

**THE UNITED REPUBLIC OF TANZANIA  
MINISTRY OF HEALTH AND SOCIAL WELFARE**



# **MANUAL**

**OF THE  
NATIONAL TUBERCULOSIS AND LEPROSY PROGRAMME  
IN TANZANIA**

**FIFTH EDITION  
2006**

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## FOREWORD

The publication of the fifth edition of the National Tuberculosis and Leprosy Programme (NTLP) manual marks a big step forward because it underscores the programme's commitment to providing the latest knowledge and developments in TB and leprosy control in Tanzania. The manual puts emphasis on integrating TB and leprosy control within the health system and extensively revised interventions to control TB in the context of HIV pandemic inline with the Interim policy developed by WHO and other partners

Tuberculosis is a major cause of morbidity and mortality in Tanzania especially among adults after HIV/AIDS and malaria. The incidence of tuberculosis has increased dramatically in the last two decades driven by the spread of HIV infection. In 2004 alone over 65,600 new TB cases were notified compared to only 11,000 in 1984. This six-fold increase has dramatically increased the workload of health care providers and overstretched the existing health systems.

Data from National Sentinel Surveillance system of the Adult Morbidity and Mortality Project (AMMP-2001) indicates that TB/HIV conditions contribute to 17.5% of the total disease burden in Tanzania for population above 5 years of age, behind AIDS (49.8%) and perinatal conditions (32.0%). Many of those affected are in the productive age group, which affects negatively growth of the national economy due to absenteeism and reduced productivity. Thus control of TB will also contribute positively to the growth of national economy and to the reduction of poverty under the National Strategy for Growth and Reduction of Poverty (NSGPR). A strong control programme will also help reduce the prevalence of the TB and leprosy in line with WHO goals and Millenium Development Goals (MDGs).

Tanzania is also in the process of eliminating Leprosy as a public health problem. The country has recorded a dramatic reduction of leprosy cases in the last 20 years from more than 35,000 cases in 1983 to about 4,000 in 2004. Strengthening community-based leprosy elimination campaigns and integration of leprosy care in all health facilities will ensure sustainability of the success achieved in eliminating the disease. This new manual provides extensive information on leprosy control appropriate for all levels of health care providers. Special emphasis is put on prevention of disabilities, care and rehabilitation of disabled people affected by leprosy in order to reduce stigma and improve the quality of life.

It is therefore paramount that NTLP and the health sector in general strengthens its efforts in the control of TB and leprosy to reduce the unnecessary suffering and loss of life especially among the young people. As we strengthen our control efforts, emphasis should be focused on quality of services rendered to ensure that we do not generate multi-drug resistant TB. Both diseases are targeted for control in the Essential Health Package which means every district will incorporate them in their comprehensive council health plans. This new revised manual will help the service providers and all those interested in TB control to achieve the desired results.

The Ministry of Health and Social Welfare and the Government is committed to intensifying its efforts to prevent and control these two diseases in collaboration with development partners and other stakeholders. I take this opportunity to express my sincere appreciation to all of them for their continuing financial and technical support.

It is my sincere hope that all health workers will find this manual useful in their daily work. What remains is for all to renew the spirit of commitment and dedication to improve the quality of services rendered to our people.

Prof. David H. Mwakyusa (MP)  
Minister for Health and Social Welfare  
2006



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Dr. G. L. Upunda  
Chief Medical Officer  
Ministry of Health and Social Welfare  
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## ABBREVIATIONS

AFB	- Acid Fast Bacilli
AIDS	- Acquired Immuno-Deficiency Syndrome
ARC	- AIDS Related Complex
ART	- Anti-Retroviral Therapy
ARTI	- Annual Risk of Tuberculosis Infection
BCG	- Bacille Calmette-Guerin
CBHC	- Community Based Health Care
CTC	- Care and Treatment Centre
CTRL	- Central Tuberculosis Reference Laboratory
CHMT	- Council Health Management Team
DCT	- Diagnostic Counselling and Testing
DMO	- District Medical Officer
DOT	- Directly Observed Treatment
DOTS	- Directly Observed Treatment, Short course
DRA	- DOT and Rifampicin Accounting register
DTLC	- District Tuberculosis and Leprosy Co-ordinator
E	- Ethambutol
ENL	- Erythema Nodosum Leprosum
EP	- Extra-pulmonary
ETR	- Electronic TB Register
EQA	- External Quality Assurance of AFB microscopy, culture
ESR	- Erythrocyte Sedimentation Rate
FDC	- Fixed Dose Combination
GLRA	- German Leprosy and Tuberculosis Relief Association
H	- Isoniazid
HIV	- Human Immunodeficiency Virus
IEC	- Information Education and Communication
IUATLD	- International Union Against Tuberculosis and Lung Diseases
KNCV	- Royal Netherlands Tuberculosis Association
MB	- Multi-Bacillary
MO	- Medical Officer
MOTT	- Mycobacteria Other Than Tuberculosis
MoH	- Ministry of Health
NGO	- Non Governmental Organisation
NTLP	- National Tuberculosis and Leprosy Programme
OPD	- Out Patient Department
PB	- Pauci-Bacillary
PCT	- Patient Centred Treatment
PGL	- Persistent Generalised Lymphadenopathy
PTB+	- Pulmonary Tuberculosis, sputum smear positive
PTB-	- Pulmonary Tuberculosis, sputum smear negative
PAL	- People Affected by Leprosy

R - Rifampicin  
RFT - Released From Treatment  
RLT - Regional Laboratory Technician  
RNE - Royal Netherlands Embassy  
RTL - Regional Tuberculosis and Leprosy Co-ordinator  
S - Streptomycin  
SDC - Swiss Development Co-operation  
ST - Sensitivity Test  
SER - Social Economic Rehabilitation  
TBL - Tuberculosis and Leprosy  
TLA - Tanzania Leprosy Association  
TLCU - Tuberculosis and Leprosy Central Unit  
VCT - Voluntary Counseling and Testing  
VMT - Voluntary Muscle Test  
WHO - World Health Organisation  
Z - Pyrazinamide  
PI - Protease Inhibitor  
NRTI - Nucleoside Reverse Transcriptase Inhibitor  
NNRTI - Non-Nucleoside Reverse Transcriptase Inhibitor  
AZT - Zidovudine  
d4T - Stavudine  
3TC - Lamivudine  
EFV - Efavirenz  
SQV - Ritonavir  
ABC - Abacavir  
LPV/r - Lopinavir/ritonavir  
IRIS - Immune Reconstitution Inflammatory Syndrome

## **BACKGROUND**

The National Tuberculosis and Leprosy Programme (NTLP) was launched by the Ministry of Health and Social Welfare in 1977 as a single combined programme. The Ministry is collaborating with various international and local developmental partners in implementing control of TB and leprosy in the country. The international development partners are the Swiss Agency for Development Co-operation (SDC), Netherlands Ministry for Development Cooperation (DGIS) through the Royal Netherlands Embassy (RNE), Development Cooperation Ireland (DCI), German Leprosy and Tuberculosis Relief Association (GLRA), Netherlands Tuberculosis Foundation (KNCV), The World Health Organisation (WHO) and Novartis Foundation for Social Development (NFSD). Some of the local NGOs include PASADA, Tanzania Leprosy Association, Rufiji Leprosy Trust, CCBRT and a number of faith-based hospitals.

The mission of the programme is to provide high quality and effective interventions to control TB and leprosy in Tanzania with a focus on gender mainstreaming, equity, accessibility and those most at risk. By intensifying its efforts, the programme will contribute positively to the country's wider efforts to meet vision 2025, the National Strategy for Growth and Reduction of Poverty (NSGPR) goals and the Millennium Development Goals, which have set clear targets. Thus the Programme aims at contributing significantly to the efforts of the country in poverty reduction.

More specifically NTLP is endeavouring to achieve the WHO targets for TB control of detecting 70% of the infectious cases and treating successfully 85% of them based on Stop TB strategy of global TB control. In addition to health facility DOTS (public-private mix), the programme has started Community based DOTS and Patient Centred Treatment Approach in selected districts. The experience gained will be scaled up to cover the rest of the country.

The programme is also collaborating with other units and programmes within the Ministry of Health and Social Welfare to scale up public-private partnership. An increasing number of private health facilities are now involved in providing TB and leprosy control services. NTLP is increasing efforts to eliminate leprosy as a public health problem by involving the communities and councils. Leprosy elimination is defined as having less than 1 case per 10,000 population. Special interventions recommended by WHO are being implemented including Leprosy Elimination campaigns (LEC) and Special Action Programme for Eliminating Leprosy (SAPEL). They are expected to accelerate this process towards reaching the WHO targets.

The Programme has also embarked on scaling up TB/HIV activities in collaboration with the National AIDS control Programme (NACP) and other stakeholders. These activities will be complimentary to and in synergy with the established core activities of TB and HIV/AIDS control.

A successful DOTS Programme is the best way of preventing the development of drug-resistant strains of TB. However, since there are already few cases of MDR-TB being notified in the country, NTLP has started putting together the basic requirements to start a DOTS-Plus strategy in collaboration and under guidance of WHO.

Over the years NTLP has developed into a strong programme based on WHO DOTS strategy which is being implemented throughout the country. The programme has adopted the new Stop TB strategy which has six components namely:

1. Pursue quality DOTS expansion and enhancement
  - a. Political commitment with increased and sustained financing
  - b. Case detection through bacteriology
  - c. Standardized treatment with supervision and patient support
  - d. Effective drug supply system
  - e. Monitoring system and impact evaluation
2. Address TB/HIV, MDR-TB and Other special challenges
  - a. TB/HIV collaborative activities
  - b. Prevention and control of drug-resistant TB including DOTS Plus
  - c. Addressing risk groups and special situations
3. Contribute to health system strengthening
  - a. Active participation in country-led and global efforts
  - b. TB control innovations that strengthen systems
  - c. Adapting innovations from other fields to strengthen TB control
  - d. Practical Approach to Lung Health - extending TB care to respiratory care
4. Engage all care providers
  - a. Public-Private Mix approaches
  - b. International Standards for TB care
5. Empower patients and communities
  - a. Community TB care
  - b. Advocacy, communication and social mobilization
6. Enable and promote research
  - a. Programme-based operational research
  - b. Partnerships to develop new diagnostics, drugs and vaccines

## **Vision and mission**

### **Vision**

Tuberculosis and leprosy diseases are controlled until they are no longer a public health problem in Tanzania.

### **Mission**

Provision of high quality and effective interventions to control TB and leprosy in Tanzania with a focus on gender mainstreaming, equity, accessibility and those most at risk

### **Objectives**

The following objectives have been developed to address current and future challenges of TB and leprosy control in Tanzania in line with the new Stop TB strategy and WHO leprosy elimination targets.

1. To increase case detection by 5% and cure rates of TB and leprosy patients by 5% and to reduce disability grade II of newly diagnosed Leprosy patients by 5% by 2009.
2. To integrate NTLP activities at different levels to conform to the ongoing Health Sector Reform by 2009
3. To develop human resources and strengthen management of TB and leprosy service delivery at all levels by 2009.
4. To implement TB/HIV collaborative programme activities in collaboration with NACP and other stakeholders by 2009
5. To establish management of multi-drug resistant tuberculosis (MDR-TB) in the country by 2009
6. To strengthen the quality of NTLP management information system with gender mainstreaming at all levels by 2009
7. To determine and monitor the magnitude of TB/HIV and leprosy burden in Tanzania by 2009
8. To involve communities in TB and leprosy care by 2009.

### **Organisational Structure of the NTLP**

NTLP is under the Epidemiology and Disease Control section within the department of Preventive Services in the Ministry of Health and Social Welfare. The programme is integrated in the existing primary health care system. All health providers are responsible for early case detection, appropriate treatment and case holding. They are also responsible for proper management of drugs and supplies, keeping accurate records and providing health education to the patient and community. Although the NTLP is intergrated within the general health services, it has a managerial and supervisory staff dealing solely with the two diseases, in order to ensure adequate technical competence in TB and leprosy control.

Administratively the NTLP operates at three levels; national, regional and district.

**National level:**

The Tuberculosis and Leprosy Central Unit (TLCU) is responsible in coordinating all activities pertaining to TB and leprosy in the country, policy formulation, planning, monitoring, evaluation, resource mobilization and coordination of drugs and supplies procurement and distribution. It is also responsible for training of staff, supervision of field activities, data aggregation and analysis, quality assurance of AFB microscopy, surveillance of drug resistance, health promotion and operational research. NTLP has reformulated its component of the Essential health package to make it suitable and user –friendly for its implementation under District Health Plans. The Central TB Reference Laboratory (CTRL) is also part of the central unit.

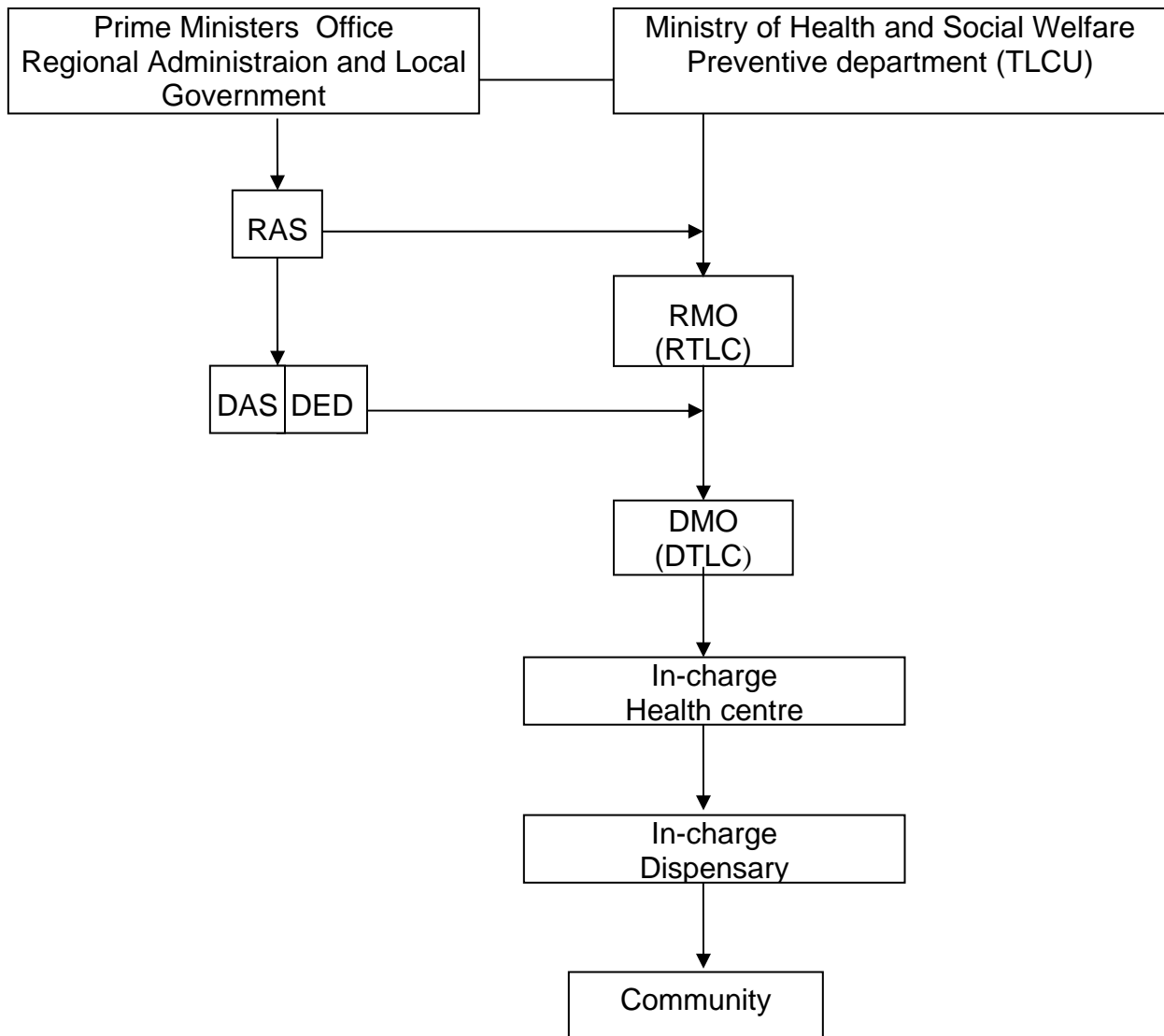
**Regional level:**

A Regional Tuberculosis and Leprosy Coordinator (RTL) works under Regional Medical Officer (RMO). He/she should be a Medical Officer or Assistant Medical Officer who is responsible in his/her own region for the tasks listed in the job description. The RTL has to work closely with TLCU and districts.

**District Level**

A District Tuberculosis and Leprosy Coordinator (DTLC) is answerable to the District Medical Officer. The DTLC should be a clinical officer or Assistant Medical Officer who is responsible for the implementation and coordination of TB and leprosy control activities within the district as listed in job description. The DTLC is the main link between TLCU through the region on one hand and health units and community on the other hand

**Figure 1: Organogram of the National Tuberculosis and Leprosy Programme.**





# 1. TUBERCULOSIS

## 1.1 General information about tuberculosis

### What is tuberculosis?

Tuberculosis is a chronic infectious disease caused mainly by *Mycobacterium tuberculosis* (and occasionally by *Mycobacterium bovis* or *Mycobacterium africanum*). These micro-organisms are also known as Acid-Fast Bacilli (AFB). The micro-organisms usually enter the body by inhalation through the lungs. Basically there are two types of tuberculosis:

**Pulmonary tuberculosis** affects the lungs and is the commonest form of the tuberculosis. This is the infectious form of the disease.

**Extra-pulmonary tuberculosis** is the disease that affects organs other than the lungs, such as pleura, lymph nodes, pericardium, spine, joints, abdomen or genito-urinary tract. It may affect any part of the body.

### Transmission

The most important source of infection is an individual with TB of the lungs coughing (sneezing, talking) infectious droplets into the air. The transmission of these tubercle bacilli occurs by airborne spread of infectious droplets.

The concentration of infected droplets in the air and the length of time a person breathes that air determine an individual's risk of exposure. Good ventilation removes nuclei droplets and so prevents nuclei to be inhaled by a person. Direct sunlight kills tubercle bacilli within minutes, but they can survive in the dark for many hours (24-48 hours).

The individual risk of infection depends on the extent of exposure to *M.tuberculosis* and the susceptibility to infection. The risk of infection for a susceptible person is therefore high with prolonged indoor exposure during the stay in a small room with a person with smear positive pulmonary tuberculosis coughing frequently. Infectious cough particles can stay in the air for prolonged periods of time or stay alive in dust. The risk of transmission of tuberculosis from a person with smear negative PTB is low and from a person with extrapulmonary TB even lower.

The risk of progression from infection to disease depends on the status of the immune system. The majority ( 90% ) of people without HIV infection who are infected with *M.tuberculosis* do not develop tuberculosis disease. Their immune system is strong enough to prevent the development of disease. At this stage the only evidence of infection may be a positive tuberculin skin test. Most people infected with TB remain with so-called "dormant bacilli" that might develop into tuberculosis disease in a later stage. The development of an intercurrent disease or condition that suppresses an individual's immune system triggers the dormant bacilli to become metabolically active and causes the infection to progress to tuberculosis disease.

Infection with HIV is currently the most common cause of immunosuppression in Tanzania. People with TB infection and HIV have a 20-30 times higher risk of developing tuberculosis disease during their lives than people without HIV infection. Other conditions like malnutrition, recurrent infections of any kind, diabetes mellitus can also cause reactivation of the TB infection.

### **Natural history of tuberculosis infection**

Droplet nuclei with TB bacilli that are inhaled are too small to be caught by the muco-ciliary defence system of the bronchi. They therefore settle in the terminal alveoli of the lungs. The tubercle bacilli favor high oxygen concentration, which stimulate the multiplication of the bacilli in the lung, preferably the apex. This primary lesion is called Ghon focus. From this lesion the bacilli spread to the nearest lymph-stations, which are in most times the hilar lymph nodes. The primary lesion combined with the hilar lymphadenopathy is called Primary Complex. The bacilli can also spread through the blood system to any other organ in the body, which can result in disseminated disease such as lymphadenopathy, meningitis, pericarditis, miliary disease etc.

The immune response develops about 4-6 weeks after the infection. The number of bacilli that have been inhaled and the strength of the immune system determine if the infection is stopped or develops into full tuberculosis disease.

In the majority of cases the immune system is strong enough to combat this primary attack. Most of the bacilli are eliminated but a few persist in a dormant stage.

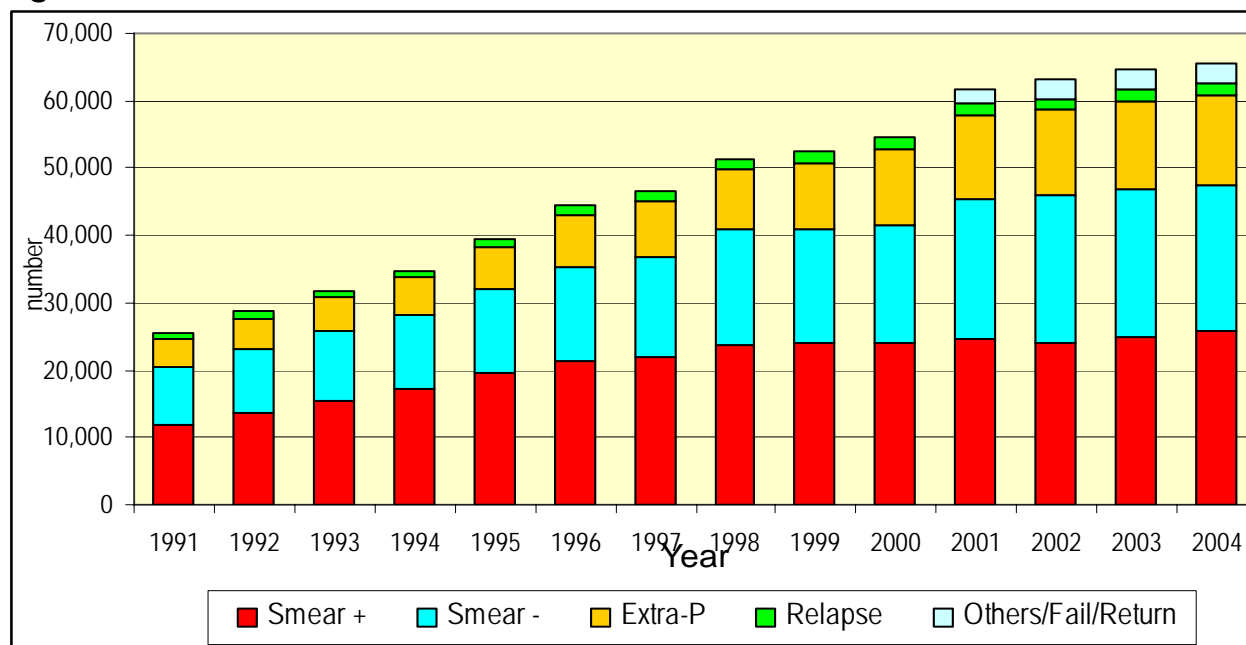
**Post Primary TB** occurs after a latent period of months to many years. It is either a re-activation of the dormant bacilli that remained after primary infection or a re-infection.

**Re-activation** of dormant bacilli is seen in individuals with weakening of the immune system due to conditions such as malnutrition, chronic/ recurrent infections, HIV infection and old age.

## **1.2 The Burden of Tuberculosis in Tanzania**

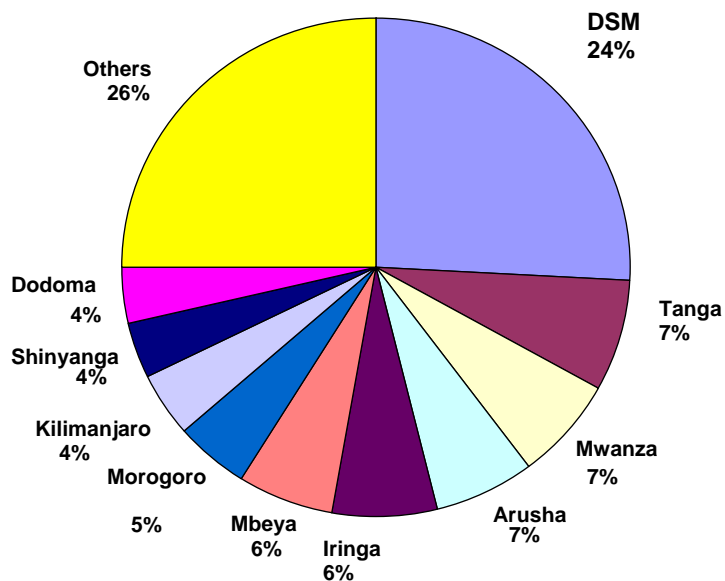
Tuberculosis continues to be among the major public health problems in the country, more than 20 years after launching of the programme. The number of tuberculosis cases has steadily increased from 11,753 in 1983 to about 65,665 in the year 2004, almost six-fold. The majority of cases appear in young adult population groups aged 15-45 years, the same age group affected by HIV/AIDS. The rapid increase of tuberculosis in Tanzania is mainly attributed to the HIV epidemic, but factors like population growth and urban overcrowding have also contributed.

**Figure 2: Trend of TB case notification from 1991 to 2004 in Tanzania**

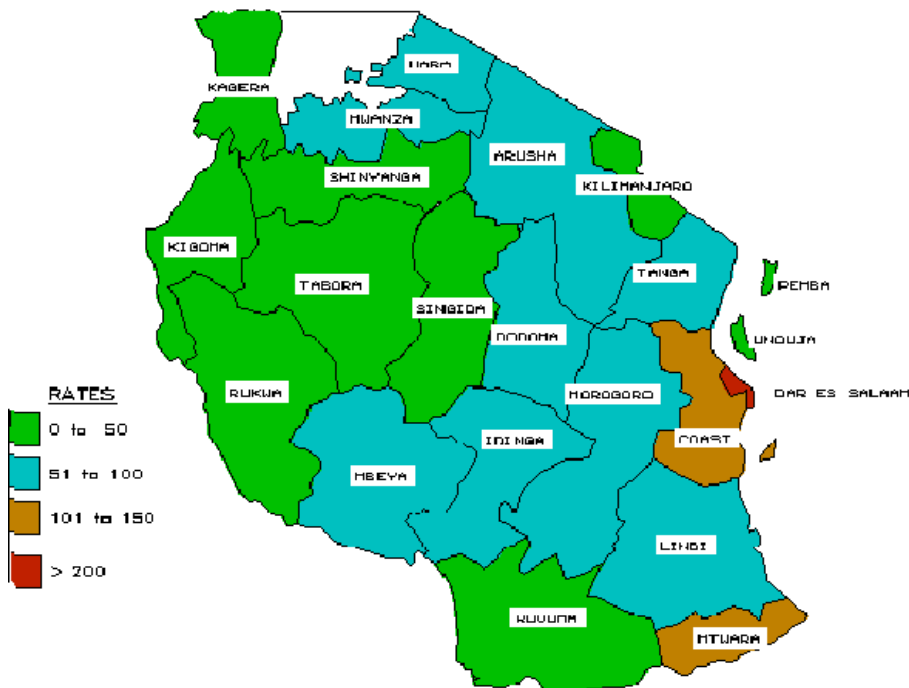


The distribution of TB in the country is not equal. Dar es Salaam contributes about 24% of all cases of TB in terms of absolute numbers. The seven regions presented in figure 3 contributed about two third of all TB cases in the country.

**Figure 3: Distribution of TB cases notified in the year 2004.**



**Figure 4: Tuberculosis notification rate (smear positive) per 100,000 population by region in 2004**



### 1.3 The Diagnosis of Tuberculosis

The highest priority in tuberculosis control is the identification and cure of all infectious tuberculosis cases, i.e. patients with sputum smear positive pulmonary Tuberculosis (PTB+), as early as possible. Priority is therefore given to the detection of bacilli in sputum samples of all suspected tuberculosis cases. The identification of tuberculosis is done through passive case finding.

The following methods of case-finding are simple and lead to the discovery of most cases of tuberculosis:

- the examination of patients who present themselves with symptoms suggestive of tuberculosis to any health facility. Every possible effort must be made to make sure that symptomatic patients attending health facilities are identified and have their sputum examined;
- The examinations of household contacts of smear positive patients, especially children and young adults. Any contact with a cough should have sputum specimen examined;
- The bacteriological examination of patients who for any reason had a chest X-ray showing a possible tuberculosis lesion;
- Educating the community and all health workers on the importance of respiratory symptoms, especially persistent and productive cough, blood stained sputum and chest

pain, particularly if they persist for 2-3 weeks or more. Patients with these symptoms should be asked to come to a health facility for examination.

### **Tuberculosis suspects**

The most common symptoms of **pulmonary tuberculosis** are:

- Persistent cough for 2 weeks or more; every patient presenting with this symptom should be regarded as a suspect;
- Sputum production, sometimes bloodstained (haemoptysis), shortness of breath, chest pain;
- Fatigue (tiredness), general malaise, loss of appetite, loss of weight, night sweats and fever.

Tuberculosis is much more probable in patients with these symptoms who are, or were, also in contact with a tuberculosis case than among those with no known contact.

The symptoms for **extra-pulmonary tuberculosis** depend on the organs involved

- chest pain from pleurisy,
- swelling of lymph nodes in tuberculosis lymphadenitis,
- pain and swelling of joints in tuberculosis arthritis, deformity of the spine in Pott's disease,
- headache, fever, stiffness of the neck and mental confusion when there is tuberculous meningitis.

#### **1.3.1 The diagnosis of pulmonary tuberculosis in adults**

The diagnosis of tuberculosis rests mainly on the identification of the tubercle bacilli by sputum smear microscopy.

Every tuberculosis suspect should submit three sputum specimens for smear microscopy within 24 hours following the schedule below;

**Spot** Patient provides on the spot sputum specimen under supervision by a staff member in an open air space or well-ventilated area. The patient is given a sputum container for collection of the second specimen.

**Morning** Patient produces the next early morning specimen and returns it to the diagnostic centre and is provided with a container for a third specimen.

**Spot** Patient produces last specimen on the spot and submits it to the laboratory.

With this approach approximately 80% of the smear positive patients will be detected on the examination of the first specimen, an additional 15% on the second and another 5% on the third specimen.

