

**NATIONAL TUBERCULOSIS CONTROL
PROGRAMME**

MANUAL



Ministry of Health, Malawi

2007

CHAPTER ONE

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

1.0 INTRODUCTION

The National Tuberculosis Control Programme (NTP) was first launched in 1964 following recommendations from the World Health Organisation¹ (WHO). In 1984, it became a recognised Directly Observed Treatment – Short Course (DOTS) Programme and currently has a 100% DOTS coverage.

The NTP is integrated into the general health services. It has managerial and supervisory staff at central, zonal and district level dealing with tuberculosis control activities.

1.1 AIM OF THE NTP

To reduce the burden of ill health due to tuberculosis until the disease is no longer a public health problem in the population of Malawi.

To achieve this the NTP is:

- Integrated into general health services, within the Ministry of Health,
- Country-wide i.e. as close to the community as possible.
- Permanent because of the nature of the disease.

1.2 PURPOSE:

To improve on an equitable basis, the case detection, quality of diagnosis and TB treatment outcomes

1.3 OBJECTIVES

1. To positively influence health-seeking behaviour of TB suspects through health promotion

Targets:

70% of smear-positive PTB cases start treatment within 2 months of onset of cough

2. To improve and maintain equitable case finding and good diagnostic practices

Targets:

90% of PTB suspects have recommended number of sputum specimens submitted

90% of smear results reliable with quality control

>85% of smear-negative PTB patients diagnosed according to NTP guidelines

>85% of EPTB patients diagnosed in adherence to NTP guidelines

40% or more of new PTB cases should be smear-positive

25% or less of all TB cases should be EPTB

80% of patients on re-treatment have sputum examined for Culture and Sensitivity

3. To enhance the capacity of NTP to deliver and monitor effective treatment

Targets:

95% or more of laboratory diagnosed smear-positive cases to start on treatment

75% or more of smear-positive PTB patients to be cured

Reduce death rates among smear positive TB cases to below 15%

Reduce transfer out (without end results) and default rates to below 5%

95% or more of smear-positive PTB patients should have smears done by the end of treatment

Treatment completion rates among smear negative PTB and EPTB to be more than 75%

¹ 8th and 9th reports of WHO Expert Committee on Tuberculosis

4. To provide care and support for TB/HIV patients and prevent TB in HIV-positive persons

Targets

90% or more of registered TB patients to be counselled and tested for HIV

>95% of all TB patients who are HIV positive start Co-trimoxazole preventive therapy within 2 months of starting TB treatment.

70% of all TB patients who are HIV positive start ARV therapy within 3 months of starting TB treatment.

5. To strengthen and maintain NTP supportive activities
6. To increase and maintain collaboration with other public health programmes, health training institutions and the private sector
7. To maintain and improve NTP management capacity
8. To produce new knowledge on TB control through relevant operational research.
9. To maintain programme monitoring and evaluation

1.4. STRUCTURE OF THE NTP

i) Central Unit

The NTP at this level is headed by the TB programme Director who is also supported by the deputy programme manager and officers responsible for research, ACSM, training, TB/HIV, drug logistics, central reference laboratory and data management. The NTP central unit reports to the Secretary for Health.

Functions of the Central Unit (CU):

- (a) Advocacy
- (b) Partnership and collaboration
- (c) Integration
- (d) Policy formulation
- (e) Development of guidelines
- (f) Monitoring and evaluation
- (g) Mentorship

ii) National Tuberculosis Programme Advisor

This position is occupied by a senior physician who has spent many years working in the NTP and who provides assistance to the NTP with advice and advocacy.

iii) Zonal Level

This level is headed by the Zonal TB Officers who report to the TB Programme Director through the Zonal Health Supervisors.

Functions of the Zonal Level:

- (a) Co-ordinating Tuberculosis Control activities in their respective zones by working closely with District health staff.
- (b) Supervising and training of District staff responsible for TB control activities and other peripheral health workers.
- (c) Compiling and analysing TB data for the zone and discussing it with the Zonal Health Supervisor (ZHSO) before sending it to central unit.
- (d) Ordering, distributing and monitoring supplies e.g. stationery for the zone.

iv) The District

TB services at this level are integrated in the general health services through provision of health education, diagnosis, treatment and patient care services. TB activities are headed by the District TB officer (DTO) who is supported by an Assistant DTO (ADTO), Focal TB Clinical Officer (FTBCO) and Focal TB Nurse (FTBN) and the laboratory technician. All these officers form a District TB Control Team. DTOs report directly to the Principal Environmental Health officer (PEHO).

The District Tuberculosis Officer (DTO) is responsible to the District Health Officer (DHO).

a) The District TB Officer (DTO)

Functions of the DTO with assistance of District TB Control Core Team

- Implementing the NTP activities in the district through health staff of the district and peripheral health units, under the technical guidance of the ZTO.
- Supervising health workers in case finding and chemotherapy of Tuberculosis patients through the DOTS strategy.
- Keeping an up to-date and accurate District Tuberculosis register.
- Compiling quarterly reports on notified cases and treatment outcomes.
- Liaising with the DHO, ZTO and District IEC Officer for training peripheral health workers.
- Supporting health workers in educating patients and the community.
- Ordering supplies - drugs, laboratory reagents and slides, sputum containers, stationery - for the district and monitoring their distribution to the peripheral health units.
- Collaborating with the laboratory service, since smear examination of sputum is indispensable to diagnosis of Tuberculosis and follow-up of chemotherapy.

b) Peripheral Level (Health Centre and Health Post)

Functions:

- Sending Tuberculosis suspects or their sputum specimens to microscopy centres for investigations.
- Carrying out treatment services including DOT
- Tracing defaulters or irregular attendees
- Keeping patients' records and submitting sputum results to the DTO.
- Conducting health promotion and education to patients and the community

c) Community

Community members are involved in TB control activities. For example, traditional healers and grocery owners may play an invaluable part in case finding and family members provide DOT.

1.6 KEY MANAGEMENT MEETINGS

Technical Working Group

This group meets every 6 months and is chaired by the NTP Director. It consists of Ministry of Health Senior Personnel and donors such as KNCV, DFID, and WHO and working partners such as REACH Trust, College of Medicine, Karonga Preventive Study, Medicin San Frontiers (MSF), Malawi College of Health Sciences and Management Sciences for Health

The terms of reference are as follows:-

- Review implementation of activities related to TB control
- Analyse issues affecting implementation of TB control
- Initiate policy development or change to facilitate implementation of strategies related to TB control
- Recommend policy development or change to facilitate implementation of strategies related to TB control

NTP Departmental Meeting

This is chaired by the NTP Director and consists of all NTP Central Unit members, a representative of the Zone TB Offices and the National TB Professional Officer (NPO) from the WHO.

They meet every Friday to monitor progress and evaluate plans in the NTP.

Programme Finance Committee (PFC)

This committee is chaired by the TB Programme Director and consists of the deputy programme manager and representatives from the accounts department of the Ministry of Health. The group meets every 3 months to review budgets and expenditures of the NTP, and to submit reports to external auditors.

Information, Education and Communication (IEC) Technical Working Group

This multi-disciplinary team is chaired by the TB Programme Director and comprises the NTP Central Unit, in addition to representatives from the media, the Health Education Unit of the Ministry of Health, the National AIDS Commission, MoH HIV unit, the College of Medicine, and community representatives e.g. Ex-TB patients. The role of the group is to manage and co-ordinate the implementation of the NTP IEC Strategic Plan. The group reports to TWG through the NTP IEC Officer.

CHAPTER TWO

GENERAL INFORMATION ABOUT TUBERCULOSIS

2.1 WHAT IS TUBERCULOSIS

Tuberculosis is a communicable infectious disease caused by a bacterium called “Mycobacterium tuberculosis”. Most infections are caused by inhalation of droplet particles (nuclei) containing virulent human strains of the bacillus. Sometimes, infection occurs with Mycobacterium bovis through drinking unpasteurised cow’s milk. About 75 – 80% of TB involves the lungs (pulmonary tuberculosis), and 20 - 25% occurs in other organs outside the lungs (extra-pulmonary tuberculosis).

2.2 EXTENT OF THE TUBERCULOSIS PROBLEM IN MALAWI

The Tuberculin Survey done in Malawi in 1994 showed that the annual risk of infection (ARI) was 0.9. In the absence of HIV infection, an ARI of 0.9 would yield around 45 new cases of smear-positive PTB per 100,000 population and around 55 new cases of smear-negative PTB and EPTB per 100,000. The expected case notification calculated from the ARI was about 10,000 cases, whereas in 1995 there were over 19,000 cases reported. This excess number of cases is due to influence of HIV on TB.

HIV accelerates the progression from infection with Mycobacterium tuberculosis to TB disease and at the same time increases the pool of infectious patients in the community. In 2000, for example, there were about 8000 smear positive cases and this was about 82 cases per 100 000 general population. Between 1985 and 2006, the annual TB case notification rate (all forms) in Malawi increased from 5000 to 27000 annually. This increase is at present the most accurate measure of the disease burden faced by the NTP in its control of TB. As long as HIV infection in the community remains high TB cases will also be high.

2.3 CLASSIFICATION OF TUBERCULOSIS

2.3.1 Pulmonary Tuberculosis (PTB).

This refers to disease involving the lungs. Patients are classified as:-

a) Smear-positive PTB

Either: a patient with at least two sputum specimens positive for acid-fast bacilli on microscopy.

Or: a patient with at least one sputum specimen positive for acid-fast bacilli on microscopy and radiographic abnormalities consistent with pulmonary TB.

Or: a patient with at least one sputum specimen positive for acid-fast bacilli on microscopy, which is culture positive for Mycobacterium tuberculosis.

b) Smear-negative PTB

Either: a patient who has been coughing for > 3 weeks with:
at least two sputum specimens negative for acid-fast bacilli on microscopy, lack of clinical response to one week of broad-spectrum antibiotics, and radiographic abnormalities consistent with pulmonary TB

Or: a patient who is severely ill with at least two sputum specimens negative for acid-fast bacilli on microscopy and radiographic abnormalities consistent with extensive pulmonary TB (interstitial or miliary).
Miliary tuberculosis is classified as pulmonary TB.

2.3.2 Extra-pulmonary tuberculosis (EPTB).

This refers to disease outside the lungs.

This includes:-

- pleural effusion
- pericardial disease
- lymphadenopathy
- peritonitis and/or gastrointestinal disease
- meningitis
- spinal or bone disease
- genito-urinary disease
- skin disease

The most common types of EPTB in Malawi are pleural effusion, lymphadenopathy, ascites and pericardial disease.

NB:- TB meningitis is a fatal disease if left untreated. The onset may be insidious, but if left untreated neurological signs may develop. The diagnosis depends on lumbar puncture, which classically shows high protein, low glucose, lymphocyte predominance and negative Indian ink stain for cryptococci. Corticosteroids may be useful to reduce meningeal inflammation: prednisolone can be given at a dose of 40mg daily for up to 4 weeks.

2.3.3 Tuberculosis in children

Children usually present with pulmonary signs and symptoms, and they include persistent cough, bronchial breathing and crepitations. In addition, there are general symptoms like failure to thrive, loss of weight, recurrent fevers and lethargy.

Children may also present with extra-pulmonary disease, the commonest forms in Malawi being lymphadenopathy, pleural effusion, spinal disease and pericardial disease.

The diagnosis of TB in children rests on clinical features, chest x-ray, tuberculin skin test (if available) and a positive family history of TB in an adult. Young children rarely cough up sputum and it is therefore unusual to confirm the diagnosis by sputum smear examination. Childhood TB should be reported according to age-groups (0 to 4 and then 5 to 14 years). Similarly treatment outcomes should be evaluated according to these age-groups.

2.4 THE MOST IMPORTANT DISEASE TYPE IN TUBERCULOSIS CONTROL

Smear positive pulmonary tuberculosis is highly infectious. Cases which are smear-negative and culture-positive, smear-negative and culture-negative or are unable to produce any sputum at all, for example, children, are about ten times less infectious than those smear-positive on microscopy.

Thus adult patients with smear positive Tuberculosis of the lungs are the main source of infection. They spread the bacilli by coughing (droplet infection). Close and prolonged contact with a patient who is smear-positive is associated with a high risk of becoming infected.

Active smear-negative cases (for instance, adults and children with pulmonary disease or extrapulmonary disease) are also treated in the NTP but they must be notified separately from those who are bacteriologically confirmed.

