number of tablets per daily dose, and dosage of S (grams) in the appropriate box below:

Cat 1: New case ☐ **Cat 2:** Retreatment ☐ **Cat 3:** Child under 12yrs ☐

2 months	3 months	2 months	2 months
RHZE	RHZE	S	RHZ

RH: Rifampicin & Isoniazid **Z**: Pyrazinamide **E**: Ethambutol **S**: Streptomycin,
H: Isoniazid

please turn over

Annex 8.2 inside

I INITIAL PHASE: Date started (*dd/mm/yy)* _____

Put an X in the appropriate box after the drugs have been directly observed, or a (---) if given for self administration and (O) if the dose was missed.

Day / **Month**	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Monthly weight

II CONTINUATION PHASE: Date started (*dd/mm/yy)* _____

	CAT I New case ☐ All types		CAT 2 Retreatment ☐ All types	CAT 3 Child under 12yrs ☐
Prescribed regimen and dosages (Indicate number of tablets per dose)	☐	or ☐	☐ | ☐	☐
	6 months HE	4 months RH	5 months RH E	4 months RH

Day / **Month**	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Monthly weight

Put an X on day of supervised drug administration. Draw a horizontal line (-----) to indicate the number of days that drugs were collected for self administered treatment and (O) on that day drugs were not swallowed

National Tuberculosis
And Leprosy Programme

MINISTRY OF HEALTH
P.O. BOX 7272, KAMPALA, UGANDA

THE REPUBLIC OF UGANDA

Annex 8.3: **REFERRAL AND TRANSFER FORM – DIRECTLY OBSERVED TREATMENT SHORT – COURSE**
PART A

Name: _____ Age_____ Sex M ☐ F☐
Address:
Sub-county, _____ Parish, _____
Village, _____ L.C 1_____
Treatment Centre; District TB No;

Type of patient: New ☐ Relapse ☐ Return after default ☐ Failure ☐

Type of T.B: Pulmonary ☐ AFB Positive☐ AFB Negative ☐

Extra pulmonary ☐ Site _____

TB/HIV

CT status; circle *one* CT1, CT2, CT3	Date tested
On ARVS *circle one* Yes No	
On CPT circle *one* Yes No	
IEC message given	**Date**
TB/HIV relationship	
TB transmission	
Prevention	
Treatment and Importance of Adherence	
Importance of DOT	
CT3 for not tested	

(Please, Mark where applicable)

I. INITIAL INTENSIVE PHASE: Date started: _____
Prescribed regimen and number of tablets

new AFB+, new AFB-, E.P	retreatment	
2RHZE	3RHZE	2S

(RH) =rifampicin/soniazid; E=enthambutol; Z=pyrazinamide
S=streptomycin

II. Continuation Phase: Date: started _____
Prescribed regimen and number of tablet:

New AFB+, new AFB, - E.P	retreatment
6EH or 4RH	5RHE

(RH) =rifampicin/soniazid; E=enthambutol; Z=pyrazinamide S=streptomycin

REASON FOR REFERRAL / TRANSFER
_____

REFERRED / TRANSFERRED TO: (Name of Health Unit) _____
(village)_____

NAME STAFF MEMBER _____DESIGNATION _____DATE _____
(Filling Form)

Part B: (To be completed by the unit to which the patient was sent and should be returned to DTLS immediately after the patient presents himself for treatment at the new unit):

From _____

To _____

Name, _____ Sex _____ Age _____

District Tuberculosis Number (as indicated in part A) _____

Date the patient arrived at the unit to which he was referred /transferred_____

Name of Staff member, _____ designation_____ Signature (Filling form)

Annex 8.4 TB Laboratory Register

Year_____ Name of Laboratory_____

Lab Serial No	Date	Name in Full and Telephone	Sex M/F	Age	Address: (1) County (2) Sub county (3) Parish (4) Village (LC1)	Name of Rx unit	Patient Number		Pre _ Rx or Follow up	Results Specimen		HIV Status CT1/ CT2/ CT3	Signature
							Suspect/ Unit No.	District TB No.		1	2		
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								
					(1) (3) (2) (4)								

Annex 8.5 part1 and 2

NATIONAL TUBERCULOSIS AND LEPROSY PROGRAMME (NTLP)
UNIT TB REGISTER

Unit TB No	Dist TB No	Name (in full), & Tel. No. or Contact Person	Sex M/F	Age	Address 1) District 2) County 3) Sub-County 4) Parish 5) Village 6) Nearest health unit			Date Treatment Started & Regimen	Disease Class (a) P/Pos P/Neg EP NSD	Type of Patient (b) N.R.F.D.O	Transfer In (c) From (1) Reason (2)	Results of Sputum Examination and Other Examinations and Date					
												PRE-Rx		Follow up			
												AFB (d)	Other (e)	2(3) (f)	DST (g)	5	(6)8
					1)	2)	3)				(1)						
					4)	5)	6)				(2)						
					1)	2)	3)				(1)						
					4)	5)	6)				(2)						
					1)	2)	3)				(1)						
					4)	5)	6)				(2)						
					1)	2)	3)				(1)						
					4)	5)	6)				(2)						
					1)	2)	3)				(1)						
					4)	5)	6)				(2)						
					1)	2)	3)				(1)						
					4)	5)	6)				(2)						
					1)	2)	3)				(1)						
					4)	5)	6)				(2)						
					1)	2)	3)				(1)						
					4)	5)	6)				(2)						
					1)	2)	3)				(1)						
					4)	5)	6)				(2)						

NOTES

(a) Record the Disease Classification as: **P/Pos** for sputum positive, pulmonary TB; **P/Neg** for sputum negative, Pulmonary TB; **EP** - Extra Pulmonary TB and the site (spinal, renal, lymph node), and **NSD** for No Smear Done.