## **Technique for collecting sputum**

### **General rules**

- A specimen collected under the supervision of a health staff is better than a specimen collected without supervision;
- Whenever possible, sputum collection should take place in the open air;
- Patients usually cooperate better if they are out of sight of other patients at the time of collection;
- Patients who have been chewing food immediately before sputum collection should rinse their mouths with water before producing sputum.
- A good specimen is required. Saliva is not useful for diagnostic purposes since it is not secretion of the lung
- Briefly explain to the patient the reasons for sputum collection;
- Fill in properly the 'Request form for Sputum Examination';
- Write on the side and on the lid of a sputum container the same number as is written on the form.

### **Sputum container**

A sputum container should have a wide mouth so that the patient can expectorate easily inside the container without contaminating outside.

### **How to collect a sputum specimen**

- Ask the patient to cough deeply. Demonstration is usually more effective than words;
- Ensure that no one is standing in front of a patient producing sputum;
- Avoid contaminating the outside of the sputum container with sputum. If the outside is contaminated, discard the container and repeat the collection with a fresh container;
- If the specimen is not suitable (e.g. if it is insufficient or if it is only saliva), ask the patient to repeat the coughing until a sufficient amount of the best possible sputum has been obtained (about 3 – 5 ml).

### **After collecting sputum specimen**

- Place the lid on the container and close it firmly;
- Wash your hands with soap and water;
- Store sputum specimens preferably in a refrigerator or else in a cool, safe and dark place, such as a cupboard that can be locked;
- Send specimens to the laboratory as soon as possible, and preferably not later than one week after the sputum was collected;
- Accompany each specimen by a duly completed 'Request Form for Sputum Examination'.

### **Transport of sputum specimens**

Sputum specimens in containers must be suitably packed and sent by any means available to the microscopy centre together with the 'Request Form for Sputum Examination'. Every staff member in every health unit is responsible for seeing that specimens are sent to the

laboratory as soon as possible. This is particularly important for specimen for culture since viability suffers rapidly if transit time is prolonged.

Lack of transport can be a difficult problem, but experience has shown that if a DTLC and DMO use all means of transport in their area, sputum specimens can reach the microscopy centre within a reasonable time (within four days).

### **Sputum smear microscopy**

Mycobacteria are "acid-fast bacilli" (AFB) seen as red rods when properly stained using Ziehl Neelsen (ZN) technique and visualized under bright field microscopy using an immersion magnification (x 100) .

In large diagnostic centres smear stained using auramine-O and are observed using fluorescence microscopy, whereby the bacilli appear as bright yellow rods against a dark background.

The number of bacilli seen in a smear reflects the infectiousness of the disease. It is estimated that 5,000 -10,000 bacilli need to be present in 1 ml of sputum to be able to detect them under a light microscope. A minimum of 100 fields should be examined before a smear is declared negative.

The results of positive sputum examination should be recorded in red ink in the laboratory register for easy identification. The laboratory staff is responsible to provide feedback of positive smear results to the clinician or TB/Leprosy coordinator for registration and initiation of treatment. Sputum results must be reported within 24 hours after the last sample is collected. If any of the sputum specimens is positive and the patient does not come back to collect the result, health staff should trace the patient using the address on the laboratory request form.

The following WHO/IUATLD recommended method of reporting should be used.

**Table 1: Reporting of smear results**

<b>Number of bacilli seen in smear</b>	<b>Results</b>	<b>Result Reported</b>
No AFB per 100 immersion fields	Negative	0
1–9 AFB per 100 immersion fields	Positive	Record exact number (1–9)
10-99 AFB per 100 immersion fields	Positive	1+
1-10 AFB per 1 immersion fields	Positive	2+
>10 AFB per 1 immersion field	Positive	3+

It is extremely important that the process of sputum collection, labelling, staining, administration and recording is accurately done. Mistakes in this process are a common

cause for false positive or false negative results and might either harm the patient or endanger the community.

### **False positive sputum smear microscopy result**

This means that the sputum result of the patient is positive but the patient does not have smear positive pulmonary tuberculosis. The common causes for false positive results are:

- Red staining of scratches on the slide
- Accidental transfer of AFBs from a positive slide to a negative one, usually in the laboratory
- Contamination of the slide or smear by environmental mycobacteria
- Contamination of the slide with food particles that are acid fast and stain red
- Mislabeling of specimens and recording errors
- Mix up of specimens.

### **False negative sputum smear microscopy result**

This means that the sputum result of a patient is negative even though the patient really has smear-positive pulmonary tuberculosis. This may arise from:-

- Sputum collection and storage problems
  - Patient provides inadequate sample
  - Sputum stored too long before smear microscopy, with overgrowth with other organisms
- Sputum processing in laboratory
  - Faulty sampling from specimen
  - Faulty smear preparation and staining
- Sputum smear examination problems
  - Inadequate time on examining the smear
  - Inadequate training of laboratory staff
- Administrative errors
  - Misidentification of patients
  - Incorrect labeling of specimens
  - Mistakes in documentation.
  - Mix up of specimens.

N.B. The sensitivity of sputum smear microscopy can be increased by concentrating the specimen by centrifugation at 3000g after decontamination with 5% sodium hypochlorite for 30 minutes. This method is highly recommended in diagnostic facilities with appropriate centrifuge machine.



## **Sputum culture**

Culture is a more sensitive method to detect mycobacteria than AFB microscopy and can detect as low as 10 bacilli/ml of sputum. However, culture methods are slow and expensive. Depending on the technique, it takes two to eight weeks before a result is obtained. Materials and equipment needed to perform culture are costly and require complex facilities with highly skilled staff. In Tanzania sputum culture for isolation of mycobacterium is performed on Lowenstein Jensen medium (a solid egg enriched) and normally for:

- Surveillance of tuberculosis drug resistance as an integral part of evaluation of NTLP performance.
- Follow-up of tuberculosis patients who fail to cure, relapse or become chronic excretors after a standardized course of treatment and who may be at risk of harbouring drug resistant organisms.

Other microbiological techniques that could be used include;

- cultivation in liquid media,
- serological techniques
- BacTec

These methods are rapid and results can be obtained from hours up to 14 days. However, their techniques need more advanced and sophisticated infrastructure and their introduction in the country requires careful planning and additional resources.

- molecular techniques – PCR, DNA probes

## **Chest X-ray**

Diagnosis of tuberculosis using chest X-ray is not reliable because there are other chest diseases that may produce similar changes. For instance, HIV infection further diminishes the reliability of chest x-ray in the diagnosis of pulmonary TB, as it often presents with an atypical pattern. Tuberculosis, therefore, should be diagnosed whenever possible by sputum examination. Chest x-ray findings suggestive of pulmonary tuberculosis in patients with a smear negative microscopy should always be supported by clinical findings and a medical officer experienced in TB should decide on the diagnosis. However, the utility of x-ray to hasten the diagnosis of smear negative pulmonary among HIV positive should be encouraged wherever available.

**There is no chest X-ray appearance typical for PTB.**

Most times a chest X-ray is not necessary when the sputum result is positive. However, one area in which x-ray and clinical information are important in the diagnosis of pulmonary smear negative tuberculosis, pulmonary tuberculosis of small children and other complicated cases of tuberculosis such as miliary tuberculosis.

Other conditions indicative of chest X-ray are when a patient is short of breath and is suspected to have conditions that need specific treatment - such as pneumothorax, a large

pleural effusion, pericarditis etc. A chest X-ray taken simultaneously with the collection of a sputum specimen is then justified.

### **Tuberculin skin test**

Tuberculin is a purified protein derived from attenuated mycobacteria. A person who has been infected with tuberculosis develops hypersensitivity to tuberculin, which is measured in millimeters of induration 48-72 hours after the tuberculin injection has been given in the skin. The test does not indicate the presence of tuberculosis disease; it only indicates mycobacterial infection. The test can be positive in a person who received BCG vaccination and who has never been infected with *M. tuberculosis*. It is often positive in individuals infected with environmental Mycobacteria Other Than Tuberculosis (MOTT) who are not infected with TB. On the other hand, a negative test does not exclude tuberculosis infection or disease. Immunosuppressive conditions such as HIV infection, malnutrition, severe bacterial infections e.g. TB itself, viral infections e.g. measles, cancers, and incorrect injection of PPD may suppress the tuberculin reaction.

The tuberculin skin test is valuable as a diagnostic tool in young children. In a child who did not receive a BCG, an induration of 10 mm or more is interpreted as positive. If the child did receive a BCG, the induration should be at least 15 mm to be positive. A positive tuberculin skin test should only be one clue to be interpreted in combination with other findings to favor the diagnosis of TB (see diagnosis of TB in children). Tuberculin test cannot be used to diagnose tuberculosis in adults for two reasons:

- A high proportion of adults is already infected with mycobacterium and therefore will test positive without suffering from tuberculosis
- People with impaired immune system due to various conditions such as those mentioned above may well have a negative tuberculin skin test despite of having active tuberculosis.

### **Instructions for doing a tuberculin skin test**

The standard Mantoux test is an intra-dermal injection of 0.1ml of a 1/10,000 dilution of PPD RT 23 in Tween 80, equivalent to 2 tuberculin units or 2 TU. The usual site is the first third of the antero-lateral part of the lower arm. Insert a needle in line and bevel outwards, keeping the needle almost parallel to the skin.

Push the needle in 2 to 3 mm and inject. If properly done a blanched weal is formed, in which the skin follicle openings can be clearly seen. The reading is done after 72 hours (in practice between 48 and 72 hours). The induration is identified by inspection and palpation. The largest diameter is measured and recorded in millimeters.

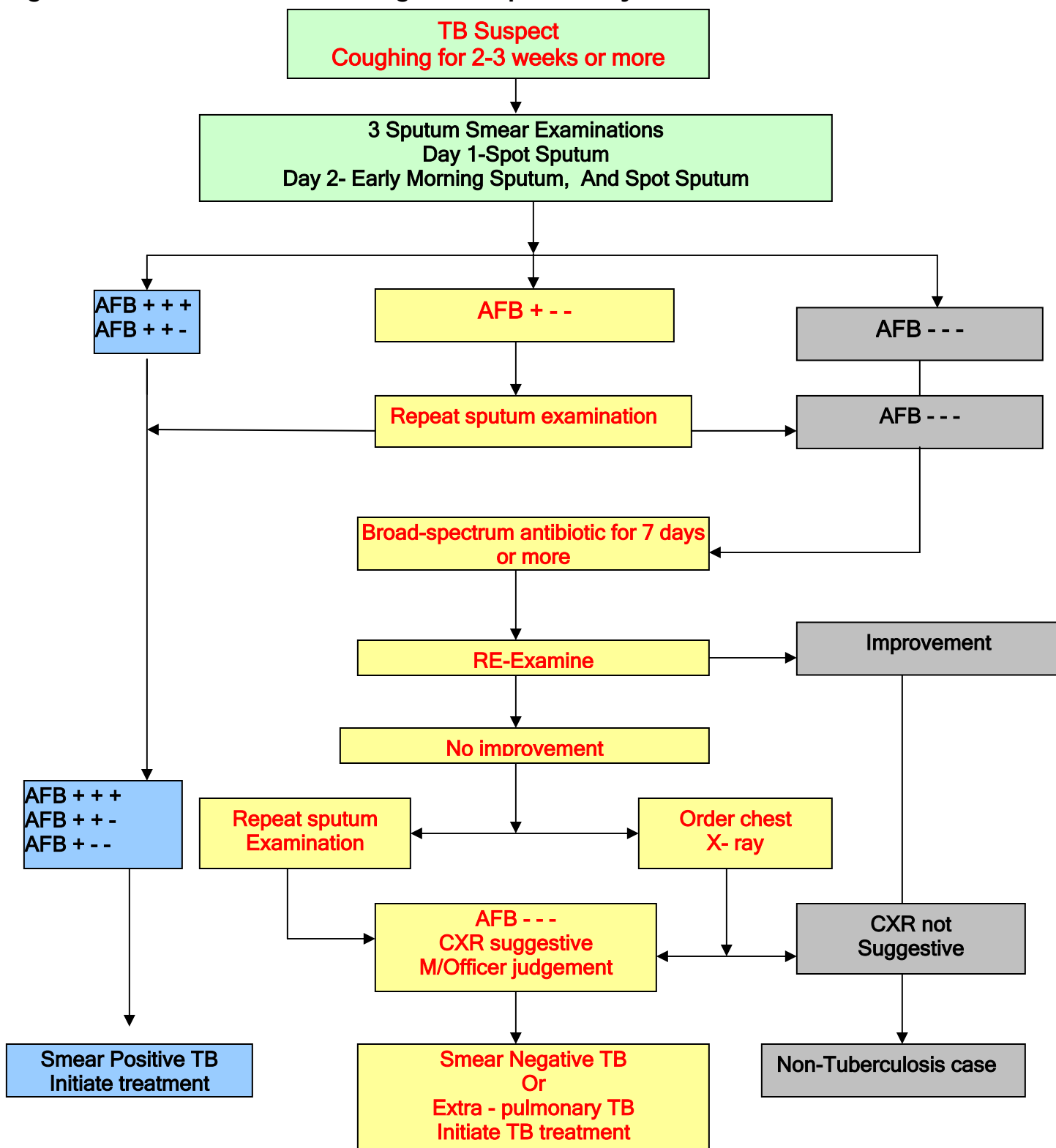
### **Erythrocyte Sedimentation Rate (ESR)**

The measure of the ESR is non-specific and should not be used as a routine diagnostic tool for tuberculosis. In most patients with bacterial infection (including TB) the ESR is raised but a normal ESR does not exclude TB disease.

**Biopsy**

Biopsy can play a role in the confirmation of the diagnosis of extra-pulmonary tuberculosis. Fine needle aspiration is another method used to obtain tissue/fluid for histopathology/cytology.

Figure 5: Flowchart on the diagnosis of pulmonary tuberculosis in adults



### **Extra-pulmonary tuberculosis**

Extra-pulmonary TB is tuberculosis in organs other than the lungs. The diagnosis is based on clinical evidence and exclusion of other possible causes. Extra-pulmonary TB is common in HIV-positive patients. If a patient has extra-pulmonary TB as well as pulmonary TB should be classified as a pulmonary tuberculosis case. It is therefore important to examine sputum specimens from patients with extra-pulmonary TB.

### **TB-lymphadenitis:**

Usually TB lymphadenitis presents as a group of firm to fluctuant, tender lymph nodes that might break through the skin. This can result in a chronic sinus but most heal leaving a scar behind. The differential diagnosis for TB lymphadenitis is persistent generalized lymphadenopathy (PGL), lymphoma, Kaposi sarcoma, metastases, and sarcoid or drug reaction.

TB lymphadenitis can be diagnosed by aspirating a little material from a fluctuant lymph node using a standard G19 needle. The material is deposited on a slide where a routine ZN staining can detect AFB in 50-70% of the cases. Where possible, patients should be referred to a larger centre for biopsy and histological investigations. The observation of any caseation is enough for the diagnosis of TB. If there is no caseation the content of the lymph node can be smeared on a slide and stained using the ZN technique for examination of AFB.

### **Pleural effusion, pericardial effusion, tuberculous ascites**

Inflammatory tuberculous effusion may occur in the pleural, pericardial or peritoneal cavities. These conditions are more frequently seen in HIV positive individuals. The main differential diagnoses are malignancy, post-pneumonic effusion, congestive heart failure and amoebic abscess.

The diagnosis is usually by exclusion of other conditions. Aspirated fluid, which is most times clear yellow straw coloured, can be investigated on AFB (rarely seen), protein level and cells. High protein level (>30 g/l) with predominant lymphocytes in the fluid aspirate is suggestive of tuberculosis.

In Tanzania, where there are limited diagnostic facilities, exudative pleural and pericardial effusion and ascites are suggestive of tuberculosis.

### **Spinal TB:**

Tuberculosis of the spine (Pott's disease) is a severe form of tuberculosis. The TB infection starts from the inter-vertebral disc and spreads along the anterior side to the adjacent vertebral bodies. The collapse of the vertebral bodies might compress the spine causing paralysis.

The diagnosis is made with a plain X-ray of the spine that shows anterior erosion of two adjacent vertebral bodies with a narrowing or disappearance of the disc space. The main

differential diagnosis is a malignancy, which most times erode the spine bodies leaving the inter-vertebral disc space intact.

### **Miliary TB:**

Miliary TB is blood-borne dissemination of tuberculosis from either a primary infection or erosion of a secondary tuberculous lesion into a blood vessel (TB bacteremia). Miliary TB is common in late stage of HIV/AIDS disease. The patient presents with signs and symptoms of a septicemia with fever, wasting, confusion etc.

The diagnosis is sometimes made with the help of a chest X-ray that shows uniformly distributed miliary (like millet seeds) shadows. However, this is seen in only approximately 25% of the cases. Bacteriological confirmation is sometimes possible from sputum, blood, CSF or bone marrow.

### **TB meningitis:**

TB of the meninges may occur from a rupture of a cerebral tuberculoma into the subarachnoid space or blood born dissemination from active infection from elsewhere in the body.

Most times, patients present with headaches, decreased consciousness and neck stiffness. The diagnosis usually rests on clinical grounds and microscopic examination of cerebrospinal fluid and biochemical tests.

It is worthy mentioning that most forms of extra-pulmonary tuberculosis are paucibacillary, it is therefore much more difficult to confirm the diagnosis by demonstration of bacilli on microscopy. However, culture can be performed if a biopsy is taken or an exudates or caseating material is sampled.

If there is no access to laboratory where culture or histology can be performed the diagnosis is based on strong supportive (clinical, biological and radiological) evidence which is used to decide on what treatment to give.

### **1.3.2 The Diagnosis of Tuberculosis in Children**

The diagnosis of TB in children can be very difficult owing to the wide range of symptoms. Sputum cannot often be obtained from children and in any case it is often negative even on culture. Symptoms in children are not typical. The diagnosis should therefore be based on clinical findings (especially failure to thrive or weight loss), family history of contact with a smear positive case, X-ray examination and tuberculin testing, culture (if available) and non-response to broad spectrum antibiotic treatment. A score chart below can help to reach the diagnosis of tuberculosis. Older children who are able to cough up sputum should go through the same assessment as adults using smear microscopy as the "gold standard".

### Score chart for the diagnosis of tuberculosis in children

A score system is one way to try to improve the diagnosis of tuberculosis in children. The basis of the score system is careful and systematic collection of relevant diagnostic information that helps to guide careful clinical judgement. A score above a certain threshold indicates a high likelihood of TB but is never evidence.

**Table 2: Score chart for the diagnosis of Tuberculosis in children**

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

*A score of 9 or more indicates a high likelihood of tuberculosis*

#### 1.4. Disease Classification

##### **Smear positive pulmonary tuberculosis (PTB+)**

Tuberculosis in a patient with at least two initial smear examinations positive by direct microscopy for Acid Fast Bacilli (AFB+),

OR

Tuberculosis in a patient with one initial smear examination positive by direct microscopy AND positive by culture for mycobacteria.

OR

Tuberculosis in a patient with one initial smear examination positive by direct microscopy for Acid Fast Bacilli (AFB+) AND X-ray abnormalities suggestive of active tuberculosis as determined by the treating Medical Doctor.

##### **Smear negative pulmonary tuberculosis (PTB-)**

Tuberculosis in a patient with three initial negative smear examinations by direct microscopy for Acid Fast Bacilli (AFB-) AND non-response to a course of broad-spectrum antibiotics, AND again three negative smear examinations by direct microscopy, AND X-ray abnormalities suggestive of active tuberculosis as determined by the treating Medical Doctor.

OR

Tuberculosis in a patient with three initial smear examination negative by direct microscopy but positive by culture for mycobacteria.

##### **Extra-pulmonary tuberculosis (EPTB)**

Tuberculosis in organs other than the lungs proven by one culture positive specimen from an extra-pulmonary site or histopathological evidence from a biopsy.

OR

Tuberculosis based on strong clinical evidence, including macroscopic evidence of specimen inspection, consistent with active extra-pulmonary tuberculosis AND the decision by a Medical Doctor to treat with a full course of anti-tuberculous therapy.

Note that in all suspect extra-pulmonary cases three sputum specimen should be examined in order to rule out pulmonary tuberculosis. Note in addition that, cases of pleurisy should be classified as extra-pulmonary tuberculosis, provided that sputum smears are negative.

#### 1.5. Case Definition

**New case:** a patient who has never had treatment for tuberculosis before or has been on treatment for not more than 4 weeks.

**Relapse:** a patient declared cured or treatment completed but who reports back to the health service and is found to be AFB positive.

**Failure:** a patient who, while on treatment, is AFB positive at 5 months or later during the course of treatment.



**Return after default:** a patient who returns to treatment, bacteriologically positive, after having interrupted treatment for two months or more and who had been on treatment for more than 4 weeks.

**Transfer in:** a patient received from another region, who has already started treatment and has already been registered in the region of origin. The results of treatment of all such cases should, if possible, be reported back to the region where the patient was notified. Within a region no patient can be considered as transferred in.

**Other:** Any TB patient who does not fit in one of the above case definitions.

- A patient with sputum smear negative TB or EPTB previously treated for sputum smear positive tuberculosis.
- A patient with sputum smear negative TB or EPTB previously treated for sputum smear negative TB or EPTB.
- A patient who remains sputum smear positive after completing a re-treatment regimen, usually referred to as "chronic case" or "chronic excretor".

**Note:** Although smear negative pulmonary and extra-pulmonary cases may also be relapses, failures or chronic cases, this should be a "rare" event, supported by pathological or bacteriological evidence.

## 1.6. Documentation on Diagnosis:

In each district every new patient and every patient who is restarted on treatment should be entered in the District Tuberculosis Register, kept by the DTLC, and in the Unit Tuberculosis register, kept at the respective health unit. The staff of the treating health unit will also complete the Tuberculosis Treatment Card. For details of the District Tuberculosis register, Unit Tuberculosis Register and Tuberculosis Treatment Card, see the appendix. The DTLC must visit the microscopy centres in his district (2 or 3 on average) every month and update the District Tuberculosis Register.

### Recording and reporting of tuberculosis cases

The main purpose of recording is to be able to collect information that enables the NTL to monitor activities at all levels. Accurate record keeping of every single patient, maintaining up-to-date registers, timely and correct reporting to the relevant levels is essential for every tuberculosis control programme. The health workers at the health facility must register immediately every tuberculosis patient who is started on treatment in the Tuberculosis Unit Register (TB03). The health worker also completes a Tuberculosis Treatment Card (TB01), which remains at the centre where the patient is receiving his/her treatment. After the patient has been recorded in the Tuberculosis Unit Register, he/she receives a Tuberculosis Identity Card (TB02) duly filled by the health worker. Treatment supporters are also responsible for filling TB identity cards of the patients they supervise.

The DTLC is responsible for the registration of every patient diagnosed with tuberculosis in the health facilities in the District Tuberculosis register (TB 04). The DTLC also checks the Tuberculosis Unit Register (TB03) to ensure that it is correctly filled, is properly maintained and is up-to-date.

On a quarterly basis the DTLC notifies the number of cases registered within his district to the RTLC by completing the Tuberculosis Case Notification Report (TB07). Simultaneously s/he also notifies the treatment outcome of TB patients that started treatment 4 quarters earlier by completing the Tuberculosis Treatment Result Report (TB08). These forms have to reach the RTLC within one month into the new quarter.

At regional level the RTLC receives all these reports, checks them and compiles quarterly regional reports using the same forms. He/she sends the filled forms to TLCU within two months into the new quarter. (See page 114)

At national level all incoming data is entered in the NTLP management information system file. TLCU produces a summary of all collected data in the Annual Report, which should be produced within 6 months into the New Year. The summarized data is used for planning and policy development.

## **1.7. Patient Education**

It is important that every patient is properly educated on the general knowledge of the disease and its management before commencing anti-TB treatment. This leads to a better understanding of the problem, change of attitude and adherence to treatment. Every health worker who diagnoses, registers and initiates treatment for a new patient must give health education.

The DTLC and the health staff administering the drugs are responsible for the continuation of education to the patient throughout the treatment.

Apart from individual education, patient education can also be given to a group of patients attending daily DOT clinics or in the ward to in-patients.

Various educational aids such as leaflets, posters and videos are important in supporting the patient education and should be used to their full potential.

### **Some of the important aspects to consider during patient education:**

- Definition, cause, source and mode of transmission of tuberculosis
- Measures to limit spread of infection
- Importance of bringing household contacts including children for examination
- Medications used (show tablets), dose and duration both for intensive and continuation phases
- Importance of daily DOT and adherence during the whole period of treatment

- Curability of tuberculosis even among HIV positive patients
- Major side effects of anti-TB drugs.
- Educate patients that drugs are provided at no cost to the patient
- Importance of submitting sputum specimen at 2/3 and 5 months for new smear positive patients and 3, 5 and 7 months for re-treatment of smear positive patients
- The importance of keeping Tuberculosis Identity card (ID).
- The procedure for transferring patients to another treatment centre
- The relationship between tuberculosis and HIV.
- An introduction or reference to HIV pre-test counseling.
- The importance of a good balanced diet and abstinence of alcohol and smoking.

**Some of the important aspects to consider for training of treatment supporters:**

- Definition, cause, source and mode of transmission of tuberculosis
- Measures to limit spread of infection
- Why is it so important for a TB patient to take the correct TB drugs for the full duration of treatment
- What is their role as treatment supporter
- How to use TB treatment card
- Making sure that the patient goes to health facility when a follow up sputum examination is due
- How to give TB drugs
- What are the possible side effects of the drugs and need for referral

**1.8. Treatment of Tuberculosis**

**1.8.1. Basic principles of TB control**

Early case finding and adequate treatment of tuberculosis patients is the corner stone of tuberculosis control. The aim of treatment is to cure TB patients, to prevent death from active TB or its late effects and to prevent further transmission of tuberculosis to the community. The DOTS strategy is the gold standard to achieve these aims and to prevent the development of anti-TB drug resistance.

In order to achieve effective treatment of tuberculosis, adequate chemotherapy should be prescribed in appropriate combination of at least three anti tuberculosis drugs (Mono-therapy must be avoided). Every confirmed tuberculosis patient should take the drugs regularly for a sufficient period of time.

In the past some clinicians advocated the so called "treatment trial" as a diagnostic manoeuvre. This approach lead to unnecessary treatment of many patients due to the tendency to jump too quickly to treatment trial without the necessary careful and thoughtful approach to diagnosis. Clinicians have to come to a decision on whether to put a patient on

treatment or not. No trials of therapy should be entertained. A patient either has TB and should be treated, or does not have TB and should not be treated.

### **Short-course chemotherapy**

Providing short-course chemotherapy is an important component of the DOTS strategy. It is the most effective way to ensure rapid sputum conversion of infectious patients, thereby stopping further transmission of *M. tuberculosis* to the community. The first short-course regimen of 8 months was introduced in Tanzania in 1987 for sputum smear positive patients only. Non-infectious patients also receive a short-course regimen since July 2001. A six months short-course regimen for new smear positive, smear negative and extrapulmonary TB was introduced in 2006.

Short-course chemotherapy has a very high success rate if properly applied in a patient with tuberculosis, diagnosed in time. The length of the regimen varies from 6 to 8 months depending on the category of disease. The six months regiment, which contains rifampicin throughout, is slightly more effective in preventing re-activation of dormant bacilli, reducing relapse especially in HIV positive tuberculosis patients.

### **Drug resistance**

There are two types of drug resistance

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

***Drug resistance among previously treated cases***(formerly "*acquired drug resistance*") Is that found in a patient who has previously received at least one month of TB therapy.

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

About 90% of newly diagnosed sputum positive cases of pulmonary tuberculosis are sensitive to Isoniazid, Rifampicin, Streptomycin and Ethambutol. Mono-resistance to Isoniazid is about 5% and that of Ethambutol is less than 1% (0.2%). Multidrug resistant TB (resistance to at least Rifampicin and Isoniazid) is about 1% in Tanzania.

### **Prevention of drug resistance**

The current anti-TB drugs are still effective in treating tuberculosis in Tanzania due to strict use of these drugs in the health system under close guidance of the NTLP. Essential elements to prevent drug resistance are:

- Prescription of the NTLP recommended regimens.
- Daily Direct Observation (DOT) of the treatment intake by a health worker or a trained community member, during all episodes where rifampicin is used

- Uninterrupted supply of good quality anti-TB drugs for the full duration of the treatment.

### **Direct Observation of Treatment (DOT)**

DOT is another important component of the DOTS strategy. Direct observation of treatment means that a supervisor watches the patient swallow the tablets. This ensures that a TB patient takes the right drugs, in the right doses, at the right intervals. In principle, DOT is always required when rifampicin is given, since rifampicin is the strongest and most valuable of currently used anti-TB drugs and one cannot afford to risk the development of rifampicin resistance because of poor compliance to medication.

This implies that DOT is provided throughout 6 months treatment for new cases and 8 months for re-treatment regimen. To ensure adherence to treatment, DOT should be provided as convenient as possible to the patient (close to the patients' home or workplace). The type of DOT is recorded in the TB register and patients identity card.

DOT services are provided through:-

1. Health facility: Health facility based DOT can either be ambulatory or inpatient (very sick or who live too far away from a DOT clinic to attend daily for ambulatory DOT). The service should be organised in such a way that is convenient to the patients. It is the duty of the health worker to make sure that drugs are available for the whole period of treatment. The health staffs should adhere to NTLP guidelines on how to observe treatment, updating ID card and treatment card.
2. Community/home based DOT: The patient in collaboration with health worker can identify a volunteer from the community or home of the patient to observe treatment. The "treatment supporter" needs to receive clear instructions together with the patient before starting this type of DOT service. The name and address of the person should be recorded on the patients' treatment card

Tuberculosis treatment should be given preferably seven days per week and never less than 6 days per week. Health staff on duty on weekend or public holidays is responsible for the provision of DOT. The arrangements for DOT must be fully integrated in the management of health services at each health facility. Health facilities providing DOT should be supervised at least once per month by the DTLC.