2.5 A TUBERCULOSIS SUSPECT

A tuberculosis suspect is any patient whom a health worker suspects to suffer from TB. TB suspects can either be pulmonary or extra-pulmonary.

a) Pulmonary TB suspects:

Pulmonary Tuberculosis can be suspected if a patient presents with the following symptoms:

Persistent cough for three weeks or more: usually accompanied by one of the following:

- Fever
- Chest pain
- Shortness of breath
- Loss of weight
- Haemoptysis

b) Extra-pulmonary TB suspects:

Symptoms or signs due to extra-pulmonary Tuberculosis will depend on the site involved. There are usually associated constitutional symptoms such as fever, night sweats and weight loss

- | | |
|----------------------|--|
| Lymphadenopathy | - enlarged lymph nodes, often in the neck |
| Pleural effusion | - shortness of breath and chest pain |
| Pericardial effusion | - shortness of breath and swelling of legs and abdomen |
| Ascites | - swelling of abdomen due to fluid |
| Spinal disease | - tender swelling of the back, sometimes with weakness of the legs |
| Meningitis | - headache, stiffness of the neck, confusion |

2.6 A TUBERCULOSIS CASE

A Tuberculosis 'case' is a patient who has been reliably diagnosed with TB.

Cases are classified into those with Pulmonary TB (either smear-positive or smear-negative) and those with Extra-pulmonary TB. The patient with smear positive TB is very important in tuberculosis control because he/she is the main source of infection. Such persons need to be diagnosed as early as possible and treated effectively to cure them and prevent a further spread of the disease to other members of the community.

2.7 STANDARDISED TUBERCULOSIS CASE DEFINITIONS

a) Site of Disease.

If a patient has both pulmonary and extra-pulmonary disease, then he/she is classified as having pulmonary disease.

If a patient has extra-pulmonary disease in several sites, then the site representing the most severe form of disease is the one used for the case definition. For example, a patient with lymphadenopathy and pericardial effusion would be defined as pericardial effusion.

b) Category of Disease.

Patients are also classified according to whether or not they have had previous treatment. This is important because patients who have been previously treated are at risk of acquired drug resistance. These categories are shown in table 1 below:

TABLE 1: TUBERCULOSIS CATEGORIES

| Category | Description |
|--|---|
| New | A patient who has never taken anti-tuberculosis drugs for more than one month. |
| Relapse | A patient who has previously been treated and completed treatment and has now developed active tuberculosis with smear-positive sputum. |
| Failure | A newly diagnosed tuberculosis patient who is sputum-smear positive 5 months or more after the start of chemotherapy. |
| Treatment interrupted (treatment after default) | A patient who interrupted treatment for more than 2 months after at least one month of chemotherapy and is subsequently found to have smear-positive tuberculosis. |
| Transfer in | A patient who has been recorded on treatment in another tuberculosis register and has been transferred to another district to continue treatment. |
| Other | A patient who does not fulfil any of the above categories. Examples are: i) chronic case- a patient who remains smear-positive after completing a re-treatment regimen under supervision; ii) recurrent TB case- a patient who has previously been treated and completed treatment and has now developed active tuberculosis with smear- negative TB or extra-pulmonary TB |

TUBERCULOSIS CONTROL METHODS

3.1 BCG VACCINATION

BCG is a attenuated strain of bovine tubercle bacilli first produced by Calmette and Guerin. It is given by intra-dermal injection to a population which is considered to be essentially non-infected (children) to protect them from developing Tuberculosis, especially severe forms of the disease, e.g. Tuberculous meningitis and miliary Tuberculosis.

BCG vaccination is given as early as possible in life preferably at birth. Direct BCG vaccination (i.e. without testing for a pre-vaccination tuberculin allergy) is the standard method of BCG vaccination in Malawi. This helps increase vaccination coverage. BCG vaccination is included in the Expanded Programme on Immunisation (EPI). Maintenance of a cold chain is of paramount importance in order to maintain the efficacy of the vaccine. The NTP follows the recommendations of EPI on BCG vaccination.

Dosage:

For children under one year of age, 0.05 ml is the accepted dosage. Children aged one year or more are injected with 0.1 ml.

Complications are uncommon, but include:

- Subcutaneous abscess at site of injection
- Ulceration at site of injection
- Swelling with or without ulceration of lymph nodes adjacent to vaccination site
- Systemic complications (these are very rare)

Treatment of complications:

- Subcutaneous abscess and ulceration at the injection site may only require pain relief with simple analgesics and cleaning of the ulcer.
- Swelling of lymph nodes adjacent to vaccination site usually requires no treatment.
- Systemic complications due to generalised BCG infection (which is very rare) may be controlled with full chemotherapy.

BCG revaccination:

Protection from BCG decreases with time, but there is no evidence that a second BCG vaccination gives additional protection. Revaccination is therefore not recommended

BCG and HIV Infection:

In the presence of HIV infection, it is thought that BCG has similar efficacy. The safety of BCG is good, although there have been case reports of adverse effects. It is currently recommended by the World Health Organization that BCG be given to children with asymptomatic HIV infection, but it should not be given to children with HIV disease or AIDS.

3.2 CASE FINDING

a) Passive case finding.

This is the way case finding is carried out in Malawi, i.e. it is based on self-referral of symptomatic individuals who consult health institutions and who are suspected as tuberculosis cases. TB suspects may also be referred to health facilities by community -based individuals or groups.

b) Active case finding

This is when health personnel actively look for TB cases. Active case finding is expensive to be done on a large scale, however, some form of active case finding (accelerated case finding) is done in Malawi mainly in HIV-VCT clinics and prisons.

NB:- It is important that health care workers identify TB suspects as quickly as possible in order to cure the individual and break the chain of transmission in the community.

3.3 DIAGNOSIS OF PULMONARY TUBERCULOSIS

(a) Sputum Microscopy

Diagnosis of pulmonary tuberculosis depends on the identification of the tubercle bacilli either by sputum smear microscopy or by culture.

Direct sputum smear examination should be done on all tuberculosis suspects, especially in patients having a cough lasting for more than three weeks. In high risk institutions where people are crowded together, for example prisons, patients coughing for more than one week should submit sputum specimens for smear microscopy.

Health institutions without microscopy facilities should, if possible, send sputum specimens or fixed slides rather than tuberculosis suspects to microscopy centres.

A maximum of three sputum smears needs to be done on each tuberculosis suspect.

It is important that sputum collection is done efficiently and effectively, and that patients and guardians are advised appropriately. Sputum specimens should be delivered to hospital laboratories quickly, and results brought back to the health facility quickly. Patients and guardians need to be informed about the diagnostic process. Health workers need to minimise the number of visits and time spent by patients at health facilities during the diagnostic process.

Details of sputum smear microscopy and Ziehl-Neelsen staining are shown in Appendix 1.

NB:- Patients with negative smears need further investigation and should never be told that there is nothing wrong with them before such investigations are done.

(b) Chest X-rays in the diagnosis of Pulmonary Tuberculosis

Chest X-ray findings suggestive of pulmonary tuberculosis in patients with smear-negative microscopy should always be supported by clinical findings and an experienced medical/ clinical officer should decide on the actual diagnosis. Chest X-ray appearances alone do not always indicate pulmonary tuberculosis. One area in which X-ray and clinical information are of even greater importance is the diagnosis of pulmonary tuberculosis in children.

3.4. DIAGNOSIS OF EXTRAPULMONARY TUBERCULOSIS

Diagnostic procedure will depend on the site of the disease. These are listed in table 2 below;

TABLE 2: EXTRAPULMONERY TB DIAGNOSIS

| Type of EPTB | Recommended investigations |
|-----------------------|---|
| Pleural effusion | Chest x-ray Aspiration of pleural fluid Laboratory tests on pleural fluid |
| Lymphadenopathy | Needle aspiration Lymph node biopsy |
| Pericardial effusion | Chest x-ray Ultrasound examination |
| Ascites | Aspiration of ascitic fluid Laboratory tests on ascitic fluid |
| Spinal / Bone disease | Appropriate x-rays |
| Meningitis | Lumbar puncture Laboratory tests on CSF |

Notes:

- Tests on pleural and ascitic fluid include protein, white blood Cells (WBCs) and differential white cell count, gram stain and Ziehl-Neelsen stain.
- Tests on needle aspiration / lymph node biopsy for macroscopic caseation, AFB and caseating granulomas on histology.
- Tests on CSF for protein, glucose, WBC and differential white cell count, gram stain, Ziehl-Neelsen stain and Indian Ink to rule out cryptococcal meningitis

If any patient with extra-pulmonary tuberculosis has a cough > 3 weeks, sputum specimens must be collected and examined for AFB.

3.5. TUBERCULIN (MANTOUX) TEST

The Mantoux test is particularly helpful in children suspected of tuberculosis who are less than 5 years old whether they have received BCG vaccination or not. A tuberculin reaction of 10mm or more indicates infection with tuberculosis. The Mantoux test is much less likely to be reactive in HIV-infected or severely malnourished children with tuberculosis. For HIV-infected children and children with severe malnutrition, a tuberculin reaction of 5mm or more is regarded as reactive.

Technique of tuberculin testing and reading is on Appendix 2.

3.6 CASE FINDING AND DIAGNOSIS

3.6.1 TB diagnostic pathway

Early identification of TB cases and putting them on effective treatment is important in TB control. Below is a practical pathway for the diagnosis of TB cases:

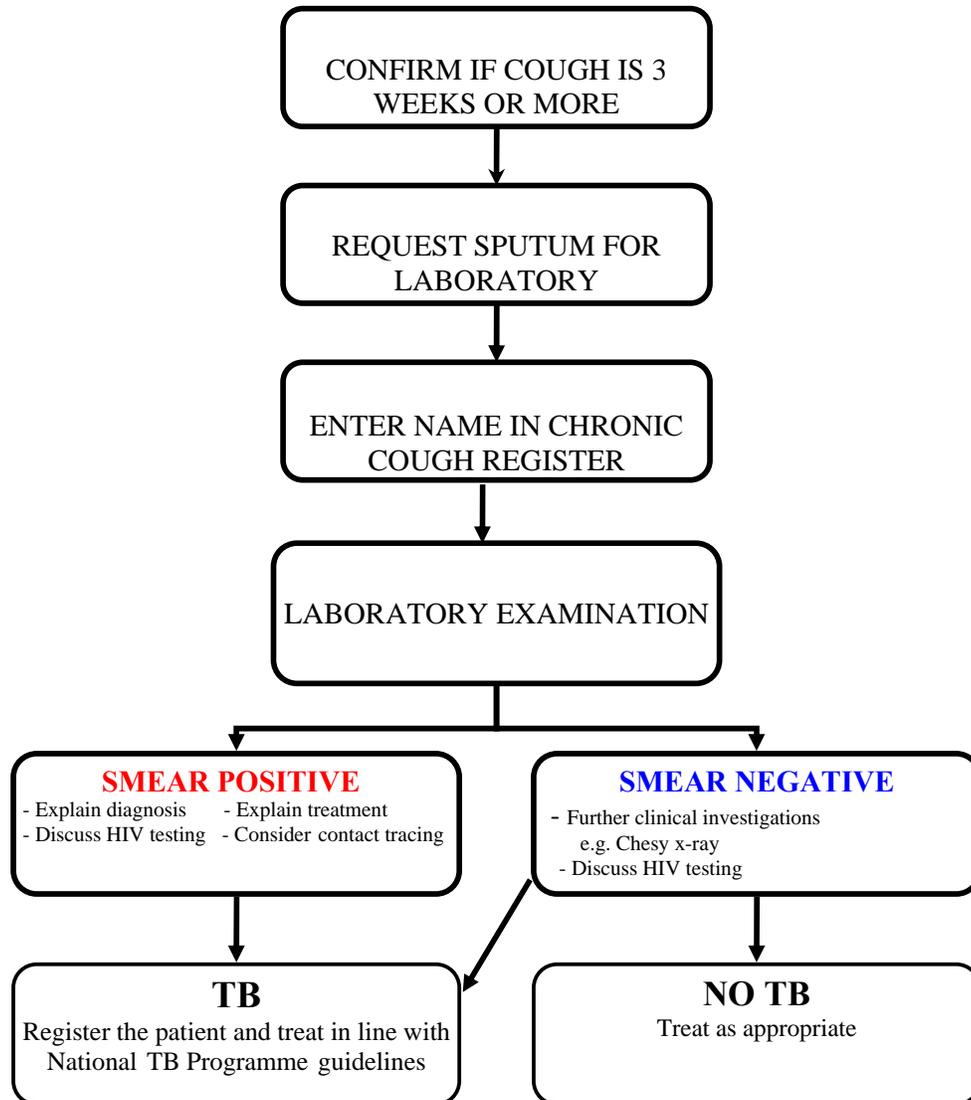


Figure 1: TB Diagnostic Pathway

3.6.2 Management of TB suspects prior to confirmation of laboratory diagnosis

While waiting for laboratory results on smear examination, symptomatic treatment may be given, if necessary including antibiotics, provided these are not anti-TB drugs.

3.6.3 Collection of sputum specimens from TB suspects

Whenever tuberculosis is suspected, three sputum specimens should be collected and sent for direct microscopy whenever, possible within a period of 7 days. These should be collected within 24 hours;

Procedure for sputum specimen collection:

Day one:

- First specimen should be collected on the spot when the suspect presents to the clinic, under the supervision of a health worker.
- The suspect should be given a second sputum container to collect an early morning specimen on the second day.