(b) Record the Type of Patient as – **N** for New; **R** for Relapse; **F** for Failure; **D** for Default; **O** for Other.

(c) Record the referral unit from which the patient has been transferred in the first line and the reason for the transfer in the second line

(d) Record the results of sputum examination {**ND** for Not done; **NEG** for 0AFB/100 Fields, **1-9** for exact number if 1 to 9AFB/100 fields; **(+)** for 10-99 AFB/100 Fields, **(++)** for 1-10 AFB/Field; **(+++)** for >10 AFB/Field} in the first line and the date when the sputum was examined in the second line.

(e) Record the Other type of test {Biopsy, Mantoux, CSF, X-Ray} and examination result in the first line and the examination date in the second line. For diagnosis of TB in children refer to recommended children algorithm.

(f) Record the examination result in the first line and date in the second line for: 1) A category 1 patient who has completed 2 months of treatment; 2) a category 1 patient whose treatment was prolonged to 3 months; 3) A category 2 patient who has completed 3 months of treatment.

(g) Record **YES** for whom Drug Susceptibility Testing **(DST)** has been requested in the first line and the date when DST was requested in the second line.

CODES: **Y**- Yes; **N**- No Date Format- **dd/mm/yy**

Annex 8.5 part1 and 2

TB/HIV Activities				Treatment Model	Issue of Anti-TB Drugs (10)										Treatment Outcome by Date						
HIV Test C/CT/ CT1/CT2 (h) Date	Patient Recvd HIV Result Y/N	CPT Y/N Start Date	ART Rx Y/N Start Date	F or C/Date Name of treatment supporter (i)	Intensive Phase (Every 2 weeks)				Continuation Phase (Monthly)						Treatment Completed (j)		Treatment Not Completed (k)				
					M1		M2								Smear Negative (Cured)	Smear result not available	Failure (Smear Positive)	Died	Transferred out Name of Unit/Date	Defaulted	Remarks
					2	4	6	8	3	4	5	6	7	8							

NOTES

(h) Record HIV Counseling and Test Results: **C** for Counseled; **CT** for Counseled and Tested; **CT1** for HIV Positive and **CT2** for HIV Negative.

(i) Record **F** if the patient is on health facility based DOT and **C** if the patient is on community based DOT (CBDOTS) and the start date on the first line; Record the name of treatment supporter assigned to a patient on CBDOTS in the second line.

(j) Record the date of dispensing drugs {**dd/mm**} in the first line and the number of days for which treatment is dispensed in the second line. Under Intensive Phase, record the information for month 3 for: a) A category 1 patient who remained sputum positive at the end of 2 months and was continued on intensive phase for one more month; b) A category 2 patients started on intensive phase for 3 months and in Month 4 for a category 2 patient who remained sputum positive at the end of 3 months and was continued on intensive phase for one more month.

(k) Record the date under 'Treatment Completed' if the full prescribed duration {6 or 8 months} of treatment has been given; Record the date under 'Smear Negative' if the sputum in the last month is negative and was negative once before {2 or 5 Months}; For Others record the date under 'Sputum Not Available'.

(l) If the prescribed duration of treatment was not completed, record the date of stopping treatment under the correct heading; if 'Transferred Out', record the date of transfer in the first line and the name of the health unit transferred to in the second line; If treatment was stopped because of failure of treatment, record the date of sputum result under 'Failure'.

Annex 8.6 District TB Register part 1 and 2

Date of Registr.	HSD TB No.	Dist TB No.	District	Names in full	Sex M/F	Age	Name of Treatment Unit (1) Unit where diagnosed (2) Unit for follow-up	Unit TB Numbers (1)Unit where diagnosed (2)Unit for follow-up	Date treatment started and Regimen	Disease Classification P/Pos P/Neg EP NSD	Type of Patient N, R, F, D, O	Transfer in From (1) Reason(2)
							(1)	(1)				(1)
							(2)	(2)				(2)
							(1)	(1)				(1)
							(2)	(2)				(2)
							(1)	(1)				(1)
							(2)	(2)				(2)
							(1)	(1)				(1)
							(2)	(2)				(2)
							(1)	(1)				(1)
							(2)	(2)				(2)
							(1)	(1)				(1)
							(2)	(2)				(2)
							(1)	(1)				(1)
							(2)	(2)				(2)
							(1)	(1)				(1)
							(2)	(2)				(2)
							(1)	(1)				(1)
							(2)	(2)				(2)

Annex 8.6 District TB Register part 1 and 2

Date and Results of sputum examination (Nos indicate month of treatment)				**DST**	**TB/HIV**				**Treatment Model**	**Treatment Outcome by Date**						
Pre-Rx	2(3)	5	6(8)	Date	HIV Test C/CT/ CT1/ CT2 Date	Pt Recvd HIV result Y/N	CPT Y/N Start Date	ART Rx Y/N Start Date	F OR C / Date Name of treatment supporter	Cured	Treatment completed	Died	**Failure**	Defaulted	Transferred out Name of Distr. Date	Remarks