## **Community Tuberculosis Care**

The NTLP is implementing community based DOT to complement health facility based DOT. Community based DOT is implemented as part and parcel of routine NTLP activities in order to expand DOTS activities beyond health facilities and to involve communities. There is a growing recognition that DOT puts too much demand on patients and therefore should be adapted to the needs of patients and to the working conditions of health care workers to minimize disruption of the services. NTLP is recommending Patient Centred TB Treatment (PCT) approach as part of community based DOT activities.

### **What is Patient Centred Treatment?**

Patient Centred TB Treatment (PCT) means that TB patients are given an opportunity to choose where their daily treatment is supervised and by whom. This means that, patients can choose to come to the health facility for their daily DOT or they can take their treatment at home with a treatment supporter of their own choice (home-based DOT).

The supporter needs to collect the drugs at weekly intervals from the health facility, to ensure that the patient takes the drugs as prescribed and to keep record of the daily intake of drugs.

As patients will be able to choose the DOT option which suits them best in view of the constraints they face in daily life, it should help them better adhere to treatment and be cured of TB. It should also reduce the burden at health facilities.

Patients would typically choose a family member or spouse to be their supporter as they can provide them with holistic support without the need for a financial incentive. The good health of the individual is considered to be enough "payback". This overcomes one of the key constraints with other community based DOT model of providing incentives to supervisors which may not be sustainable on a large scale.

Patients opting for home-based DOT will continue to have regular contact with the health services, though not on a daily basis. As the burden of supervising the daily drug intake for some patients will be reduced, health workers will have more time to counsel patients.

## **Key steps to provide home-based DOT**

### ***Ask patients to identify a supporter***

Ask the patient to identify a treatment supporter who will:

- Remind and watch the patient take their drugs everyday
- Mark the Identity card after the drugs are taken
- Collect the drugs every week from the health facility
- Inform the health worker of any problems encountered
- Accompany the patient to the health facility when needed

### ***Orient the supporter***

- Carefully explain the tasks above to the supporter.
- Check that the supporter can carry out the tasks.
- Demonstrate how to provide DOT and how to mark the drug intake.
- Explain possible side-effect and what needs to be done.
- Make sure that the supporter fully understand the tasks.

### **Provide enough drugs to last until the next visit.**

- Cut up the blister pack to prepare daily blister strips, which contain the exact number of tablets that a patient needs to take each day.
- Explain how many tablets the patient should take each day.
- Agree on the date of the next visit and note this on the Identity and treatment cards.
- Ask patients to bring back the empty blister packs and Identity card during each visit to the health facility.
- Draw a horizontal line in the TB treatment card to cover the number of days drugs have been supplied

### ***Keep regular contact with the patient and supporter***

- Ask the supporter and patient to return every week to collect more drugs in the intensive phase and every two weeks in the continuation phase.

### ***What to do during the visit of the supporter / patient to health facility?***

- Take the time to talk to the supporter and patient on each visit.
- Help them to resolve any problems that they have encountered
- Check the daily treatment record when re-supplying drugs.
- Check that the TB Identity card record corresponds to the empty blister packs.
- Discuss any problems in filling out the treatment record.
- Check and put "X" on the horizontal line of the TB treatment card where patient did not swallow the drugs
- Provide the supporter with enough drugs until the next scheduled visit

### **When to start the continuation phase?**

Patients (except those who are sputum smear positive), start the continuation phase after they complete the two month intensive phase of treatment.

For new sputum smear positive patients need to have a follow up sputum smear examination after the completion of the intensive phase of treatment (end of 2<sup>nd</sup> month),

- If the result is negative, start the continuation phase of treatment.
- If the result is positive, extend the intensive phase for an additional one month.
- If the follow-up sputum examination is still positive at the end of 3<sup>rd</sup> month, start the continuation phase. Send a sputum sample for culture and sensitivity testing to the earmarked reference laboratory.

For Re-treatment sputum smear positive patients send a follow up sputum smear examination after the completion of the intensive phase of treatment (end of 3<sup>rd</sup> month),

- If the result is negative, start the continuation phase of treatment.
- If the follow-up sputum examination is still positive at the end of 3<sup>rd</sup> month, start the continuation phase. Send a sputum sample for culture and sensitivity testing to the central reference laboratory.

### **How to provide treatment in the continuation phase?**

Show patients and /or treatment supporter the new drugs to be taken, tell them how many tablets they need to take and for how long.

Explain that daily DOT is needed in the continuation phase as well.

Offer patients on health facility based DOT the possibility of home-based DOT with a supporter of their choice.

If they choose home-based DOT, follow the steps mentioned above.

The supporter needs to collect the drugs once every two weeks.

Follow the same procedure mentioned above for home-based DOT.

**For re-treatment patients, health facility based DOT will be used for both intensive and continuation phase**

### **When is treatment completed?**

Patients (except those who are sputum smear positive) will complete treatment after taking the drugs as directed for the full 6 months under DOT.

For new smear positive patients need to have further follow-up sputum examinations at the end of the 5<sup>th</sup> month to determine if they have been cured.

For re-treatment smear positive patients need to have further follow-up sputum examinations at the end of the 5<sup>th</sup> and 7<sup>th</sup> month to determine if they have been cured.

### **What to do at the end of treatment?**

Congratulate the patient and the supporter.

Record the treatment outcome on the treatment card.

For additional information on community TB care is available in community based DOT and PCT guidelines

## **1.8.2. TB treatment categories**

TB patients are grouped in four main categories.



- Category I**..... New sputum smear positive PTB and New patients with severe forms of EPTB
- Category II**..... Relapse, Treatment failure and Sputum smear positive return after Default
- Category III**..... New sputum smear negative and EPTB (less severe forms)
- Category IV**..... Chronic cases

**Table 3: Severe and less severe extra pulmonary TB cases**

Severe extra-pulmonary TB	Less severe extra-pulmonary TB
<ul style="list-style-type: none"> <li>• Meningitis</li> <li>• Miliary</li> <li>• Pericarditis</li> <li>• Bilateral or extensive unilateral effusion</li> <li>• Spinal</li> <li>• Intestinal</li> <li>• Genito-urinary tract</li> </ul>	<ul style="list-style-type: none"> <li>• Lymphnode</li> <li>• Unilateral pleural effusion</li> <li>• Bone (other than spine)</li> <li>• Peripheral joint</li> <li>• Adrenal gland</li> </ul>

**1.8.3. TB treatment regimens**

TB regimens are divided into the initial phase (intensive) and continuation phase. In the intensive phase the majority of TB bacilli are rapidly killed and infectious patients become non-infectious within one to two weeks. There are always bacilli that remain metabolic inactive, hiding in tissue or macrophages. These are called persisters or semi-dormant and they need much longer treatment before they are killed. The drugs in the continuation phase kill the persisters and thus preventing a relapse after completion of treatment.

There are six essential, first-line anti-TB drugs. Thiacetazone was formerly used in continuation phase of the standard treatment but was abandoned because of the severe side effects in HIV positive TB patients.

There are many combinations possible to come to an adequate short course regimen. In Tanzania the NTLP, uses four regimens depending on the patient’s treatment category in line with IUATLD and WHO recommendations. Currently RHZE, RH and EH are available as a fixed-dose combination (FDC). The other recommended FDC is RHZ indicated for children.

**Table 4: Mode of action, potency and recommended dose of anti TB Drugs**

Essential Anti-TB drugs	Mode of action, most important target	Potency	Recommended dose in mg/kg	
			Daily	3/weekly
Isoniazid (H)	Bactericidal, kills metabolic active bacilli	++++	5 (4-6)	10 (8-12)
Rifampicin (R)	Bactericidal, kills semi-dormant bacilli	++++	10 (8-12)	10 (8-12)
Pyrazinamide (Z)	Bactericidal, kills intracellular bacilli	+++	25 (20-30)	35 (30-40)
Streptomycin (S)	Bactericidal, kills metabolic active bacilli	+++	15 (12-18)	15 (12-18)
Ethambutol (E)	Bacteriostatic	++	15 (12-18)	30 (25-35)
Thiacetazone (T)	Bacteriostatic	++	3	NA

### Fixed Dose Combination (FDC)

Fixed Dose Combination is the combination of 2, 3 or 4 drugs in the appropriate dose in one tablet and is called FDC. Starting from 2006 Tanzania introduced in a phased manner 4 drug FDCs for all TB patients in line with the WHO/IUATLD recommendations in order to improve overall results and reduce the risk of multi-drug resistance. These drugs are provided in blister packs.

The advantages of 4FDCs are:

- They improve compliance with treatment as most patients need to take only 3 or 4 tablets per day during intensive phase of treatment instead of 10-12 tablets if single tablets are used.
- Errors in prescribing or supplying drugs are less likely as the selection of pills and dosage recommendation are more straightforward, thus simplifying the management of drug supply considerably.
- Drug resistance is less likely to occur as patient swallow all drugs, eliminating the risk of mono-therapy which reduces the risk of emerging drug-resistance considerably.
- Improved drug management because ordering, procurement, distribution and dispensing/handling at different levels are easier as there are fewer items with a single expiry date to deal with.

FDCs have the disadvantage that if a severe side effect occurs, all drugs have to be stopped and the patient has to continue treatment with re-introducing single drugs as described in Table 11. In order to manage side effects, 5% of single drugs will be supplied to all hospitals.

The programme only uses FDC formulations recommended by WHO, which are:

- 4FDC RHZE: rifampicin 150 mg-isoniazid 75 mg-pyrazinamide 400 mg-ethambutol 275 mg
- 3FDC RHZ: rifampicin 150 mg- isoniazid 75 mg-pyrazinamide 400 mg
- 3FDC RHZ for children only: rifampicin 60 mg- isoniazid 30 mg-pyrazinamide 150 mg
- 2FDC RH for daily use: rifampicin 150 mg- isoniazid 75 mg
- 2FDC RH for three weekly use: rifampicin 150 mg- isoniazid 150 mg
- 2FDC RH for children: rifampicin 60 mg- isoniazid 30 mg
- 2FDC EH: ethambutol 400 mg- isoniazid 150 mg

This means that, regimens of Category I and Category III will be shortened from 8 to 6 months with the introduction of RH in the continuation phase instead of EH.

**The new regimens for Category I, Category II and Category III are:**

**Category I: 2 RHZE/4 RH**      New sputum smear positive PTB  
 New seriously ill patients with severe forms of tuberculosis

The 2RHZE/4RH regimen requires daily observed treatment by a health worker or by treatment supporter throughout the 6 months duration.

**Table 5: Dose-body weight relation for patients treated with category I treatment regimen.**

Duration of treatment	Drugs	CHILD			ADULT	
		Pre-treatment weight				
		5-10 kg	11-20 kg	21-30 kg	31-50 kg	>50 kg
2 months intensive phase, daily observed	RHZE 150/75/400/27 5	½ tablet	1	2	3	4
4 months continuation phase, daily observed OR  6 months continuation, monthly supply, self administered	RH 150/75	½ tablet	1	2	3	4
	EH 400/150	¼ tablet	½	1	2	2

**Category II 2 SRHZE/1 RHZE/5 RH<sub>3</sub>E<sub>3</sub>**

**Relapse, Treatment failure and sputum smear positive return**

**Table 6: Dose-bodyweight relation for patients treated with category II treatment regimen.**

Duration of treatment	Drugs	CHILD			ADULT	
		Pre-treatment weight			Pre-treatment weight	
		5-10 kg	11-20 kg	21-30 kg	31-50 kg	>50 kg
2 months intensive phase, daily observed	S i.m	15 mg/kg	15 mg/kg	500 mg	750 mg	1 g*
	RHZE 150/75/400/275	½ tablet	1	2	3	4
1 month intensive phase, daily observed	RHZE 150/75/400/275	½ tablet	1	2	3	4
5 months continuation phase, 3 weekly observation	RH 150/150**	½ tablet	1	2	3	4
	E 400	¼ tablet	½	1 ½**	3**	4**

\* Patients older than 50 years of age should not exceed a dosage of 750 mg Streptomycin. Streptomycin should not be given to pregnant women.

\*\* Notice the higher dose-formulation of RH increase of dosage of ethambutol in the three weekly regimen!

The re-treatment regimen is the last opportunity for a patient to get cured. Therefore re-treatment must be administered under strict DOT during the entire treatment. The NTLP recommends three months admission during intensive phase especially for those patients with a history of poor adherence. The continuation phase is administered daily or thrice weekly under health facility supervision (DOT) on ambulatory bases.

Patients with a relapse or failure might possibly harbour resistant bacilli. It is therefore important that before any patient is started on a category II re-treatment regimen, at least one sputum sample is collected and sent to CTRL for culture and susceptibility testing (see drug-resistance).

**Category III 2 RHZE/4 RH**

New sputum smear negative and extra-pulmonary TB (less severe forms)

**Table 7: Dose-bodyweight relation for patient treated with category III treatment regimen.**

Duration of treatment	Drugs	CHILD			ADULT	
		Pre-treatment weight			Pre-treatment weight	
		5-10 kg	11-20 kg	21-30 kg	31-50 kg	>50 kg
2 months intensive phase, daily observed	RHZE 150/75/400/27 5	½ tablet	1	2	3	4
4 months continuation phase, daily observed OR	RH 150/75	½ tablet	1	2	3	4
6 months continuation, monthly supply, self administered	EH 400/150	¼ tablet	½ tablet	1	2	2

The 2RHZE/4RH regimen requires daily observed treatment by a health worker or by treatment supporter throughout the 6 months duration.

**Category IV: Chronic patients**

These are patients who remain or become sputum smear positive after completing a fully supervised re-treatment regimen.

It is important to identify patients with Multi Drug Resistant (MDR) TB among chronic patients. Not every chronic patient is an MDR-TB case. Many of these patients, although persistently smear positive, may still be partially or fully sensitive to the first line anti-TB drugs. This situation may occur due to poor adherence to therapy (patients who collect their drugs but don't take them "hidden defaulters") or chronic diseases such as chronic malabsorption which is quite common in HIV positive patients.

**Multi Drug Resistant TB**

The emergence of drug resistant mycobacterium tuberculosis, especially multi-drug resistant (MDR) strain is fairly a new phenomenon and indeed poses a threat to the success of National TB and Leprosy programme

Drug resistant TB is caused by inadequate therapy for drug susceptible TB. Three terms describe its variation:

1. Mono resistant; resistant to only one anti tuberculosis drug.
2. Multi drug resistant (MDR); resistant to at least isoniazid (INH) and rifampicin (RIF). These drugs are considered to be the 2 most effective anti tuberculosis drugs
3. Poly-resistant; resistant to more than one anti tuberculosis drug, but not combination of INH and RIF.

### **Extent of MDR-TB problem**

The problem of drug resistant TB is growing in several hot spot countries throughout the world. About 98% of all TB deaths occur in developing countries where surveillance for resistance of TB isolates to anti TB drugs is uncommon

### **Risk factors in persons with history of tuberculosis**

Suspicion for drug-resistant TB should be high if the patient has one or more of the following characteristics in current or prior treatment:

- large bacillary load with extensive bilateral or cavity disease
- lack of conversion of smear/culture to negative during therapy
- Lack of improvement or partial improvement in TB symptoms.
- Worsening of TB symptoms or X-ray findings
- Non adherence or intermittent or erratic drug taking.
- Lack of directly observed therapy (DOT) or poorly supervised treatment
- History of an inappropriate treatment regimen

### **Risk factors in person WITHOUT prior TB history**

Clinical suspicion of drug resistance should occur when patient with TB symptoms and sign has history of or more of the following:

- Exposure to a person with documented drug resistant TB
- Residence or working in an institution or setting where drug resistant TB is documented

### **Diagnosis of MDR-TB**

The diagnosis of MDR-TB frequently requires a high index of suspicion. Once it is suspected, sputum for acid fast bacilli (AFB) smear, culture and susceptibility testing are collected. Prompt turnaround of time for laboratory results is of paramount importance in rapid diagnosis and appropriate treatment of multi-resistant TB (MDR-TB). In order to ensure rapid diagnosis of *M. tuberculosis* and drug resistant TB, the following turnaround times should be achieved by laboratories:

- a) Sputum specimen should be read WITHIN 24 hours of collection
- b) AFB smear reports should reach physician within 24 hours of specimen receipt in the laboratory
- c) Positive culture identification should occur within 14 days of specimen collection.
- d) Isolate should be definitively identified as *M. tuberculosis* within 17-21 days of specimen collection
- e) Drug susceptibility test results should be reported to physician within 28 days of specimen collection.

### **Treatment of patients presenting with a second episode of active tuberculosis**

Patients presenting with a second episode of active tuberculosis may be due to relapse or re-infection. This is particularly true especially for people living with HIV/AIDS (PLHA). It is therefore important to take an exact history and review the previous case definition and

treatment regimen of the patients who present with the second episode of active tuberculosis. This will determine the choice of the current treatment regimen, which should be superior to the previous regimen. This implies that some patients with a case definition “OTHER” will qualify for the Category II retreatment regimen when they were treated with category I regimen in the past. Others will receive a Category I or III treatment regimen. The choice of treatment is made by patient’s physician in collaboration with the DTLC. In all situations a sputum specimen should be taken for culture.

**Table 8: Case definition and treatment of patients with a second episode of active TB**

PREVIOUS DIAGNOSIS AND TREATMENT	PRESENT DIAGNOSIS AND TREATMENT OF CHOICE	CASE DEFINITION
<p><b><u>SM+ PTB</u></b></p> <ul style="list-style-type: none"> <li>• 2RHZE/6EH</li> </ul>	<p><b><u>SM+ PTB</u></b></p> <ul style="list-style-type: none"> <li>• 2SRHZE/1RHZE/5RH<sub>3</sub>E<sub>3</sub></li> </ul>	<b>RELAPSE</b>
<p><b><u>SM+ PTB</u></b></p> <ul style="list-style-type: none"> <li>• 2RHZE/4RH</li> </ul>	<p><b><u>SM+ PTB</u></b></p> <ul style="list-style-type: none"> <li>• 2SRHZE/1RHZE/5RH<sub>3</sub>E<sub>3</sub></li> </ul>	<b>RELAPSE</b>
<p><b><u>SM- /EP TB</u></b></p> <ul style="list-style-type: none"> <li>• 2RHZE/4RH →</li> <li>• 2RHZ/6EH →</li> <li>• 2RHEZ/6EH →</li> <li>• 2RHZ/4RH →</li> </ul>	<p><b><u>SM+ PTB</u></b></p> <ul style="list-style-type: none"> <li>• 2SRHZE/1RHZE/5RH<sub>3</sub>E<sub>3</sub></li> </ul>	<b>RELAPSE</b>
<p><b><u>SM+PTB</u></b></p> <ul style="list-style-type: none"> <li>• 2RHZE/6EH →</li> <li>• 2RHZ/6EH →</li> <li>• 2RHZE/4RH →</li> </ul>	<p><b><u>SM- /EP TB</u></b></p> <ul style="list-style-type: none"> <li>• 2SRHZE/1RHZE/5RH<sub>3</sub>E<sub>3</sub></li> </ul>	<b>OTHER</b>
<p><b><u>SM- /EP TB</u></b></p> <ul style="list-style-type: none"> <li>• 2RHZE/4RH →</li> <li>• 2RHZ/6EH →</li> <li>• 2RHZE/6EH →</li> <li>• 2RHZ/4RH →</li> </ul>	<p><b><u>SM- /EP TB</u></b></p> <ul style="list-style-type: none"> <li>• 2SRHZE/1RHZE/5RH<sub>3</sub>E<sub>3</sub></li> </ul>	<b>OTHER</b>

**Treatment of children**

In principle TB treatment in children does not differ from that in adults. Nearly all pulmonary TB in children is sputum smear negative (actually smear “not done”) or extra-pulmonary tuberculosis and thus fall into category III. However, severe forms of TB such as meningitis, miliary TB or TB of the spine should be defined as category I. Treatment can be provided with adult formulation following the dose-body weight relationship presented in the tables for the different categories.

If child formulations are available the following treatment dosage should be used.

**Table 9: Dose-bodyweight relation for children treated with category I and III treatment regimen.**

	Drugs Child formulation	CHILD					
		Pre-treatment weight					
		<7 kg	8-9 kg	10-14 kg	15-19 kg	20-24 kg	25-29
2 months intensive phase, Daily observed treatment	RHZ 60/30/150/mg	1	1.5	2	3	4	5
4 months continuation phase Daily observed treatment	RH 60/30 mg	1	1.5	2	3	4	5

For children with severe forms of TB, Ethambutol is recommended at a dose of 15 mg/kg (2RHZE/4RH). The feared side effect of retro-bulbar neuritis is rarely seen and only in children taking higher dosages exceeding 20 mg/kg for a long period of time. Nevertheless, if there is any doubt, an alternative regimen for young children can be applied, 2RHZ/4RH.

It is not necessary to extend RH treatment to eight months as Isoniazid and rifampicin are both potent bactericidal drugs. An exception is made for treatment of complicated TB such as TB meningitis, TB of spine where a minimum of 6 months continuation should be completed.

During continuation phase parents/guardians can supervise DOT to their children and keep record of the medication. Parents/guardians should collect the drugs once per week from a health facility.

Children who develop tuberculosis following BCG vaccination, which is sometimes seen in HIV positive children (see BCG), should be treated with 2{RH}E/4RH, as *M.bovis* is usually resistant to Pyrazinamide.

### Treatment in special cases

**Pregnancy:** Always ask women if they are pregnant before commencing treatment. Most anti-TB drugs are safe during pregnancies except streptomycin, which causes permanent deafness in the fetus therefore it should be avoided during pregnancy.

**Breastfeeding:** Full TB treatment of the mother is the best way to prevent tuberculosis in the baby. Mother and child can stay together for the entire duration of treatment. In mothers with pulmonary tuberculosis, the baby should



receive INH preventive treatment (5 mg/kg) for 6 months followed by BCG vaccination.

- Oral contraceptive:** Rifampicin interacts with oral contraceptives and reduces their efficacy. Women using oral contraceptives should be advised to use pills with a higher dose of oestrogen (50 mcg) or change to another method.
- Liver disease:** Most anti-TB drugs can cause liver damage. In case a patient develops jaundice, treatment should be stopped and restarted as soon as the jaundice resolves. In severely ill patients start streptomycin and ethambutol only. If the patient improves follow with a gradually step-up introduction of Isoniazid followed by rifampicin until full dose. Monitor liver functions and clinical picture. If the condition deteriorates stop the drug which was last added. Patients with established chronic liver disease should never receive Pyrazinamide. The treatment given is 2 RHE/4RH for Category I and III patients and 2 SRHE/6 RHE for Category II patients.
- Renal failure:** Isoniazid, Rifampicin and Pyrazinamide are almost entirely excreted by the liver and therefore safe to use. Streptomycin and Ethambutol are excreted by the kidneys and should either be avoided or given in a reduced dosage. The safest regimen for patients with renal failure is 2 RHZ/4 RH combined with pyridoxine to prevent Isoniazid induced peripheral neuropathy.
- HIV:** Rifampicin stimulates the activity of the liver enzyme system, which metabolizes Protease Inhibitors (PIs) and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs). This can lead to decreased blood levels of PIs and NNRTIs. The other way around, the PIs and NNRTIs enhance the liver enzyme system, which influences the blood levels of rifampicin resulting in ineffective TB treatment or drug toxicity. Nucleoside Reverse Transcriptase Inhibitors (NsRTIs) can cause peripheral neuropathy, which can result in an added toxicity caused by isoniazid.

#### **1.8.4. Combined treatment of TB and HIV**

In patients who have both tuberculosis and HIV, the priority is to treat tuberculosis. However patients with HIV- related TB can have anti-retroviral treatment (ART) and anti-TB treatment at the same time, but this has to be managed carefully under supervision of an experienced physician, in line with guidelines from the National AIDS Control Programme (NACP)

Careful judgment of when to start ART is necessary. For example in an HIV positive TB patients on anti-TB treatment who has a high risk of dying (low CD4 and/or poor clinical condition) the start of ART alongside with the anti-TB treatment can be life saving. On the other hand, in an HIV positive TB patient with a CD4 count of 350 or more and/or in relative good clinical condition, who does not appear to have a high risk of dying, it is safer to postpone ART until the anti-TB treatment has been successfully completed. This decreases the risk of immune reconstitution syndrome (IRIS) and avoids the risk of drug interaction between rifampicin and Protease Inhibitors (PIs). If ART is combined with rifampicin containing anti-TB treatment, the combination of efavirenz + 2 NRTIs should be used (contraindicated in pregnancy).

### **Immune Reconstitution Syndrome**

Occasionally HIV positive TB patients may experience a temporary exacerbation of signs and symptoms of TB with or without an aggravated radiographic manifestation after beginning anti-TB treatment. This paradoxical reaction in HIV infected TB patients is a result of immune reconstitution. This can occur when ART is given to patients on anti-TB treatment. Signs and symptoms include fever, lymphadenopathy, central nervous system lesions and worsening of the chest X-ray appearance. TB treatment failure should be excluded before diagnosing immune reconstitution syndrome. In severe reactions prednisone 1-2 mg/kg for 1-2 weeks can be given (thereafter gradually decreasing dosage).

### **The role of adjuvant steroid therapy**

Steroid therapy given in addition to anti-TB treatment is beneficial in tuberculosis meningitis, pleural TB with large effusion and TB pericarditis.

The recommended dosage in TB meningitis and TB pericarditis is 40-60 mg/daily for 1-4 weeks, gradually decreasing the dosage over several weeks. For children, the recommended dosage is 1-2mg/kg bodyweight daily for 4 weeks.

Other less frequent conditions, which can benefit from steroid treatment are:

- TB laryngitis with airway obstruction.
- Massive lymphadenopathy with signs of obstruction of airway.
- TB of the renal tract to prevent ureteric scarring.
- TB of adrenal glands causing hypo-adrenalism.
- Severe hypersensitivity reaction to anti-TB drugs.

Although steroids are immuno-suppressants they can be used in HIV positive patients as the overall benefit in the context of above conditions, outweighs the risk from other opportunistic infections.

### 1.8.5. Preventive Treatment

The aim of preventive treatment is to prevent progression from TB infection to disease. Isoniazid given at a dose of 5 mg/kg daily for 6 months is an effective preventive treatment. TB disease develops in only 10% of all the individuals infected with *M.tuberculosis*. However in HIV infected individual this can be up to 50%. Identification and treatment of all infected individuals in Tanzania is expensive and logistically not feasible. However certain high-risk groups can be targeted for preventive therapy.

- Infants of mothers with sputum smear positive PTB. A breast feeding infant has a high risk of contracting TB from the mother and a high risk of developing disease especially when HIV positive. The baby should receive isoniazid 5 mg/kg daily for 6 months followed by BCG.
- All children under 5 years of age in contact with sputum smear positive PTB patients should be examined. If there are no signs of active TB, the child should be put on preventive treatment of isoniazid 5mg/kg/daily for 6 months. If the child has signs and symptoms suggesting the presence of active TB, s/he should be registered and treated with a full anti-TB course.
- HIV infected individuals have a much higher risk of developing TB disease from re-activation of latent TB or reinfection. Preventive therapy with isoniazid gives protection mainly against recent TB infection but is less protective against re-activation of an old infection.

#### **Isoniazid Preventive Treatment (IPT) in HIV positive patients/clients**

IPT is not an alternative for the DOTS strategy for controlling TB. However IPT is recommended in HIV positive patients who do not have active TB disease and who have an increased chance of contracting TB infection. This can prevent many cases of active TB. Before preventative isoniazid treatment is considered in an HIV positive patient/client, the presence of an active TB disease should be excluded as much as possible. This is done through clinical assessment, sputum examination and chest X-ray.

The most important target groups for IPT are:

- HIV positive health workers
- HIV positive household contacts of TB patients
- HIV positive prisoners
- Hospitalized HIV positive patients
- Other HIV positive individuals in congregate settings

Isoniazid should be given for six months, 5 mg/kg (max. 300 mg) per day. Treatment is self-administered but the patient should be monitored on a monthly basis checking adherence, effectiveness and side effects. Isoniazid should be stopped in those who develop side effects.

The programme will continue to provide enough isonized to all eligible health facilities throughout the country in collaboration with NACP and other stakeholders

### **Cotrimoxazole preventive therapy (CPT) in HIV positive TB patients**

CPT has proven to be beneficial to patients infected with HIV, including HIV positive TB patients, preventing several secondary bacterial, fungal and parasitic opportunistic infections (OI). This reduces morbidity and hospital admission for OI significantly. The 6-8 months TB treatment provides a unique opportunity to provide CPT concurrently since adherence to treatment is a major concern for both TB treatment and CPT. Both treatments are provided free-of-charge for the duration of TB treatment. After completion of TB treatment the patients/clients will be advised to continue CPT.

Co-trimoxazol is provided as trimethoprim 80 mg/ sulfamethoxazole 400 mg two times per day. The duration of CPT will be life long unless the patient receives ART. Side effect to CPT are rare.

All clinicians and other providers should refer to appropriate clinical guidelines by NACP.

#### **1.8.6. Side effects of treatment**

The majority of TB patients complete their treatment without developing any significant side effects of the anti-TB drugs. However, a few of them will develop side effects, which makes it necessary to educate and monitor patients on possible side effects. The decision to change treatment because of side effects should be taken with great care to prevent inadequate treatment and should always be taken by a clinician in consultation with a TB coordinator. Every patient should be educated on the most common side effects of the drugs. An explanation should be given on what is seen as a minor and what is a major side effect. Patients with major side effects must be referred to the district or regional hospital for further evaluation and treatment.