Day two:

- The third specimen should be collected on the spot during delivery of the second specimen, under the supervision of a health worker.
- Every effort must be made to obtain three specimens.
- For patients living far away, it may be necessary to keep them overnight in the hospital.

NB;-

Should the first spot specimen be positive by microscopy and the patient not return with the second specimen, an immediate follow-up must be made for the patient to prevent spread of infection in the community.

GENERAL RULES ON SPUTUM COLLECTION

Sputum collection should be done in the open air (or ventilated room) away from other people to avoid infecting them. Patients should clean their mouths if they have been eating.

Before collecting sputum

- Explain the reason for collecting sputum.
- Demonstrate how to cough
- Demonstrate how to open and close sputum container.
- Fill the laboratory request form accurately and properly.
- Write patient's name on the body of the container and not on lid.

How to collect a Sputum Sample

- Ask the patient to cough deeply (demonstrate).
- 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.
- The volume of the sputum should be 3 to 5 ml.

After collecting a Sputum Specimen

- Ensure that the container is firmly closed.
- Wash your hands with soap and clean water.
- Store sputum specimen preferably in a refrigerator or in a cool, safe and dark place.
- Do not use laboratory request form for wrapping specimen.

3.6.4 Transportation of sputum specimens

Every health worker is responsible for sending sputum specimens to the laboratory as soon as possible to ensure examination is done within one week of collection. Use any available means of transport.

- The specimens should be packed carefully, preferably in a transport box.
- Make sure that no specimen goes to the laboratory without a laboratory request form.

3.6.5 Who collects sputum specimens

Health workers, community members and individuals can collect sputum specimens and send for microscopy.

3.6.6 Specimen for culture and sensitivity tests

- Priority for culture and sensitivity should be given to relapse cases, treatment after default and treatment failures.
- For each patient, specimens for culture and sensitivity should be collected in two universal bottles.
- Ensure that screw caps are tight to prevent leakage during transportation.
- Ensure bottles are labelled with the patient's name.
- Storage of sputum for culture must be under refrigeration.
- Specimens for culture and sensitivity should reach the TB Reference Laboratory within 7 days of collection.
- The specimens should be collected before TB treatment starts.

3.6.7 Interpretation of sputum results

- a) If at least two results are positive for Acid Fast Bacilli (AFB), register the patient for smear positive treatment.
- b) If only one result out of three is positive for AFB, refer the patient to a clinician for chest X-ray.
- c) If the x-ray in (b) is abnormal then register and treat for sputum positive tuberculosis. If the x-ray is normal then reconsider the diagnosis.
- d) If all the three sputum results are negative for AFB and the x-ray is abnormal, treat the patient for smear negative tuberculosis. Patients with a normal x-ray who remain symptomatic should be referred to a clinician for further investigations.

3.6.8 Registration of TB patients

All TB patients should be registered in the district TB register. All patients transferred from other treatment centres should be registered in a transfer-in register. Patients from other countries should be registered in foreigners' register.

2.6.9 Childhood TB

Recommended approach to diagnose TB in children includes:

- a) Careful history including history of TB contact and symptoms consistent with TB
- b) Clinical examination including growth assessment
- c) Tuberculin skin test
- d) Sputum microscopy when possible (especially in older children)
- e) HIV test

Important risk factors for TB infection in children are close contact with a recently diagnosed sputum smear-positive case and for TB disease are young age of under 5 years, HIV infection and severe malnutrition.

The presence of 3 or more of the following should strongly suggest a diagnosis of TB:

- chronic symptoms suggestive of TB e.g. cough, weight loss, fatigue, fever
- physical signs highly suggestive of TB
- positive tuberculin skin test
- chest X-ray suggestive of TB

CHAPTER FOUR

4.1. TREATMENT OF TUBERCULOSIS

Patients should not be started on tuberculosis treatment until a firm diagnosis has been made. Effective treatment is the most important measure for TB control because it can produce a rapid reduction in the transmission of TB and the magnitude of TB in the community. Effective treatment depends on the following factors: use of at least three drugs in the initial intensive phase of treatment, and use of two drugs in the continuation phase of treatment: all drugs should be given in the correct dosage, taken regularly and for the required length of time. These factors also prevent the development of drug resistance tuberculosis.

4.2. DIRECTLY OBSERVED TREATMENT (DOT)

Directly observed treatment is one element of the DOTS strategy, i.e. the WHO recommended policy package for TB control. Direct observation of treatment means that a supervisor watches the patient swallowing the tablets. This ensures that the TB patient takes the right drugs, in the right doses, at the right intervals. Supervisors are usually health workers, but in the context of decentralisation of care in Malawi, supervisors may also be guardians or community members.

NB:-All drugs containing rifampicin should be given by directly observed treatment.

4.3 ANTI-TUBERCULOSIS DRUGS

There are combined tablets (Fixed Dose Combinations-FDCs), single tablets and streptomycin for injection as shown below:

Combination Tablets:

Adult Formulations

RHZE contains: Rifampicin 150mg
Isoniazid 75mg
Pyrazinamide 400mg
Ethambutol 275mg

RHE contains : Rifampicin 150mg
Isoniazid 75mg
Ethambutol 275mg

RH contains: Rifampicin 150mg
Isoniazid 75mg

Paediatric Formulations

RHZ contains: Rifampicin 60mg
Isoniazid 30mg
Pyrazinamide 150mg

RH contains: Rifampicin 60mg
Isoniazid 30mg

E contains: Ethambutol 100mg

Single tablets:

Z (pyrazinamide) contains: Pyrazinamide 400mg

E (ethambutol) contains: Ethambutol 400mg

H100 (isoniazid) contains: Isoniazid 100mg

Injections:

S (streptomycin) contains: Streptomycin 1g

4.4 DOSAGE OF DRUGS IN RELATION TO BODY WEIGHT FOR FDC

Table 1: Dosages of FDC formulations

| ADULTS | | | |
|-------------------|----------------------------------|-------------------------------------|--------------------------------|
| Body weight in kg | Initial phase 2 months | | Continuation phase 4 months |
| | [RHZE] [R150/H75/Z400/E275] | | [RH] [R150/H75] |
| | Number of tablets* | | Number of tablets* |
| 30-37 | 2 | | 2 |
| 38-54 | 3 | | 3 |
| 55-74 | 4 | | 4 |
| 75 and over | 5 | | 5 |
| CHILDREN | | | |
| Body weight in kg | Initial phase 2 months | | Continuation phase 4 months |
| | [RHZ] (R60/H30/Z150) | E100 | [RH] (R60/H30) |
| | Number of tablets or sachets* | Number of tablets or sachets* | Number of tablets or sachets* |
| < 7 | 1 | 1 | 1 |
| 8-9 | 1.5 | 1.5 | 1.5 |
| 10-14 | 2 | 2 | 2 |
| 15-19 | 3 | 3 | 3 |
| 20-24 | 4 | 4 | 4 |
| 25-29 | 5 | 5 | 5 |

4.5 TREATMENT REGIMENS IN NEW ADULTS AND CHILDREN WITH TB (Regimen 1)

Initial intensive phase: In district and CHAM hospitals newly diagnosed TB patients are admitted for two weeks in hospital where they receive daily treatment. The remaining six weeks of the intensive phase is taken daily either in hospital or in the community according to the patient's DOT option. The DOT options are either hospital, Health centre, guardian or community member supervision.

In central hospitals, patients are started on ambulatory treatment depending on the condition of the patient from the first day, but treatment is on daily basis just like the district hospitals.

Continuation phase: Patients take supervised drugs which they collect from the nearest health facilities every fortnight.

4.6. Tuberculosis Meningitis

The regimen for adult and childhood cases of tuberculous meningitis is different from above. This is because of the serious nature of the disease. The regimen is 2SRHZ/7RH; regimen and doses are in **APPENDIX 6,7 and 8.**

The regimen consists of two months of streptomycin, rifinah and pyrazinamide given under supervision on a daily basis followed by seven months of daily rifinah.

4.7 TREATMENT REGIMENS FOR PATIENTS PREVIOUSLY

TREATED FOR TUBERCULOSIS (Regimen 2).

For Relapse, Return after default, Treatment Failure and Recurrent Tuberculosis.

2SRHZE/1RHZE/5RHE

This regimen consists of two months of daily streptomycin, rifampicin, isoniazid, pyrazinamide and ethambutol given under supervision, one month of daily rifampicin, isoniazid, pyrazinamide and ethambutol given under supervision followed by five months of daily rifampicin, isoniazid and ethambutol given under supervision.

NB:-

Sputum positive cases that have previously taken anti-tuberculosis drugs for one month or more must be suspected of discharging tubercle bacilli resistant to one or more anti-TB drugs. These patients must submit sputum specimens for drug sensitivity testing before starting the re-treatment regimen.

4.8 USE OF ANTI-TUBERCULOSIS DRUGS IN SPECIAL SITUATIONS

Special problems occur in TB patients, which from time to time influence the choice of drugs and their dosage.

Pregnancy and Reproductive Health:

Streptomycin is potentially ototoxic and may cause deafness in babies. Streptomycin should **not** be given in pregnancy. There is no evidence that isoniazid, rifampicin, pyrazinamide and ethambutol are teratogenic, and these drugs may be safely used in pregnancy..

Rifampicin stimulates formation of liver enzymes and therefore can reduce the effectiveness of the oral contraceptive pill. Health workers should advise patients on TB treatment to take alternative contraception while on rifinah.

Renal impairment and renal failure:

Drugs such as rifampicin, isoniazid and pyrazinamide are excreted almost entirely by routes other than renal, i.e. by metabolism or biliary excretion, and therefore they can be given in normal dosage to patients with renal failure. Streptomycin is excreted exclusively and ethambutol predominately by the kidney, and their doses should be reduced and given less frequently in renal failure.

Liver impairment and liver failure

Isoniazid, rifampicin and pyrazinamide are recognised to be hepatotoxic. Patients with active liver disease (ie. with jaundice, ascites) who develop tuberculosis should not receive pyrazinamide or rifampicin. They should be given streptomycin, isoniazid and ethambutol for intensive phase of treatment, and isoniazid and ethambutol for maintenance treatment. If the jaundice is acute and severe, treat initially with just streptomycin and ethambutol.

Epilepsy

Rifampicin induces liver enzymes that metabolise phenobarbitone. There is reduction in phenobarbitone levels. Advise patients to increase the dose of phenobarbitone

TB/ART

Rifampicin induces liver enzymes that metabolise nevirapine (NVP), and consequently NVP level is reduced to about 30%. Low NVP levels may increase the risk of the HIV becoming resistant to the drug and thus compromise the effectiveness of the ART. However, the extent of this risk is not known and there is evidence from small studies that NVP levels, although lowered by Rifampicin, are still in the effective range.

CORTICOSTEROIDS AND TUBERCULOSIS

Adjunctive therapy with corticosteroids, in conjunction with anti-tuberculosis drugs, may be appropriate in particular forms of tuberculosis. Prospective controlled trials have shown that corticosteroids are beneficial in tuberculosis meningitis, pericardial and pleural disease.

In tuberculosis meningitis, patients with altered consciousness, neurological defects or spinal block should be given prednisolone 40 mg daily for 30 days, followed by a gradual reduction in dose in the succeeding weeks.

In pericardial effusion and constrictive pericarditis, patients should be given prednisolone 60 mg for 4 weeks, 30 mg for the next 2 weeks and tapering to zero over the next 2 weeks.

In large pleural effusion, patients show more rapid response in acute symptoms and more rapid disappearance of pleural fluid if given prednisolone 40 mg daily for 1 - 2 weeks..

4.9 MANAGEMENT OF HOUSEHOLD CONTACTS OF SMEAR-POSITIVE TB CASES

- a) **Children aged 5 years and over :**
If symptoms are present they should be investigated for tuberculosis and treated if tuberculosis is present. However, the NTP is advocating for active case finding for all household members.
- b) **Children below 5 years:**
All children should be screened. Screening depends on facilities, but ideally children should be assessed clinically, receive a tuberculin test and undergo a chest x-ray. If there is no evidence of active TB, the child should receive isoniazid preventive therapy (5mg / kg daily for 6 months). If the child is diagnosed with TB, the child should be registered and treated for TB according to the NTP guidelines.

Note: Children who are household contacts of smear-positive TB cases should be assessed even if tuberculin test and chest x-ray are not available. If the child is well and less than 5 years, he receives isoniazid preventive therapy. If a child contact of any age has symptoms suggestive of TB, he or she must be referred for further assessment.
- c) **Babies born of mothers with smear-positive PTB:**
The child should be given isoniazid (5 mg / kg daily for 6 months). At the end of 6 months, the child should be vaccinated with BCG. Breast-feeding is safe and should be continued.
- d) If a child develops symptoms while on isoniazid preventive therapy, the child must be investigated for active TB. If TB is diagnosed, isoniazid should be stopped and anti-TB treatment instituted according to the guidelines.