Annex 8.7

SUB-COUNTY HEALTH WORKER REGISTER

DRUG DELIVERY AND PATIENTS' ADHERENCE

TB No 1)District 2) Unit	Name in full and Telephone No.	Address 1) Parish 2) village	Issue of Anti TB drugs and Patient's Adherence 1)Drug delivery date 2) No of Missed doses										Treatment Outcome	Name of Treatment Supporter and Telephone No.
1		1	1											
2		2	2											
1		1	1											
2		2	2											
1		1	1											
2		2	2											
1		1	1											
2		2	2											
1		1	1											
2		2	2											

Annex 8.8

NATIONAL TUBERCULOSIS/LEPROSY PROGRAMME

QUARTERLY REPORT ON NEW AND RETREATMENT CASES OF TUBERCULOSIS

Patients registered during [ ] quarter of 20

Name of District TB/Lep Supervisor (DTLS)

_____ **District** _____

Date Form Completed: _____ **Signature** _____

A) NEW CASES, RELAPSES, FAILURES AND DEFAULTERS:-

PULMONARY TUBERCULOSIS																					
SMEAR POSITIVE									SMEAR NEGATIVE						NO SMEAR DONE					
New Cases			Relapses		Failures		Defaulters		New		Relapse		Defaulter		New		Relapse		D, *F*	
M	F	T	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F

EPTB		TOTAL ALL TYPES TB		
M	F	M	F	OVERALL

B) SMEAR – POSITIVE NEW CASES:

Age group	0 –4	5 – 14	15 – 24	25 - 34	35 – 44	45 - 54	55 – 64	65+	TOTAL
Male									
Female									

C) TB/HIV SECTION FOR TB PATIENTS REGISTERED DURING THE QUARTER

Type of patient	No. offered HCT		No. tested for HIV		No. HIV pos.		No. on CPT		No. on ART	
	M	F	M	F	M	F	M	F	M	F
New smear Pos. TB										
New smear neg. TB										
EPTB										
Other types of TB										
Total										

D) PATIENTS REGISTERED DURING THE QUARTER ON DOT

Sex	DOT Status		
	Number registered TB patients	Number on facility based DOT	Number on community based DOT
M			
F			

Explanations:-

- **1st quarter = Jan. Feb. Mar., 2nd quarter = Apr. May Jun**
  3rd quarter = Jul. Aug. Sep., 4th quarter = Oct. Nov. Dec.
- **Block 'B' is the breakdown of the totals in the first three boxes in block 'A'**
- **Patients that are registered in the District Register as TRANSFER IN do not appear on this report**
- **Block "C" is a breakdown of TB patients registered during the quarter by TB/HIV services offered.**
- **Block "D" is a breakdown of "DOT" status of patients registered during the quarter**
- **Patients are reported in the quarter in which they are registered in the District TB Register. Thus, the patient may be diagnosed and put into Treatment's Unit Register at the end of March, for example, but only registered into the District Register in April – he will appear in the statistics for the 2nd quarter. This means that the DTLS can begin to work on the statistics on the first day of the next quarter.**
- **The report should be handed to the Zonal Supervisor before 15th of the month following the end of the quarter being reported on. ZTLS will validate and forward the reports to the Ministry of Health by 28th of the same month.**
- **Please keep the district register up to date; otherwise you will not be able to fill this form correctly and in time.**

Annex 8.8

Name of District _____ Date completed _____

Quarterly report on Programme Management

1. Number of TB cases registered during the above quarter by treatment category.

	Regimen	No registered/treated
New smear positive	**Cat. 1**	
New smear negative	**Cat. 1**	
New extra pulmonary	**Cat. 1**	
Relapse (Positive)	**Cat. 2**	
Failure (Positive)	**Cat. 2**	
Return after default (Positive)	**Cat. 2**	
Children smear positive	**Cat. 3**	
Children smear negative	**Cat. 3**	
Children extra pulmonary	**Cat. 3**	
No smear done	**Cat. 1**	
Others (specify regimen)		
Total		

2. Sputum conversion rate at end of intensive phase in smear positive patients enrolled on SCC one quarter previously (4-6 months ago) ***(i.e. in patients notified the previous quarter)***

Smear positive cases registered during previous quarter	Smear not done at end of intensive phase	Sputum conversion at:				Smear remaining positive at end of intensive phase		Total
		2 months		3 months				
		No	%	No	%	No	%	
New smear pos cases Cat. 1								
Children smear pos Cat. 3								
Relapse cases pos Cat. 2								
Failure pos Cat. 2								
Return after default pos Cat. 2								

3a. Sputum examination for case finding

Number of suspects examined for case finding by microscopy	
Number of sputum examinations for case finding	
Number of smear positive patients discovered	

3b. Sputum examination for follow up

Follow up sputum microscopy	2-3 months	5 months	8 months	Total
Number of patients examined				
No of cases smear positive				

4. Report on facilities offering TB/HIV Collaborative services

	No of D &T Us in the district	No providing HIV testing to TB patients	No providing CPT to TB patients	No providing ART to TB patients
Hospitals				
Health Centre IV				
Health Centre III				
Health Centre II				
Private Clinics				

5. Supervisory activities to TB Diagnostic & Treatment Units

No of D & T Units in the district	No. of D & T Unit Visited	No. of days spent on supervision

Report Certified by: Name/Title _____ Signature_____ Date_____

Annex 8.9

NATIONAL TUBERCULOSIS / LEPROSY PROGRAMME

Report on the Results of Treatment of Tuberculosis Patients Registered 12 - 15 Months Earlier

Name of District: _____ **Name of District TB / Leprosy Supervisor :** _____	**Patients registered during** [ ] **Quarter of** 20	**Date form completed** _____ **Signature:** _____