Skin itching without a distinct rash is a common side effect of all drugs. First try to exclude other obvious causes, such as scabies, fungal infection etc. If necessary, treat with anti-histamines and continue with anti-TB treatment while observing the patient frequently. If a serious rash develops, stop the anti-TB treatment. Wait for the rash to resolve and re-introduce anti-TB treatment gradually. The table below summarises the most common side effect for each drug

**Table 10: Side effects of TB drugs**

<b>Drug</b>	<b>Common side effects</b>	<b>Rare side effects</b>
<b>Isoniazid</b>	<ul style="list-style-type: none"> <li>• <b>Peripheral neuropathy:</b> More common in HIV positive patients and alcoholism. Give pyridoxine 100 mg/d</li> <li>• <b>Hepatitis:</b> If hepatitis is suspected or jaundice is observed the treatment should be stopped. Restart gradually when hepatitis is cleared.</li> </ul>	<ul style="list-style-type: none"> <li>• Pellegra: give nicotinamide 300 mg daily</li> <li>• Agranulocytosis</li> <li>• Skin rash</li> <li>• Joint pains</li> <li>• Convulsions</li> </ul>
<b>Rifampicin</b>	<ul style="list-style-type: none"> <li>• <b>Gastrointestinal:</b> nausea, vomiting, abdominal pain, anorexia</li> <li>• <b>Reduced effect of oral contraceptive:</b> Advise different contraceptive method.</li> <li>• <b>Hepatitis:</b> see above</li> </ul>	<ul style="list-style-type: none"> <li>• Acute renal failure</li> <li>• Shock</li> <li>• Trombocytopenia</li> <li>• Skin rash</li> <li>• Flue syndrome (intermittent doses)</li> <li>• Cutaneous syndrome Flush, rash, pruritis, conjunctivitis</li> </ul>
<b>Pyrazinamide</b>	<ul style="list-style-type: none"> <li>• <b>Joint pains:</b> large and small joints can be involved. Treat with aspirin/ibuprofen</li> <li>• <b>Hepatitis:</b> see above</li> </ul>	<ul style="list-style-type: none"> <li>• Gastrointestinal</li> <li>• Skin rash</li> <li>• Aneamia</li> </ul>
<b>Ethambutol</b>	<ul style="list-style-type: none"> <li>• Impaired vision/color blindness due to <b>optic neuritis:</b> rarely if dose is not exceeding 15 mg/kg. Stop the drug, consult ophthalmologist.</li> </ul>	<ul style="list-style-type: none"> <li>• Joint pains</li> <li>• Skin rash</li> </ul>
<b>Streptomycin</b>	<ul style="list-style-type: none"> <li>• <b>Auditory/vestibular nerve damage:</b> risk increases with dose and age. The drug should be stopped when the patient is complaining of dizziness, ataxia or ringing sounds in ears.</li> <li>• <b>Local numbness</b> on place of injection</li> </ul>	<ul style="list-style-type: none"> <li>• Renal failure</li> <li>• Skin rash (mucous membrane may be involved)</li> </ul>

Drug induced hepatitis is sometimes seen and can be caused by any of the drugs. Hepatitis in most cases is caused by Isoniazid or Pyrazinamide and rarely by Ethambutol. Hepatitis presents with anorexia, jaundice and in most cases with liver-enlargement. Try to exclude other causes but if drug induced hepatitis is likely, stop all treatment. Re-introduce anti-TB treatment as soon as the jaundice has disappeared. Start with the same initial treatment as in most cases the hepatitis does not return. If signs of hepatitis re-occur it is better to give the least toxic anti-TB treatment streptomycin and ethambutol only.

### **Re-introduction of anti-TB drugs following a drug-reaction**

In most cases it is not known which drug is responsible for the drug-reaction. The treatment should be re-introduced starting the anti-TB drugs one at a time, increasing the dosage slowly. With the current and increasing use of FDCs, this might be a problem. RTLC should therefore always stock a few tins of drugs which are not in fixed dose combinations to be able to treat these patients. Start with isoniazid as this is the least likely cause of a drug-

reaction. Start giving a challenge dose (in case of isoniazid 50 mg in an adult). If there is no reaction (itching and or rash) build up the dose over a 4 days period to the normal level. Then add rifampicin as this is the next least likely cause of a reaction. Gradually increase the dose again and add the next drug after 4 days etc. A reaction after adding a drug identifies the causative drug, which should then be stopped.

**Table 11: Re introduction of TB drugs following a drug reaction**

Anti-TB Drug	Day 1 (challenge dose)	Day 2	Day 3	Day 4
Isoniazid	50 mg	100 mg	200 mg	300 mg
Rifampicin (RH)	75 mg	150 mg	300 mg	Full dose
Pyrazinamide	250 mg	500 mg	1 g	Full dose
Ethambutol	100 mg	200 mg	400 mg	Full dose
Streptomycin	125 mg	250 mg	500 mg	Full dose

### 1.8.7. Treatment Monitoring

Monitoring tuberculosis patients during treatment is vital in order to establish patients' treatment outcome and to measure the national programme effectiveness. Bacteriological monitoring (sputum check for AFB) is needed in sputum smear positive cases.

Routine sputum smear examination of an early-morning sputum at the end of the intensive phase is required. The majority of patients will have converted to negative sputum. If the sputum is still positive at the end of the intensive phase, the intensive phase treatment (RHZE) should be continued for another month. The sputum is checked again at the end of the third month but regardless of the result, the patient should continue with the continuation regimen (RH). If the result is positive after three months, a sputum sample should be sent to TB Reference Laboratory for culture and susceptibility testing.

Patients on Category II re-treatment, failing to convert after three months intensive phase should continue one more month with RHZE and have their sputum checked at the end of the fourth month. If the sputum smear is still positive after 4 months, at least one sputum sample should be sent for culture and susceptibility testing. The patient should continue on the Category II continuation phase treatment RHE.

All smear positive patients should have another early morning sputum sample checked at 5 and 7/8 (re-treatment) months. A negative smear at 5 and 7/8 months means that the patient is bacteriologically cured. A positive result means treatment failure.

All sputum results (0, 2,3, 5 and 7/8 months) should be registered with date and laboratory number in the District Tuberculosis Register.

For smear negative and extra-pulmonary TB cases, clinical monitoring of the treatment response is sufficient. Routine monitoring of treatment response by chest X-ray is not necessary.

At the end of the 6 or 8 months treatment the patient is discharged and the treatment outcome registered in the patient treatment card, unit and district registers.

**Cured** A sputum smear positive patient who is smear negative at the end of treatment and on at least one previous occasion.

**Treatment completed:** A patient who has completed treatment but for whom smear results are not available at the end of treatment.

**Failure** A patients who remains or becomes again smear positive at 5 months or later.

**Died** A patient who dies for any reason during TB treatment.

**Defaulter** A patient who interrupts treatment for two consecutive months or more.

**Transferred out** A patient who has been transferred to a treatment centre in another region and whose treatment result is not known.

Other definitions that are not listed as treatment outcomes but commonly used:

**Treatment success;** The sum of patients who are cured and those who have completed treatment.

**Unfavourable treatment outcome;** The sum of patients who died, failed treatment, defaulted and transferred out.

**Absentee** Health facility based DOT: Patients who fail to attend the clinic for three consecutive days are considered to be absentees and tracing action should start within three days. This applies both for intensive and continuation phase.

Home based DOT: Treatment supporter who failed to collect drugs during his/her scheduled appointment should be traced together with his/her patient in the following three days. This applies both for intensive and continuation phase.

Defaulter tracing is in actual fact absentee tracing. Absentees should be traced before they become genuine defaulters. Tracing of absentees

should be a weekly routine activity of every DOT centre. On a fixed day in the week, the unit register and patient treatment cards should be checked which results in a list of absentees.

New smear positive TB patients on treatment who are considered "treatment failures" should be re-entered in the district TB register with a new registration number. They should be treated with category II retreatment regimen. At least one sputum sample should be sent to the CTRL for culture and susceptibility testing.

Patients who interrupted their treatment for two months or more (defaulters) and who return to treatment should first have three sputum samples examined. If the patient is found to be negative, the original treatment can be restarted for the full length of period (6 months). The treatment outcome of these patients is entered as described above. However if the patient is found to be sputum smear positive, he/she should be re-entered with a new registration number under the case definition of "return after default". The re-treatment regimen for Category II patients should be given.

Patients who have been on treatment for 6 or 8 months and do not have results of sputum at the end of treatment should be recorded as "treatment completed". Every effort should be taken to make sure that all smear positive patients check their sputum sample at the end of treatment. Treatment completed outcome among smear positive TB patients should not be entertained.

A patient who is transferred to another region should get a transfer form (TB/LEP 02), which he/she should deliver to the DTLC of the receiving district before proceeding to the clinic of choice. The DTLC will record the patient with his/her existing registration number, clearly indicating where the patient has come from, under the case definition of "transfer in" in the district register. As soon as the treatment outcome of the patient is known the DTLC should report this treatment outcome to the DTLC of the district where the patient was originally registered, by completing and returning the treatment outcome of transferred patients (TB 11) through the RTLC or by any other means. In principle no patient should receive a treatment outcome of "transferred out".

### **Monitoring of TB/HIV activities**

All TB patients will be offered counselling and testing of HIV. All TB/HIV activities will be monitored using TB/HIV forms and register.

The information collected will include number of TB patient screening for HIV, TB patient with HIV, patient with TB/HIV co-infected referred to HIV care and other services, TB/HIV patients started on ARV and CPT. This information will be reported quarterly following routine NTLR reporting system.

### **Monitoring of home based DOT activity**



Patients receiving treatment under home based care will be monitored and reported using routine NTLP system. Information will include number of patients enrolled and their treatment outcomes.

## **1.9. Other important principles in Tuberculosis control**

### **Infection control in health institutions**

Tuberculosis infection is not the same as tuberculosis disease. Many health workers are infected with tuberculosis without ever developing disease. Transmission of infection can partially be prevented with infection control measures, which are especially important for those who are more exposed to TB than others (e.g. health workers). The following are Important infection control measures and precautions:

- The greatest individual risk of developing TB disease is HIV infection. All health workers should therefore be made aware of the increased risk of developing TB when they are HIV positive
- Infection of TB takes place through airborne transmission of bacilli that are coughed up by an untreated smear positive case. Therefore early detection of infectious cases and appropriate treatment are the most important way to stop transmission. Once a patient has commenced treatment, infectiousness diminishes rapidly. It is therefore not necessary to isolate TB patients who are on treatment.
- Unrecognized infectious TB cases are found among individuals with chronic cough. In the outpatient departments coughing patients should wait outside or in well-ventilated areas. They should be encouraged to cover their mouth and nose when coughing or sneezing. Normal masks do not protect medical staff against inhaling infected droplets and are therefore not recommended as a preventive measure for health staff.
- TB suspects need to be examined in a well-ventilated room. Avoid contact between TB patients and PHA HIV positive patients, which can be difficult as the two patient groups have a large overlap.
- Health workers working in hospital departments where patients (suspects) with tuberculosis are admitted should be advised to have an HIV test. If tested positive, they should avoid work in general and tuberculosis wards.

### **Laboratory safety**

Laboratory personnel involved in sputum collection, AFB staining and microscopy do have an advantage in the sense that they know that they are working with infectious material. If precautions are taken to prevent the formation and exposure to aerosols, laboratory staff have no increased risk of getting infected with tuberculosis. Safety cabinets are not essential in preventing tuberculosis infection in routine district hospital and health centre laboratories.

Only laboratories processing tuberculosis cultures require safety cabinets, as the aerosols escaping from culture bottles with a positive growth are highly infectious. It is important to check the negative flow of the cabinet on a regular basis. Self-made cabinets should be avoided at all times. Some of these cabinets have no airflow or even a "positive" airflow in the opposite direction, which makes it dangerous to work in front of them.

Sputum smear staining and examination should be conducted in a well-ventilated room.

- Containers should be carefully opened. Avoid vigorous shaking of the sputum.
- Sputum smear preparation should be done carefully in a well ventilated place. When biological safety cabinets are available they can be used for this procedure but they are not essential.
- Infectious material (containers, broken applicator sticks, and swabs) should be discarded carefully by incineration.
- For general cleaning normal detergents are adequate (Lysol or phenol derived soap mixtures are recommended).

### **BCG vaccination**

BCG (Bacille Calmette-Guerin) is a live attenuated vaccine derived from *M. bovis*. In Tanzania, BCG vaccination is included in the Expanded Programme of Immunization (EPI). The vaccine is given intra-dermally in the upper part of the right arm at a dose of 0.05 ml to all neonates shortly after birth. The dose increases to 0.1 ml if the vaccine is given to children older than one year.

BCG protects young children against disseminated and severe forms of tuberculosis, e.g. TB meningitis, miliary TB. BCG has little or no protection against the development of TB in adults. However, it gives some protection against the development of leprosy.

BCG vaccination may cause lymphadenitis or an abscess in the axillar or supra-clavicular region. In most cases the condition is self-limiting but severe forms should be treated with isoniazid 5 mg/kg daily for 6 months and needle aspiration in case of an abscess.

In HIV positive neonates BCG rarely causes disseminated infection of *M. bovis* which if it occurs should be treated with 2{RH}E/4RH. The WHO recommends that in countries with a high prevalence of tuberculosis, like Tanzania, BCG should be given to all neonates, regardless of the HIV status, immediately after birth. The possible benefits of BCG outweigh the possible disadvantages. However, BCG should not be given to children who present with clear signs and symptoms of HIV-disease or AIDS.

### **Tuberculin surveillance**

Tuberculin surveys measure the rate of TB infection in a population of children that are not vaccinated with BCG. With this information one can then estimate the annual risk of tuberculosis infection (ARTI). In Tanzania, tuberculin surveys are done at five years intervals. The first three rounds of tuberculin surveys (1983-1988, 1988-1993, 1993-1998) show that

the risk of TB infection in Tanzania has been stable (ARTI of approximately 1%) despite a doubling of the number of notifications of infectious TB cases due to HIV. The number of infections per notified case has thereby halved, which can only be attributed to the impact of the previous NTLP activities. Transmission of tuberculosis was expected to increase under the current pressure of HIV but has been contained under the current effective NTLP programme.

The tuberculin survey will continue in order to monitor the effect of HIV on the TB transmission and to monitor the number of infections per notified case as an indicator of the NTLP performance.

### **Drug resistance surveillance**

The monitoring of the levels of anti-TB drug resistance among TB patients is an important instrument to measure the long-term NTLP performance.

Drug-resistance is measured in two ways:

1. Routinely every DTLC should send sputum samples of all smear positive re-treatment patients (failure, smear positive relapse and smear positive return after default) to TB reference laboratories for culture and susceptibility testing. If the susceptibility test shows any drug-resistance we assume that these patients acquired this resistance during the last treatment and we consider their resistance as acquired drug resistance. Regular feedback of bacteriological results should be sent back to RTLC/ DTLC.
2. On a regular basis CTRL will conduct a national cross sectional drug resistance survey. A number of diagnostic centres, which are randomly sampled, are asked to send sputum samples of all new smear positive cases diagnosed within a certain timeframe to CTRL. All these specimens are cultured and tested for their susceptibility for anti-TB drugs.

### **Quality control of AFB sputum smear microscopy at district level**

Reliable quality smear microscopy at district level is a key component of the DOTS strategy in Tanzania. The NTLP launched a new standardized quality assurance system in 2000. This system is based on international accepted principles provided by WHO and IUATLD and summarized in a comprehensive national manual to support regional and district health staff with the implementation and supervision of the quality assurance.

The quality assurance system is based on three components.

- Bi-annual external quality assessment of all district diagnostic units by the Regional Laboratory Technicians (RLT) or an experienced laboratory staff member, in collaboration with the RTLC. The RLTs complete a standard checklist, which includes an extensive review of the laboratory register and a blind reading of a random sample of 20 slides (10 positive and 10 negative) per unit. The completed checklists are returned to TLCU/CTRL where the data is analyzed.

- Bi-annual external quality assessment of the Central TB Reference Laboratory by a supra-national reference laboratory through the exchange of batches of mycobacterial strains which are checked on the susceptibility to TB drugs.
- CTRL prepares a set of six slides and sends them to major peripheral diagnostic centres. The slides are read by microscopists and results returned to CTRL .This is part of annual proficiency testing.

Following the data collection and data analysis of the above activities, creative problem solving provides the basis of quality improvement. The current method allows DTLC/RTL/RLT to solve many problems “on the spot” or at district level. The data analysis should also form the basis for the preparation of an annual plan and budget at district, regional and national level.

### **The role of the private sector**

The NTLP recognises the important role private health institutions can play in control of TB.

### **Principles for collaboration with the private sector**

- The NTLP will seek collaboration with private institutions (including the private for profit sector) in all situations where this is likely to improve accessibility to TB care and improve TB control performance.
- The services provided by the private institution must meet the set requirements of NTLP policies and standard of services.
- Tuberculosis is a notifiable disease and each patient starting TB treatment must therefore be notified to NTLP. The services will be included in the routine programme monitoring and supervision system.
- It is important to underline that the treatment of every tuberculosis patient in Tanzania is free of charge despite the introduction of cost-sharing schemes.
- The private sector recognises that sputum smear microscopy is the gold standard for the diagnosis of tuberculosis and recognises Direct Observed Treatment Short course strategy (DOTS) as the national strategy for tuberculosis control and supports this in all its aspects.
- The NTLP in return provide the private institution with support in training and supervision of staff members involved in the TB management. Drugs and supplies needed for the proper diagnosis, treatment and recording of the patients are provided free of charge by the NTLP, provided that proper accounting and reporting systems are put in place in accordance to NTLP guidelines

### **TB control in health care institutions and congregate setting**

In health care institutions and congregate settings, where people with TB and HIV are frequently crowded together, TB infection is increased. Measure to reduce TB transmission includes administrative, environmental and personal protective measures. Administrative measures should include early recognition, diagnosis and treatment of TB especially infectious cases. Environmental protection includes maximizing natural ventilation and using ultraviolet radiation (if applicable).

The NTLP will continue to collaborate with institutions like prison, army, police and occupational health services where this is likely to improve the accessibility and quality of TB care and control. Similar to the approach of these institutions, the NTLP will continue to collaborate in the implementation of TB control activities in refugee camps. The principles for collaboration with any of these institutions or with e.g. NGOs providing health services in refugee camps is the same as for the collaboration with the private sector.

## 2. TUBERCULOSIS AND HIV

The HIV epidemic has spread rapidly in Tanzania since the mid-eighties. The current surveillance data estimate that 7-10% of the population is infected with HIV with the highest prevalence found in urban areas and among young adults. HIV is the most important cause of the rapid increase of the current TB epidemic. The life time risk of developing TB in an individual who is HIV negative is 5-10%, while in HIV positive the risk is 50%. Individuals infected with *M. tuberculosis* who get infected with HIV have a 20-30 times higher risk of developing tuberculosis disease than those who are HIV negative. HIV also increases the susceptibility to infection with *M. tuberculosis*. HIV is the most powerful factor known to increase the risk of TB. TB can occur at any time in the course of progression of HIV infection. About 50% of all TB patients in Tanzania are co-infected with HIV.

The impact of HIV on TB control

- Increase in the number of TB cases in the general population
- Increased cases in congregate settings (prisons, refuge camps, mines, health care institutions, boarding schools)
- Increase in the proportion of sputum-smear negative TB patients
- Over diagnosis of sputum-smear negative TB (a proportion of HIV related problems are wrongly diagnosed as TB)
- Disseminated and extra-pulmonary tuberculosis is more common and more difficult to diagnose
- Lower cure rates due to higher mortality and defaulter rates
- Higher recurrence of TB due to relapse or re-infection
- Stigmatization of TB patients by health workers and community
- Increased laboratory workload and treatment supervision

### Impact of TB on HIV

Tuberculosis may accelerate the process from asymptomatic HIV infection into symptomatic or AIDS. TB increases the mortality among HIV positive patients and the incidence of other opportunistic infections. Early detection and proper treatment of tuberculosis will therefore influence not only the life expectancy but also the quality of life of a person living with HIV/AIDS (PLHA).

### Pattern of HIV-related TB

HIV not only increases the number of TB cases, but also alter the clinical course of TB diseases. As HIV infection progresses, CD4+ T-Lymphocytes decline in number and function. The cells play an important role in the body's defence against tubercle bacilli. Thus, the immune system becomes less able to prevent the growth and local spread of *M. tuberculosis*. Disseminated and extra pulmonary disease is more common.

## Pulmonary TB

Even in HIV-infected patients, PTB is still the commonest presenting feature. Clinical picture, sputum smear results and CXR appearance in early and late HIV infection often differ as shown in table 12.

**Table 12: Pulmonary PTB 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
CXR appearance	Often cavities	Often infiltrates with no cavities

## Extrapulmonary TB

The commonest forms of extra pulmonary TB are: pleural effusion, lymphadenopathy, pericardial disease, milliary disease, meningitis, Spinal TB (Pott's disease) and disseminate TB

## HIV-related TB in Children

As in adult, the natural history of TB in a child infected with HIV depends on the stage of HIV disease. Early in HIV infection, when immunity is good, the signs of TB are similar to those in a child without HIV infection. As HIV infection progress and immunity declines, dissemination of TB becomes more common. Tuberculosis meningitis, milliary TB, and widespread tuberculosis lymphadenopathy occur.

### 2.1. HIV Testing Policy in TB Patients

HIV testing for TB patients will be offered on a routine basis as part of medical examination in TB/HIV patients. This is in line with UNAIDS statement of 2004 which state that: "*Diagnostic HIV testing is indicated whenever a person shows signs or symptoms that are consistent with HIV-related disease or AIDS to aid clinical diagnosis and management. This includes HIV testing for tuberculosis patients as part of their routine management.*"

### Diagnostic Counselling and HIV Testing

NTLP is recommending Diagnostic Counselling and HIV Testing (DCT) to all TB patients. DCT is preferred because it is not time consuming and requires minimal training. It is expected that health facility staffs will be empowered to have counselling skills so that any health worker can provide DCT. Counselling will help to advice HIV positive TB patients how to protect themselves from re-infection and their partners from contracting HIV infection and proper management of other opportunistic infections. Counselling also provides psychological support to both HIV infected and those affected by HIV/AIDS. Appropriate IEC on TB-HIV to patients and the community together with provision of counselling and testing services will

not only contribute to a gradual break down of the strong stigma and denial but will also provide opportunity for TB and HIV prevention and care support services.

Those who are found to be HIV negative have to be advised on how to remain HIV negative and they are referred to VCT sites for further counselling and second HIV test. Partners of TB patients tested for HIV are also referred to VCT centres.

### **Voluntary Counselling and Testing**

Voluntary counseling and Testing (VCT) is one of the HIV prevention interventions initiated by the client. It gives the clients an opportunity to confidentially explore and understand his or her HIV risks and to learn his or her HIV test result.

A VCT intervention includes two counseling sessions: the pre-test counseling session and the post-counseling session. At the pre-counseling session, the client is prepared for the test by a trained person to receive pertinent information and determine his readiness to take the test. He/she is also given the opportunity to consider the impact of positive result on his/her life.

Following the testing the client shall be counseled again to prepare him/her to receive and cope with the results and decide, with the help of the counselor, steps he can take in order to remain negative or to live positively with the HIV virus. The counselor deals with the feelings arising and assists the client to develop a risk-reduction plan.

### **Pre-test counselling**

The intention of pre-test counselling is to provide all the necessary information so that the patient can make an informed decision to have HIV test done. The patient needs to get informed on what the test involves and on the implications of a positive or negative result.

Counselling should be strictly confidential. The counsellor should provide information in a dialogue with the patient. He or she should always try to build up a relationship with the patient that is based on trust and support.



**Table 13: Important aspects to be discussed during pre-test counselling Sessions**

<p>1. Assess the patients knowledge on TB and the relation of TB with HIV</p>	<ul style="list-style-type: none"> <li>• Transmission of TB</li> <li>• Treatment of TB, compliance</li> <li>• TB can be cured</li> <li>• Prevention of TB</li> <li>• Relationship TB-HIV</li> </ul>
<p>2. Assess the risk of the patient having acquired HIV infection</p>	<ul style="list-style-type: none"> <li>• Multiple sex partners</li> <li>• Sex with commercial sex workers</li> <li>• Unprotected sex</li> <li>• Sexual partner with risk behavior</li> <li>• Previous blood transfusion</li> <li>• Intravenous drug use</li> </ul>
<p>3. Assess the patients knowledge on HIV</p>	<ul style="list-style-type: none"> <li>• Transmission of HIV</li> <li>• Value of testing</li> <li>• Management of HIV</li> <li>• Consequences of living with HIV</li> </ul>
<p>4. Assess the patients ability to live positively with a positive HIV result</p>	<ul style="list-style-type: none"> <li>• Patient expected reaction to a positive result</li> <li>• Who provides emotional, social, economical support (home based care programme?)</li> <li>• Impact on relationship, work, future health</li> </ul>

**Post-test counselling**

The purpose of this counselling is to discuss the result the test and plan for future care, treatment and support services. Whatever the result, confidentiality should be observed. Show an open and sympathetic interest in the result, the reaction of the patient to the result and discuss what it means for the person.

If the result is HIV-positive encourage the patients to disclose information to someone of her/his choice for ongoing support. Patients might react with shock, depression, anger, guilt etc. Try to organize emotional, psychological or even economical support within local community services (home based care programmes), support groups or with friends or family. Other issues that need to be discussed are safe sexual behaviour, nutrition, avoiding other infections, chemoprophylaxis and options of treatment. Once tuberculosis has been diagnosed, anti-TB treatment should be initiated immediately.

If the result is HIV-negative always discuss measures how to remain negative from HIV infection by practicing abstinence, faithfulness and/or appropriate use of condoms. One should be aware that the test does not become positive until 8-12 weeks after infection. During the window period (from acquiring infection to the time one becomes positive for HIV) the patient can transmit HIV although may test negative. HIV negative TB patients are advised to repeat the HIV test after 3 months. During the period of three months, the patient is advised to practice safe sex.

Basically, DCT provision follows the same procedures as VCT. The main differences between DCT and VCT are:

VCT	DCT
<ul style="list-style-type: none"> <li>• Individual seeks HIV CT</li> <li>• First user of the test result is the client who uses the information to make personal life decisions</li> <li>• Counseling focuses on individual risk behaviour and risk reduction</li> <li>• Anonymous or confidential services may be offered</li> <li>• Duration 1-2 hours</li> </ul>	<ul style="list-style-type: none"> <li>• Individual seeks medical care</li> <li>• HIV CT recommended and offered by HCW</li> <li>• First user of the test result is the health care worker to make a correct diagnosis and provide appropriate treatment</li> <li>• Services provided are confidential and documented in medical record to ensure continuity of care</li> </ul>

## 2.2. TB Screening among PLHA

NTLP will promote screening for TB among PLHA in collaboration with NACP as part of intensified case finding. The screening will be done using as a minimum, a set of questions based on symptoms and signs to identify TB suspects. The questions will be asked by trained counselors at services provision sites. Screening will be followed by early diagnosis and prompt treatment. This aims at improving chances of survival, quality of life and reducing transmission of TB in the community.

## 2.3. Provision of Isoniazid Preventive Therapy (IPT)

Currently, there is no enough evidence and experience of the impact of large scale preventive treatment in Tanzania. However, IPT can be provided in selected individuals. If Isoniazid preventive treatment is given, active TB must always be excluded first (sputum examination, clinically, history, chest X-ray).

- IPT should be given to individuals with latent infection of *M. tuberculosis* in order to prevent progression to active disease. TB preventive therapy is an intervention that should be part of the package of care for people living with HIV. In these patients, the risk of developing tuberculosis is reduced by about 60% and their survival is also prolonged. The protective effect is expected to last for 18 months. It is however, important to exclude active TB before starting IPT. IPT is given at a dosage of 300 mg daily for 6 months for adults. For children the dosage is 5mg/kg body weight daily for six months. IPT should only be offered in the following situations (prerequisites)
- Availability of quality supportive counselling
- Effective screening for active TB before initiating TB preventive therapy

- Capacity for follow up and monitoring of patients to encourage adherence to preventive therapy treatment,
- Capacity to manage side effects and exclude active TB during IPT

**Eligibility for TB Preventive Therapy among PLHA**

All HIV positive people with no signs and symptoms suggestive of active TB and with positive tuberculin skin test are eligible for TB preventive therapy.

Tuberculin skin test should be offered to all HIV infected individuals where possible. Staff should be trained to provide quality tuberculin skin test using the Mantoux technique.

For patients with history of TB treatment:

- Patients who had active tuberculosis in the past 2 years should not be considered for preventive therapy.
- Patients who were treated for tuberculosis more than 2 years earlier may be considered because they may have already been re-infected with TB.
- Patients on anti-retroviral therapy should not be offered TB preventive therapy, as there is currently no evidence of added benefit.
- Patients who receive TB preventive therapy and who require to start antiretroviral therapy can complete their TB preventive therapy even if the ART is started as there is no interaction between isoniazid and the current ART regimen used.

**Table 14: Strategies to Exclude Active Tuberculosis before Initiating IPT**

It is essential to exclude active tuberculosis in every patient prior to starting preventive therapy. This is critical in order to avoid drug resistance when a single drug is given to patients with active TB who require full regimen.

**Symptoms and signs to be noted**

Patients for TB preventive therapy should be specifically asked about signs and symptoms of tuberculosis:

- Cough of 2 weeks or more
- Evening fevers
- Night sweats
- Weight loss
- Pleuritic chest pains and haemoptysis
- Other symptoms suggesting extrapulmonary TB

**Investigations to be done**

All patients with 1 or more signs and symptoms must be investigated further for TB and are not immediately eligible for TB preventive therapy

## 2.4. Measures to decrease the burden of HIV in TB patients

In order to decrease the burden of HIV in TB patients is recommended:

1. Provide HIV Counselling and Testing  
HIV Counselling and Testing should be offered to all TB patients.
2. Introduce HIV preventive methods  
Measure should be introduced to reduce sexual, parenteral and vertical transmission of HIV which includes safe sex, and systematic and correct use of condom, diagnosis and treatment of STIs, blood safety and PMCT
3. Provision of Cotrimoxazole Preventive Therapy (CPT)  
CPT is used in prevention of several secondary bacterial and parasitic infections in eligible adult and children living with HIV/AIDS. TB patients are illegible for this therapy.
4. Ensure HIV care and support services  
All TB/HIV co-infected patients should be provided with clinical care as part of comprehensive AIDS care strategy which includes management of OIS, nursing care, palliative care, home care, counseling and social support.
5. Provide ARV to TB patients  
ARV improves the quality of life and greatly improves survival of PLHA. It is a lifelong treatment requiring a high adherence rate to achieve long term benefits and minimize the development of drug resistance. ART should be offered to all eligible TB/HIV positive patients.

### Prophylactic treatment using Cotrimoxazole (CPT)

All TB patients co-infected with HIV are eligible for CPT.