4.10 DEFAULTING FROM DRUG COLLECTION

An action should be taken to bring the patient back on treatment if he/she has stopped taking anti- TB drugs either during the intensive or the continuation phase of treatment. An action has to be taken within three days after the day the patient was due for his/her drug collection

4.12 MANAGING TRANSFER-OUT AND TRANSFER-IN PATIENTS

When patients transfer out to another treatment facility, it should be indicated in the district TB register. The date of transfer-out and the new treatment facility must be indicated. Transfer-out forms must accompany the patient and must be sent to the new treatment facility and to the DTO of the receiving district. A copy of each transfer-out form must be kept at the original treatment unit by the TB Officer: these should be kept in a special transfer-out folder.

When patients transfer in from another facility, these should be registered in the transfer-in register. Results of treatment outcome must be entered in the transfer-in register; and results must be communicated to the original treatment unit. Transfer-in registers must be properly filled in. Just like the main register, TB officers must indicate when quarters start and finish. All transfer in forms must be kept in a special transfer-in folder.

NB:

TB patients being transferred out during the intensive phase of treatment **MUST** carry their drugs for the remaining period of the intensive phase.

4.13 RECORDING RESULTS OF TREATMENT.

It is vital for assessing programme performance, that accurate recording of treatment outcome results are entered in the TB registers and treatment cards. Treatment cards in patients who have completed treatment or died or defaulted must be collected from health centres.. These treatment cards must be kept safely and in chronological order in the TB office.

a) Recording results in smear-positive TB patients.

At the end of the treatment course in each individual patient, results of chemotherapy should be recorded as follows:-

| | |
|-------------------------------|---|
| Smear negative (Cured) | Patient who is smear negative at or one month (cured) prior to the completion of treatment and on at least one previous occasion |
| Treatment completed | Patient who has completed treatment (taken a full course of treatment) but in whom smear results are not available on at least two occasions prior to the completion of treatment |
| Failure | Patient who remains or becomes again smear positive at 5 months or more during chemotherapy |
| Died | Patient who dies for any reason during the course of their chemotherapy |
| Defaulted | Patient who has interrupted the treatment for more than two consecutive months before the end of course of treatment |
| Transferred out | Patient who has been transferred to another treatment centre and in whom the treatment results are not known |

b) Recording Results in smear-negative TB patients.

The NTP now follows up smear-negative PTB and extra-pulmonary TB patients. Repeat sputum examination is not done during follow up, and the outcome measures recorded are:-

- Treatment completed
- Died
- Defaulted
- Transferred Out
- Unknown – i.e. no information available

TUEBERCULOSIS COMPLICATIONS AND THEIR MANAGEMENT

5.1 PULMONARY TUBERCULOSIS

- (i) Haemoptysis (coughing blood): If severe, this may need admission to hospital for bed rest, sedatives and probably for transfusion. Patients should undergo a chest x-ray in the event of severe haemoptysis in order to rule out potentially treatable conditions such as aspergilloma or bronchiectasis
- (ii) Pleural effusion (collection of fluid or pus between the lungs and the chest wall): This may subside with treatment but sometimes aspiration is necessary to relieve symptoms of dyspnoea. Empyema (collection of pus alone) should be drained.
- (iii) Spontaneous pneumothorax (collection of air between the lungs and the chest wall): This may occur with sudden onset of shortness of breath. Pneumothorax requires admission to hospital for drainage with an underwater seal.
- (iv) Fibrosis (scarring) of the lungs: This may lead to cor- pulmonale (right-sided heart failure). Symptomatic treatment may be required.
- (v) Coughing due to residual lung damage sometimes with expectoration of large volumes of sputum. The patient may require only symptomatic treatment provided that the sputum is negative for AAFB.

5.2 EXTRA-PULMONARY TUBERCULOSIS

Complications will depend upon the site of the disease:

- Tuberculosis of the spine may present paraplegic symptoms (weakness of the lower limbs). Refer the patient to the hospital at the earliest possible moment.
- TB meningitis may result in cranial nerve damage. Patients require high doses of steroids.
- TB lymphadenitis can cause cold abscesses and suppurating fistulae. Patients need drainage of abscesses.
- Pericardial effusion may cause “heart failure”. Patients require high doses of steroids. Cardiac tamponade (ie distress associated with shock) may necessitate pericardial aspiration – this should be done by an experienced clinician
- Pleural effusion can result in respiratory failure. Patients require drainage if they have difficulties in breathing.

ADVERSE DRUG REACTIONS AND THEIR MANAGEMENT

6.1. SIDE EFFECTS OF ANTITUBERCULOSIS DRUGS

Side effects of anti-tuberculosis drugs should be looked for and treated. Some of them can be hazardous for the patient's health or may force the patient to stop treatment.

STREPTOMYCIN

Minor side effects such as local reaction at injection site, numbness around the mouth and tingling sensation soon after the injection.

Major side effects include cutaneous hypersensitivity, vestibular and auditory nerve damage, including that of the foetus, and renal damage.

Management:

For minor side effects the dose can be reduced by 0.25gram until tolerated.

For cutaneous hypersensitivity (see 5.2).

Vestibular and auditory nerve damage are dose and age related. The dose of 1 gram is therefore reduced to 0.75gram in persons weighing less than 55kg and in those aged 45 years or more. Damage to the vestibular and auditory nerve usually occurs in the first 2 months and is manifested by ringing in the ears, giddiness, ataxia and/or deafness. The condition is reversible if the drug dosage is reduced by 0.25gram. If the above reactions are severe, the drug is stopped.

ISONIAZID

Side effects include: various skin rashes, hepatitis, and peripheral neuropathy (paraesthesia, numbness and limb pains).

Rare side effects include convulsions, pellagra, arthralgia, anaemia, agranulocytosis, and lupoid reactions.

Management:

For various skin rashes (see 6.2)

Peripheral neuropathy: giving vitamin B6 (pyridoxine) 10mg daily or vitamin -B complex may prevent this. Pyridoxine 10mg per day is especially useful in HIV-infected patients because of their added risk of HIV-related peripheral neuropathy. For established peripheral neuropathy, pyridoxine should be given at larger doses of 50mg to 75mg daily.

For hepatitis (see 6.3)

RIFAMPICIN

Side effects include gastro-intestinal reactions, hepatitis, generalised cutaneous reactions, thrombocytopenic purpura, and on intermittent dosage "the flu syndrome" which consists of fever, chills, malaise, headache and bone pains.

The gastrointestinal symptoms such as anorexia, nausea, abdominal pain and vomiting occur soon after administration and can last several hours. Patients should be warned that rifampicin colours urine, tears and sweat red or orange .

Rare side effects include osteomalacia, pseudomembranous colitis, pseudoadrenal crisis, acute renal failure, and shock.

Management:

For gastrointestinal reactions, reassure the patient or give the drug after an evening meal.

For hepatitis (see 6.3)

For serious effects such thrombocytopaenic purpura, shock, acute renal failure, or haemolytic anaemia the drug must be stopped immediately and never used again.

PYRAZINAMIDE

Side effects include arthralgia and hepatitis.

Rarer side effects include gastro-intestinal reactions, cutaneous reactions, sideroblastic anaemia.

NB:

Pyrazinamide may cause arthralgia (joint pains) due to the inhibition of the renal tubular secretion of uric acid by the drug, and high concentrations of uric acid can lead to gout (swollen and tender joints).

Management:

For joint involvement: simple treatment with aspirin usually minimises the symptoms or indomethacin may be used for more severe joint involvement. If frank gout occurs then treatment with allopurinol is required.

For hepatitis (see 6.3)

ETHAMBUTOL

The main side effect is retrobulbar neuritis. Rarer side effects include generalised cutaneous reactions, arthralgia, peripheral neuropathy.

NB:

Ethambutol may produce impairment of vision, a decrease in visual acuity, blurring and red-green colour blindness. However, the toxicity is dose dependent and occurs rarely when 15mg/kg-body weight is given or 25mg/kg-body weight is given three times weekly. All patients should be warned that if visual symptoms occur an ocular (eye) examination should be undertaken. Impaired vision usually returns to normal within a few weeks of stopping the drug.

Management:

For visual problems, an ocular examination should be undertaken and if in doubt the drug should be stopped. Impaired vision usually returns to normal within a few weeks of stopping the drug.

5.2 CUTANEOUS AND GENERALISED HYPERSENSITIVITY REACTIONS

Skin reactions

- If a patient complains of itching without a rash, symptomatic treatment with anti-histamines may be tried. However, the patient must be very carefully watched, and if a rash develops then all treatment should be stopped because of the risk of precipitating a severe reaction.
- If the rash is severe, or if there is evidence of mucosal involvement, hypotension or severe illness, corticosteroid treatment should be instituted. Oral prednisolone 40 - 60 mg should be given daily until there is a response. The amount of prednisolone is gradually reduced in the following days according to the patient's response.
- In severe reactions antituberculosis treatment sometimes has to be stopped for 3 - 4 weeks.

Re-introduction of anti-tuberculosis drugs.

Once the reaction has subsided, drugs are reintroduced according to Girling's standard guidelines using increasing challenge doses.

Challenge doses

| Drug | Day 1 | Day 2 | Day 3 |
|--------------|--------------|--------------|--------------|
| Isoniazid | 50mg | 300mg | 300mg |
| Rifampicin | 75mg | 300mg | Full dose |
| Pyrazinamide | 200mg | 800mg | Full dose |
| Ethambutol | 100mg | 400mg | Full dose |
| Streptomycin | 125mg | 500mg | Full dose |

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

If the initial cutaneous reaction was severe, smaller initial challenge doses should be given, approximately one tenth of the doses shown for DAY 1.

If a patient is recommenced on an adequate anti-tuberculosis treatment regimen (e.g. isoniazid, rifampicin and pyrazinamide), then rechallenging with the implicated drug (e.g. streptomycin) is not advisable.

6.3. DRUG INDUCED HEPATITIS

Mild transient symptomless increases in serum liver transaminases occur during the early weeks of treatment. There is no need to interrupt or change treatment unless there is anorexia, malaise, and vomiting or clinically evident jaundice with hepatic enlargement. Clinical features of concern include: protracted vomiting, mental changes and signs of bleeding - these all suggest impending acute liver failure.

If jaundice or any of the clinical features suggestive of acute liver failure develop, all drugs must be stopped until the jaundice or hepatic symptoms have resolved and the liver function tests have reverted to normal. If liver function tests cannot be measured, then it is advisable to wait an extra two weeks after the jaundice has disappeared before recommencing anti-tuberculosis therapy.

Once the drug-induced hepatitis has resolved, the drug regimen can be re-introduced, although it is safer to avoid pyrazinamide. Therefore, in the initial phase a regimen of isoniazid, rifampicin and ethambutol could be used followed by rifampicin and isoniazid in the continuation phase. However, if there has been severe hepatitis, it is probably safer to use the previous standard regimen of "streptomycin, isoniazid and ethambutol".

Severely ill patients with tuberculosis who develop drug-induced hepatitis should have the drug regimen stopped. If it is felt that anti-tuberculosis treatment should continue, then interim therapy may be started with streptomycin and ethambutol.

6.4 SYMPTOM BASED APPROACH TO MANAGEMENT OF DRUG REACTIONS.

Minor side effects not requiring treatment to be stopped:

| Symptoms | Drug | Management |
|------------------------|--|---|
| Abdominal pain, nausea | related to rifampicin | give oral drugs to the patient last thing at night |
| Burning of the feet | related to isoniazid peripheral neuropathy | continue isoniazid; give pyridoxine 50 mg - 75 mg daily Large doses of pyridoxine may interfere with the action of isoniazid (Wherever possible, pyridoxine 10 mg daily should be given routinely with isoniazid) |
| Joint pains | related to pyrazinamide | continue pyrazinamide; use aspirin or non-steroidal anti-inflammatory drug |
| Red urine | related to rifampicin | reassure the patient |
| Women on rifampicin | Rifampicin may reduce the effectiveness of the oral contraceptive pill | Alternative contraception should be provided |

Major Side effects requiring treatment to be stopped:

| Symptoms | Drug | Management |
|--|--|--|
| Deafness | related to streptomycin | <ul style="list-style-type: none"> • Auroscopy to rule out wax • Stop streptomycin if no other explanation. • Use ethambutol instead |
| Dizziness | if true vertigo and nystagmus, related to streptomycin | <ul style="list-style-type: none"> • Stop streptomycin; • If just dizziness with no nystagmus, try dose reduction for one week, but if no better stop streptomycin. • Use ethambutol instead |
| Generalised reactions including shock, | may be due to rifampicin, pyrazinamide and/ or | <ul style="list-style-type: none"> • Stop all medication • Use different combination of drugs |

| | | |
|------------------------|--|---|
| purpura | streptomycin | |
| Jaundice | related to drug-induced hepatitis. | <ul style="list-style-type: none"> • Stop all antituberculosis drugs until jaundice and liver function tests revert to normal (see below) |
| Skin itching | related to all anti-tuberculosis drugs | <ul style="list-style-type: none"> • Stop antituberculosis drugs |
| Visual impairment | related to ethambutol | <ul style="list-style-type: none"> • Visual examination • Stop ethambutol |
| Vomiting +/- confusion | suspect drug-induced hepatitis | <ul style="list-style-type: none"> • Urgent liver function tests (LFTs) • If LFTs not available, stop anti-tuberculosis drugs and observe. |

7.0 DOCUMENTATION IN TB CONTROL

It is very important that there be a good recording and reporting system in Tuberculosis control, especially of all valuable information.