Patients reported during quarter [A] *			**Type of Patient**	**Cured** (1)	**Treatment completed** (2)	**Died** (3)	**Failure** (4)	**Default** (5)	**Transferred to another district (6)**	**Total number evaluated (Add 1 to 6) =B**	**No. not evaluated (A-B) ***
Male	Female	Total	NEW CASES								
			Smear positive								
			Smear-negative								
			No smear done								
			Extra-pulmonary								
			Total								
Male	Female	Total	RETREATMENT CASES								
			Smear-positive relapses								
			Smear-positive failures								
			Smear-positive treatment after default								
			Others treated with Category 2								
			Total Category 2								

- Of those excluded _____ (number) from evaluation of chemotherapy for the following reasons: _____
- **Report on the Results (cumulative) TB/HIV services offered to TB patients registered 12 - 15 months ago**

Types of TB	**No. offered HCT**		**No. tested**		**No. HIV positive**		**No. HIV + started on CPT**		**No. HIV + started on ART**	
	M	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**
New smear positive PTB										
New smear negative PTB										
Extra-pulmonary TB										
Other types of TB										
Total										

Report Certified by: Name/Title _____ **Signature**_____ **Date**_____

11th August 2009

Annex 8.10

Ministry of Health

NATIONAL TUBERCULOSIS AND LEPROSY PROGRAMME

REQUEST FORM FOR CULTURE AND SENSITIVITY TESTS FOR M. TUBERCULOSIS

1.0 Patient Identification:

NAME OF PATIENT: _____ SEX_____ ____AGE_____

HEALTH FACILITY: _____ DISTRICT: _____

Type of patient: Mark X in appropriate box

New patient ☐ Failure case ☐ Other (specify) _____

Defaulter ☐ Relapse ☐

2.0 **Anti-Tuberculosis treatment Received**	**From**	**Till**
Isoniazid	_____	_____
Streptomycin	_____	_____
Rifampicin	_____	_____
Ethambutol	_____	_____
Pyrazinamide	_____	_____

3.0 Reason for culture and sensitivity: _____

4.0 Specimen Details: Specimen type: _____ Collection Date _____H/U Lab No._ __

Specimen collected at (**Tick √):** 0 Month 2(3) Months 5Months (6)8 Months

Requested by (Name):_____ Phone_____

Signature: _____ Date: _____ _____

FOR NTRL LABORATORY USE ONLY

NTRL Lab No _____ Date Received: _____

Laboratory Results:

Test	**Date**	**Smear Result (Pos/Neg)**	**Grading (+, ++, +++)**	**Culture Result to follow on date**	**Sensitivity results to follow in on date**
ZN					
***FM**					

*Fluorescent Microscopy

Culture and Anti-TB drug Sensitivity Test Results:

Culture results		**Sensitivity results**		
Date	**Results**	**Date**	**Drug**	**Sensitive (S)/ Resistant (R)**
			Streptomycin	
			Isoniazid	
			Rifampicin	
			Ethambutol	
			Pyrazinamide	

Culture Results Key: 1-100 colonies; IC= Innumerable colonies; CG= Confluent Growth

Tech Name: _____Signature: _____Date: _____Lab No. ____

Verified by: Name: _____ Signature: _____ Date: _____

Ministry of Health

Intensified TB Case Finding Form

Use the form to suspect:

TB in People living with HIV, contacts of smear positive cases and in HIV care settings

This form should be administered by either a health care provider or lay provider at the health facility (The form should not be self-administered)

Date of TB Assessment: _____ Name of district: _____

Name of Health facility: _____

Location :_____(e.g. OPD, HIV Clinic etc.)

Name of Individual: _____ Age: _____ Sex: _____

District of Residence: _____ Sub county: _____

Village/LCI/Zone: _____

1. Has the patient been coughing for 2 weeks or more? **Yes** ☐ **No** ☐
2. Has the patient coughed up sputum stained with blood? **Yes** ☐ **No** ☐
3. Has the patient had persistent fevers for 3 weeks or more? **Yes** ☐ **No** ☐
4. Has the patient had noticeable weight loss (more than 3 kg) in the last one month? **Yes** ☐ **No** ☐
5. Has the patient had night sweats for 3 weeks or more? **Yes** ☐ **No** ☐

Guide for Actions to take

- If **yes to question 1 or 2;** request for sputum test and refer to clinician for further investigations. ***Direct the patient to a designated area for people with chronic cough.***
- **If no to question 1 and 2 and yes to any other question;** refer to clinician for further investigations
- **If no to all questions:** repeat TB Assessment at subsequent visits

Record of Information at Health facility level

1. *If you are in a clinic attending to patients enrolled in HIV care record this information on the comprehensive ART card; this information should then be transferred to the Pre ART or ART register.*
2. *If you are in any HIV care setting (not attending to patients enrolled in HIV care e.g. OPD) and the patient is found to be a TB suspect record this information in a TB suspect register.*

Annex 8.12

Ministry of Health

TB/HIV REFERRAL FORM

FILL APPROPRIATE SECTION ONLY
Section A: To be used by clinician referring a TB patient to HIV care clinic/health facility, HCT or PMTCT

Patient name_____ Date_____

Unit TB No._____

Cotrimoxazole started: yes _____ no_____ Date started_____

Date TB treatment started: _____

Current TB medications: (Mark with X the TB regimen patient is taking)

2RHZE/6EH ☐ 2RHZE/4RH ☐ 2SRHZE/1RHZE/5RHE ☐ 2RHZ/4RH ☐ Other (specify)_____

Referred from (name of clinic/facility) _____ Referred to_____

Reason for referral: 1. HCT ☐ 2. ART ☐ 3.CPT ☐ 4.PMTCT ☐ 5.Others (specify) _____