Dosage:

- Adults dosage : One double strength tablet (160/800 mg) or two single strength tablets once a day
- For children dosage see the table below:

**Table 15: Cotrimoxazole Prophylaxis for the HIV-exposed Child**

Weight	Dosage and Formulation
Below 10 kg	5 mg/kg syrup
Between 10 - 15kg	1/2 tablet single strength
Above 15kg	2 tablets single strength

It should be noted that baseline Liver Function Tests (LFT) and Renal Function Tests (RFT) are required before long term administration of Cotrimoxazole

#### Duration:

- Prophylaxis is for life for both adults and children who are not on ARVs.
- For those on ARV's, cotrimoxazole prophylaxis can be stopped if CD4+ is >200
- Children who are born to HIV infected women can stop prophylaxis when HIV infection has been reasonably ruled out and the risk of exposure has ceased.
- Children older than 18 months can continue with the prophylaxis only if the diagnosis of HIV infection has been confirmed by serology

#### Criteria for stopping:

- Occurrence of severe side effects such as severe cutaneous reactions, or such as fixed drug reactions
- If ART is initiated and CD4+ count is above 200 cells/ml in adults or above 15% of total lymphocyte count in children
- Renal and/or hepatic insufficiency or severe haematological toxicity if anti retroviral agents are used

#### Follow up:

- Regular follow up initially every month for the first three months, then every three months if the medication is well tolerated.
- It is mandatory to monitor for side effects and adherence. Monitoring includes assessment of skin reactions, measurements of haemoglobin, and white blood counts every six months and when clinically indicated.

#### **Use of ARVs for patients with tuberculosis disease and HIV co-infection**

- Antiretroviral therapy is recommended for all patients with TB with a CD4+ count <200 cells/mm<sup>3</sup> and should be considered for TB patients with CD4+ <350 cells/mm<sup>3</sup>. Treatment of TB remains a central priority for patient management and should not be compromised by ART. On the other hand, case fatality rates in many patients with TB during the first two months of TB treatment are high in particular when they present with advanced HIV disease, and ARV in this setting might be life-saving.
- Patients with TB merit special consideration because co-management of HIV and TB is complicated by rifampicin drug interactions with NNRTIs and PIs, pill burden, adherence and drug toxicity. Taking the available data into account, the first line treatment recommendation for patients with TB and HIV co-infection is (AZT or d4T) + 3TC+ EFV. The 800 mg dose of EFV achieves higher drug levels comparable to those seen in the absence of rifampicin and thus may reduce the chance of HIV drug resistance, but also can increase the toxicity risk.
- SQV/r in combination with the NRTI backbone is an alternative to EFV although resistance is a clear risk with suboptimal adherence. ABC is another alternative to EFV with the advantage of low pill burden, has no interaction with rifampicin, and has the

advantage of being able to be given to children under 3 years of age for whom appropriate EFZ dosing information is not yet available.

**The following two scenarios summarise the management of patients co-infected with HIV and TB:**

**Patient develops tuberculosis while on antiretroviral therapy:**

Antiretroviral therapy should be continued throughout TB treatment, with changes as follows:

- First line drugs: Substitute Nevirapine for Efavirenz. If this is not possible (e.g. intolerant of Efavirenz or significant risk of falling pregnant), Nevirapine may be substituted with Abacavir or Saquinavir/ritonavir.
- Second line drugs: Lopinavir/ritonavir should be changed to Saquinavir/ritonavir (dose: 400/400 mg every 12 hours – 3 extra caps of ritonavir). This should be continued until 2 weeks after completion of TB treatment, when the extra ritonavir can be stopped.

**Patient presents with TB before commencing ART:**

- If the patient has a CD4+ count of more than 350 cells/mm<sup>3</sup>, antiretroviral therapy is not yet needed. The need for antiretroviral treatment should be reassessed on completion of TB treatment.
- If the patient has a history of WHO Stage 4 illness and/or a CD4+ count of 200 –350 cells/mm<sup>3</sup>, complete 2 months of TB therapy before commencing ART.
- If the patient has a CD4+ count of less than 200 cells/mm<sup>3</sup> or other serious HIV related illness, make sure that the patient is tolerating TB treatment before initiating ART. Patients in this group should be started on first-line therapy consisting of d4T/3TC/EFV, for adults and AZT/3TC/EFV for children of age >3years. If age < 3years refer to specialist or paediatrician in HIV clinic.

**Table 16: Special considerations of ART in TB and HIV co-infected patients**

CD4 > 350	Treat TB first, re-asses for ART after completion of TB treatment
CD4 200 – 350	Treat TB first for two month before starting ART
CD4 < 200 or CD4 < 15%	Begin ART as early as 2 weeks after TB treatment initiation

**N.B:**

For patients who are diagnosed to have TB while on ART should continue with ART while introducing anti-TB drugs. However, if the patient was on Nevirapine (NVP) this should be changed to Efavirenz (EFV)

### 3. LEPROSY

#### 3.1. General Information about Leprosy

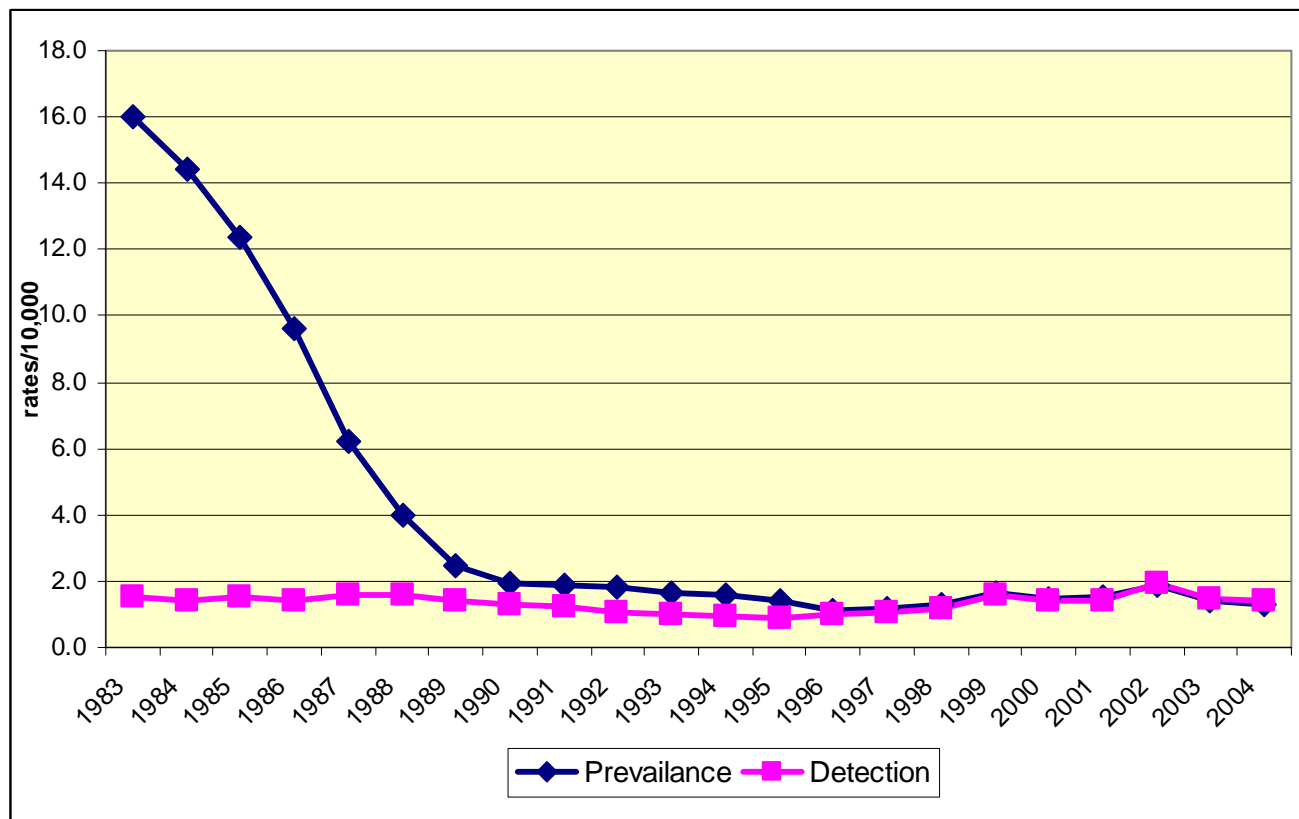
##### What is leprosy?

Leprosy is a chronic infectious disease caused by *Mycobacterium leprae* (*M.leprae*). It mainly affects the skin, the peripheral nerves and mucous membranes. It is a disease mainly of human beings, which affects people of all races, all ages and both sexes. Similar to tuberculosis, leprosy bacilli are mainly transmitted through infectious droplets that are spread by an infectious individual through coughing and sneezing. Patients carrying many leprosy bacilli are called multibacillary patients (MB). They are the main source of infection. People may carry the bacilli but not develop the disease. These people who are called healthy carriers are also probably able to transmit the bacilli to others. Individuals with few bacilli in their body are called paucibacillary (PB). Like healthy carriers, they are not a significant source of infection. Skin contact with leprosy patients is no longer considered to be an important means of transmitting leprosy infection. Leprosy has a very long incubation period (3-30 years, average 5 years). Only a proportion of the infected population gets the disease (5-10%). The majority of people have a natural immunity to *M. leprae* that is strong enough to prevent the development of disease after infection. Individuals with a partially impaired immunity have a higher chance to develop **paucibacillary** leprosy (the form with few bacilli) and those with a low natural immunity to *M. leprae* a higher chance to develop **multibacillary** disease. Factors related to poverty increase the risk of developing the disease. *M. leprae* invades mainly macrophages and cells protecting peripheral nervous system called Schwann cells. After *M. leprae* enters the cell it starts multiplying and causes immunoresponse. It is this process which causes inflammation of skin and the peripheral nerves.

#### 3.2. Situation of Leprosy in Tanzania

Leprosy is a special public health problem as it is still an important cause of permanent disability and continues to have a very negative social image in the community, frequently responsible for discrimination and stigmatisation. Multiple Drug Therapy (MDT), the cornerstone of leprosy control, was introduced in the Tanzania National TB/Leprosy Programme in 1983 and countrywide coverage was reached in 1990. This resulted in a rapid decline of the number of registered leprosy cases on treatment from nearly 35,000 cases in 1983 to about 5,000 in the year 2000. However, the number of newly notified cases has not significantly changed.

**Figure 6. Leprosy rates 1983 - 2004 in Tanzania.**

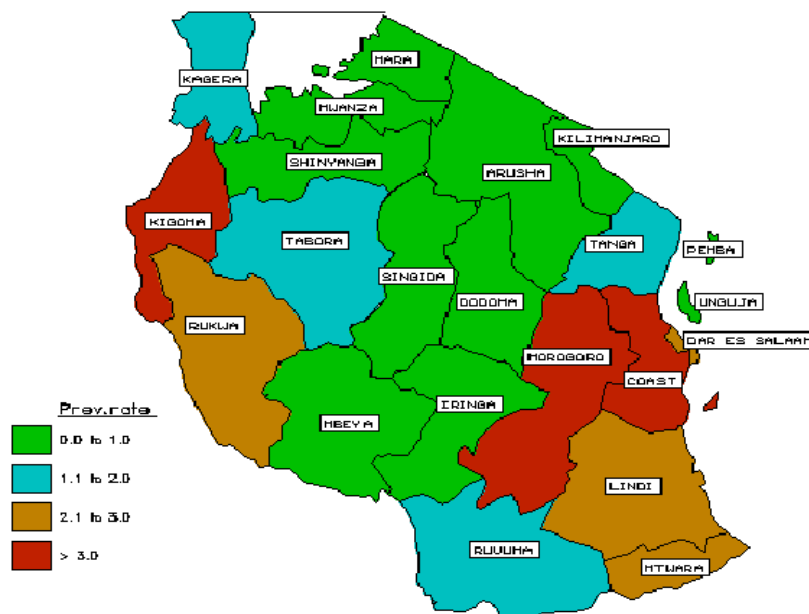


The World Health Organisation (WHO) has defined elimination of leprosy as the reduction of the leprosy prevalence to a level below 1 case per 10,000 population. This has not yet been reached as the case detection rate in Tanzania in the year 2003 is still above 1 per 10,000 population.

Treatment schedules with various combinations of Rifampicin and Isoniazid (Prothionamide, Dapsone and Isoniazid) were used until 1996, when the NTLP changed the treatment to WHO MDT. Better MDT services combined with Leprosy Elimination Campaigns and greater involvement of the community should make it possible to eliminate leprosy in Tanzania.



Figure 7: leprosy prevalence rate per 10,000 population in Tanzania, 2003



### 3.3. Leprosy control activities

Most activities planned by the NTLP to reach the WHO elimination goal are focusing on the following areas:

- Raising community awareness on the disease
- Early case detection.
- MDT available to every health facility where there is a leprosy patient at all times and free of charge.
- Preventing disability by early diagnosis and appropriate treatment of leprosy disease, reactions and other complications.

#### Essential elements to accelerate the process towards leprosy elimination;

Leprosy Elimination Campaigns (LEC), primarily targeted on early finding of undetected leprosy cases in the community. This is achieved by raising community awareness and participation, strengthening of existing MDT services through further decentralization and capacity building of health workers.

#### Special Action Projects for the Elimination of Leprosy

(SAPEL) aim to provide MDT services for patients living in difficult to access areas or for those belonging to isolated population groups (nomads, fishermen, islanders, prisoners). Both activities target early diagnosis and MDT treatment to all diagnosed leprosy patients which is given free of charge. This will also contribute to the reduction of transmission of the disease, prevention of disabilities and decrease the level of stigma in the community.

The main objective of leprosy control is early detection, treatment of all leprosy patients and prevention of disability from the disease. Although treatment results with MDT are fairly good in Tanzania, the number of newly detected leprosy patients with disability has not significantly declined. The disability grade 2 of newly diagnosed leprosy patients has slightly declined from 15% in 1994 to 10% in the year 2003. Primary prevention of disability can be achieved by early case detection and treatment of disease and leprosy reactions. The earlier leprosy is recognised, the less nerve damage can occur. Community awareness on leprosy can be increased through health education. Providing friendly and good services with high cure rates will also advocate earlier detection. It is well known that one third of all leprosy patients has or develops a leprosy reaction during the first year of contact with the health service, therefore it is important to identify these patients early and treat them adequately in order to prevent disability.

### 3.4. The Diagnosis of Leprosy

The diagnosis of leprosy relies on passive case-finding that is patients presenting to the health facility when they have symptoms suggestive of disease. Staff at any health facility should be able to recognize early features of leprosy and examine suspects properly.

#### When to suspect leprosy?

In an endemic area like Tanzania any individual with one or more of the following signs or symptoms is a suspected leprosy case and should be examined appropriately:

- One or more pale or reddish, hypo-pigmented patch(es) on the skin with or without loss of sensation
- Painless swelling or lumps in the face and/or earlobes
- Enlarged and/or tender nerves
- Burning sensation of the skin
- Numbness or tingling of hands and/or feet
- Weakness of eyelids, hands and/or feet
- Painless wounds or burns on the hands and/or feet

Any trained health worker should examine a suspect leprosy patient and be able to make an appropriate diagnosis. If one is not sure of the diagnosis, the suspect should be seen by the DTLC during clinic days or referred to the nearest clinic that is visited by the DTLC or other trained personnel.

#### How to diagnose leprosy?

The diagnosis of leprosy must be based on the history of the symptoms and careful clinical examination of the person for signs of leprosy. Only in rare instances is there a need to use laboratory and other investigations to confirm a diagnosis of leprosy. Diagnose an individual as having leprosy if **ONE** of the following **CARDINAL SIGNS** is positive:

- |  |
|--|
| <ol style="list-style-type: none"><li>1. Skin lesion with loss of sensation</li><li>2. One or more enlarged peripheral nerves</li><li>3. A positive skin smear</li></ol> |
|--|

**The skin lesion** can be single or multiple and in many cases less pigmented than the surrounding skin. Sometimes the lesion is reddish or copper-coloured. The skin lesion may show loss of sensation on light touch, a key feature in leprosy. Lesions can present in many ways, but macules (flat), papules (raised) or sometimes nodules are the most common. When patients suffer from a leprosy reaction (see page 96) they can also have tender lumps in the skin.

**One or more thickened nerve trunks**, often with signs of nerve function impairment, are considered a cardinal sign. But in the absence of skin lesions and/or a positive skin smear, nerve thickening by itself without sensory loss and/or muscle weakness, may not be a reliable sign of leprosy.

In a proportion of cases a **skin smear** taken from the affected skin may be **AFB positive** under light microscopy. This is diagnostic for leprosy.

### **History taking**

Proper history taking and collection of certain information on the patient are very important for understanding the patient's situation and for tracing a lost patient. The following information must be obtained:

- General information: all three names, sex, year of birth, full address including the name of village/street leader and distance from home to clinic, occupation,
- Main complaints, including date of onset, site of first lesions, subsequent changes and development of the disease, previous treatment received.
- Contact information: other leprosy cases in the patient's household,

### **Physical examination**

Physical examination should always be done in adequate daylight and fully respecting the person's privacy. The person is asked to undress. Always explain what is going to follow when proceeding with a systematic examination.

- **Examination of the skin**

Start with the head, neck, shoulders and arms followed by trunk, buttocks and legs. **Look** for any discolouration of the skin, thickening or swelling.

**Note** the characteristics of lesions such as shape (nodules, patches), surface (rough, smooth, dry, moist), colour (hypo-pigmented, redness), tenderness of the skin lesion(s), margin, satellite lesion(s) with or without central healing, loss of hair and absence of sweating; number, size and distribution.

**Test** sensation in one or a few typical skin patches with a wisp of cotton wool as follows:

- Roll the end of the wisp into a fine point;
- Explain to the person that the purpose of the test is to see how well the skin feels.
- Touch the skin with this point of cotton wool until it just bends; the person is expected to touch with one finger the exact spot that is tested;

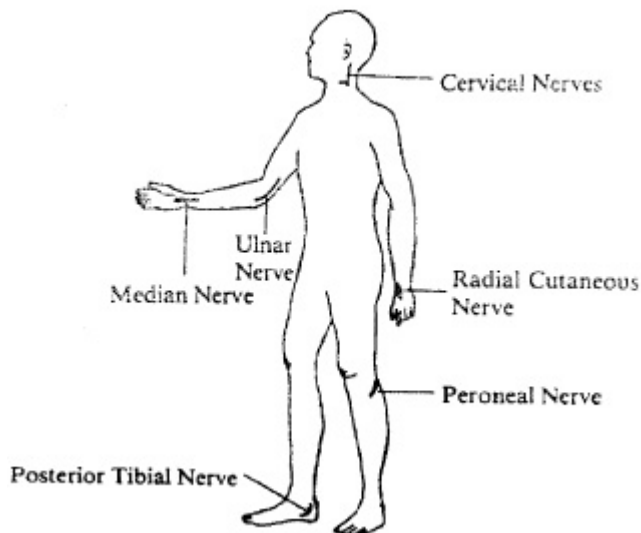
- Do a trial test after the explanation by touching the person on normal skin with the eyes open so that s/he can see exactly what is done. Repeat several times until the person has demonstrated to you that s/he understands the purpose of the test;
- Then do the testing with the person's eyes closed. First test on normal skin. When s/he points correctly, test in the skin patch(es); compare the person's response by intermittently testing an area of normal skin. Watch at every touch that she/he keeps the eyes closed. A person who repeatedly does not feel touch in a lesion, has loss of sensation and thus shows a cardinal sign of leprosy;
- Sometimes a patient points accurately to areas of normal skin, but points more than 2 centimetres away from where the skin in a patch is tested. This is called misreference and shows diminished sensation in the patch. If consistent during repeated testing of a patch, misreference becomes cardinal sign of leprosy.

**Other skin condition may mimic leprosy. If you are not certain please check with the list of other possible skin diseases (differential diagnosis) as shown on *page 124***

- **Palpation of the nerves**

For the assessment of the thickness of a nerve you should know the normal size of that nerve. This can be learned by examining nerves on yourselves and on suspected leprosy patients. Always compare the left with the right side. Palpation of the nerve is done with two or three fingers by rolling the nerve on the surface of the underlying bone. Try to get an impression of the thickness, the consistency (firmer or softer than usual) and tenderness. Figure 8 shows the nerves that can be affected by leprosy and that are easily accessible for examination. Thick and/or tender nerves, especially in combination with other signs and symptoms of leprosy, are diagnostic for leprosy.

**Figure 8: Places where superficial nerve trunks can be palpated.**



• **Examination of other organs**

Depending on the duration of the disease and the spread of leprosy through the body, various other organs may show signs typical for leprosy: -

- Look for diffuse or nodular swelling of the face and ears, may be with ulcerating nodules
- Check eyebrows for any loss of hair
- Check the ear lobes, they may be elongated and hanging down
- Note depression or even collapse of the bridge of the nose
- Look for blockage, bleeding or ulceration inside the nose
- Examine the mouth: the palatum may show nodules and even ulceration. Check the teeth, they may be loose
- If you hear the patient speak with a hoarse voice, the vocal cords may be damaged due to leprosy. Sometimes one can hear a soft whistling sound on breathing
- Palpate the breast tissue in male patients, it may be swollen (gynaecomastia), pointing to involvement of testicles
- Check the testes and scrotum for nodules, infiltrations. Note the size of the testes. Small soft testes are usually the result of damage by *M. leprae*. Ask for symptoms of infertility or impotence.

Many of the above signs occur in patients with the multibacillary form of leprosy.

**Conclusion of the examination**

**Decide**, after completing the history and examination of the skin, nerves and other organs, **whether the person has leprosy or not.**

- When the diagnosis “leprosy” is sure, **complete the full examination and record all information** accurately on the Patient Record Card (LEP01).
- If you are not certain, have a **skin smear** examined. Procedures are described in Appendix **2, page 127**.
- If the skin smear is negative and there is the slightest doubt, one should avoid the diagnosis and categorize the person as “**leprosy suspect**”.

It is important to realize that the diagnosis of leprosy has a major impact on the individual and his family. Suspect leprosy cases should be educated on the basic facts of leprosy and should be advised to return to the clinic if the symptoms get worse or persist for more than three months. Alternatively, refer the patient to the higher level for diagnosis

### **3.5. Assess the extent of disease**

Once the diagnosis of leprosy is made the next step is to assess the extent of disease. Do the following examinations to establish a baseline record, especially of sensation and muscle strength, for immediate action and future follow up. All information should be accurately recorded in the patient card:

#### **Nerve function tests**

Nerve trunks are mixed nerves and as such carry three types of nerve fibres:

- Autonomic fibres, which stimulate sweat glands to moisten the skin.
- Motor fibres, which stimulate muscle function.
- Sensory fibres, which carry messages of sensation from skin to brain.

All or any one of these fibres may be damaged. It is therefore necessary to assess each nerve function separately. Any loss of function will indicate possible damage to the relevant nerve fibres.

#### ***Autonomic nerve function***

Assess autonomic nerve function loss by looking for dry skin, especially on the palm of the hand or the sole of the foot.

#### ***Motor nerve function***

By testing muscle strength, you can find out if the motor nerve fibres function normally. To know what is normal, you should first learn the normal range of movement and strength of many different people

<b>PROCEDURE FOR VOLUNTARY MUSCLE TESTING</b>
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Testing for the strength of voluntary muscles (VMT) should be conducted by an experienced and qualified health worker. Where this is not possible, the testing should be done by the DTLC or RTLC. Voluntary Muscle Test (VMT) consists of testing the motor (muscle) function of several peripheral nerves especially among leprosy patients with suspected nerve damage. All muscle movements should be executed fully and strong against the resistance of the examiner's hand. Indicate normal function with S for "strong" and a weakened function (reduce strength, less than normal movement) with W for "weak". In case there is no muscle action at all, indicate P for "paralysed".

#### Facial nerve function

- Ask the patient to **CLOSE THE EYES** as in sleep; record any lid gap in millimetres. A lid gap of more than 5 mm necessitates immediate action to prevent damage.
- Test the strength of eyelid muscles by asking the patient to close the eyes tightly and to resist the gentle efforts of the examiner to part the eyelids.

#### Ulnar nerve function

- Ask the patient to move his little finger all the way in (touching the side of the ring finger) and all the way out. Is the movement full?
- If movement is full, ask the patient to hold his **LITTLE FINGER OUT** fully while you give resistance to the outward movement at the base of the finger by pushing it in. Record your findings accordingly.

#### Median nerve function

- Ask the patient to bring the **THUMB UP AND ACROSS**, in front of the index finger but as far away from it as possible. Focus attention for movement at the thumb base rather than at the tip. Can the patient achieve this testing position? Is movement full?
- Now test the strength of this movement. Instruct the patient to maintain the starting position while you push out/across, away from the little finger.

#### Radial nerve function

- Test the **EXTENSION OF THE WRIST** by asking the patient to lift the wrist against the palm of the examiner's hand.

#### Peroneal nerve function

- Ask the patient to fully **LIFT UP HIS FOOT**, check to see if the movement is full (no more movement available at the joint).
- Test for power in the testing position. Provide resistance to the top of the foot by pushing down.

### PROCEDURE FOR SENSATION TESTING

Sensation test (ST) is testing for sensation of cornea, hands and feet.

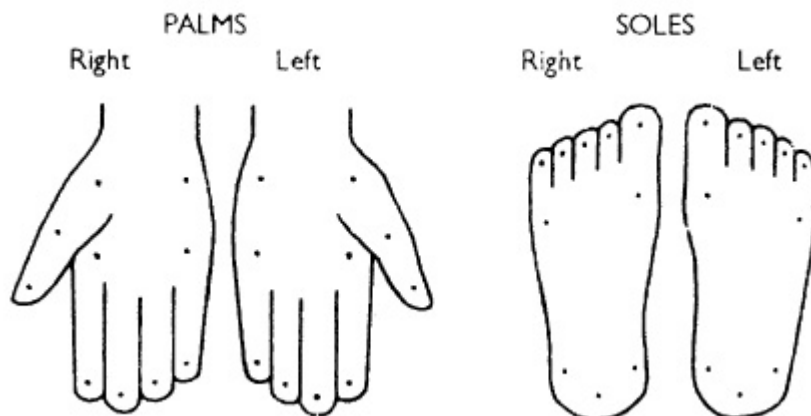
#### Eyes:

- Observe the eyelids of the patient when you talk to him/her. If the patient is blinking regularly, you can assume that the corneal sensation is normal.
- If the patient does not blink, record loss of corneal sensation.

### Hands and feet:

- Gently touch the skin with a ballpoint pen tip on each of the 10 testing points shown on the hand and foot maps (touch = small indentation, little more than the weight of a ballpen).
- Ask the patient, first with the eyes open and then with the eyes closed, to point with one finger exactly to the point touched.
- Support the hand or foot well; avoid stimulating other sensory pathways:
  - Avoid moving joints (proprioception);
  - Avoid giving too much pressure (deep sensation).
- Record sensation on the hand and foot maps on the patient's record card. If he/she can touch within 2 cm, record '✓' (tick) at the place on the map. If s/he cannot point to the place touched, record 'X'.

**Figure 9: Hands and feet sensation testing points**



### Eye examination

Particular attention needs to be paid to the eyes. Examine eyes carefully under good light, preferably daylight. Apart from loss of eyebrows, check:

- Cornea on clearness, ulcers or scars
- Conjunctiva on redness indicating infection: conjunctivitis (peripheral redness), iridocyclitis (diffuse redness) or keratitis (redness around the cornea).
- Pupil on regular and round shape. Check the pupil reaction to light and for signs of cataract.
- Eyeball pressure for glaucoma
- Vision by asking the patient to count fingers:



### **Vision test**

Stand six meters 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 3 or 4 times different numbers of fingers and ask the patient to count aloud. If s/he can count fingers at 6 meters, record 6/60 for that eye. If the patient cannot count fingers at 6 meters, the patient has severe visual impairment. Test also the other eye.

### **Other examinations of other organs**

Leprosy can affect a few organs other than skin and the peripheral nerves, *see page 75*.

### **Disability and disability grading**

Accurate baseline disability assessment and recording is important for the management of leprosy complications. Disability is defined as difficulty or inability to perform certain acts considered normal for a human being because of impairment. In leprosy control the word disability is used in a much wider sense and includes also visible deformities.

All disabilities found during examination of the peripheral nerves, eyes, hands, feet and other organs should be noted or recorded on the Leprosy Patient Card (LEP01). This includes:

- injured cornea
- loss of vision
- clawed fingers
- clawed toes
- wrist drop
- foot drop
- skin cracks and wounds on palms and soles together with sensation loss
- absorption of bone together with sensation loss
- scarring together with sensation loss.

This should then be followed by assessing the disability grade using the **WHO disability grading system**. Each eye, hand and foot needs to be graded separately. The highest value of the leprosy disability grade for any part should be taken as the overall disability grading of each new and any other leprosy patient.

**Table 17: WHO disability grading**

<b>DISABILITY GRADE</b>	<b>EYE</b>	<b>HAND/FEET</b>
Grade 0	No eye problem due to leprosy No loss of vision	No anaesthesia, no visible deformity or damage
Grade 1	Eye problems due to leprosy, but vision intact (6/60 or better, can count fingers at 6 metres)	Anaesthesia present, but no visible deformity or damage
Grade 2	Lagophthalmos, iridocyclitis or corneal opacity. Vision severely affected (<6/60 or unable to count fingers at 6 metres)	Visible deformity or damage, with anaesthesia.

### **3.6. Classification of leprosy**

The main purpose of classification is to decide on the treatment regimen (MDT) to be given to the patient. Leprosy is classified into two groups depending on the number of bacilli present in the body. Patients considered to harbour many bacilli belong to the multibacillary (MB) group; those with few bacilli form the paucibacillary (PB) group. Classification is also important as it may indicate the degree of infectiousness and the possible problems of leprosy reactions and further complications.

There are two methods of classifying leprosy, based on:

- the number of leprosy skin lesions
- the presence of bacilli in the skin smear

Skin smears are recommended for all new doubtful leprosy suspects and relapse or return to control cases.

Classify patients as follows:

<p><b>Multibacillary (MB) leprosy</b></p> <p><input type="checkbox"/> patients with six or more leprosy skin lesions</p> <p><input type="checkbox"/> positive skin smear</p> <p><b>Paucibacillary (PB) leprosy</b></p> <p><input type="checkbox"/> patients with one to five leprosy skin lesions</p> <p><input type="checkbox"/> negative skin smear</p>
--

If there is any doubt regarding the classification, the patient should be classified and treated as a multibacillary case. This certainly applies to patients who have been treated in the past and of whom insufficient information is available on the treatment previously used.