Careful recording of information improves the patient's care, management and enables assessment of the activities of the tuberculosis programme.

The following documents should be used.

NB:

All TB Forms and Registers are at the back of this manual under Appendix 8

(a) CHRONIC COUGH REGISTER - FORM 1

This should be at every health unit preferably at the out patient department.

All those patients who have been coughing for three weeks or more and are suspected to have TB should be registered in this register.

When the chronic cough register is properly used, it helps the health facility to see their case detection.

(b) TUBERCULOSIS LABORATORY REGISTER – FORM 2

Kept at laboratories carrying out sputum examination for tubercle bacilli.

For each smear examined, the information required must be entered by the microscopist or technician who carries out the smear examination.

The Register gives information on the number of suspects examined, the number of smear-positive cases detected, the laboratory serial number and results of smear examination for follow up of treatment.

The TB Officer needs to check regularly whether all patients with positive smears in the Tuberculosis Laboratory Register are put on treatment. TB officers must indicate the TB registration number in the remarks column of the laboratory register of those who have started on treatment.

(c) DISTRICT TUBERCULOSIS REGISTER – FORM 3

This is maintained at all treatment centres. It is a requirement to register all TB patients started on treatment. These include new cases, relapses, failures, treatment after default, and recurrent cases.

NB:

Transfer-in patients are recorded in a separate register for easy follow up.

(d) HEALTH CENTRE REGISTER - FORM 3A

This is kept at health centres and at private clinics for recording and evaluating patients receiving treatment at the unit referred from registering units.

(e) TUBERCULOSIS TREATMENT CARD – FORM 4

Kept in all health units giving treatment

When treatment has been completed, the card should be returned to the district hospital and retained by the DTO in his office.

(f) TUBERCULOSIS OUT-PATIENT IDENTITY CARD - FORM 5

Kept by patient.

Health workers use this card to identify TB patients and assist them appropriately, e.g supplying drugs and collecting follow up sputum specimens. Health workers should remember to fill in the date of next appointment in the appropriate column.

(g) REQUEST FORM FOR SPUTUM-SMEAR EXAMINATION - FORM 6

This form is filled whenever a patient has submitted specimens for sputum examination. Health workers should remember to write patients particulars, district TB registration number (for follow-up cases) and reason for examination in the appropriate spaces. This form is kept in all health units.

(h) REQUEST FORM FOR CULTURE AND SENSITIVITY TESTS - FORM 7

Health workers should use this form whenever they are sending specimens for TB culture and sensitivity testing at the CRL. This form is kept at all registration centres. Remember to collect culture specimens before commencing TB treatment.

(i) QUARTERLY REPORT ON CASE FINDING - FORM 8

This form is used for reporting all TB cases registered at each registration centre in each cohort. It is filled by registration centres and sent to the Zonal TB officers for aggregation, record keeping and analysis.

(j) QUARTERLY REPORT ON TREATMENT OUTCOME - FORM 9

This form is used for reporting TB treatment outcome for patients started on treatment. It is filled by registration centres and sent to the Zonal TB officers for aggregation, analysis and planning.

(k) TUBERCULOSIS REFERRAL/TRANSFER FORM - FORM 10

This form is filled when transferring patients. Four copies of this form should be filled. One to be kept by the health unit in a special file, the other to be taken by the patient to where the patient is referred, one to be mailed to where the patient is referred, and the fourth one is mailed to the DTO where the patient is going. Health workers must follow up all transfer out patients to ensure that they continue receiving their treatment. This form is kept at all health units.

(l) RIFINAH MONITORING BOOK - FORM 11

Kept at all health units and is used to monitor use of Rifinah. Health workers must indicate end of day consumption and balances and must document any losses e.g. vomiting or falling down.

(m) TB DRUG ORDER BOOK - FORM 13

This document should be kept by all units and should be used to order anti-TB drugs either from the pharmacy or from the TB officer. Remember to use this book whenever drug orders are made.

(n) DISTRICT TB OFFICER SHADOW FILE - FORM 14

Used by the TB officer. This is a duplicate of the drug stock levels in the hospital pharmacy. TB officers must update this book on weekly basis.

(o) ZONAL TB OFFICER SHADOW FILE - FORM 15

Used by the Zonal TB Officer. This is a duplicate of drug stock levels at regional medical stores. Zonal officers must update this book on monthly basis and whenever the Regional medical stores has received new consignment.

(p) DRUG REQUISITION RECORD BOOK - FORM 16

Used by Zonal TB Officer to approve and track drug requisitions received from facilities.

(q) DISTRICT TB SUPERVISION - FORM 17

Used by supervisor from Central Level and zonal offices to collect standardised TB data during their quarterly support visits..

(r) DTO SUPERVISORY CHECK LIST FOR HEALTH CENTRE SUPERVISION - FORM 18

Used by DTOs to collect standardised TB data during their monthly support visits.

(s) TUBERCULOSIS LABORATORY QUARTERLY REPORT - FORM 19

This form is used by the TB laboratory supervisors to collect TB laboratory data on quarterly basis.

(t) TUBERCULOSIS SUSPECT REFERERAL FORM – FORM 20

This form is kept at all units. It has a Chichewa version and is used to refer all patients suspected to have pulmonary tuberculosis. All community members or groups involved in TB control activities should use this form to refer suspects to the nearest sputum collection point.

TB AND HIV INFECTION

8.1 Background:

Human immunodeficiency virus (HIV) infection is spread most commonly by sexual intercourse, through contact with, blood or blood products, other body fluids and from mother to child transmission of HIV during pregnancy, birth and breast-feeding. Infection with HIV leads to extensive destruction of the immune defence mechanisms of the body. As a result, those infected with HIV become ill with severe and often deadly diseases to which persons without HIV infection would not usually be susceptible. When recognised opportunistic diseases accompany HIV infection, the affected person is said to have the acquired immunodeficiency syndrome (AIDS).

8.2 How TB is affected by HIV

The development of TB following infection with TB micro organisms is usually prevented by the actions of the immune system, and this explains why a relatively small proportion of those individuals who have been infected with TB go on to become ill with the disease. When the protection provided by the immune system is reduced by HIV infection, the TB micro organisms, which are dormant within the body of an individual who has been infected, begin to multiply, causing TB.

In settings where both infections (TB and HIV) are common and occur in the same individuals, the number of cases of TB increases due to the increased risk of development of active TB. In 2003, it was reported that tuberculosis incidence was 8.3 times higher in HIV-positive than HIV-negative African population. In Africa, HIV prevalence in tuberculosis is 38% while in Malawi, about 70% of TB patients are HIV-seropositive. The increased numbers of TB cases will lead to an increase in the transmission of TB micro organisms in the community. To reduce this excess transmission, it is imperative to rapidly identify and treat all infectious cases of TB.

8.3 Impact of HIV on TB

HIV has its impact on TB in a number of ways, each of which is a potential threat to TB control.

8.3.1 TB notification cases

In the last 20 years, TB notification cases have increased by a factor, from as low as 5000 TB cases in 1985 to 27610 TB cases in 2005, mainly because HIV:

- Increases the risk of disease reactivation in people with latent TB infection.
- Increases susceptibility to new TB infections. Marked increase in cases is observed, particularly in smear-negative pulmonary TB and extra-pulmonary TB cases.

8.3.2. Delayed diagnosis.

The community has linked TB and HIV together leading to a misconception that all TB patients have HIV. This may lead to a delay in diagnosis because patients are afraid they will be labelled as HIV-infected. Delayed diagnosis can lead to poorer treatment outcomes.

8.3.3 Increased morbidity and mortality.

HIV-positive TB patients often run a stormy course while on anti-TB treatment with fevers, chest infections, recurrent diarrhoea, candida and bacteraemia. Adverse reactions to anti-TB drugs are also more frequent leading to interruptions of treatment and occasional fatalities. HIV positive patients have a much higher mortality during and after anti-tuberculosis treatment compared with HIV negative patients. For example in Africa the proportion of patients dying while on anti-tuberculosis treatment is 16-35% in HIV positive individuals not receiving antiretroviral and compared to 4-9% in HIV-negative.

8.3.4 Recurrence of TB after completing treatment.

Rates of recurrent TB disease in co-infected patients previously treated for TB are high suggesting a need for secondary Isoniazid preventive treatment (IPT).

8.3.5 Drug resistance.

Several outbreaks of multi-drug resistant TB (MDR-TB) have been reported from industrialised countries and southern parts of Africa amongst patients with HIV. Recently XDR-TB has also been reported in these same settings. HIV does not itself cause MDR-TB, but it can increase the spread of this dangerous condition by increasing susceptibility to infection and accelerating the progression from infection to disease.

8.4 Implementing TB-HIV collaborative activities

Malawi was one of the countries in Africa that piloted the WHO coordinated collaborative TB/HIV activities through the ProTEST project. Lessons learnt from the ProTEST initiative resulted into countrywide scale up of collaborative TB/HIV activities. Comprehensive package of joint TB/HIV services should including these activities:

8.4.1 HIV testing and counselling (HTC) for TB patients

HTC is an entry point for HIV prevention, treatment and care for HIV-infected TB patients. Currently less than half of the TB patients registered annually are tested for HIV indicating that not all TB patients are offered this service. The NTP policy stipulates that all TB patients on registration for anti-TB treatment should be routinely offered HTC.

Once diagnosed with TB, the patient should be offered HIV testing and counselling with an option of opting out. This therefore entails implementation of provider-initiated, diagnostic HIV testing following these standard operating procedures:²

- HIV testing should be carried out if the HIV status is unknown or was previously reported as negative.
- If a patient was previously tested, as HIV positive but has no documented evidence of this fact, the test should be repeated.

8.4.2 Cotrimoxazole preventive therapy (CPT)

CPT should be given to HIV-infected TB patients to reduce the occurrence of other opportunistic infections and deaths regardless of whether the patients are on ART or not:

- Health care workers should ensure that all HIV-infected TB patients are offered CPT as soon as HIV status is known.
- Contradictions to cotrimoxazole should be ruled before commencing treatment
- The current recommendation is that CPT once started should be given indefinitely if a CD4 count is not available for the patient monitoring. If the CD4 count is available then CPT can be discontinued if the CD4 count rises above the threshold for starting CPT.

8.4.3 Provision for ART in HIV-infected TB patients

Free antiretroviral drugs are being offered in all public hospitals (including CHAM) and some health centres. Free antiretroviral therapy services are also available in some private hospitals and clinics. Guidelines for the use of antiretroviral drugs have been developed³:

- All HIV infected TB patients are potentially eligible for ART, because they are either categorised as WHO clinical stage 3 or 4.
- HIV positive TB patients should be referred to the ART clinic at some point during the initial phase of anti-TB treatment preferably at 6 weeks to be assessed and booked for group counselling so that at the start of continuation phase the patients are ready to commence ARV drugs.
- The TB treatment card should include a reminder during the second month about referring HIV positive patients for ART
- TB patients who are also on ARV drugs should have their information about ART entered in the TB register and TB treatment card

² Embedding HIV testing and counselling within the TB diagnosis and registration process should be socially and culturally sensitive to ensure that patients are not coerced into having an HIV test.

³ Treatment of AIDS. Guidelines for the use of anti-retroviral therapy in Malawi. 2nd edition.

The current first ARV regimen constitutes a fixed combination of Stavudine, Lamivudine and Nevirapine (d4T+3TC+NVP). Nevirapine interacts with rifampicin if concurrently given. To minimize the occurrence of adverse reactions when ARV drugs and TB treatment are started at the same time as well as reducing pill burden, it is recommended that HIV infected TB patients should start ART after completing the initial phase of TB treatment. However, if the patient is already on ARV drugs and later develops TB, anti-TB treatment and ART should continue in the usual way.

8.4.4 Isoniazid preventive therapy for HIV-infected persons without active tuberculosis

Isoniazid preventive therapy (IPT) for 6-9 months reduces tuberculosis prevalence by about 60% in HIV infected individuals with tuberculin skin test (TST), and by about 40% when used irrespective of TST results. This low cost intervention has been little used in Africa, with only Botswana achieving countrywide implementation. The low use of IPT relates to concerns about possible promotion of drug resistance.