Name of referring Clinician_____

Section B: To be used by clinician referring an HIV patient/client to TB clinic/health facility

Patient name _____ Date_____

Patient ID number_____

Cotrimoxazole started: yes____ no_____ Date started: _____

Date ART started: _____ Prescribed ART regimen: _____

Referred from (name of HIV care clinic/facility) _____Referred to_____

Name of referring Clinician_____

Reason for referral: 1. TB diagnosis 2. TB treatment 3.INH 4.Others (specify) _____

Section C: Additional referral Notes: _____

_____

Signed: _____

- - Fold and tear here - - - -

Annex 8.13

National TB/Leprosy Programme (NTLP)
Register of TB suspects

Year_____

Date	TB Suspect Number	Name of TB suspect	Sex M/F,	Age	Address 1) District 2) Sub county 3) Village/LCI/Zone	Result of HIV test	Date Sputum sent to laboratory	Date results received	Results of sputum examination Specimen 1	2	Date TB started and Unit TB No.	Remarks
					1) 2) 3)							
					1) 2) 3)							
					1) 2) 3)							
					1) 2) 3)							
					1) 2) 3)							

Annex 8.14

Stock Card

Program _____

Facility Name _____ Location_____

Item Description:	Item Code:
Unit of Issue:	
Minimum Stock Level:	Maximum Stock Level:

Date	Voucher Number	Received from/ Issued to	Quantity received	Quantity Issued	Losses/ Adjustments	Stock Balance	Initials

Annex 8.15

Month: **Year:**

Tuberculosis Drugs Dispensing Log																		
Drug	**Amount Dispensed to User**																	**Total**
(RHZ) + (E) one-week blister strip 225/150/750 + 800 mg																		
RHZE tablet 75/150/275/400/ mg																		
EH two-week blister strip 400/150mg																		
RH (Adult) tablet 150/100 mg																		
RH (Pediatric) tablet 60/30 mg																		
Ethambutol tablet 400 mg																		
Pyrazinamide (Pediatric) tablet 150 mg																		
Streptomycin vial 1 mg																		

In the box, write in the total number of the product given to a patient at one time, by dispensing unit as listed above. At the end of the month add up the numbers in the boxes for the total for the month.

Annex 8.16

Uganda National Tuberculosis/Leprosy Programme
Facility Report and Request for Drugs

Ministry of Health
Republic of Uganda

Months Covered :_____ Date compiled:_____

Facility Name: _____ Facility Code: _____ Health Sub-district:_____ District:_____

	A	B	C	D	E	F	G	H	I
Drug	Beginning Balance	Received this Review Period	Dispensed	Losses or Adjustments *	Ending Balance Physical Inventory =(A+B-C) +/- D	4 Months Dispensed **	Quantity Needed F-E	Quantity Issued	Remarks
(RHZ) + (E) one-week blister strip 225/150/750 + 800 mg									
RHZE tablet 75/150/275/400/ mg									
EH two-week blister strip 400/150 mg									
RH (Adult) tablet 150/100 mg									
RH (Pediatric) tablet 60/30 mg									
Ethambutol tablet 400 mg									
Pyrazinamide (Pediatric) tablet 150 mg									
Streptomycin vial 1 mg									

Patient Statistics

# of New Cases
_____

#of Re-treatment Cases
_____

# of Child Cases
_____

# of Transfers In
_____

* Explain losses and adjustments: _____

** Four Months Consumption = total quantity dispensed in this report plus previous report.

In-Charge Name: _____ Signature: _____ Date:_____

Approved by: DTLS Name: _____ Signature: _____ Date:_____

Issued by: Storekeeper Name: _____ Signature: _____ Date:_____

Annex 8.17

Uganda National Tuberculosis & Leprosy Programme
District Report and Request for Drugs

Ministry of Health
Republic of Uganda

Months Covered: _____

Date compiled:_____

District:_____ Zone:_____ Name of DTLS:_____ Signature:_____

	A	B	C	D	E	F	G	H
Drug	Beginning Balance	Received this Report Period	Issued	Losses or Adjustments*	Ending Balance Physical Inventory = (A+B-C)+/- D	Quantity Needed	Quantity Issued	Remarks
(RHZ) + (E) one-week blister strip 225/150/750 + 800 mg						Computer will calculate		
RHZE tablet 75/150/275/400/ mg								
EH two-week blister strip 400/150 mg								
RH (Adult) tablet 150/100 mg								
RH (Pediatric) tablet 60/30 mg								
Ethambutol tablet 400 mg								
Pyrazinamide tablet 150 mg								
Streptomycin vial 1 mg								

Issued by: Name: _____ Signature: _____ Date: _____

Received at zone by: Name: _____ Signature: _____ Date: _____

Received at district by: Name _____ Signature: _____ Date: _____

Annex 9.1 Leprosy Record Card Front Page

National Tuberculosis / Leprosy Programme Uganda MF52/2009

MINISTRY OF HEALTH LEPROSY RECORD CARD	Treatment centre Unit Reg. No.	District Leprosy No. Date

Name	M ○	F ○	Age	PB ○	MB ○	Skin smear B.I. Date:

Occupation	Year of birth	Method of Detection Self report	Referral	Contact examination
District	Tribe		Referred by:	Name of contact + relation:
County	Next of kin	New ☐ Relapse ☐	Transfer in ☐	Return from default ☐
Sub county	Place of birth	Onset of disease	Onset of MDT	MDT Regimen PB /MB
Village	Home-clinic distance	Released from treatment ☐	Defaulted ☐	Died ☐ / Transferred out