### 3.7. Case Definitions

Leprosy cases are only categorised in order to standardize recording and reporting. The definitions do not have a direct influence on the choice of treatment.

**New case:** A Paucibacillary (PB) or multibacillary (MB) leprosy patient who has never been treated before.

**Relapse after MDT:** A patient who has previously been treated and completed a full course of Multi Drug Treatment (MDT) and who returns with active disease.

Patients should be considered to have active disease when they present with one or more of the following:

- reddish and/or elevated skin lesions, especially at the edge of the patch
- appearance of new skin lesions since last examination
- new nerve involvement since last examination
- lepromatous nodules (MB)
- Positive skin smear

**Return after default:** A leprosy patient with either PB or MB leprosy, with active disease

returning after having defaulted treatment, that is a PB patient not having received any treatment for more than 3 months and an MB patient not having received treatment for more than 6 months. (For further explanation, see the section on defaulter management *page 94*)

**Transfer in:** A leprosy patient coming from another region, who has already started treatment and is already notified in that region.

**Other:** Any leprosy patient who does not fit in the above categories, including patients who return with active disease and who were previously treated with a course of DDS.

### 3.8. Differential diagnosis of leprosy

There are many skin conditions that look like leprosy and it can be difficult to differentiate them. The most important criteria to differentiate leprosy from other skin conditions are of two cardinal signs skin conditions which should be differentiated are as follows:-

- **Pityriasis alba:** this is a form of eczema which occurs predominantly in children and adolescents. Multiple hypopigmented, vaguely bordered, very finely scaling patches are found on the face and trunk and sometimes on the extremities. These can persist for years, sometimes reacting to steroid cream but most times clearing spontaneously with time.
- **Lichen simplex:** there is most times one well-circumscribed lesion of lighter thickened skin, which is very itchy. It is caused by continuous scratching or rubbing on a part of the skin that started itching. The vicious circle of itch-scratch-lichenification-itch can be broken if the patients stops scratching. Coal tar or zinc ointment can be given to reduce the itching.
- **Nutritional dyschromia:** single or multiple, ill defined, hypopigmented lesions can occur, usually over the cheeks, due to lack of vitamins. The patches will disappear on treatment with vitamins.
- **Pityriasis versicolor:** this is a common, chronic, superficial fungal infection caused by a yeast. Multiple, small, hypopigmented macular lesions without loss of sensation and often itching. They most times clear within six weeks with an appropriate anti-fungal treatment (imidazole crème twice daily with combination of selenium sulphide shampoo, twice weekly, if scalp is involved)
- **Tinea corporis (ringworm):** a common fungal infection presenting in a typical round lesions, which show scaling at the periphery, or in concentric rings. Most times one or few lesion on arms, face or shoulders. Can be treated with antifungal treatment like imidazole or Whitfield ointment, twice daily, for 4 weeks.
- **Vitiligo (leucoderma):** a common, sometimes familial depigmentation of the skin. It can start at any age but most times in young adults and progresses from small round white maculas to larger lesions with often bizarre shapes. There is no loss of sensation or any other signs or symptoms of leprosy. The skin feels normal. There is no treatment. Patients need to be reassured that it is only a change of colour. Lesions on sun-exposed parts of the body might need protection against sunburn.
- **Psoriasis:** this is chronic, recurrent, inherited, non-infectious skin disease caused by an abnormal fast turnover of the skin cells. The skin grows too fast, becomes too thick forming silvery-white scales, which easily bleed when scratched. Treatment is temporary as the disease is recurrent. It can be treated with a combination of Salicylic

acid 2-10% and coal tar 5-10% ointment or sulphur 5% in coal tar 5-10%. Serious cases can be treated with strong topical steroid crème once or twice daily.

- **Birthmark:** hypo- or hyper-pigmented lesions of different sizes which have been present since birth and do not change.
- **Onchocerciasis:** (in endemic areas) hypo-pigmented maculas and signs of scratching are often the manifestations of onchocerciasis. There is itching but no loss of sensation. In a later stage of the disease there are mottled lesions particular in loins and armpits. Previous complaints of itching exclude leprosy.
- **Syphilis:** secondary syphilis presents as a generalised symmetric rash, which can mimic almost any other skin condition. Ask for the history of a genital ulcer 1-2 months prior to the onset of the rash. Secondary syphilis should be treated with benzathine penicillin 2.4 million units (IM) weekly for three weeks.
- **Kaposi sarcoma :** the nodules are firm and have a purplish colour. They are usually located at the feet but can be present elsewhere.
- **Neurofibromatosis:** Multiple deeply pigmented soft nodules, which usually appear in adulthood.

### 3.9. Recording and Reporting of Leprosy

As in tuberculosis control, accurate record keeping of all patients, maintaining up-to-date patient record cards and registers and timely and correct reporting to the relevant level is essential.

Health Workers (HWs) of peripheral health units who are trained in leprosy can diagnose leprosy in new patients and record their findings on the Leprosy Patient Record Card (LEP01). When there is no doubt on classification, the GHW can start MDT and record attendance in the Leprosy Unit Register (LEP03) and on the Leprosy Identity Card (LEP02). When there is doubt about the diagnosis or when the patient has been treated before, the HWs should refer the suspect to the Tuberculosis and Leprosy Coordinator. All (new and previously treated) patients need to be seen by the DTLC as soon as possible, certainly within three months.

The DTLC is responsible first of all for **confirmation of the diagnosis** of new and previously treated patients. He/she should then repeat a complete physical examination including VMT/ST for the baseline examination and take skin smears if indicated and if they haven't been done before.

After confirming the classification, the DTLC should complete the patient record card before the patient is entered in the Leprosy District Register (LEP04). All treatment units keep a Leprosy Unit Register (LEP03) that is maintained by the unit health staff, but needs to be checked or completed by the DTLC on every visit.

The DTLC notifies newly registered leprosy cases on a quarterly basis to the RTLC by completing the Leprosy Case Notification report (LEP07) using the case definitions given below. The Quarterly Report on Leprosy Treatment Results (LEP09) includes the treatment outcome of MB patients notified in the quarter ending 24 months earlier and of PB patients notified in the quarter ending 12 months earlier. The quarterly reports also include information on number of patients with reaction and the outcome of reaction treatment. On an annual basis the DTLC has to report on the activities and progress made in Prevention of Disabilities (POD) in his/her district by completing the Annual Report on POD (LEP10).

All these forms have to be handed to the RTLC during the quarterly meeting (within two weeks into the new quarter). This allows the RTLC to check all district data with the district leprosy register. District reports should then be sent to TLCU and have to reach the Ministry of Health latest six weeks / before the end of the second month into the new quarter. However, the region should compile a quarterly report for local use. TLCU will check and compile all data.

The data are analysed and used for assessing district and regional performance. TLCU will seek clarification where necessary and give feedback during the NTLP meetings. Eventually a summary is produced in the NTLP annual report.

### **3.10. Health Education**

Health education at the time of diagnosis and during the course of treatment is essential, not only for good treatment success but also to prevent new or further disabilities. Good health education will also contribute to a better understanding and acceptance of the disease by the patient, relatives, friends and community. Together with increased awareness in the community, the leprosy stigma might disappear and suspect patients will hopefully report at an earlier stage.

The initial health education talk is given by the trained HW or by the DTLC when the diagnosis is confirmed and the patient registered. Health education continues during treatment and in this stage can also be provided by other health workers. When health education is given to groups of patients at OPD or in hospital wards, diseases such as HIV, tuberculosis, malaria, also should be addressed.

Important messages for a newly diagnosed leprosy patient are listed below but this list is not exhaustive.

#### **Health Education at diagnosis on leprosy disease and chemotherapy**

Ask first what the patient knows about the disease. Explain that

- it is an infectious disease
- transmission is through the air by inhaling infectious droplets
- known (cultural) misconceptions on the above issues
- Multiple Drug Treatment using blister packs is free of charge and will cure the patient. Explain the use of the blister pack and the necessity of completing the 6 or 12 months regimen
- the major side effects of anti-leprosy drugs
- Leprosy may damage nerves, causing loss of sensation and/or weakness of muscles which leads to disability
- signs of nerve impairment
- signs of leprosy reactions and possible treatment.

Provide health education materials whenever available.

For patients who come already with nerve function impairment, give health education on prevention of (further) disabilities. Explain

- the ABC of prevention of complications (*see Prevention Of Disabilities page 112*)
- how to avoid further damage to hands, feet, eyes, etc. in case of sensation loss or loss of motor function
- the need and possibilities for corrective surgery

Give IEC material for educating the patient is relatives and friends.

### **3.11. Treatment of Leprosy**

#### **3.11.1. Basic principles of leprosy treatment**

The aim of leprosy control is to cure patients, to detect and treat leprosy reactions, to prevent further damage to nerves and other tissue in patients with an already existing disability and to prevent further transmission to other community members.

Multi Drug Treatment (MDT) is the only adequate chemotherapy that will kill bacilli. MDT is a combination of a minimum of two anti-leprosy drugs, prescribed in the correct dosage, taken regularly for a period of 6-12 months. Multi bacillary (MB) patients are treated for a period of 12 months while paucibacillary (PB) cases are treated for 6 months. Treatment of leprosy with only one drug will result in development of drug-resistance, therefore mono-therapy should be avoided.

Treatment of leprosy reactions and other complications are part and parcel of leprosy management and control.

#### **Multiple Drug Treatment**

Tanzania adopted the WHO recommended MDT regimens since 1996. Based on the classification of Multibacillary or Paucibacillary, the patient receives a combination of rifampicin, dapsona and clofazimine in case of MB or rifampicin and dapsona in case of PB.

Both regimens are given in the form of a blister pack on a monthly basis. The patient should thus attend the nearest clinic where she/he is registered to collect blister pack and for clinical assessment.

The patient takes the first dose under direct observation of a health worker: that means the health worker should ascertain that the patient really has swallowed the capsules and tablets. For the following 27 days the patient then takes the medicine without being supervised by the health worker.

### 3.11.2. Treatment Regimens

The drugs and dosages for PB and MB for both adults and children is shown in the table 16 below

#### *Dosage (Adult MB)*

***Monthly Treatment: Day 1***

Rifampicin 600 mg (2 x 300mg)  
Clofazimine 300 mg (3 x 100mg)  
Dapsone 100mg

***Daily treatment: Day 2 – 28***

Clofazimine 50mg  
Dapsone 100mg.

***Duration of treatment***

12 blister packs to be taken within a period of between 12 - 18 months

#### *Dosage (Child MB 10-14 years)*

***Monthly Treatment: Day 1***

Rifampicin 450 mg (3 x 150mg)  
Clofazimine 150 mg (3 x 50mg)  
Dapsone 50 mg

***Daily Treatment: Days 2-28***

Clofazimine 50 mg every other day  
Dapsone 50 mg daily

***Duration of treatment***

12 blisters packs to be taken within a period of between 12 - 18 months



**Dosage (Adult PB)**

**Monthly Treatment: Day 1**

Rifampicin 600mg (2x300mg)

Dapson 100mg

**Daily Treatment: Days 2 – 28**

Dapson 100mg

**Duration of treatment**

6 blisters packs to be taken within a period of between 6 – 9 months

**Dosage (Child PB 10-14 years)**

**Monthly Treatment: Day 1**

Rifampicin 450mg(3x150mg)

Dapson 50mg

**Daily Treatment: days 2 – 28**

Dapson 50mg

**Duration of Treatment**

6 blisters packs to be taken within a period of between 6 – 9 months

**BLISTER PACK FOR MULTIBACILLARY (MB) PATIENTS**



**BLISTER PACK FOR PAUCIBACILLARY (PB) PATIENTS**



### 3.11.3. Side effects of MDT drugs

The majority of leprosy patients complete their treatment without developing any significant side effects. Dapsone is a relatively safe drug in the dosage used in MDT. Patients taking monthly rifampicin rarely experiences toxic effect of the drug. Clofazimine is well tolerated and has few side effects virtually non-toxic. However few patients might develop side effects and therefore patients need to be educated and monitored on these possible side effects. The decision to stop and change treatment because of side effects should be taken with great care to avoid inadequate treatment. **Use the table of Annex ..** to explain to every patient what the most common side effects can be. Whenever a patient complains, check if it may be the result of a side-effect of one of the drugs.

**Table 18: Possible side effects of leprosy drugs**

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

#### **3.11.4. Treatment in special cases**

**Pregnancy:** The standard MDT regimens are considered safe, both for mother and child and should therefore be continued during pregnancy.

**Tuberculosis:** Patients suffering from both tuberculosis and leprosy require appropriate anti-tuberculosis therapy in addition to the MDT. Rifampicin must be given in the dose required for the treatment of tuberculosis. Once the anti TB treatment is completed the patient should continue his monthly rifampicin for leprosy treatment.

**HIV:** The management of a leprosy patient infected with HIV is the same as that of any other patient. The response and cure rate of HIV positive patients is the same as in other patients. The management, including treatment of reactions, does not require any modifications.

#### **3.11.5. Monitoring of Treatment**

MDT should be provided to the patient as close to the patient's home as possible. Based on the geographical distribution of health facilities, the availability of trained staff and the patient's wish, the health worker and or DTLC decides where MDT should be delivered. In principle every health facility should be able to provide MDT. The staff needs to be trained on leprosy management as described in the NTLT Training manual for health workers.

Patients should have access to treatment on any day immediately after finishing the Blister pack, but they should be given an appointment to attend a fixed clinic day in order to be reviewed and assessed by a trained health worker or DTLC. The trained health worker or DTLC should arrange leprosy clinics in every three months. The DTLC in collaboration with the district pharmacists is responsible for the supply of MDT drugs, and drugs for treating reactions. The health worker and/or the DTLC is responsible for the regular nerve function assessment of the patient. S/he should update the Leprosy Patient Card (LEP01) with the findings of the VMT/ST. Progress should be recorded in the card. The health worker in consultation with the DTLC should take action when deterioration is noted. There should always be a minimum of three blister packs in stock for every patient attending that clinic at any given time.

Under normal circumstances patients should not be given more than one month (one blister pack) drug supply. Those patients who can not come on monthly basis to a health facility due to problems such as long distance, impassable roads during the rainy season, nomadic life-style etc, may be given drugs for more than one month, sufficient to cover the expected period of absence. Under exceptional circumstances a full course supply can be given. When patients are given more than one month supply, it is better to involve a formal or informal community leader or relative who will then be oriented to support the patient to complete

the full course of treatment (accompanied MDT). Such patients should be advised to report to the nearest health facility if they develop any complication.

Each time a patient comes to a health facility to collect an MDT blister pack, the staff should ask the patient about new complaints regarding nerve function impairment. If there are any complaints, the health worker should conduct nerve function tests to assess for nerve damage. If there are indications of nerve damage, the patient should be managed appropriately as described under management of reactions. In case of uncertainty, the health worker should refer the patient to the DTLC. The health staff is also responsible for tracing a patient who does not attend for two consecutive months. When the patient is found, she/he should be persuaded to continue with treatment (see defaulter management).

Health staff of MDT clinics is also responsible to maintain appropriate patient records, which includes updating the Leprosy Identity Card (LEP02) and Leprosy Unit Register (LEP03).

### **Compliance to MDT**

#### **Paucibacillary leprosy**

- PB patients should receive 6 doses to be taken within a maximum period of nine months. When collecting the 6th dose the patient should be released from treatment (treatment completed)
- Every effort should be made to enable patients to complete chemotherapy. A patient whose treatment is cumulatively interrupted for more than three 'months' or patient who has missed three doses of MDT in total and hence cannot complete the 6 doses within 9 months, should be recorded as defaulter.
- If a defaulter returns later to the clinic, s/he should be given ONE-second course of PB MDT.

#### **Multibacillary leprosy**

- MB patients should receive 12 doses to be completed within a maximum period of 18 months. When collecting the 12th dose of MDT the patient should be released from treatment (treatment completed).
- Patients who fail to collect the 12 doses of MDT within 18 months should be given ONE second chance to complete a full course of MB MDT. The procedures for a second course of MB MDT is as follows:
  - A patient whose treatment is cumulatively interrupted for more than six 'months' or A patient who has missed 8 doses of MDT in total and hence cannot complete the 12 doses within 18 months, should be recorded as defaulter.
  - When a defaulter reports at a clinic, a second course of MDT should be started after the importance of regular treatment has been discussed with the patient. Patients who restart treatment must be entered into the District Leprosy Register again with a new number as return after default and thus should be included in another treatment cohort for assessing completion of treatment.
  - Every effort should be made to ensure that patients complete the second course of MDT as recommended.

- After completion of the second course of MDT the patient should be recorded as treatment completed.
- A patient who fails to complete the second course should **only** be commenced on the third course of MB MDT after consultation with RTLCs

### **Monitoring clinical improvement**

A leprosy patient who fails to improve during treatment may have a reaction or may be a suspect drug-resistant case (treatment reaction is described **on page ...**). However, with the proper use of multi-drug treatment the chance that leprosy bacilli develop drug resistance is virtually nil.

To "prove" that this patient is harbouring drug-resistant bacilli the DTLC must arrange that the patient takes daily supervised treatment of all his leprosy drugs. If s/he fails to improve or gets worse, it is likely that s/he has (acquired) drug resistant leprosy. In this case the RTLC should be consulted for further investigation and management.

In order to avoid emergency of drug resistance Health workers should always give Multi Drug Therapy (MDT) to leprosy patients and never give mono-therapy.

### **Defaulter management**

There are various reasons for patients. not collecting MDT doses or defaulting. Patients may move to other places, where they may or may not continue treatment. Some patients experience unpleasant MDT side effects and may decide to stop treatment. Others feel cured following few months treatment. Again others may have no confidence in the treatment. Some may have experienced rude behavior of health workers and will stop treatment for those reasons. Patient may defaulter when they don't receive regular supply of MDT drugs in health facility

When a patient does not attend clinic, try to get information about him/her from the other patients. If possible, send a reminder to the patient or inform the Community Health Worker. Patients on MDT who did not collect their drugs for more than two months are potential defaulters and should be traced by health staff of the centre where the patient is getting treatment, in collaboration with the DTLC. If an absentee is traced, find out the reason for non-attendance. Appropriate further action should then be taken. S/he should be persuaded to continue treatment. If possible involve relatives or village leaders as well to ensure that the patient completes the treatment.

### **3.11.6. Recording and Reporting**

When the patient has completed MDT, write the treatment result on the patient record card (LEP 01) and in the unit and district registers.

The definitions of treatment outcome are summarised below:

<b>Treatment</b>	<p>PB patient: A patient who has received a full MDT treatment made up of <b>Completed</b> 6 PB MDT packages within 9 months for PB patients.</p> <p>MB patient: 12 MB MDT packages within 18 months for MB patients.</p>
<b>Died</b>	A patient who dies for any reason during treatment.
<b>Defaulter</b>	<p>PB patient: A patient whose treatment is cumulatively interrupted for more than three 'months' or patient who has missed three doses of MDT in total and hence cannot complete the 6 doses within 9 months.</p> <p>MB patient: A patient whose treatment is cumulatively interrupted for more than six months or a patient who has missed 8 doses of MDT in total and hence cannot complete the 12 doses within 18 months.</p>
<b>Transferred out</b>	A patient on MDT treatment transferred to another region and who's treatment outcome is not known.at the time cohort report is due

Do a complete physical examination including VMT/ST before releasing the patient from treatment. Fill the results in the patient record card and **compare VMT/ST at the end of treatment with the baseline assessment at start of MDT**. Score the result as IMPROVED, NO CHANGE or DETERIORATED and enter the result in the patient treatment card, the unit register and district register. Tabulate and report in the quarterly cohort report on treatment outcome.

Give all necessary health education and remind the patient to come back whenever she/he has complaints compatible with reactivation of the disease or a complication.

### 3.12. Leprosy Reaction

A leprosy reaction is the sudden appearance of acute inflammation in the lesions (skin patches, nerves, other organs) of a patient with leprosy. This is due to an alteration in the immunological status of the patient. **Reactions are the major cause of nerve damage and disability in leprosy**. Therefore they should be detected as early as possible and treated promptly.

Leprosy reactions are part of the natural course of the disease and can occur at any time. Reactions commonly occur during the early part of the disease. Sometimes patients report

for the first time to a health unit because of a leprosy reaction. Some reactions are seen after completion of treatment.

Clinically one can find swelling and redness of skin lesions, which are warm and sometimes tender when touched. There may be swelling, pain or tenderness of nerves, signaling neuritis, which is often accompanied by loss of nerve function (sensory and/or motor). New lesions may appear. Always ask the patient how long she/he has had these complaints.

Besides RTLCs and DTLCs, all health workers in a health unit providing MDT should be aware of the dangers, frequency and signs and symptoms of leprosy reactions.

The diagnosis and treatment of severe reaction is urgent because of the risk of permanent nerve damage.

*The risk of developing nerve function impairment can be predicted as follows:*

PB patients with no nerve function loss at diagnosis	1% – 2%
PB patients with nerve function loss at diagnosis and MB patients with no nerve function loss at diagnosis	16%
MB patients with nerve function loss at diagnosis	65%

The health workers and DTLCs should explain carefully to all patients who start MDT the following;-

- The possible occurrence of reactions
- The signs and symptoms of reaction in skin and nerves
- That the occurrence of leprosy reactions does not indicate that MDT is not effective.
- That a reaction is not an adverse side effect of the drugs
- That MDT should therefore always be continued during a reaction.

There are two types of reactions.

- Reversal Reaction (RR) or type I reaction
- Erythema Nodosum Leprosum (ENL) or type II reaction.

### **3.12.1. Reversal Reaction (RR) or type I reaction**

This is the most common type of reaction. This occurs in 10 - 20% of PB patients and in up to 40% of MB patients. It is important to make a difference between mild and severe reactions. Only the severe reactions need treatment with corticosteroids (e.g. prednisolone).

A reversal reaction is considered **severe** if:

- One or more nerves are painful or tender on palpation (neuritis), with or without signs of nerve damage (loss of sensation and/or muscle weakness)
- Muscle weakness developed or increased within the last six months (compare VMT with previous VMT).
- Loss of sensation developed or increased within the last six months (compare ST with previous ST).
- A raised red lesion around an eye.
- Skin lesions have become red, raised and ulcerative.
- In addition to above criteria, there may be oedema of hands and feet.

Sometimes there is a gradual change in strength or loss of sensation without the typical signs of neuritis (nerve pain/tingling/tenderness). This indicates the presence of *silent neuritis* requiring also treatment with prednisolone and rest. It can only be found if the DTLC does routinely the VMT/ST.

All other reactions without nerve involvement are classified as mild reactions.

Any health worker should be able to suspect leprosy reactions based on the above symptoms. Depending on the condition of the patient the health worker should consult the DTLC at the earliest opportunity or refer the patient immediately.

#### **THE IMPORTANCE OF VMT / ST**

Doing VMT/ST at least once quarterly is important for the following reasons:

- To detect early changes in nerve function.
- To detect silent neuritis.
- To indicate the need for medical treatment.
- To monitor the effectiveness of medical treatment, recovery of nerve function.
- To identify health education needs on specific self care/need for protective aids.

The time spent doing VMT/ST provides an important opportunity to provide “one to one” health education and for the patient to report any changes of nerve function.

#### **Treatment of Reversal Reactions:**

During reaction treatment, continue MDT until the course is complete. Reversal reactions sometimes occur after completion of a full MDT course. The management of these cases is the same, but explain to the patient that the reaction is not a relapse of the disease and that appropriate prednisolone treatment prevents nerve damage.

#### **Mild reactions:**

These can be controlled by rest and the usual doses of analgesics (such as aspirin, paracetamol, ibuprofen).

#### **Severe reactions:**



Treat severe reaction with prednisolone. Most patients can be treated ambulatory, preferably using blister calendar packs: the complete standard treatment is available as Prednipac®. Prednisolone tablets available in a health facility can also be used as indicated in the table below. Refer to the nearest hospital immediately those patients who are really very sick (high fever, severe pain) due to severe reversal reaction. The standard schedule of the treatment of reversal reactions with prednisolone is as follows:

**Table 19: Standard treatment with prednisolone of severe RR in MB and PB patients**

40 mg daily (8 tablets of 5mg or 1 tablet of 40mg Prednipac	2 weeks
30 mg daily (6 tablets of 5mg or 1 tablet of 30mg prednipac	2 weeks
20 mg daily (4 tablets of 5mg or 1 tablet of 20mg Prednipac	2 weeks
15 mg daily (3 tablets of 5mg or 1 tablet of 15mg Prednipac	2 weeks
10 mg daily (2 tablets of 5mg or 1 tablet of 10mg Prednipac	2 weeks
5 mg daily (1 table of 5mg)	2 weeks
<b>Total</b>	<b>12 weeks</b>
<b>Continue MDT during treatment of reversal reaction</b>	

**Monitoring of standard prednisolone treatment**

It is advised to give that the the first 4 weeks of prednisolone should be supervised by a health worker on a weekly basis to assess improvement. Thereafter the patient can collect new blister packs every fortnight. At each visit the health staff should enquire about problems and side effects. If there is no improvement, patients should immediately be referred to the DTLC or a hospital. Health workers should be reminded to refer those who do not improve within two weeks after starting standard treatment. Signs of clinical improvement are subsiding fever, pain and oedema.

In the hospital, the dose of prednisolone should be adjusted, especially in the presence of severe nerve pain and/or acute motor paralysis. However, it is recommended, to start with a 60 mg dose, which should be be tapered off slowly as shown below on Table 15. In exceptional cases (very sick patients, body weight above 60 kg) give 80 mg prednisolone for a few days until the acute inflammation subsides. In such severe cases and in those with recurrent reactions it is important to give a 20 mg maintenance dose for 10 weeks, as this will increase the chance of full recovery.

**Table 20: Hospital treatment with prednisolone of severe RR in MB and PB patients**

60 mg daily (12 tablets of 5 mg prednisolone)	1 week
50 mg daily (10 tablets of 5 mg prednisolone	1 week
40 mg daily (8 tablets of 5 mg prednisolone)	2 weeks
30 mg daily (6 tablets of 5mg prednisolone)	2 weeks
20 mg daily (4 tablets of 5 mg prednisolone)	10 weeks
15 mg daily (3 tablets of 5 mg prednisolone)	2 weeks
10 mg daily (2 tablets of 5mg prednisolone )	2 weeks

5 mg daily of (1 tablet of 5 mg prednisolone)	2 weeks
Total	22 weeks
Continue MDT during treatment of reversal reaction	

If a nerve remains very painful and swollen after two or more weeks of high dose prednisolone, there may be a nerve abscess and surgical decompression should be considered. Refer the patient to a specialist centre where possible. If the signs of reaction return when lowering the dose of prednisolone, the dose should be increased until the reaction subsides and an even slower process of tapering off the prednisolone should be followed.

### **Precautions before starting prednisolone**

Prednisolone is a powerful hormonal drug, which can be dangerous if not given properly. Instruct the patient to keep strictly to the prescribed treatment, as a sudden interruption or ending of the treatment can cause severe side effects, which can lead to death. Give the treatment schedule and explanation on paper, so that the patient has a reference.

Prednisolone may worsen any other existing infection. It is therefore important to treat existing infections like dysentery, trachoma, worm infections, scabies, etc. Treatment for the above conditions should be started immediately and does not need to wait until the treatment is completed before starting prednisolone.

### **Prednisolone side effects**

There are many complications and side effects of prednisolone.

The most common are:

- Exacerbation of infections, which have not been treated fully (e.g. tuberculosis, amoebic dysentery, etc.).
- Abdominal discomfort, which can be treated with antacid.
- Exceptionally patients develop stomach ulcers, which will make them vomit blood or pass black-coloured stool.
- Signs of diabetes, such as thirst, frequent micturation, fatigue.
- General illness and fever.

Patient with above complications should be referred to hospital

### **Education of patients**

Before the start of treatment with prednisolone, give the patient an explanation of:

- the need for daily and continued treatment with prednisolone and the expected duration of the course;
- expected effect on the pain reduction within a few days and loss of feeling and/or strength improvement after considerable period;
- The arrangements for examination and drug collection every two weeks at the nearest health facility;

- The need to report immediately if pain increases, loss of feeling increases and/or strength decreases;
- The need to report immediately if any general illness and/or fever develops;
- The need to report immediately if any side-effect of the drug occurs.

### **Supportive measures**

Additional to prednisolone, it is important to provide complete rest to the affected nerve(s) until the symptoms disappear. It might be useful to immobilise the affected limb with a splint.

When the signs of acute inflammation have subsided, other measures, especially physiotherapy, play an important role in the management of patients with reactions.

### **Follow-up during reaction treatment**

At four-weekly intervals, the DTLC should examine the patient (VMT/ST assessment) and record the findings. When nerve function deteriorates the patient should be referred to the hospital for admission.

Patients on ambulatory treatment with prednisolone who *missed less than 4 weeks* treatment, should continue with the same dose of prednisolone as they were taking before they stopped.

Patients who *miss more than 4 weeks* of prednisolone treatment should start a full course of prednisolone again unless there are no signs of nerve damage anymore.

### **Recurrence of severe reversal reaction**

When a patient has responded positively on a previous course of prednisolone but the reaction recurs or nerve function deteriorates, the DTLC may start a second course of prednisolone, provided there are no contra-indications. The examination procedures as given above should be repeated.

If there is no clinical improvement on the second course of prednisolone the DTLC should refer the patient to the hospital. Patients who responded well to prednisolone but develop a reaction for the third time, should also be referred to hospital.

## **3.12.2. Erythema Nodosum Leprosum (ENL) or type II reaction**

ENL occurs only in multibacillary leprosy patients. An estimated 5 to 10% of MB patients develop an ENL reaction. There are mild and severe ENL reactions. In general ENL presents as tender reddish skin nodules with fever, joint pain and malaise. Some patients may develop **Severe ENL reaction** which is often recurrent and chronic. It can present with:

- Ulcerating nodules (necrotising ENL)
- Tender nerves with or without loss of sensation or motor weakness
- Painful red eye (s) due to iridocyclitis

- Painful swollen testes (orchitis)
- Painful swollen fingers (dactylitis)
- Oedema of lower arms and legs

Very few patients may even develop a dual reaction of ENL and RR simultaneously. Patients with ENL sometimes present in a serious, life threatening condition and immediate recognition and treatment in a hospital is necessary. The reaction is often triggered by special circumstances like emotional stress, other (infectious) diseases such as malaria, TB; pregnancy or childbirth, etc.