There is currently no policy in Malawi for the use of IPT among HIV-infected persons without active TB.

8.4.5 Active TB case finding in HIV testing and counselling clinics

Up to 10% of HIV-infected individuals have active tuberculosis when first seeking knowledge of their HIV status. Symptomatic screening detects most, but not all, active TB cases. TB culture and not chest X-rays seems to add substantially to sensitivity and specificity. Every opportunity should be taken to screen HIV-infected individuals for active TB, just as every patient with tuberculosis should be screened for HIV.

8.4.6 Increased collaboration and coordination between the TB programme and the Clinical HIV Unit and other stakeholders

Collaboration and coordination can mean referral of patients and suspects between TB and HIV services, some provision of joint TB/HIV services, or complete integration of tuberculosis and HIV/AIDS clinics. The National tuberculosis programme in Malawi provided a model for the scale delivery of ART. Successful implementation of joint TB/HIV services should demand for joint TB/HIV planning, capacity building, training and monitoring and evaluation between TB programme and Clinical HIV Unit. Practical steps that will enhance collaboration at implementation level should include:

- Placing HIV parameters in TB monitoring and reporting tools
- Provider-initiated HIV testing and counselling of TB patients
- Provision of cotrimoxazole preventive therapy
- Routine referral for ART (requires provider-initiated HIV testing and counselling for all patients)
- Offering of anti-tuberculosis drugs and antiretroviral therapy drugs from the same place
- Provision of full ART clinical and TB registration services in the same health facility
- Screen of all HIV-positive persons for active TB

8.4.7 Monitoring and evaluation of collaborative TB/HIV activities

The following indicators should be used to collect data for TB/HIV activities:

- Proportion of TB patients with known HIV status
- Proportion of TB patients requiring a new HIV test who receive a new test
- HIV prevalence among TB patients (with known HIV status)
- Proportion of HIV positive TB patients started on cotrimoxazole
- Proportion of HIV positive TB patients started on ART

To collect data based on the above indicators, the TB register should incorporate HIV variables as follows:

HIV test history

- Not discussed
- Recent HIV negative result
- Past HIV positive result
- Never tested
- Old negative test
- Not tested
- New negative test
- New positive test

Cotrimoxazole

- Circle yes or no
- Write date when CPT started

Antiretroviral therapy

- Circle yes or no
- Write date when ART started
- Write ARV number (facility code and patient number)

8.4. 8 Treatment of HIV-related infections.

TB patients often develop HIV-related infections, which require treatment in addition to TB treatment. Some of the common HIV-related infections and complications and their treatments are shown in the table below.

| Symptom | Likely aetiology | Suggested Treatment |
|---|---|--|
| Sores in the mouth | Oral candidiasis | Nystatin pessaries/drops |
| Pain on swallowing | Oesophageal candidiasis | Ketoconazole or Fluconazole |
| Breathlessness | Exclude anaemia, pneumothorax, large pleural effusion, heart failure, <i>Pneumocystis carinii</i> pneumonia | Treat any underlying pathology which is identified |
| New Cough (especially during the initial phase of TB treatment) | Exclude lower respiratory tract infection | Cotrimoxazole Amoxicillin |
| Persistent severe headache | Cryptococcal or bacterial meningitis (needs lumbar puncture) | Fluconazole Antibiotics |
| Burning pain in feet | HIV or INH peripheral neuropathy | Pyridoxine Amitryptiline |
| Chronic diarrhoea | Pathogens include:- Isospora belli Cryptosporidium spp Microsporidia | ORS Cotrimoxazole – if no response followed by metronidazole – if no response followed by albendazole |

DRUG RESISTANT TUBERCULOSIS

9.1 Definitions.

Resistance of the tubercle bacilli to anti-TB drugs is a world-wide problem. In general, there are two types of drug resistance: Primary resistance (resistance in newly diagnosed TB cases) and secondary resistance (resistance in previously treated TB cases).

Multi-drug resistant TB (MDR-TB)

Multi-drug resistant TB means resistance to at least rifampicin and isoniazid.

Extensively-drug resistant TB (XDR-TB).

Extensively drug-resistant tuberculosis (XDR-TB) is defined as MDR-TB that is also resistant to any fluoroquinolone, and at least one of the three injectable second line anti-TB drugs (capreomycin, kanamycin and ampicacin).

Currently, the laboratory capacity in Malawi cannot diagnose XDR-TB and as such an agreement has been made with Medical Research Council in South Africa to be analysing MDR-TB samples from Malawi for XDR-TB. XDR-TB is almost incurable since it is resistant to most of the important second line drugs.

9.2 Extent of drug resistance in Malawi.

Routine data⁴ indicates that drug resistance to isoniazid and rifampicin in newly diagnosed cases in Malawi is at about 2.5%. Currently there are no XDR-TB patients registered within the Malawi NTP, possibly due to inability of the Central Reference Laboratory.

The cause of drug resistance is inadequate therapy for TB. This may be because of inadequate treatment, poor adherence to treatment, use of monotherapy, sub-optimal dosage and poor drug absorption. HIV-infected persons are more susceptible to new TB infections and therefore more likely to acquire drug-resistant TB.

9.3 Treatment of Drug-resistant TB.

Multi-drug resistant TB treatment requires the use of second line anti-TB drugs, which are expensive, toxic and have to be taken for at least 18-24 months to obtain a cure. Currently there are no second line anti-TB drugs for the MDR-TB patients in Malawi. However, the NTP is in process of purchasing these drugs. Nonetheless a decision is yet to be made whether these patients will be managed in the community or in a specialised hospital.

The current recommendations from the NTP for the treatment of MDR-TB are:-

- Provide isoniazid and ethambutol (there is some evidence that this reduces the excretion of AFB)
- Avoid admitting the patient to general hospital wards; if hospital admission is necessary then patients should be admitted to a special side ward which has good ventilation. While in these wards, the patients should wear a mask if health care workers and visitors enter the room
- Advise the patient at home to sleep in a separate room from the rest of the family (if possible), to wear a mask when sitting with the family in a room, to have the rooms well ventilated and to use a fan blowing air from the family towards the patient

NB:-

Extensively drug resistant TB (XDR-TB) is almost incurable since it is resistant to most of the important second line drugs.

9.4 Actions of the National TB Programme to combat drug resistance

Several actions are needed to try and control the spread of MDR-TB in the country. These can be summarised as follows:

1. Training of both government health workers and of private practitioners.
2. Public education on treatment adherence.
3. Drug monitoring and drug audit.

⁴ NTP data bank

4. Surveys of drug resistance.
5. Serious disciplinary action regarding anti-TB drug theft.
6. Influencing prevention of vendors, shopkeepers and health personnel from selling anti-TB drugs.
7. Influencing restriction of use of anti-TB drugs

CHAPTER TEN

10.1 TB HEALTH PROMOTION AND EDUCATION

- Health promotion and education is a key contributor to the NTP's goals. It is a tool used across all aspects of TB control, from advocacy through case finding to treatment.
- Advocacy is used to make sure that TB services are consistent priority at every level and resources are allocated accordingly.
- Case finding requires that health workers and the community are aware of the signs and symptoms of Tuberculosis and the TB suspects be able to take appropriate action to access TB diagnostic services.
- Health promotion is again an indispensable tool and contributes to early case detection followed by early treatment with all the benefits to treatment outcomes.
- Health workers attending to out patients at out-patients department at every health delivery setting should be very well conversed with TB as a disease and diagnosis procedures. They should make sure that at OPD section, frequent health education sessions should be done by the TB officer, Clinician, Nurse or the health education officer at the district.
- This can be supplemented by communication devices such as TV and radios including health education drama group available at the hospital can also be used to provide TB information whilst the patients are waiting for diagnosis.
- A list of topics or themes is developed by the health education officer in coordination with the TB officers for the routine health education sessions at the hospital.
- Once diagnosis has been made education of TB patients should start immediately after a suspect is diagnosed with TB. The TB officers, the TB Nurse, clinician or the DTOs are responsible for patient education. Creation of a good patient provider relationship coupled with good interpersonal skills is central to following of the advice by the patient.

All the health workers that provide information to TB patients should make sure that TB patients are always provided with relevant information before they are put on treatment.

10.2 KEY TB AND TB/HIV MESSAGES

- ✓ Tuberculosis is a disease caused by germs. It spreads most easily when it is in a person's lungs.
- ✓ People with TB have many different symptoms. The major symptom of TB in the lungs is coughing for more than 3 weeks. It is important to go to health facility for a check up.
- ✓ TB spreads to others when someone with TB coughs or sneezes
- ✓ It is important for a TB patient to take all the prescribed TB drugs as scheduled, for the whole duration of treatment to avoid the disease becoming resistant to drugs.
- ✓ To prevent spread of tuberculosis, it is important :
 - To take treatment and be cured of TB
 - To always cover the mouth and when coughing and sneezing
- ✓ Choice of DOTS: hospital, health centre or guardian based after hospitalized treatment where indicated.
- ✓ All smear-positive patients must have follow-up sputum smear examination at 2 and 5 months.
- ✓ Importance of adherence to treatment during the whole treatment period that apart from ensuring cure, it prevents the development of TB resistant strains that is difficult to treat.

- ✓ Adverse reactions to TB treatment
- ✓ It is important for TB patients to eat a well balanced diet, avoid alcohol and smoking.
- ✓ TB and sex: TB patients can have sex if they so wish while on TB treatment

In addition to the above key messages, TB patients must be given information and be tested for HIV;

- Some people with TB have HIV as well. It is important to get tested.
- TB is curable even when the patient is co-infected with HIV.
- Benefits of testing for HIV include provision of cotrimoxazole preventive therapy and ARVs for HIV positive TB patients

Health workers are the prime sources of TB information as such having adequate and correct information about TB is important. Provision of TB information to TB patients should be done frequently. Information, education and communication (IEC) materials should supplement the health education.

After the one on one interaction with the TB patient, the DTO should make sure that TB education should be done in all the TB wards two times in a week. To supplement the information dissemination, the DTO should invite different ex-TB patients to provide moral support to the patients fortnightly (every two weeks). These people will provide good advice based on living experiences with the disease.

The TB ward chairperson should be provided with information on TB and should provide this information on daily basis to fellow patients and the guardians.

The DTOs should make sure that they always coordinate with district health promotion officers in conducting health education sessions with all the target groups.

APPENDIX 1 a:

PREPARATION OF SPUTUM SMEAR, ZIEHL-NEELSEN STAINING AND REPORTING OF MICROSCOPY RESULTS

Staining procedures: principles

Whether the staining is by conventional Ziehl-Neelsen (Z-N) method or by one of the fluochrome procedures, the mycobacterial property being examined is the retention of carbol fuchsin and related dyes after exposure to acid alcohol.

Acid fastness is indicated by red stained bacteria against a blue or green background (Z-N) or alternatively by bright yellow fluorescent mycobacteria against a dark background.

Using a wire loop or an applicator stick, select the most yellow purulent portion of the sputum and spread onto a clean, labelled slide. The slide must be cleaned with methylated spirit or alcohol before making the smear. Spread the sputum sample as thinly as possible over two-thirds of the slide, 20 mm by 10 mm. Flame the loop between each successive specimen until red hot.

Fix the smear by passing the slide through a flame five times for four seconds, with the slide turned away from the flame. Take care not to apply too much heat.

Ziehl-Neelsen staining:

1. The fixed slides are placed on a staining rack with the sputum smears uppermost and their edges separated.
2. The slides are covered with filtered carbol fuchsin stain.
3. Heat the slide gently from below until steam is seen rising from the stain. A thick piece of wire or stick with a cottonwool ball wrapped round on end and dipped in spirit, and spirit lamp or any other appropriate source of heat are used for this purpose, on no account must the stain boil or the smears dry out. If accidentally some stain is lost from the smear, it must be replaced and reheated.
4. The hot stain is left on the slides for 5 minutes.
5. Rinse the slides individually in a gentle stream of running tap water until all free stain is washed away.
6. Decolourize with 3% acid alcohol (3ml hydrochloric acid in 97ml methylated spirit or alcohol). The decolourizing solution is poured onto the slides to cover them completely and left on for 3 minutes. Rinse the slides individually in a gentle stream of running tap water until all free stain is removed. If too much stain is left on the smear and they are still visibly red, the decolourizing process must be repeated until most of the stain has been removed. An adequately decolourized smear is colourless or slightly pink.
7. Counterstain with either 0.1% or 0.3% methylene blue for approximately 30 seconds. Rinse the slides individually in a gentle stream of running tap water until all free stain is washed away. Let the slides dry completely in the air. Do not wipe or BLOT.
8. Examine the slide first with 40x objective and then with oil immersion lens. Move the slide systematically to avoid repeating examination of the same field. Wipe the oil immersion lens off after each positive slide to prevent transfer of bacilli. If the smear has been correctly stained and decolourized, and if acid-fast bacilli are present they will appear as pink to bright red rods, singly, in pairs or in small clusters on a blue or green background. Look at the slide for long enough.