Characteristics of skin lesions (*tick as appropriate):*

			EYE EXAMINATION		
Number ☐ Single	☐ 2 to 5	☐ 6 or more			
Type ☐ Patches		☐ Nodules	Counting fingers at six metres: *R*		*L*
Loss of sensation in lesions ☐ Definite	☐ Doubtful	☐ Absent	☐ ☐	Can count Cannot count	☐ ☐
Surface raised ☐ Edge only	☐ Whole-lesion	☐ Not at all	Corneal sensation: (Spontaneous blink) *R*		*L*
Reaction ☐ Present	☐ Absent		☐ ☐	Present Absent	☐ ☐

Nerve examination

Nerve	Cervical		Ulnar		Median		Radial cut.		Peroneal		Tibial	
	R	L	R	L	R	L	R	L	R	L	R	L
Enlarged												
Tender												

Contact Examination

Name	Relationship	Attended examination				
		200	200	200	200	200

Contact Examination (continued)

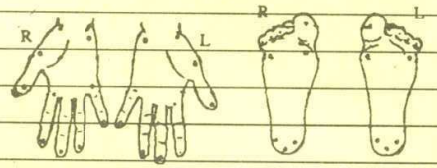
Name	Relationship	Attended examination				
		200	200	200	200	200

RECORD OF CLINIC ATTENDANCE

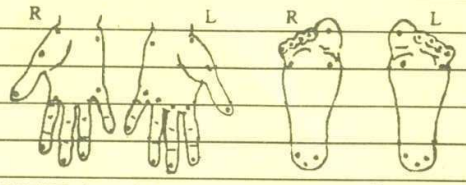
Date	Blisters issued	Date	Blisters issued	Date	Blisters issued

PERIODICAL EXAMINATION:

Date	
BI:	VMT/ST change in last 6 months YES ○ NO ○
	Disability grading: R[G] L[E] R[H] L[H] R[F] L[F]



Date	
BI:	VMT/ST change in last 6 months YES ○ NO ○
	Disability grading: R[E] L[E] R[H] L[H] R[F] L[F]

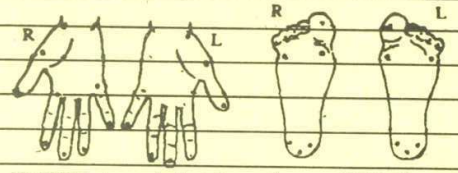


Annex 9.1 Leprosy Record Card Inside Left

Annex 9.1 Leprosy Record Card Inside Right

PERIODICAL EXAMINATION:

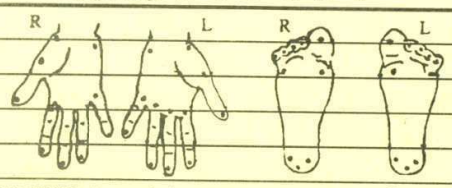
Date	
BI:	



VMT/ST change in last 6 months YES ○ NO ○

Disability grading: R^E L R^H L R^F L

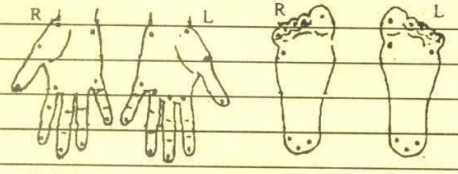
Date	
BI:	



VMT/ST change in last 6 months YES ○ NO ○

Disability grading: R^E L R^H L R^F L

	Review on completion of treatment.