### Treatment of ENL

Treat **mild ENL** reactions with rest and analgesics (e.g., aspirin 600 mg 8 hourly) for one week. Re-examine the patient for signs of new nerve damage at weekly intervals. If no improvement after six weeks with analgesics or if signs of a more severe ENL reaction occur, the treatment should be changed to prednisolone.

Refer a patient with **severe ENL** to the nearest hospital for appropriate examinations and treatment by a physician or RTLC.

Treatment with MDT should always continue until the standard MDT course is complete. Give patients with severe ENL reaction an adequate dose of analgesics to control fever and pain. Use a standard course of prednisolone in dosage not exceeding 1 mg per kg. body weight for a maximum duration of 12 weeks as shown in the tabl below. This may be sufficient to suppress the immune reaction and restore the nerve function.

**Table 21: The standard treatment schedule prednisolone:**

Week	daily dose prednisolone	1	2	3	4	5	6	7
1.	mg	50	50	50	50	40	40	40
2.	mg	40	30	30	30	30	20	20
3.	mg	20	10	10	10	5	5	5

### Recurrent ENL

A few patients get recurrent episodes of ENL as soon as the dose of prednisolone comes below 20 or 15 mg per day. This is called chronic or recurrent ENL. It carries the risk of prednisolone dependence and thus increases also the risks of prednisolone side effects. Such patients are better management by providing them with clofazimine.

The general principle of managing severe recurrent ENL is as shown below:

- If still on antileprosy treatment, continue with the standard MDT course until it is complete.
- Use adequate dose of analgesics to control fever and pain.

- Use a standard course of prednisolone in dosage not exceeding 1 mg per kg. body weight for a maximum duration of 12 weeks
- Start clofazimine 100mg three times a day for a maximum of 12 weeks
- Taper the dose of clofazimine to 100mg twice a day and then 100 mg once a for 12 – 24 weeks.

The table below shows the schedule to treat patients with **recurrent ENL** with Clofazimine which may last up to 1 year:

**Table 22: Treatment of recurrent ENL**

<b>Duration (months)</b>	<b>Dose of Clofazimine</b>
1 - 3	1 capsule of 100mg three times daily
3 - 6	1 capsule of 100mg two times daily
6 - 12	1 capsule of 100mg once daily

**Remember: Treatment with MDT should always continue until the MDT course is complete.**

**Management with clofazimine and corticosteroids:**

This is indicated in cases with severe ENL who are not responding satisfactorily to treatment with prednisolone alone or where the risk of toxicity with corticosteroids is high.

- If still on antileprosy treatment, continue with the standard MDT course until it is complete.
- Use adequate dose of analgesics to control fever and pain.
- Use a standard course of prednisolone in dosage not exceeding 1 mg per kg. body weight for a maximum duration of 12 weeks
- Start clofazimine 100mg three times a day for a maximum of 12 weeks
- Complete the standard course of prednisolone. Continue with clofazimine as above
- Taper the dose of clofazimine to 100mg twice a day and then 100 mg once a for 12 – 24 weeks.

During the first month of treatment with 300 mg Clofazimine per day, maintain prednisolone at the dose with which the patient does not experience signs and symptoms of ENL. Thereafter prednisolone should be tapered off with 5 mg every two to four weeks until it can be stopped, while Clofazimine is given according to the above schedule. Note that the speed of tapering off the dose of Clofazimine will be determined by the clinical improvement of the patient.

When signs of ENL recur during lowering the dose of Clofazimine the previous higher dose should be given again. Then tapering off should be done over a longer period.

### 3.12.3. Responsibilities of health workers regarding treatment of reactions

The in-charge of the peripheral health unit is responsible for the following:

- history taking and examination of the patient
- giving initial dose of prednisolone and immediate referral of patients to the DTLC or hospital if there is suspicion of a reaction or an indication of nerve function deterioration
- see patient after every two weeks; question the patient regarding new nerve function impairment and, in case of complaints, refer to the DTLC
- identification of complications and refer to the DTLC immediately
- retrieval of patients when not attending
- treatment of concurrent conditions prior to prednisolone treatment
- referral to hospital, if necessary.

The **DTLC** is responsible for:

- confirmation of the diagnosis of reactions
- checking for contra-indications to prednisolone treatment
- starting treatment with prednisolone
- VMT and ST examinations. Follow-up of patients at least monthly and when called to do VMT/ST at least once a month
- referral to hospital, if necessary
- recording of treatment and follow-up details on Patient Record
- Card
- giving health education to patients.

### 3.13. Relapse After MDT

**Relapse after MDT** concerns a patient who has previously been treated and completed a full course of Multi Drug Treatment (MDT) and who returns with active disease. Relapse is due to multiplication and spread of surviving leprosy bacilli in the patient's body.

Signs of relapse are:

- Active skin lesions: insidious appearance of new lesions and/or enlargement of old lesions.
- New nerve impairment. Enlargement and/or tenderness in nerves, which were previously not affected. Loss of sensation and or muscle weakness in places that were previously functioning normal.

Above signs can, however, also be observed in patients with a leprosy reaction (reversal reaction or ENL) after completing a full course of MDT.

It is difficult to distinguish, on clinical grounds alone, between a relapse and a reaction. An important diagnostic criterion for the differentiation is the period between the release from MDT and the occurrence of new signs and symptoms of active disease. In general a reaction

occurs within two years and a relapse usually after two years following release from treatment.

**Table 23: Difference between RR reaction and relapse**

<b>Features</b>	<b>Type 1 reaction</b>	<b>Relapse</b>
Time interval	Generally occurs during chemotherapy or within 6 months of stopping treatment, up to 2years after RFT	Usually occurs long after chemotherapy is discontinued, generally after an interval of 2 years or more
Onset	Abrupt and sudden	Slow and insidious
Systemic disturbance	May accompanied by fever or malaise	Never accompanied by fever or malaise
Old lesions	Some or all become erythematous, shiny and considerably swollen with infiltration	The margins of some may show erythema
New lesions	Usually several	Few
Ulceration	Lesion may break down and ulcerate	Ulceration is unusual
Subsidence	With desquamation	Desquamation does not occur
Nerve	Many nerves may be involved, with pain, tenderness, and motor disturbances occurring rapidly	May occur only in the a nerve; motor disturbance develop very slowly
Response to steroids	Excellent	Not distinctive

- If skin smears were taken in the past and can still be made reliably (Quality Control of AFB microscopy is undertaken regularly and results are satisfactory), this should be done for comparison. An increase in the Bacillary Index (BI) of acid fast bacilli (AFB) by at least 2+ from the same site as a previous skin smear and specific infiltration plus positive AFB in the histopathology of a suspected lesion is conclusive;
- Any patient with a positive Morphological Index (MI) in the skin smear is regarded as a relapse.

**Tasks of the DTLC when suspecting relapse**

- examine carefully any patient returning after MDT with signs and symptoms of a relapse;
- preferably take a skin smear and ask for BI and MI results;
- collect all relevant documents of the previous treatment, so that comparison with the new situation is possible;
- Consult the RTLC in all suspect relapse cases (or another experienced clinician) before starting treatment.

**Treatment of relapse**

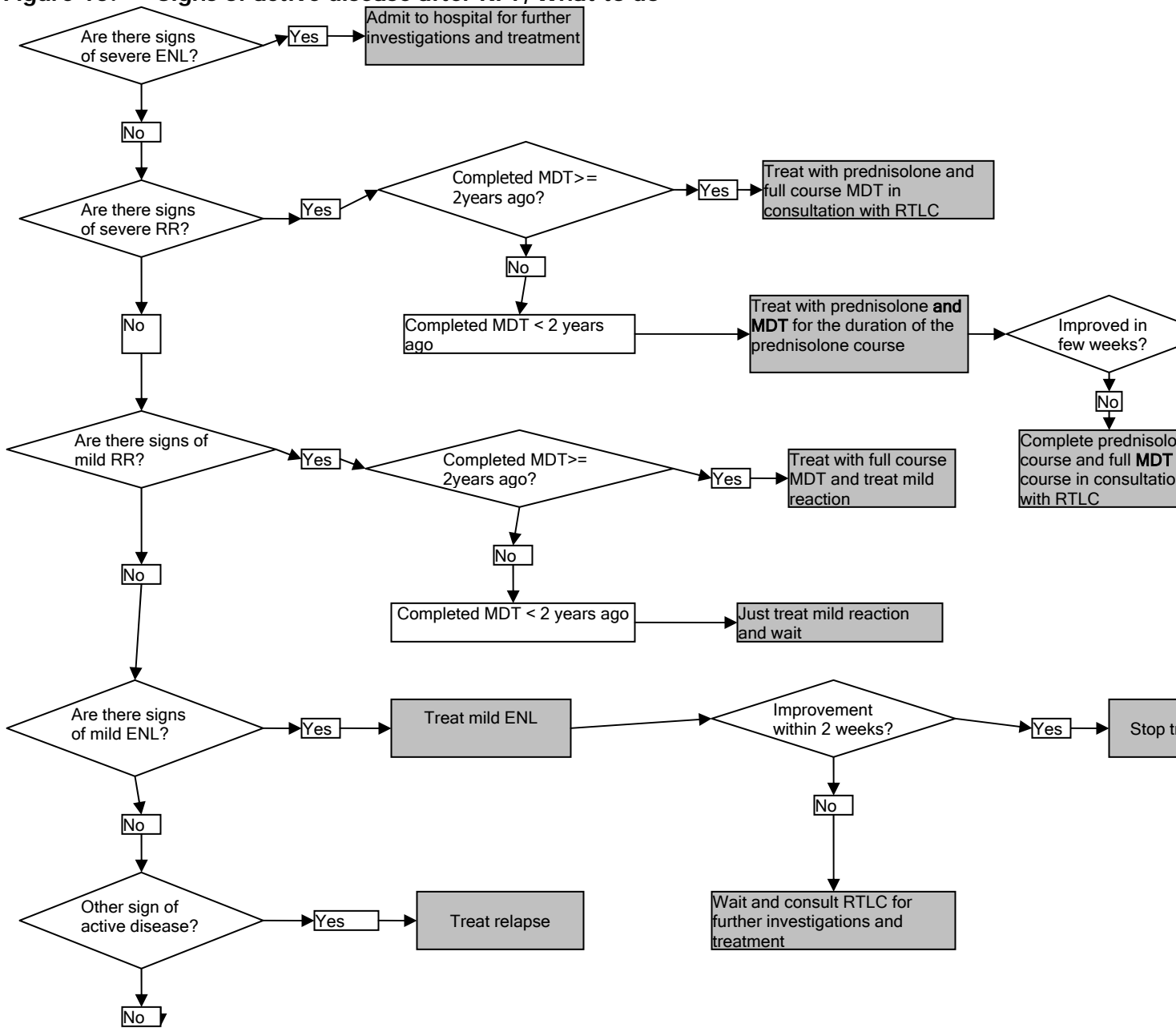
All patients with relapse should be treated with a full course of MB MDT:

- If the previous MDT course was stopped *more than 2 years ago*, give a full course of MB-MDT. If there is a severe reversal reaction, treat with a standard course of prednisolone.
- If the previous MDT course was stopped *less than 2 years ago*, start MDT treatment. Add a standard course prednisolone if there is a severe reversal reaction and observe the following conditions.

- If the patient improves within a few weeks, stop MDT at the end of the prednisolone course.
- If the patient does not improve within a few weeks, give a full MDT course. Refer to hospital if signs of severe reaction persist.
- Refer patients with severe ENL to a hospital for examination and treatment as indicated earlier.
- Patients with mild RR and the previous MDT was stopped *more than two years ago* should be treated for minor reaction together with a full course of MDT.
- If the MDT was stopped *less than 2 years ago*, only the minor reaction is treated. The patient should be instructed to return if the condition worsens. See the flow chart overleaf.



**Figure 10: Signs of active disease after RFT, What to do**



**Recording, registration and reporting of relapse**

Record on the Patient Record Card the clinical findings, the treatment (standard / other) with prednisolone, the results of treatment with prednisolone and the final diagnosis. Only patients matching the definition of "relapse after MDT" and after confirmation by the RTLC should be recorded, registered and reported. All other patients, "return after default", or those returning with active disease after having completed a full course of DDS in the past ("relapse after DDS"), are all to be classified as "other"

### **3.14. Prevention of Disabilities (PoD)**

PoD is part and parcel of a leprosy control programme. It comprises of all activities which lead to diminishing the occurrence of permanent nerve damage and its consequences.

The key to prevent disabilities is good communication with the patient and the community at large, resulting in mutual trust and understanding of the disease. It is important to convince patients, relatives and other community members to report suspected leprosy patients as early as possible.

#### **Prevention of disability consists of three important levels**

The three levels are:

1. early diagnosis and treatment of leprosy disease and associated reactions;
2. to ensure that patient with disabilities due to leprosy do not worsen;
3. physical and social rehabilitation of those persons affected by severe deformities and destitution.

These conditions are further explained in detail here below.

#### **3.14.1. First level prevention**

Early diagnosis and treatment of leprosy disease and associated reactions is the first level of prevention. Therefore the community should be educated on early symptoms of leprosy and patients should be instructed on how to recognize signs and symptoms of leprosy reactions with nerve involvement. If nerves are involved, treatment with prednisolone should be commenced as early as possible.

**Early diagnosis and prompt treatment with MDT is the best way to prevent disabilities!**

#### **3.14.2. Second level prevention**

Where the above actions have failed or when patients come late or are detected too late by the health service, the result is permanent nerve damage that leads to further disabilities. The second level of prevention is to ensure that these disabilities do not worsen

Most disabilities result directly or indirectly from loss of function of peripheral nerves supplying the eyes, hands and feet. Incomplete eye closure (poor or no blink) results in dryness of the cornea, injury and eventually vision loss and blindness. Nerve function loss in the hands and feet results in loss of sensation and sweating, which can lead to skin cracks,

injury, wounds and secondary infection. Loss of muscle strength will cause function loss, joint stiffness, contractures and an increase in the risk of further damage.

People with irreversible nerve damage have a life long risk of worsening their disabilities (secondary disabilities) if they don't take appropriate measures.

The key to preventing secondary disabilities lies in good communication that should result in convincing the patient to adapt his/her behaviour in daily life in such a way that the existing disabilities don't get worse. In many cases simple daily care and exercises have proved to be effective in keeping the skin supple, the joints mobile and even restore muscle strength in case of partial paralysis (paresis). Wearing shoes with a hard outer sole and a soft inner sole can prevent much damage to insensitive feet.

**Early detection of leprosy reactions and prompt treatment with prednisolone is the next best way to prevent disabilities!**

The NTLP is providing footwear to leprosy patients with insensitive feet free of charge. The footwear is centrally produced and distributed to all regions and districts twice per year. In addition, local shoemakers are provided with materials to make special shoes and boots and to do repairs. Nevertheless the patients should be encouraged to buy their own footwear as much as possible and to take care of the necessary repairs.

It is often difficult for people to change habits of daily life and persons with disabilities encounter many practical problems as they seek to adopt self-care. Thus staff needs to train them carefully and in a practical way, to gently motivate them to persevere and to help them solve the problems of self-care implementation. The full understanding and co-operation of the family is essential for success. Thus health education on the importance of self-care should be extended to members of the patient's immediate family.

Practical education on self-care includes the **"ABC of preventing complications"**, proper care of ulcers and exercises to avoid stiffness or contractures. Instruct the patient repeatedly on the following:

**A. Avoid Injury**

Continuous or repetitive moderate pressure on one anaesthetic area of the skin is the most common and important cause of injury. To avoid injury patients must learn also to use their eyes and think:

Hands and feet

- Stay away from hot or sharp objects
- Bandage tools that are frequently used or cover the hands;
- Avoid working with the same tool for a long time; change from one task to another when working with tools
- Wear protective footwear and thus avoid sharp objects, like thorns

- Avoid tight shoes or sandals
- Walk with short steps, avoid running
- Avoid walking long distances without resting
- Avoid unnecessary long standing and squatting, change position regularly
- Avoid standing or sitting close to fire.

#### Eyes

- Think and Blink. Patient should learn to actively blink his/her eyes several times per minute, especially when dust or dirt is around.
- Avoid contact with dust or dirt by wearing a hat, (sun) glasses and/or face cloth.
- Cover the eyes during the night with a clean piece of cloth. Apply eye drops (castor oil or methyl cellulose) at night to prevent drying out of the cornea.

### **B. Be careful with dry cracked skin and eyes with lagophthalmos**

#### Hands and feet

- Soak hands and feet daily in cool water for 30 minutes. If available, add soap or salt.
- If no bucket available: wrap a piece of cloth drenched in water around hands and feet.
- After soaking scrape off the hard skin using e.g. pumice stone. This should then immediately be followed, while hands and/ or feet are still wet, by applying oil or vaseline on the skin.

#### Eyes

- In case of paresis of eyelids (lagophthalmos, eye lid gap <5mm), tell the patient to exercise the eyelids by closing them tightly for 5 seconds only using the muscles around the eyes. Do this 30-40 times, three times per day.
- If lid gap is >5mm, refer the patient for tarsorrhaphy or other reconstructive surgery. Also ectropion and entropion can be operated.

### **C. Check daily for the first sign of injury**

This should become a routine activity of every patient in the evening.

#### Hands and feet

- Look for small cuts, blisters, thorns or swollen areas.
- Feel the feet and hands and test for hot areas of the skin as a sign of possible infection.
- Press the skin of affected areas to see if there are any tender spots.

#### Eyes

- Check daily for any dirt in the eyes or redness.
- Remove dirt with a clean cloth and/or clean (boiled) cooled water.

If the daily check shows that there is any sign of injury, the patient should treat this seriously. Rest is the key factor. When the above measures fail (as elaborated under A, B and C), an ulcer may develop.

### **Ulcers**

An ulcer is a localized necrotic lesion of the skin or mucous surface in which the superficial epithelium is destroyed and deeper tissues are exposed in an open sore.

A septic ulcer is an infected ulcer. The ulcer has purulent discharge. The surrounding tissue is warm, red and swollen. This may be associated with fever and enlargement of the lymph glands.

### **Care of ulcers**

Regardless its size, an ulcer will heal fastest when:

- The foot/hand has complete rest. For a foot it means no walking or walking under complete protected immobilization with a Plaster of Paris (POP). For the hand the patient can use a sling or splint in the anatomical rest position.
- The ulcer is kept clean. This is achieved by soaking the affected foot or hand in soapy or salted water for 30 minutes twice per day. The ulcer should then be dressed with a clean cloth or dressing. Antibiotics are only needed in case of spreading infection (redness, warmth, swelling, lymphadenitis and fever).

### **Prevention of contractures**

All exercises can prevent stiffness and decrease existing contractures. Active exercises can in addition strengthen the muscles.

Any patient with paresis of any kind should start appropriate active exercises, whereby the patient should use his weakened muscles to maintain suppleness, strengthen the muscles of the affected hand/foot and improve the function.

All patients with a total paralysis of hand or foot should start the appropriate passive exercises whereby e.g. the patient uses his good hand to straighten the fingers of his paralysed hand.

The DTLC or any other experienced person (rehabilitation officer) should instruct patients how to do the exercises.

Patients should be supplied with leaflets explaining all the exercises. Exercises should be done 20-30 times, three times per day. Report progress on the patient card and/or the POD journal.

In areas where there are many people affected with leprosy (PALs), formation of self care support groups should be promoted.

Teach health worker how to instruct patients about self care, how to measure the effects and when to refer to hospital if there is no improvement. In hospitals where there is a physiotherapist he/she should be involved in teaching patients on self care

### **Referral criteria for surgical treatment**

The majority of leprosy patients can and should be treated on outpatient basis at the nearest health facilities to their home. However, there are certain conditions that need specialized care and hospital attendance for which admission is necessary. Patients who need these services will be referred to specialized hospitals through the RTLC. It is necessary to report all these patient to the national level annually.

### **How to select candidates who could benefit from septic and rehabilitative surgery**

#### **Eyes**

- When a patient cannot close one or both eyes (lagophthalmos), especially when this goes together with red eye, exposure keratitis, cornea ulcer, etc.
- When a lower eyelid is paralysed (ectropion).
- When the upper eyelid is inverted and eye lashes scratch the cornea (entropion).

Refer immediately patients with eye complications such as "red eye" and/or diminished vision. Simple conjunctivitis can be treated at the peripheral level, but iritis, keratitis, corneal ulcer, lagophthalmos and glaucoma should be referred to an ophthalmologist.

#### **Hands**

- Acute infection of the hand is characterized by all signs of inflammation of the palm (palmar spaces) of the hand and along tendon sheaths and synovial sacs, with or without oedema of the dorsum of the hand. Acute infection may be caused by perforating trauma, spreading tendovaginitis from finger infection. Such conditions need urgent surgery for drainage together with antibiotics, splints and physiotherapy.
- Chronic infections / non-healing ulcers may lead to osteomyelitis with sequestra and/or osteoarthritis. These conditions may be diagnosed by using a probe, massaging for pus, feeling for hypermobility and checking for crepitations. Chronic infections/non-healing ulcers can be treated by a doctor trained in preventive and septic surgery.

Any patient with neuritis or a nerve function impairment that started not longer than 6 months before needs to be treated first with a (long) course of corticosteroids.

#### **Feet**

- Septic condition of the (fore) foot with pus, but without drainage
- Ulcer with deep infection: The following should be done to elicit the signs of deep infection in an ulcer.
  - probe the depth of the fistula/ulcer
  - massage the tissue to squeeze and look for pus

- press the joints for crepitations and/or pus
- look for:
  - \_ soft tissue infection
  - \_ osteoarthritis
  - \_ sequestrum
- Ulcer with undermined edges, usually over a joint.
- Larger plantar ulcer (greater than 3 x 3 cm).
- When an ulcer shows no progress in healing with conservative treatment including real bed rest.
- When there is an ulcer scar with a recurrent ulcer overlying a bony prominence as pressure point or a joint (when movement reduction with a POP splint does not help).
- Semi fixed or fixed clawing of toes without ulcers (for upgrading the foot to fit a shoe).
- Chronic ulcers on the toes and sequestra.
- If a patient comes with signs of a sprained ankle without a history of trauma, thus with a swollen, warm and painful ankle joint, with hypermobility and crepitations, even when little or no abnormalities on the X-ray can be seen: this is likely **tarsal disintegration**, which is an emergency!

#### **Indications for Below Knee Amputation:**

Amputation should be considered as a last resort intervention when other conservative procedures have failed. All possible measures should be taken to avoid amputation and preserve the limb. Some of the few indicators for amputation are as listed below.

- Chronic ulcer with obvious malignancy (squamous cell carcinoma) for which no local solution can be found (e.g. forefoot amputation not possible due to extent of tissue involvement)
- Chronic deep ulcer if no structures remain to support walking
- Gross deformity of the foot, not possible to upgrade with surgery
- Deep fungal infection (Madura foot).

Patients with severe destructive septic conditions (where debridement doesn't succeed and certainly when there is a vital indication) should be operated upon *immediately* and undergo amputation in any nearest-by hospital. Superficial ulcers should first be treated with a standard conservative approach (bed rest, soaking, dressing, including trimming of the ulcer edge). Only when there is a large ulcer with a flat granulating bottom can a skin graft be done. Also such patients may then be referred.

There are a number of general hospitals in Tanzania with medical officers specifically trained in septic and preventive leprosy surgery. Other hospitals have orthopaedic workshops where specific protective footwear, prostheses and crutches are made and supplied. The Leprosy Surgeon of the Flying Doctors from AMREF visits some hospitals. Few hospitals offer plastic surgery or rehabilitative leprosy surgery. For patient needing such services should be referred to the DTLC.

**Ulcers under the 5<sup>th</sup> metatarsal base and under the heel are HIGH RISK ULCERS and need referral to hospital!**

**Table 24: Referral hospitals for leprosy patients**

Hospital	Region	Reconstructive surgery	Orthopaedic workshop
Bukumbi	Mwanza	+	
Bugando Medical Centre	Mwanza	+	+
Kolandoto	Shinyanga	+	
Shirati	Mara	+	+
Muhimbili National Hospital	Dar es salaam	+	+
CCBRT	Dar es Salaam	+	+
Sikonge	Tabora	+	+
Dodoma General Hospital	Dodoma		+
Sekoutoure hospital	Mwanza	+	
Songea Regional Hospital	Ruvuma	-	+
Peramiho	Ruvuma	+	+
Kabanga	Kigoma	+	
Turiani hospital	Morogoro	+	+
nazareth	Morogoro	+	
KCMC	Kilimanjaro	+	+
Mnazi Mmoja Hospital	Zanzibar	+	+

### **3.14.3. Third level of prevention of disability**

This is basically physical and social rehabilitation of those persons affected by severe deformities and destitution. These patients can be rehabilitated by means of community based rehabilitation, sometimes reconstructive surgery, or vocational training. It is important to link physical and social - economic rehabilitation (SER) of PAL. The NTLP should facilitate the provision of SER to PAL through the department of Social and Welfare (in te Ministry of Labour and Social Welfare), NGOs and Community based Organisations (CBO).

#### **How to select candidates who could benefit from rehabilitative surgery.**

Priority for rehabilitative surgery is given to young people and children, to individuals in danger of losing their job or to those who may regain employment after surgery. The patient should be motivated to accept rehabilitation.

The DTLC should arrange for referral of leprosy patients who may benefit from rehabilitative or cosmetic surgery in consultation with RTLC. Depending on where certain services are available, the coordinator can refer the patient to the appropriate centre. Rehabilitative surgery is teamwork of surgeon, nursing staff and a physiotherapist with specific training in leprosy rehabilitation.



Indications for rehabilitative surgery are thus:

- lagophthalmos with exposure of cornea
- mobile claw hand
- mobile thumb with paralysed abduction/opposition
- mobile hand drop
- mobile foot drop.

Before referral, make sure the patient has:

- no signs of active leprosy and has completed MDT
- no sign of reaction and/or has completed a prednisolone course
- no skin infection, no scabies
- accepted a long process of rehabilitation.

Indication for orthopedic appliance:

- A patient with a below knee or an above knee amputation
- A patient with severe deformity of foot needing orthopaedic shoes.

#### **3.14.4. Rehabilitation**

Rehabilitation and reintegration of patients in society can only be achieved by sustained efforts of the patients, the health worker and the community as a whole. It is necessary to make the most of the patient's abilities rather than focusing on their disabilities. This can be achieved more effectively through a community-based approach than through the traditional institution based approach, which is not only highly expensive but also often inappropriate.

The following points should be emphasized in rehabilitation:

- rehabilitation should take place in the environment in which the patient lives, which might require some adaptation of the home
- priority should be given to POD by simple methods with emphasis on self-care, ie. what the patients can do themselves to prevent development and/or worsening of disabilities
- health education should form an important component of rehabilitation
- health workers should receive adequate training in POD
- rehabilitation of leprosy patients should preferably be an integral part of general rehabilitation services.

#### **3.14.5. Recording, registration and reporting of POD activities**

All disabled leprosy patients (with grade 1 and grade 2 disabilities) should be registered in the POD Register (LEP06). This register enables the DTLC to monitor the impact of self-care or any other intervention on the disability of the patient.

The DTLC should see all disabled patients who are still on MDT at least once every quarter.

Disabled patients who have been discharged from treatment should be seen once per year, for a minimum of three years. The findings of these reviews must carefully be recorded in the POD Register. The DTLC reports on the total number of interventions and their impact once per year to the RTLC, by completing the Annual Report on POD (LEP10). The RTLC should compile all reports from all districts in the region and submit to national level..

## **4. APPENDICES**

### **4.1. District management of NTLP activities**

#### **Planning, Monitoring and Evaluation**

Health sector reforms are aiming towards improvement of health services through delivery of cost effective intervention strategies. The main objectives of these reforms are to empower council health management teams (CHMTs) to take full responsibility in planning, supervision, monitoring and evaluation of health care delivery. TB/Leprosy control activities should be integrated into comprehensive council health plans.

The basis of a proper integration of NTLP in the district will depend on:

- Thorough evaluation and monitoring of TB and leprosy control activities based on programme indicators
- Timely and accurate planning and budgeting
- Proper communication with CHMT and other stakeholders

#### **Creation of a District NTLP Health Profile**

The DTLC is responsible for a proper evaluation and monitoring of the TB and leprosy control activities in his/her district. He/she should collect all relevant information, which forms the basis for the development of the district plan of NTLP activities.

The DTLC should obtain an accurate district profile from the CHMT members. A good profile contains information on population, socio-economic conditions, religion, health status and a map of the district. Important health indicators to be monitored are the Top 10 morbidity and mortality figures per age and sex group, nutritional status, EPI coverage, maternal mortality and information on health service infrastructure.

Besides this general profile, a DTLC should monitor important NTLP indicators and create a TB and leprosy profile of the district. This profile contains the standard reported indicators such as notification rate (by age and sex distribution), type of TB and treatment outcome. The DTLC should add data compiled during his/her supervision visits on number of diagnostic/ treatment centres, quality of laboratory services, available staff and training needs, drugs and supply stocks and specific problems such as TB-HIV, urban TB, TB among refugees etc.

#### **Planning and Budgeting District NTLP Activities**

The Health Sector Reforms have now reached the phase whereby CHMTs have to plan and budget for their annual district health activities. CHMT should identify all TB and leprosy control activities to be included into CCHP and the DTLC should be fully involved in the planning process. NTLP will provide essential package for district to enable them to plan and budget for NTLP services

## **Communication**

The DTLC is a co-opted member of the CHMT, which means that he/she will only attend CHMT meetings when requested by the members. It is therefore essential that the DTLC plays an active role in promoting the NTLP services in the district. Proper communication with CHMT members and other key stakeholders is essential. He/she should attend CHMT meetings as often as possible. The DTLC has to update the CHMT on the TB and leprosy situation in his/her district on a regular basis. Copies of quarterly reports, supervision reports and an annual report should be presented to the CHMT through the District Medical Officer (DMO). On the other hand, key CHMT members should be invited to attend zonal NTLP meetings.