Reporting of microscopy results

The staining method used should be stated as well as the number of acid-fast bacilli seen in the smear. The number of bacilli found is very important because it relates to the degree of infectiousness of the patient and also

to the severity of the disease. Therefore the microscopy results must be given quantitatively as well as qualitatively. The following example of reporting is sufficiently quantitative to be useful to the clinician.

IUATLD recommended method:

| | |
|--|---------------------------------|
| No AFB per 100 oil immersion field: | 0 or negative |
| 1 to 9 AFB per 100 oil immersion fields: | Scanty (or record exact number) |
| 10 to 99 AFB per 100 oil immersion fields: | 1+ |
| 1 to 10 AFB per field: | 2+ |
| More than 10 AFB per field: | 3+ |

All positive results should be recorded in red ink.

For details of collection, storage and transportation of sputum specimen and on examination for tuberculosis by direct microscopy, see IUATLD Technical Guide 5th edition 2000 for *Sputum Examination for Tuberculosis by Direct Microscopy*.

APPENDIX 1b.

FLUORESCENT STAINING PROCEDURE

- Fix smear by heating.
- Flood entire smear with auramine 0 for 10 minutes.
- Rinse with tap water.
- Decolourise with 3% acid -alcohol for 5 minutes.
- Rinse with tap water
- Counterstain either with 0.1% potassium permanganate or methylene blue for 30 seconds
- Rinse with tap water.

Allow the smears to air dry-Do not blot.

APPENDIX 2:

TECHNIQUES OF TUBERCULIN SKIN TESTING

There are several tuberculin tests available, but the most commonly used and the most accurate is the mantoux test. Tuberculin is a protein derivative of mycobacterium which measures an individual's immunoreactivity to tubercle bacilli.

The procedures described below are extracts from the WHO technical Guide on tuberculin testing and reading in 1963*. The only differences in this test are (I) the recommendation to inject 2 TUP PD Rt 23 with Tween 80 (instead of 1 TU of the same tuberculin) and (II) the use of disposable syringes and needles. However, these changes have generally been applied in the last decade in most tuberculin surveys.

Techniques of injection (Mantoux test)

The WHO standard tuberculin test is carried out with 2 TU PPD Rt 23 with Tween 80 added as stabilising diluent.

Special disposable 1ml syringes graduated in hundredths of milliliters are used with 25 or 26 gauge, 10mm long, disposable needles.

The test is given on the dorsal aspect of the forearm. The needlepoint is inserted in the superficial layer of the skin of the forearm while the skin is slightly stretched in the direction of the needle and lengthwise on the arm. The syringe is held by the barrel only and the plunger is not touched until the needlepoint has been satisfactory inserted. The 0.11ml volume is slowly injected and the finger is removed from the end of the plunger before the needle is withdrawn.

The injection should raise a flat, anaemic weal with pronounced pits and a steep border line. If the injection is made into the deeper layers of the skin (as shown by dome-shaped and less anaemic weal), this will scarcely affect the result of the ensuing tuberculin reaction but may tend to make it more difficult to read.

The volume injected should be exactly 0.1ml as read on the graduation of the syringe and should not be gauged by the size of the anaemic weal raised by the injection as this is inaccurate.

APPENDIX 3: TREATMENT REGIMENS FOR NEW TB CASES EXCEPT TB MENINGITIS

2RHZE / 4RH

- 2 months (8 weeks) initial intensive phase of treatment comprising:
 - 2 weeks daily RHZE (combined in one tablet) in hospital
 - 6 weeks daily RHZE in hospital or under health centre supervision or under guardian supervision
- 4 months continuation phase of treatment comprising daily RH

Administration of drugs at hospital discharge

When patients are discharged from hospital, they will be given the drugs needed for the remainder of the initial phase. TB officers and nurses are responsible for packaging the drugs for the patients.

Patients will take these drugs to their nearest treatment centre (e.g. health centre) and hand over the drugs to the health care worker in charge of TB control. There must be a signature from a health care worker at the health centre and a signature from the patient/guardian on either the Treatment Card or DOTS monitoring form that the drugs have arrived safely in the health centre.

For those under health centre supervision: the TB officer will give blister packs of drugs sufficient for 6 weeks treatment. Health care centre staff will administer the drugs to the patients by direct observation on daily basis and this will be recorded in the treatment cards and identity card.

For those under guardian-based supervision: the TB officer will give blister packs for a total of 6 weeks treatment. Health care centre staff will give **two weeks supply** of drugs to the guardian and this will be repeated at two week intervals until the initial phase is completed.

Forms to be given at hospital discharge:

On discharge from hospital, the patient will be given an OPD Identity card, a TB Treatment Card, a referral form, and for those receiving guardian-based supervision a DOT Monitoring Form.

Guardian based supervision:

Guardian-based supervision will be offered to all patients.

A guardian is a person related to the patient, who can read and write and who takes responsibility for directly observing the swallowing of the drugs, the filling in of DOT forms and drug collection at 2 week intervals from health centre or hospital.

Guardians will be given DOT forms, the details of which will be filled in by TB officers. There is one DOT form for one patient for the initial phase of treatment.

DOT forms will be kept by guardians. Guardians must fill in the **number of tablets of RHZE or RHZ (E) in each column.**

TWO MONTH SPUTUM SMEAR EXAMINATION.

When 8 weeks of initial phase of treatment are completed, two activities take place.

First, all patients are changed to the continuation phase of treatment, i.e. daily RH.

Second patients with smear-positive PTB submit two sputum specimens for microscopy. Guardian-based patients will be given a sputum container when given their last 2 weeks supply of drugs. **The patient must return to the health centre at the end of the initial phase with a filled sputum container and must give a second on the spot sputum at this visit.**

- If the 2-months sputum results are negative the patient stays on continuation phase (Daily RH).
- If the 2-months sputum results are positive, the patient is contacted and re-admitted to hospital. The patient stays on continuation phase and if a week has passed the patient submits another sputum sample.

- If the second 2-months sputum is negative, the patient stays on continuation phase and gets discharged home.
- If the result is positive, the patient is changed to daily RHZE. This is continued with the patient admitted in hospital.
- Repeat sputum smears are checked at weekly intervals.
- If the sputum result becomes negative the patient is discharged to continuation phase.
- If the sputum result is still positive, the patient continues on daily RHZE for a total of 4 weeks at which point the patient is changed to daily RH. At this point, take sputum for culture and sensitivity in two universal containers and discharge the patient.
- **Remember to check sputum at 5 months: if still positive collect another sputum sample for culture and sensitivity and the patient started on re-treatment as a treatment failure.**

APPENDIX 4:

DOSAGES FOR ADULTS (REGIMENS 1 AND 2)

| ADULTS | | |
|-------------------|--|--|
| Body weight in kg | Initial phase 2 months | Continuation phase 4 months |
| | [RHZE] [R150/H75/Z400/E275] Number of tablets* | [RH] [R150/H75] Number of tablets* |
| 30-37 | 2 | 2 |
| 38-54 | 3 | 3 |
| 55-74 | 4 | 4 |
| 75 and over | 5 | 5 |

APPENDIX 5: DOSAGES FOR CHILDREN

| CHILDREN | | | |
|-------------------|---|---|--|
| Body weight in kg | Initial phase 2 months | | Continuation phase 4 months |
| | [RHZ] (R60/H30/Z150) Number of tablets or sachets* | E100 Number of tablets or sachets* | [RH] (R60/H30) Number of tablets or sachets* |
| < 7 | 1 | 1 | 1 |
| 8-9 | 1.5 | 1.5 | 1.5 |
| 10-14 | 2 | 2 | 2 |
| 15-19 | 3 | 3 | 3 |
| 20-24 | 4 | 4 | 4 |
| 25-29 | 5 | 5 | 5 |

APPENDIX 6:

TUBERCULOUS MENINGITIS IN ADULTS AND CHILDREN

2SRHZ / 7RH

- 2 months daily intensive phase of SRHZ in hospital followed by;
- 7 months continuation phase of RH on the preferred option (in hospital, under health centre supervision or guardian supervision).

Doses for adults and children are shown in the Table.

| | DAILY DURING WEEKS 1 - 8* | | | DAILY DURING WEEKS 9 - 32 |
|-----------------------------|------------------------------|------|------|------------------------------|
| | S | RH | Z | RH |
| Pre-treatment weight | | | | |
| Over 55 kg | 1g | 4 | 4 | 4 |
| 40 -55kg | 0.75g | 3 | 3 | 3 |
| 25 - 39kg | 0.5g | 2 | 2 | 2 |
| 20 - 24kg | 15mg/kg | 1.5 | 1.5 | 1.5 |
| 15 - 19kg | 15mg/kg | 1.5 | 1.5 | 1.5 |
| 9 - 14kg | 15mg/kg | 1 | 1 | 1 |
| 5 - 8kg | 15mg/kg | 0.5 | 0,5 | 0.5 |
| 0 - 4kg | 15mg/kg | 0.25 | 0.25 | 0.25 |

APPENDIX 7:

THE RE-TREATMENT REGIMEN (Category II)

For Relapse, Return after default, Treatment Failure and Recurrent Tuberculosis

2SRHZE/1RHZE/5RHE

- 2 months daily intensive phase of SHRZE followed by
- 1 month daily RHZE in hospital and
- 5 months of daily continuation phase of RHE on the preferred option

Doses for adults and children are shown in the Table.

| ADULTS | | | | |
|-------------------|-------------------------------------|---|-------------------------------------|-----|
| Body weight in kg | Initial phase 3 months | | Continuation phase 5 months | |
| | [RHZE] [R150/H75/Z400/E275] | | [RHE] [R150/H75] | |
| | Number of tablets* | | Number of tablets* | |
| 30-37 | 2 | | 2 | |
| 38-54 | 3 | | 3 | |
| 55-74 | 4 | | 4 | |
| 75 and over | 5 | | 5 | |
| CHILDREN | | | | |
| Body weight in kg | Initial phase 3 months | | Continuation phase 5 months | |
| | [RHZ] (R60/H30/Z150) | | [RH] (R60/H30) | |
| | Number of tablets or sachets* | E100 Number of tablets or sachets* | Number of tablets or sachets* | |
| | | | E100 | |
| | | | Number of tablets or sachets* | |
| < 7 | 1 | 1 | 1 | 1 |
| 8-9 | 1.5 | 1.5 | 1.5 | 1.5 |
| 10-14 | 2 | 2 | 2 | 2 |
| 15-19 | 3 | 3 | 3 | 3 |
| 20-24 | 4 | 4 | 4 | 4 |
| 25-29 | 5 | 5 | 5 | 5 |

NB:-

All patients on re-treatment regimen receive streptomycin during the first 2 months. The weight bands are shown below:

| Pre-treatment weight | Streptomycin |
|-----------------------------|---------------------|
| Over 55 kg | 1g |
| 40 -55kg | 0.75g |
| 25 - 39kg | 0.5g |
| 20 - 24kg | 15mg/kg |
| 15 - 19kg | 15mg/kg |
| 9 - 14kg | 15mg/kg |
| 5 - 8kg | 15mg/kg |
| 0 - 4kg | 15mg/kg |

Note 1: Before starting treatment, two sputum specimens must be sent to the CRL for culture and sensitivity testing

Note 2: Sputum smear results are examined at three months.

APPENDIX 8:

TB FORMS AND REGISTERS

FORM 1: CHRONIC COUGH REGISTER

| Date Sputum Brought To Health Unit | Name of Patient | Sex M F | Age | Full Address of Patient | Results of sputum Examination and Date Results Received | | | Remarks Include Date Patient Referred to Hospital |
|------------------------------------|-----------------|------------|-----|-------------------------|---|-----|-----|---|
| | | | | | 1st | 2nd | 3rd | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

Note: Enter all Patients in this Register who present with cough for 3 weeks or more

FORM 6: NATIONAL TUBERCULOSIS PROGRAMME SPUTUM EXAMINATION REQUEST FORM

Name of Treatment Unit _____ Date _____

Patients Name _____ Age _____ Sex

| | |
|---|---|
| M | F |
|---|---|

Village/Street _____ District _____
 Type of TB: Pulmonary Extra-Pulmonary

| | | | | |
|--------------|-------------------------|-----|-----|-----|
| New Patient* | Follow-up Examination** | 2mo | 5mo | 7mo |
|--------------|-------------------------|-----|-----|-----|

Specimen Identification No _____ Patient's District Register No. _____

Date of sputum Collection _____ Signature of Specimen Collector _____

* there are diagnosed new or relapsed cases
 ** these are patients on chemotherapy; enter District TB No.