VMT/ST change in last 6 months YES ○ NO ○

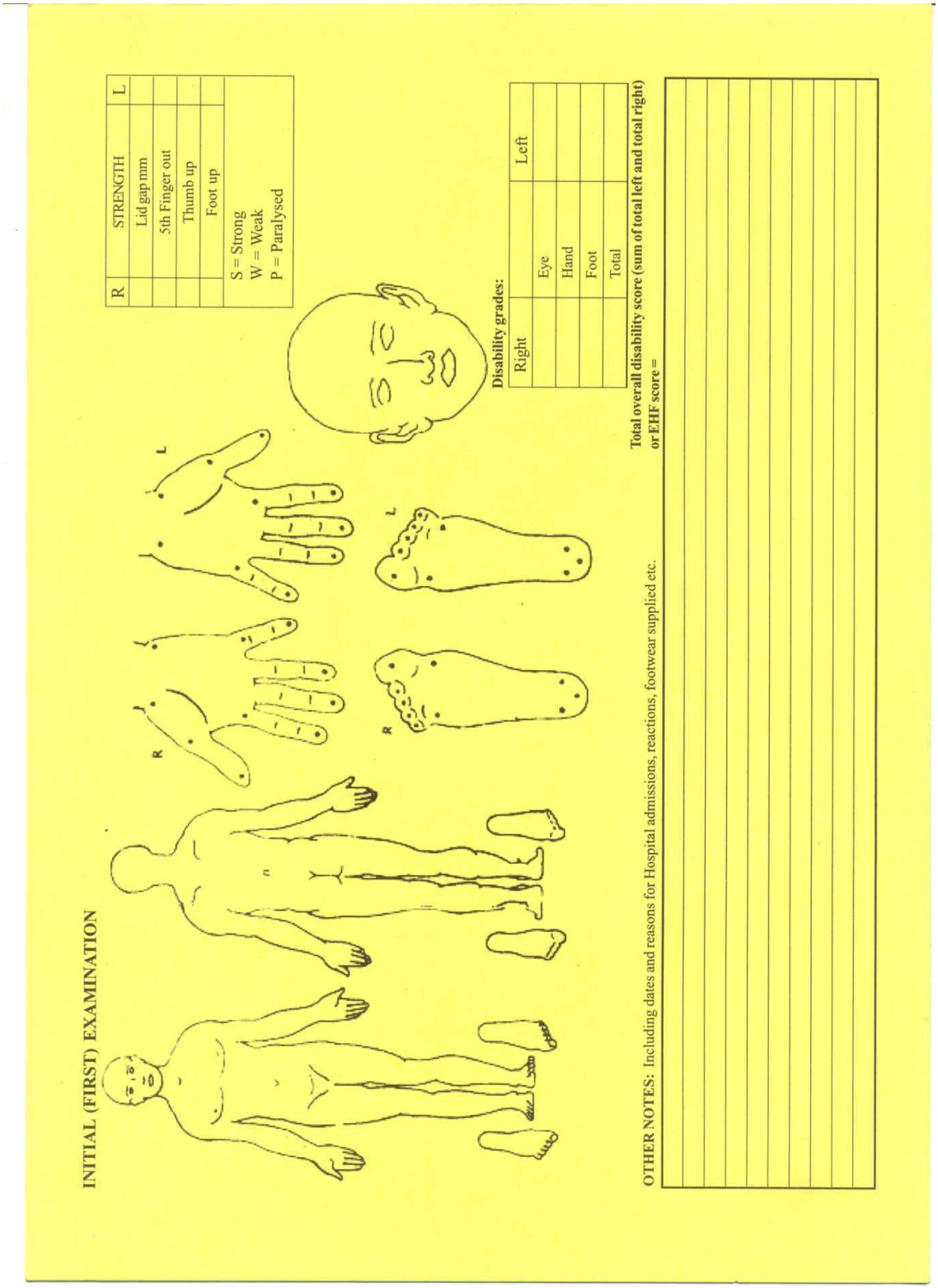
Disability grading: R^E L R^H L R^F L

MUSCLE STRENGTH ASSESSMENT

(S = Strong W = Weak P = Paralysed:)

	R							L						
							Dates							
							lid gap mm							
							5th finger out							
							thumb up							
							foot up							

Annex 9.1 Leprosy Record Card Back Page



INITIAL (FIRST) EXAMINATION

R	STRENGTH	L
	Lid gap mm	
	5th Finger out	
	Thumb up	
	Foot up	

S = Strong
W = Weak
P = Paralysed

Disability grades:

Right		Left
	Eye	
	Hand	
	Foot	
	Total	

Total overall disability score (sum of total left and total right) or EHF score =

OTHER NOTES: Including dates and reasons for Hospital admissions, reactions, footwear supplied etc.

Annex 9.2 Unit Leprosy Register R Hand side

Date of Reg.	Unit Lep. No.	Dist. Lep. No.	Name in full and Next of kin	Sex M/F	Age	Address in full (1). County 2. Sub-County 3. Parish 4. Village		Classification MB/PB	Date Start Treat.	Disability Grade at start of Treat.	EHF Score	Category N.R/M R/O, D	Transer in from
						1	3						
						2	4						
						1	3						
						2	4						
						1	3						
						2	4						
						1	3						
						2	4						
						1	3						
						1	4						

For definations and instructions see inside of front and back cover of register.

Annex 9.2 Leprosy Unit Register L hand side

Skin smear		Date Treatment Received												Treatment Outcome							
1. B1	Year	Month												Treat. Compl.	Default	Died	Transfer Out	Other	Disability Grade at End of Treatment	EHF Score	Rema
2. Date		Jan.	Feb.	Mar.	April	May	Jun.	July	Aug.	Sep.	Oct.	Nov.	Dec.								
1.																					
2.																					
1.																					
2.																					
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Annex 9.3 District Leprosy Register L hand side

Date of Registr.	District Leprosy No.	Names (in full) and Next of kin	Sex M/F	Age	Name of Treatment Unit (1) Unit where diagnosed (2) Unit for follow-up	Unit numbers (1) (2)	Date treatment started and regimen	Disease Classification PB/MB	Category of patient N,R/M,R/O,D	Trans in From (1) Reason
					(1)	(1)				(2)
					(2)	(2)				(1)
					(1)	(1)				(2)
					(2)	(2)				(1)
					(1)	(1)				(2)
					(2)	(2)				(1)
					(1)	(1)				(2)
					(2)	(2)				(1)
					(1)	(1)				(2)
					(2)	(2)				(1)
					(1)	(1)				(2)
					(2)	(2)				(1)
					(1)	(1)				(2)
					(2)	(2)				

Annex 9.3 District Leprosy Register R hand side

Date and results of skin smear		REACTION	DISABILITY GRADES								DATE TREATMENT STOPPED				Remarks
(1) date smear taken		(1) Date	(1) Initial (2) End of MDT												
(2) result, B1		(2) RR/ENL	RE	LE	RH	LH	RF	LF	GR	EHF	Completed	Transfer out	Defaulted	Died	
(1)	(1)	(1)	(1)												
(2)	(2)	(2)	(2)												
(1)	(1)	(1)	(1)												
(2)	(2)	(2)	(2)												
(1)	(1)	(1)	(1)												
(2)	(2)	(2)	(2)												
(1)	(1)	(1)	(1)												
(2)	(2)	(2)	(2)												
(1)	(1)	(1)	(1)												
(2)	(2)	(2)	(2)												
(1)	(1)	(1)	(1)												
(2)	(2)	(2)	(2)												
(1)	(1)	(1)	(1)												
(2)	(2)	(2)	(2)												
(1)	(1)	(1)	(1)												
(2)	(2)	(2)	(2)												

Annex 9.4 Leprosy Clinic Appointment card

MINISTRY OF HEALTH

NATIONAL TUBERCULOSIS/LEPROSY PROGRAMME

Clinic Appointment Card

Name: _____ Age _____ Male ☐ Female ☐

Village _____ Parish _____

Sub-county: _____

DISTRICT _____

TREATMENT CENTRE: _____

Unit Reg number: _____ District Reg number : _____

TYPE: **PB** ☐ **MB** ☐

This card should be carried by the patient and presented where the patient goes for treatment.