### **4.2. Supervision:**

In order to ensure quality services, supportive supervision will be conducted at three levels; National (TLCU); Regional (RTLC); and District level (DTLC). Where appropriate supervision will be conducted in collaboration with laboratory technicians, pharmacists, administrators, RHMT and CHMT members. For quality supervision and consistency, a checklist will be used at all levels. The mandate and frequency of supervision visits at each level is elaborated below.

#### **Supervision of the health facilities**

The DTLC is responsible for TB and leprosy services at facility level. He/she should visit each diagnostic centre at least once per month and each DOT and MDT facility once per quarter. At the microscopy centre the DTLC should check for laboratory quality assurance procedures, drug management and accuracy records. As part of the integration of services and resources the DTLC will have to split his supervision into two parts; matrix and separate supervision visits. During matrix supervision visits the DTLC will:

- facilitate availability of TB and leprosy drugs
- facilitate referral of patients to higher levels.
- Check on laboratory quality assurance
- Check accuracy and completeness of data management at health facilities
- Conduct community education

However, the DTLC may also plan separate supervisory visits to accommodate for TB and leprosy clinics, individual problem oriented supervision, patient/community education, defaulter tracing etc. Each DTLC should summarise his/her main findings of the health facilities visited using the standard check list and produce a report to be submitted to the CHMT and higher level.

#### **Supervision of the district by the RTLC/RLT**

The RTLC should visit each district at least once in a quarter. RTLC should accompany the Regional Laboratory staff member responsible for the external quality assurance to all diagnostic centres.

The main activities of the RTLC during his/her supervision are reviewing accuracy of registration and reporting and checking drug supplies and accountability by comparing drug use with the drug-ledgers, Unit registers and actual drug stock. RTLC should ensure that TB and leprosy services are implemented according to NTLG guidelines. During supervision the RTLC evaluates the quality and frequency of the supervision of the DTLC. The DTLC performances must be assessed and RTLC should always summarize his/her observations and recommendations in an oral and written feedback to the DMO with a copy to the RMO and TLCU.

### **Supervision of the region by TLCU/CTRL**

TLCU should visit each region at least once per year. Regions with specific problems should be visited more frequently. Every visit is in principle made jointly with a laboratory technician from CTRL. Visits should be made together with the RTLC to a number of districts. The regional supervision visit, forms an important part of the performance assessment of the RTLC and observation of staff at work.

Based on the review of the previous supervisory reports, quarterly reports and input from TLCU/CTRL (e.g. new policy guidelines) the supervisor should identify several items for discussion with the regional and district TB coordinators.

At the end of the visit, findings and recommendations should be summarized and discussed with the RMO and RTLC. The TLCU/CTRL should always provide a written feedback to the RMO/DMOs.

## **4.3 Job descriptions**

### **Health worker in relation to tuberculosis and leprosy**

- To diagnose tuberculosis and leprosy patients among suspects attending clinics
- To sensitise patients to bring their household/ members for examination;
- To initiate treatment based on DOT/MDT if diagnosis has been established;
- To educate tuberculosis and leprosy patients to adhere treatment;
- To educate patients, communities on tuberculosis and leprosy;
- To trace tuberculosis and leprosy patients who miss their scheduled treatment and retrieve defaulters;
- To refer patients who develop complications, such as leprosy reactions, eye complications or adverse drug reactions, according to defined policies;
- To train leprosy patients with disabilities on self-care;
- To refer patients with doubtful diagnosis or suspected as a relapse of leprosy to the DTLC or any other experienced clinician;
- To maintain and update regularly tuberculosis and Leprosy Unit Registers, and patients treatment cards; records of VMT/ST
- To keep records of findings on self-care in patients with disabilities;
- To keep as a minimum one month stock of drugs for tuberculosis and leprosy treatment;

### **District Tuberculosis and Leprosy Coordinator (DTLC)**

- To facilitate implementation of NTLP strategies in the district under CHMT and technical guidance of the RTLC
- To support health workers in tuberculosis and leprosy case-finding, diagnosis and treatment in all health facilities in the district.
- To supervise and monitor management of tuberculosis and leprosy in the district and especially to ensure that:
  - TB and leprosy is diagnosed based on agreed algorithms and protocols
  - All patients receive treatment as prescribed
  - The unit and district registers are kept up-to-date
  - Leprosy patients are examined at the prescribed intervals: three monthly VMT/ST and review of every patient prior to release from treatment
  - To supervise diagnosis and management of leprosy complications
  - To refer tuberculosis and leprosy patients who may benefit from expert management
  - To provide health facilities with supervision schedules covering one year
  - To visit AFB diagnostic and DOT centres every four weeks and other facilities once every 2 or 3 months and provide feedback
  - Prepare supervisory report to CHMT and RTLC
  - To support health facilities to trace irregular patients and defaulters
- To ensure that there is a three months stock of TB and leprosy drugs, stationery and laboratory supplies in collaboration with district pharmacist
- To ensure appropriate use of TB and leprosy drugs in the district;
- To facilitate training of health staff in line with NTLP policy guidelines
- To facilitate involvement of health staff in educating the patients and communities about leprosy and tuberculosis
- To organise and supervise prevention of disability and rehabilitation activities for leprosy patients in the district and liaise with RTLC for specialised services.
- To compile quarterly reports on case notifications and treatment outcome for tuberculosis and leprosy patients;
- To disseminate and use the data of TB and leprosy for making an informed decision by CHMT and other stakeholders at district level
- Proper use and maintenance of the motorcycle
- To ensure that all sputum specimens of relapse tuberculosis patients and those put on re-treatment regimen for other reasons are sent to the reference laboratory
- To ensure sputum specimens from new and re-treatment tuberculosis patients are sent to reference laboratory for culture and sensitivity testing and MDR surveillance
- To collaborate with the district laboratory technologist in ensuring the quality of AFB microscopy.

### **Regional Tuberculosis and Leprosy Coordinator (RTLC)**

- To be responsible for the management (Planning, supervision, implementation, monitoring and evaluation) of NTLP activities at regional level

- To regularly visit (at least once every 3 months) all the districts in the region in order to supervise and support the DTLCs and health workers in the region
- To assist and advise the CHMT, DTLC and other health staff in the diagnosis, treatment and prevention of leprosy and tuberculosis
- To ensure a three months supply of tuberculosis and leprosy drugs in the region in collaboration with the pharmacist and provide feedback to TLCU
- To facilitate and coordinate health education and training activities through training sessions of the NTLP, in seminars, learning institutions and on-the-job within the region
- To collect, analyse, and send the correct data on leprosy and tuberculosis control statistics and activities in the region to the RMO and TLCU
- To compile disseminate and use regional data of tuberculosis and leprosy for making an informed decision
- To supervise and facilitate prevention of disability and rehabilitation activities for leprosy patients in the region and liaise with specialised services, if necessary also outside the region
- To identify, collaborate and implement operational research on tuberculosis and leprosy in the region
- To be responsible for effective and efficient utilisation of the NTLP vehicle and motorcycles made available to the RTLC and DTLCs respectively
- To ensure that all sputum specimens of relapsed tuberculosis patients and other smear positive patients on re-treatment are sent to the reference laboratory for culture and sensitivity testing
- To advise the CHMT/RHMT on tuberculosis and leprosy activities to be included in the district/region health plan
- To collaborate with the regional laboratory technologist in ensuring the quality of AFB microscopy.

### **Tuberculosis and Leprosy Central Unit (TLCU)**

- To be responsible for the management (planning, implementation, supervision, monitoring and evaluation) of the NTLP in the country, including all curative and preventive aspects of tuberculosis and leprosy control
- To monitor progress of the control measures in the country and where necessary, adjust the policy guidelines of the NTLP in collaboration with consultants in the field of tuberculosis and leprosy
- To ensure that the network of laboratories is properly supervised and quality control activities are carried out
- To ensure 12 months supply of tuberculosis and leprosy drugs in the country and monitor the proper use and consumptions based on quarterly reports
- To collect, compile, analyse and submit statistical data and activity reports to the Director of Preventive Services;
- To disseminate and use tuberculosis and leprosy data for making an informed decision
- To ensure that all health workers and programme staff are properly trained in tuberculosis and leprosy

- To do annual supervision and supportive visits to each region and advise the Regional Medical Officer and District Medical Officers on NTLP matters
- To collaborate with other stakeholders working in the field of HIV/AIDS in the control of TB/HIV
- To initiate, coordinate and collaborate on operational research related to the control of tuberculosis and leprosy in the country
- To collaborate and maintain active contact with the developmental partners
- To initiate, coordinate and facilitate health education to patients and the community on tuberculosis and leprosy
- To ensure availability and proper use of transport facilities at all levels
- To advocate for adequate resources necessary to implement tuberculosis and leprosy control activities in the country

#### **Health Facility Laboratory Technician/Microscopist**

- To facilitate proper sputum specimen collection (spot, morning spot) and registration;
- To perform proper smear microscopy and recording of results in the NTLP laboratory request form and register
- To ensure that sufficient laboratory reagents are supplied in collaboration with District laboratory technician and DTLC
- To ensure safe disposal of infected used materials, e.g. sputum containers and microscopic slides
- To keep positive and negative slides for quality control following the NTLP guidelines
- To ensure proper care, use and safety of the microscope.

#### **District Laboratory Technologist/Technician**

- To supervise and ensure quality AFB microscopy in districts
- To collect, store and transport sputum specimen for culture and sensitivity testing to reference laboratory in collaboration with the DTLC
- To ensure that sufficient, quality-controlled stains and reagents are supplied to the health facilities
- To assist AFB microscopy training programmes in the district

#### **Regional Laboratory Technologist**

- To perform all duties as the district laboratory technologist/technician
- To plan and supervise AFB smear microscopy in the region and organise training of laboratory workers involved in AFB microscopy in collaboration with the RTLC
- To ensure availability of three months supply of laboratory reagents and stationary in collaboration with the RTLC and the regional pharmacist

#### **Zonal Reference Laboratory Technologist**

- To ensure that, all positive culture slopes are sent to the central TB reference laboratory as soon as possible (within 14 days) for susceptibility and species identification tests
- To ensure that quality control procedures on smear and culture slopes techniques are carried out, and recording of results is done accurately. A summary report on the



laboratory workload should be sent to the central TB reference laboratory every 6 months for compilation

- To ensure that all smear and culture equipment facilities are taken care of and maintained properly.
- To participate in supervision of AFB microscopy in the zone and training of laboratory workers involved in AFB microscopy in collaboration with the RTALC
- To conduct skin snip smear for AFB microscopy for referred leprosy patients

### **Central Reference Laboratory Technologist**

- To conduct AFB microscopy, culture, susceptibility and species identification tests on sputum specimen of new and retreatment patients received from districts and zonal reference laboratories
- To conduct skin snip smear for AFB microscopy for referred leprosy patients
- To develop policy guidelines and standards regarding AFB microscopy throughout the country
- To plan and carry out surveillance of resistance of Mycobacteria tuberculosis
- To participate in planning, training, supervision and carrying out regular quality control of AFB microscopy activities
- To collect, compile and analyse data on smear and culture results from the reference laboratories
- To disseminate and use data on AFB microscopy and MDR TB surveillance for TB and leprosy control activities
- To ensure availability of laboratory equipments reagents and stationery at all levels in line with the NTLP guidelines
- To initiate, coordinate and collaborate in operational research of relevant TB/Leprosy control activities.

### **Regional Pharmacist**

- To receive, document, store and distribute TB and leprosy drugs, reagents and supplies in the region in collaboration with the RTALC
- To generate a quarterly stock position of TB and leprosy drugs, reagents and supplies in the region including the regional pharmacy and district pharmacies (all hospitals and health centres).
- To report the regional stock position to the RMO and RTALC for subsequent ordering of next consignment of TB and leprosy drugs, reagents and supplies through MSD
- To issue TB and leprosy drugs and supplies to district stores after verification and authorisation by the RTALC
- To supervise district pharmacies and drug stores to ensure that NTLP drugs and supplies management guidelines are correctly implemented.

### **District Pharmacist**

- To receive, document, store and distribute TB and leprosy drugs, reagents and supplies in the district in collaboration with the DTALC

- To generate a district quarterly stock position of TB and leprosy drugs, reagents and supplies including the district pharmacy, all hospitals and health centres
- To report the district stock position to the DMO and DTLC for subsequent ordering of next consignment of TB and leprosy drugs, reagents and supplies from the region
- To issue TB and leprosy drugs and supplies to health facilities after verification and authorisation by the DTLC
- To supervise health facilities and drug stores to ensure that TB and leprosy drugs and supplies are managed correctly according to NTLP guidelines

### **Physiotherapist in a health facility**

- To recognize early signs of nerve damage in leprosy patients and refer for further treatment.
- To relieve pain from neuritis and swelling during reaction using various modalities such elevation, splinting affected joint, active and assisted exercises.
- To train people affected by leprosy on exercises during reactions to maintain muscle strength and joint mobility.
- To train people affected by leprosy on self care of eyes, hand and feet including functional exercises to prevent joint stiffness, muscle wasting and deformities.
- To treat PALs using various physical therapy modalities to prevent worsening of impairments and to reduce disabilities from patients with severe deformities.
- To restore normal tone of muscles and preserve the physiological properties of paralysed or paresed muscles.

### **Supervision instructions**

The following are points to check when doing a supervision visit to hospitals and peripheral health units. The checklist can be used by TLCU members, RTLCs and DTLCs. The answers to the questions are either yes/no or good/average/poor, or numerical data resulting from analysis of the registers and reports. Additional comments can be given in the space provided.

“*Good*” means: according to the standard, “*Average*” means problem identified leading to increased cost or workload, “*poor*” means problem identified that can hinder the patients chances of getting cured or be hazardous to staff health.

Instructions are provided here on how to use the supervision report TB/LEP04.

### **Supervision Schedule**

Check for the presence of the safari schedule and, for the past 6 months, assess how many times the unit has been visited.

### **Registers and case notification**

- Check cards and registers for being up-to-date, complete and accurate;
- Check one quarterly case notification report from the district register;
- Check one outcome of treatment report from the district register;

- Check for patients in the unit register who are not in the district register;
- Check for patients continuing treatment while declared "Cured" or "Treatment Completed" in the district register.

### **Hospital/Clinic**

- Check the starting time of the clinic and the waiting times of the patients;
- Check the condition of the wards and the beds;
- Compare the number of patients attending with the number registered for treatment for that particular clinic day;
- Check whether retrieving of defaulters is done, and by whom, when and with what result.

### **Staff performance and patient knowledge**

- Observe the performance of the staff while doing a clinic regarding correctness of diagnosis and patient management;
- Check knowledge of the staff on self-care;
- Check knowledge of the patients on all aspects of the disease and the treatment;
- Check knowledge of the patients on self care;
- Assess the attitude of the health worker(s) towards patients and other staff.

### **Laboratory (see laboratory checklist)**

- Check the general condition, space, ventilation, cleanliness, presence of water in the laboratory;
- Check whether three specimens are collected within 24 hours by the "spot-morning spot" collection strategy;
- Check the transit times of specimens sent to the reference laboratory;
- Spot-check a few positive and negative slides for quality and for presence of AFBs. Take 3 smears for re-reading to the reference laboratory;
- Count the number of specimens examined over the past 3 months and divide by number of working days per microscopist;
- In the laboratory register check whether the last 5 AFB positive tuberculosis patients diagnosed in the previous one month are indeed put on treatment;
- In the district register check whether the last 5 AFB negative tuberculosis patients diagnosed have indeed three times a negative smear.

### **Drugs and supplies**

- Check the physical condition, safety, and administrative procedures of the drugs store;
- Check for any expired drugs;
- Spot check the stock position of a random sample of drugs, supplies and spare parts but including: rifampicin/isoniazid combined tablets, rifampicin/dapsone (and clofazimine) packets, prednisolone, microscopes, methylene blue, methanol, tyres, sprockets, chains;
- Check all ledgers for completeness and good order;
- Spot-check stores ledger balances of drugs, supplies and spare parts by physically counting and verifying balances;

- Spot-check pharmacist copies of issue notes with originals issued to DTLC to verify that they agree. Carry the issue notes book to the district.

**Transport**

- Ask to see the logbook and check that it is up-to-date, and that the current km reading agrees with the reading from the vehicles/motorcycles speedometer;
- Ask to see the quarterly vehicle/motorcycle reports to verify that they correspond correctly to the logbook entries for the period;
- When visiting a district hospital or peripheral health unit verify that the visit entered in the logbook has been made by checking the visitors book of the hospital/unit;
- Check whether relevant spare parts are available in required quantities (see spare parts control form).

**Integrated activities:**

- Check if NTLP activities are included in the district health plan;
- Check sources of funding for TB/Leprosy control activities;
- Ask if there are joint TB/HIV activities in the district/health facility;
- Check if community DOT/PCT is implemented in the district
- Check if the RMO/DMO is involved in the disbursement and accounting for NTLP funds.

**4.2.4 Report format of NTLP Supervision visit**

Region .....; District .....Health facility .....; Section/Unit .....

Date supervisory visit .....

Summary of supervisory activities					
1.					
2.					
3.					
4.					
Section/Unit	Problem Identified	Solution proposed	Time work	Responsible	Remarks

**Remarks**

Any additional comments and recommendations for future reference.

## 4.5. Documentation

### General remarks

Accurate keeping of records of all individual patients, maintaining up-to-date registers and reliable reporting is essential to the proper management of the programme.

Reports are used for monitoring, evaluation, planning and budgeting purposes. Most reports are taken from the District Tuberculosis and Leprosy registers and are therefore only as accurate as those registers. It is therefore of utmost importance for the RTALC and DTLC to ensure that the District Tuberculosis and Leprosy registers are at all times up-to-date, complete, accurate and reliable. It is imperative that data collected at any level be used locally for planning and monitoring purposes. For example data generated at the district level should be analysed and disseminated to relevant stakeholders in making evidence based decisions in the control of TB, TB/HIV and leprosy

The number and designs of cards, forms and registers have been further limited and kept as simple as possible without compromising the information captured on good standard of patient care and assessment of the programme performance.

In principle, the administrative approach to TB, TB/HIV and leprosy diseases is the same, but in most instances different sets of documentation were prepared for the two diseases. All efforts have been taken to ensure that the different sets are as consistent as possible.

In generating reports, the RTALC should scrutinise all report from every districts before submitting to TLCU for compilation and evaluation. It should be noted that simple counting or calculating errors cause an unnecessary delay (and extra costs) in entering the NTLP data in the computers. Currently, NTLP is capturing TB information from district register into a computer using electronic TB register software developed by BOTUSA in collaboration with US Center for Disease Control and prevention (CDC), USA. Future reports from region and districts will be generated using this software. Computerization of leprosy data will be considered once the generic software is available

All reports should be completed in the first week following the reporting quarter (not later than one month). Note that, reports refer to cases registered during the reporting quarter and not to cases diagnosed during that same quarter. For example, a patient diagnosed during the first quarter and registered in the second quarter should be included in the report of the second quarter. Therefore, immediately after the end of each period analysis of the registered and reported cases can be done.

The following is a report preparation and submission schedule of NTLP quarterly reports:

<b>Period</b>	<b>Dead line to reach RTALC</b>	<b>Deadline to reach TLCU</b>
---------------	---------------------------------	-------------------------------

1 <sup>st</sup> quarter	30 <sup>th</sup> April	31 <sup>ST</sup> May
2 <sup>nd</sup> quarter	31 <sup>st</sup> July	31 <sup>st</sup> August
3 <sup>rd</sup> quarter	31 <sup>st</sup> October	30 <sup>th</sup> November
4 <sup>th</sup> quarter	31 <sup>st</sup> January	28 <sup>th</sup> February

## **Recording and reporting documents**

### **Tuberculosis**

TB 01 Tuberculosis treatment card  
 TB 02 Kadi ya kifua kikuu  
 TB 03 Tuberculosis unit register  
 TB 04 Tuberculosis district register  
 TB 05 Tuberculosis laboratory register  
 TB 06 Culture and sensitivity request form  
 TB 07 Tuberculosis Quarterly case notification report form  
 TB 08 Tuberculosis drugs and supplies calculation and order form  
 TB 09 Tuberculosis Quarterly treatment results report form  
 TB 10 Tuberculosis culture and DST register  
 TB 11 Treatment outcome of transferred tuberculosis patients  
 PCT 1 Treatment supporter card

### **Leprosy**

LEP 01 Leprosy patients record card  
 LEP 02 Kadi ya Ukoma  
 LEP 03 Leprosy unit register  
 LEP 04 Leprosy district register  
 LEP 05 Leprosy laboratory register  
 LEP 06 POD register  
 LEP 07 Leprosy quarterly case notification report form  
 LEP 08 Leprosy drugs and supplies calculation and order form  
 LEP 09 Leprosy quarterly treatment results report form  
 LEP 10 Annual report on prevention of disabilities  
 LEP 11 Treatment outcome of transferred leprosy patients

### **Combined**

TB/LEP 01 Request form for AFB microscopy  
 TB/LEP 02 Referral/Transfer form  
 TB/LEP 03 Regional TB/Leprosy drugs and laboratory material stock position  
     report form  
 TB/LEP 04 Supervision checklist form

- TB/HIV 01 Quarterly report of TB/HIV notification
- TB/HIV 02 Quarterly report on treatment outcome of TB/HIV patients notified in the quarter ending 12 months earlier
- TB/HIV 03 TB/HIV referral/transfer form

**Report preparation**

**Quarterly case notification report (TB07, TB/HIV 01 and LEP07)**

To prepare a report identify all patients registered during the relevant quarter and count them. Then, using columns "category" and "smear result at 0 month", count the number of new smear positive tuberculosis patients, TB/HIV patients (and new PB and MB patients), the number of relapses (and leprosy relapses after MDT), the number of smear negative tuberculosis patients and the number of patients returned to control or other additions. Similarly, all patients registered during the relevant quarter who are TB/HIV co-infected should be reported separately using TB/HIV 01. Then, from the new patients only, count the numbers according to age and sex, using the method of ticking each patient in a table as presented here in the table below:

**Sex and age distribution table (tally table)**

Male	Age group	Female
	0 – 14	
	15 – 24	
	25 – 34	
	35 – 44	
	45 – 54	
	55 – 64	
	65+	
	<b>Total</b>	

When all the new patients are recorded in this way, countercheck the totals with the total count done previously and repeat the exercise to correct when necessary. Then record the data on the form.

**Quarterly report of Treatment outcome (TB09, TB/HIV 02 and LEP09)**

For this report the information is obtained from the District Register under the section "Results of treatment outcome ". Cases recorded previously under "Category of Patient" as "Transfer in "must not be included. Treatment outcome should be recorded in the District Register at this period (12 months after the quarter of notification has elapsed for tuberculosis and PB leprosy patients, and 24 months after the half year of MB leprosy patients). If no result is recorded in the District Register the patient must be declared "Out of

Control". The same method of ticking can be used as earlier on mentioned. , Using a pencil, tick the patients in the boxes on the report form itself.

Separate reporting is done for the following categories of tuberculosis patients:

1. New smear positive tuberculosis,
2. New smear negative
3. New extra-pulmonary cases
4. Relapses
5. Failure cases
6. Returns to control
7. other cases put on re-treatment

Likewise, all patients registered during the relevant quarter who are TB/HIV co-infected their treatment outcome should be reported separately using TB/HIV 02

And for leprosy patients, separately for PB and MB:

1. New cases including reactions
2. Relapses after MDT
3. Returns to control
4. Relapses after DDS and other cases

Finally, the total number of patients evaluated should be the same as the number previously notified. This also counts for the reporting on changes in disability grading. If there are differences, give reasons for example double registration, false positives, etc. on the appropriate place in the form.

### **How to use the POD register (LEP06)**

Upon receiving the POD register, fill the name of the district and DTLC, and write the current year.

Every patient with disabilities resulting from leprosy is to be registered in the POD register: start with all newly reporting patients. Enter also patients with longstanding disabilities, especially those receiving footwear, when you meet them in the course of the year.

*Note: new patients with recent nerve function loss (of less than 6 months duration) have a leprosy reaction and need treatment with corticosteroids. They need to be re-examined every two weeks (see page 102) and monthly by the DTLC (page 103). New patients on MDT with longstanding loss of sensation or other disabilities are continuously at risk for deterioration of their condition and need to be reviewed at least once every quarter. The findings must be recorded on the Patient Record Card. All patients need thorough and repeated health education (see pages 112 – 117).*



**Baseline record:** examine each individual leprosy patient with disabilities, within one month after detection of a new patient or immediately upon registration of a known person with disabilities. Do a complete VMT/ST and enter the patient's disability scores in the columns on the left hand page, using the key at the bottom of that page. If a part of the assessment was not done, use an asterisk (\*), don't leave the box blank.

Depending on the disabilities that the patient has, decide on the interventions needed to improve the patient's condition and to prevent further complications. Record the date the intervention was started or explained.

**Review record:** re-examine each patient after one year (not necessarily in December) in order to compare her/his situation with the previous year and to monitor progress in POD. Fill in the year of examination in the first REVIEW SCORES OF THE YEAR ...on the right hand page of the POD register. Fill the date of the examination for each patient separately.

Test vision, do VMT/ST and check for wounds and cracks. Record the findings in the Leprosy Patient Record Card (LEP 01). Compare the findings for each eye, hand and foot with the baseline record and score **I** for "improved", **NC** for "no change" or **D** for "deteriorated" in the respective columns. Under the heading REVIEW SCORE tick for each patient ONE of the choices "improved", "no change" or "deteriorated". Score any deterioration as "deteriorated", even if there is improvement elsewhere. As long as there are no changes elsewhere, score any improvement as "improved".

If there is no change or the patient's condition has worsened, consider other intervention(s) than last year; convince the patient that s/he has to take good care her/him self; refer to the leprosy referral hospital if necessary.

When the year has finished, add all individual patient scores per page (so for example 7 NC, 2 I and 1D for ten patients) and compile these scores for all patients registered in the POD register and report in the Annual POD Report LEP 10. Repeat reviews once a year for at least three years.

#### 4.6. NTLP codes for regions and districts

Region Code	Region Name	District Code	District Name	Region Code	Region Name	District Code	District Name
01	Dodoma	01	Kondoa	02	Arusha	01	Monduli
		02	Mpwapwa			02	Arumeru
		03	Kongwa			03	Arusha
		04	Bahi			04	Karatu
		05	Dodoma urban			05	Ngorongoro
		06	Chamwino			06	Longido

03	Kilimanjaro	01	Rombo	04	Tanga	01	Lushoto
		02	Mwanga			02	Korogwe
		03	Same			03	Muheza
		04	Moshi rural			04	Tanga rural
		05	Hai			05	Pangani
		06	Moshi urban			06	Handeni
		07	Siha			07	Kilindi
05	Morogoro	01	Kilosa			08	Tanga urban
		02	Morogoro rural			09	Mkinga
		03	Kilombero	06	Pwani	01	Bagamoyo
		04	Ulanga			02	Kibaha
		05	Morogoro urban			03	Kisarawe
		06	Mvomero			04	Mkuranga
71	Kinondoni	01	Mwananyamala I			05	Rufiji
		02	Mwananyamala II			06	Mafia
		03	Magomeni	72	Ilala I	01	Mnazi mmoja
		04	Tandale I			02	Amana
		05	Tandale II			03	Vingunguti
		06	Sinza			04	Chanika
		07	Lugalo			05	Ukonga
		08	Mbezi			06	Tabata
73	Temeke	01	Temeke wailes			07	Buguruni
		02	Mbagala	74	Ilala II	01	IDC
		03	Tambukareli			02	MNH TB ward
		04	Kigamboni			03	Mwaisela
		05	Yombo vituka			04	Private hospital
		06	Keko	09	Mtwara	01	Mtwara rural
08	Lindi	01	Kilwa			02	Newala
		02	Lindi rural			03	Masaki
		03	Nachingwea			04	Tandahimba
		04	Liwale			05	Mtwara urban
		05	Ruangwa			06	Nanyumbu
		06	Lindi urban	11	Iringa	01	Iringa rural
10	Ruvuma	01	Tunduru			02	Mufindi
		02	Songea rural			03	Makete
		03	Mbinga			04	Njombe
		04	Songea urban			05	Ludewa
		05	Namtumbo			06	Iringa urban

12	Mbeya	01	Chunya	07	Kilolo
		02	Mbeya rural		
		03	Kyela		
		04	Rungwe		
		05	Ileje		
		06	Mbozi		
		07	Mbarali		
		08	Mbeya urban		
15	Rukwa	01	Mpanda west	01	Iramba
		02	Sumbawanga rural		
		03	Nkasi		
		04	Sumbawanga urban		
		05	Mpanda east		
		06	Kirando-Nkasi		
17	Shinyanga	01	Bariadi	02	Singida rural
		02	Maswa		
		03	Shinyanga rural		
		04	Kahama		
		05	Bukombe		
		06	Meatu		
		07	Shinyanga urban		
		08	Kishapu		
19	Mwanza	01	Ukerewe	03	Manyoni
		02	Magu		
		03	Mwanza north		
		04	Kwimba		
		05	Sengerema		
		06	Geita		
		07	Misungwi		
		08	Mwanza south		
		09	Mwanza east		
22	Unguja	01	North A & B unguja	04	Singida urban
		02	South & Central Unguja		
		03	Town & west Unguja		
25	Pemba	01	North Pemba	05	Tabora urban
		02	South Pemba		
14	Tabora	01	Nzega	01	Kigoma
		02	Igunga		
		03	Uyui		
		04	Urambo		
16	Kigoma	01	Kibondo	02	Kasulu
		02	Kasulu		
		03	Kigoma rural		
18	Kagera	01	Karagwe	03	Kigoma urban
		02	Bukoba rural		
		03	Muleba		
		04	Biharamulo		
20	Mara	01	Tarime north	05	Ngara
		02	Serengeti		
		03	Musoma rural		
		04	Bunda		
		05	Musoma urban		
		06	Tarime south		
21	Manyara	01	Babati	06	Bukoba urban
		02	Hanang		
		03	Mbulu		
		04	Simanjiro		
		05	Kiteto		

**4.7. NTLP records, registers and forms**

4.8.

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