NTLP UGANDA

Clinic appointment card
Second face.

MDT REGIMEN: PB Adult ☐
PB Child ☐
MB Adult ☐
MB Child ☐

Attendance record:

Date drugs given	Number of blister packs given	Date next appointment	Remarks

Annex 9.5 Disability Register

NTLP REPORTING FORM ON PEOPLE WITH LEPROSY RELATED DISABILITIES
ZONE:
DISTRICT:
HSD:
H UNIT:
Quarter: Year:

Date reg	Ser No.	Name	Age (yrs	Sex	Treat	DG	Ins. Feet	Foot ulc	Ft wear	Description of disability or other
					Rx or RFT		y/n	y/n	y/n	comment

glra-ug-pod-10.06

Annex 9.6 front and back faces

Ministry of Health, Uganda

NATIONAL TUBERCULOSIS/LEPROSY PROGRAMME

QUARTERLY REPORT ON LEPROSY CONTROL ……Quarter of 20…

DISTRICT/HSD_____ NAME OF DTLS/FOCAL PERSON_____

District/HSD population _____

Number of Health Units in the District /HSD_____ Number of units providing MDT services ____

TREATMENT REGISTER

Male Ad	Male Ch	Fem. Ad	Fem Ch		PB Ad	PB Ch	MB Ad	MB Ch
				Patients on treatment at beginning of quarter				
				New cases – list them overleaf				
				Relapses – list them overleaf				
				Other additions e.g. transfer in				
				TOTAL ADDITIONS				
				Deaths				
				Released from treatment				
				Defaulted				
				Other deductions e.g transfer out				
				TOTAL DEDUCTIONS				
				TOTAL ON MDT AT END OF QUARTER				

Ch : child of less than 15 years of age.

DISABILITY REGISTER

				Disabled still on MDT
				Disabled no longer on MDT
				Have at least one insensitive foot (all)
				With ulcers (all)

Annex 9.6 front and back faces

NEW CASES STARTED ON TREATMENT THIS QUARTER

Unit number	Name	Age	Sex	PB/MB	Smear Pos/Neg	Disability grade. O,1,2 – give details

RELAPSES AND TRANSFERS PUT ON TREATMENT THIS QUARTER

Relapses:

Unit number	Name	Age	Sex	Previous Type PB/MB	Previous treatment MDT/DDS	Now PB/MB	Smear Pos/Neg	Disability Grade, 0,1,2

Transfers:

Unit number	Name	Age	Sex	Leprosy type PB/MB	Transfer IN / OUT	District transferred from/to

If there are more new cases, relapses, or transfers, please continue on another sheet.

CASE FINDING ACTIVITIES CARRIED OUT THIS QUARTER

Method	Number of people examined	Number of cases found
Contact surveillance		
Other surveys (schools, other)		
Examination of general suspects		
Total		

Annex 9.7

Ministry of Health, Uganda

NATIONAL TB/LEPROSY PROGRAMME
QUARTERLY REPORT ON OUTCOMES OF LEPROSY TREATMENT[1]
_____ QUARTER OF 20___

DISTRICT/ HSD_____ **NAME OF DTLS/ FOCAL PERSON**_____

PAUCIBACILLARY (PB) CASES REPORTED IN .....QUARTER 1 YEAR AGO.

	Reported	Completed MDT[2]	Transferred out	Defaulted	Died	Reclassified as MB	Not evaluated[3]	Total
New cases								
Return from default								
Transfers in								

MULTIBACILLARY (MB) CASES REPORTED IN ..... QUARTER 2 YEARS AGO.

	Reported	Completed MDT[4]	Transferred out	Defaulted	Died	Not evaluated[3]	Total
New cases							
Return from default							
Transfers in							
Relapses							

Ntlp uga Jul 06

[1] This report should be completed and dispatched together with the Quarterly Report on Leprosy Control.

[2] PB cases who completed 6 doses of MDT in 9 months
[3] State reason for not evaluating, at the bottom of the table
[4] MB cases who completed 12 doses of MDT in 18 months

Annex 10: Discharge form for both TB and Leprosy patients

UGANDA NATIONAL TUBERCULOSIS
& LEPROSY PROGRAMME

CERTIFICATE OF DISCHARGE FROM TREATMENT

District TB/LEP No. _____

Treatment Centre: _____

This is to certify that:

Name: _____

_____

Address: DISTRICT: _____

County: _____

Sub-County: _____

Village: _____

has completed the prescribed course of treatment for

TUBERCULOSIS ☐ LEPROSY ☐

He/She started treatment - Date: _____

and completed treatment - Date: _____

Date: _____ Signed: _____ (D.T.L.S.)

This card is filled and issued to all TB or Leprosy patients who have documented evidence of completing the full course of treatment in the recommended period.