RESULTS (To be completed in laboratory)

Lab. Serial No _____

(a) Appearance of sputum to the eye:

Muco-purulent /Blood-stained /Saliva

(b) Microscopy:

| Date | Specimen | Results* | Positive (grading) | | | |
|------|----------|----------|--------------------------|--------------------------|--------------------------|--------------------------|
| | | | +++ | ++ | + | Scanty (>3) |
| | 1 | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 2 | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 3 | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

* Write Negative or Positive

Date _____ Examined by (Signature) _____

The completed form with results should be sent to the treatment unit.

FORM 7:

**NATIONAL TUBERCULOSIS PROGRAMME
TB LABORATORY SPUTUM CULTURE AND SENSITIVITY REQUEST FORM**

REQUEST FOR CULTURE AND SENSITIVITY TESTS

District Address.....
 Person Requesting Examination: Name:..... Position.....
 Date Specimen were collected:

District/Laboratory Serial Number:

Sputum taken at Month 0 Month 2 Month 5 Month 8
 Others (Specify)

Name of Patient Age (Yrs):..... Sex.....
 Patient TB Register Number:..... Date Treatment Started...../...../.....

Type of Patient and Site of Disease:

Type of Patient: New Relapse Failure Return After Default Chronic excretor

Site: Pulmonary Extra pulmonary (Specify).....

| TB Chemotherapy Given Date | From | To |
|----------------------------|-------|-------|
| Isoniazid | | |
| Streptomycin | | |
| Rifampicin | | |
| Pyrazinamide | | |
| Ethambutol | | |
| Kanamycin | | |
| Cycloserin | | |
| Ethionamid | | |
| Ofloxacin | | |

Specimen type:

Sputum Local Laboratory Smear Result 1st 2nd 3rd Specimen
 Others (specify):.....

Reference Laboratory results:

Reference Laboratory Serial Number:

Microscopic Examination:

| Specimen | Neg | 1-9 (scanty) | 1+ | 2+ | 3+ |
|----------|-----|--------------|----|----|----|
| 1 | | | | | |
| 2 | | | | | |

Culture Results:

| Specimen | Neg | ≤ 50 colonies actual count | >50 – 100 col 1+ | >100 – 200 col 2+ | >200 col 3+ |
|----------|-----|----------------------------|------------------|-------------------|-------------|
| 1 | | | | | |
| 2 | | | | | |

Comments:.....

Result of Sensitivity Testing

| Drug | Date | Sensitive | Resistant | Drug | Date | Sensitive | Resistant |
|---------------------|------|-----------|-----------|-------------------|------|-----------|-----------|
| <u>Isoniazid</u> | | | | <u>Kanamycin</u> | | | |
| <u>Streptomycin</u> | | | | <u>Cycloserin</u> | | | |
| <u>Rifampicin</u> | | | | <u>Ethionamid</u> | | | |
| <u>Pyrazinamid</u> | | | | | | | |
| <u>Ethambutol</u> | | | | | | | |

Name: Signature: Date:

The Central Unit will send: the **blue** copy with result of culture and sensitivity tests to the treating physician
 the **pink** copy with result of culture and sensitivity tests to the Zonal TB Officer

FORM 8:

**QUARTERLY REPORT ON CASE FINDING
NATIONAL TUBERCULOSIS PROGRAMME - MALAWI**

Quarterly report on new, relapses recurrent and other cases of Tuberculosis

Patient registered during
..... quarter of 20.....

Name of DTO _____

Date of completion of this form:/...../.....

Name of district: _____

Signature _____

BLOCK 1

| SMEAR POSITIVE TUBERCULOSIS | | | | | | SMEAR NEGATIVE | | | | EXTRAPULMONARY | | | | GRAND | | |
|-----------------------------|---|---|---------|---|-------|----------------|---|--------|-----|----------------|-------|---|-------|-------|---|--|
| NEW | | | RELAPSE | | OTHER | NEW | | RECURR | NEW | | RECUR | | TOTAL | | | |
| M | F | T | M | F | M | F | M | F | M | F | M | F | M | F | T | |
| | | | | | | | | | | | | | | | | |

BLOCK 2

AGE GROUP DISTRIBUTION

| AGE GROUP CAT. | 0 – 4 | | 5 – 14 | | 15 – 24 | | 25 – 34 | | 35 – 44 | | 45 – 54 | | 55 – 64 | | 65 + | | TOTAL | | | |
|-----------------|-------|---|--------|---|---------|---|---------|---|---------|---|---------|---|---------|---|------|---|-------|---|---|--|
| | M | F | M | F | M | F | M | F | M | F | M | F | M | F | M | F | M | F | T | |
| Positive (new) | | | | | | | | | | | | | | | | | | | | |
| Relapse cases | | | | | | | | | | | | | | | | | | | | |
| Negative (new) | | | | | | | | | | | | | | | | | | | | |
| EPTB (new) | | | | | | | | | | | | | | | | | | | | |
| Positive Others | | | | | | | | | | | | | | | | | | | | |
| Recurrent | | | | | | | | | | | | | | | | | | | | |

Explanations on how to fill in the form

District Register number = identification number of the district

Quarters: 1st quarter = January, February, March

2nd quarter = April, May, June

3rd quarter = July, August, September

4th quarter = October, November, December

Block 1: NEW, relapse, recurrent and other CASES of Tuberculosis registered during quarter of year _____

Fill in the quarter and the year

Column (1) : SMEAR POSITIVE
NEW CASES

- Patients with pulmonary tuberculosis, sputum smear-positive who have received anti-tuberculosis Treatment

Column (2) : SMEAR POSITIVE Relapses

- patients with pulmonary tuberculosis, sputum smear-positive who have declared cured but have now got the disease again.

Column (3) : SMEAR-NEGATIVE CASES

- patients with pulmonary tuberculosis, having a negative Sputum for AFB, in whom the diagnosis of tuberculosis was made by means other than sputum microscopy.

Column (4) : EXTRA-PULMONARY
TUBERCULOSIS

- patients with tuberculosis of organs other than the lungs.

Column (5) : TOTAL Males
Females
Total

- Add **all male** patients in columns 1 + 2 + 3 + 4

- Add **all female** patients in columns 1 + 2 + 3 + 4

- **all patients** (males + Females) in columns 1 + 2 + 3 + 4.

Block 2: SMEAR-POSITIVE NEW CASES: from column (1) above

In this block enter the patients (already recorded in Block 1, column (1) according to their sex and age group. If the exact age of a patient, at the time of his registration, is unknown, it should be estimated to the nearest 5 years, e.g. 15,20,25, etc.

FORM 9:

QUARTERLY REPORT ON TREATMENT OUTCOME

NATIONAL TUBERCULOSIS PROGRAMME
MALAWI

**REPORT ON THE RESULTS OF TREATMENT OF SMEAR-POSITIVE PULMONARY
TUBERCULOSIS PATIENTS REGISTERED 12-15 MONTHS EARLIER**

| | | |
|---|---|---|
| Name of District _____ Name of District Tuberculosis Officer _____ quarter of 19 | Patients registered during <input type="checkbox"/> <input type="checkbox"/> | Date of completion of this form: _____ 19 ____ Signature: |
|---|---|---|

| Total No of smear-Positive patients Registered during The above quarter | Regimen | (1) | (2) | (3) | (4) | (5) | (6) | Total number Evaluated (Sum of columns 1 to 6) |
|---|---------------------------|-----------------------|--|------|--------------------------|-----------|---------------------------------|--|
| | | Cure (smear-negative) | Treatment Completed (no smear-results) | Died | Failure (smear-positive) | Defaulted | Transferred to another district | |
| M F T | | | | | | | | |
| | 1. New cases | : | : | : | : | : | : | : |
| | 2. Re-treatment | : | : | : | : | : | : | : |
| | 2.1 relapses | : | : | : | : | : | : | : |
| | 2.2 others(failure cases) | : | : | : | : | : | : | : |
| | 2.3 Total | : | : | : | : | : | : | : |
| | | : | : | : | : | : | : | : |
| | | : | : | : | : | : | : | : |

* Of those excluded _____ (number) from evaluation of chemotherapy for the following reasons: _____

FORM 10:

TUBERCULOSIS REFERRAL/TRANSFER FORM
(fill out in triplicate with carbon paper between sheets)

Name of Referring/Transferring Unit: _____

Name of Unit to which patient is referred (if known): _____

Name of patient: _____ Age: _____ Sex: _____

Address: _____

District TB Registration No.: _____ Date Treatment started: _____

Type of treatment: Short-course chemotherapy for new patient
 Short-course chemotherapy for previously patients
 Other

Drugs patient receiving: _____

Diagnosis: _____

Remarks: _____ Signature: _____

Designation: _____

For use by Treatment Unit where patient has been referred.

Name of patient _____ District TB Registration No: _____

Age: _____ Sex: M. F

Date Referred/transferred: _____

The above named reported at this Treatment Unit on: _____

Signature: _____

Designation: _____

Name of Treatment Unit: _____

District: _____ Date: _____

Send this part back to the Referring Unit as soon as patient has reported and
Been registered.

FORM 11:

RH DAILY MONITORING BOOK

HEALTH UNIT:

NAME OF DRUG:

MONTH:

YEAR:

| NO. | NAME OF PATIENT | REG NO. | DAYS REGIMEN | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|--------------------------------|-----------------|---------|--------------|---|---|---|---|---|---|---|---|---|----|----|----|
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| | | | | | | | | | | | | | | | |
| DAILY TOTAL CONSUMPTION | | | | | | | | | | | | | | | |
| DRUG RECEIVED | | | | | | | | | | | | | | | |
| DAILY BALANCE | | | | | | | | | | | | | | | |
| POT PILL COUNT (PPC) | | | | | | | | | | | | | | | |
| DIFFERENCES | | | | | | | | | | | | | | | |

DOCUMENT 1.

FORM 12:

ANTI-TB DRUG BALANCE RECORD BOOK

HEALTH UNIT:

NAME OF DRUG:

| NO. | NAME OF PATIENT | REG NO. | DAYS REGIMEN | | | | | | | | | | | | | | | |
|--------------------------------|-----------------|---------|--------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
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| DAILY TOTAL CONSUMPTION | | | | | | | | | | | | | | | | | | |
| DRUG RECEIVED | | | | | | | | | | | | | | | | | | |
| DAILY BALANCE | | | | | | | | | | | | | | | | | | |
| POT PILL COUNT (PPC) | | | | | | | | | | | | | | | | | | |
| DIFFERENCES | | | | | | | | | | | | | | | | | | |

DOCUMENT 2.

FORM 13:

ANTI TB DRUG ORDER BOOK

NAME OF UNIT:

DATE:

NAME OF DRUG

| NAME OF DRUG | DRUGS ON HAND | DRUGS ORDERED | DRUGS ISSUED | TOTAL | NAME & SIGNATURE (ORDERING OFFICER) | NAME SIGNATURE (ISSUING OFFICER) |
|------------------------|---------------|---------------|--------------|-------|-------------------------------------|----------------------------------|
| RHZE | | | | | | |
| RHZ | | | | | | |
| S 1g | | | | | | |
| RHE | | | | | | |
| H 100 mg | | | | | | |
| E₁₀₀ | | | | | | |
| RH | | | | | | |
| Cotrim. | | | | | | |

DOCUMENT 4.

FORM 14:

DISTRICT TB OFFICER SHADOW FILE

NAME OF DRUG

CODE NO.....

| DATE | REQUISITION NUMBER | DRUGS ON HAND | RECEIPT | ISSUES | BALANCE | SIGNATURE (RECIPIENT) | SIGNATURE (TB OFFICER) |
|------|--------------------|---------------|---------|--------|---------|-----------------------|------------------------|
| | | | | | | | |
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DOCUMENT 5.

FORM 15:

ZONAL TB OFFICER SHADOW FILE

NAME OF REGION:

NAME OF DRUG:

CODE NO:

| DATE | NAME OF UNIT | REQUISITION NO. | ISSUE VOUCHER NO. | DRUGS ON HAND | RECEIPT | ISSUES | BALANCE | SIGNATURE DESK OFFICER | SIGNATURE RTO |
|------|--------------|-----------------|-------------------|---------------|---------|--------|---------|------------------------|---------------|
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DOCUMENT 6.

FORM 16:

DRUG REQUISITION RECORD BOOK

NAME OF REGION:

NAME OF DRUG:

| DATE REQUISITION APPROVED | REQUISITION NO | RH | PZA | INH (300g) | S 1g | S 5g | EH | E | R | Signature |
|---------------------------|----------------|----|-----|------------|------|------|----|---|---|-----------|
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DOCUMENT 7.

FORM 17:

TB SUPERVISION – TARGET FORM

HEALTH FACILITY _____ DATE _____

TBO _____ OI _____

LABORATORY VISIT: QUARTER _____

(Check Slides _____) (Check Reagents _____)

Microscope(s):number _____ In working order _____

SPUTUM LAB.REGISTER: QUARTER _____

Total Number Suspects (New plus Follow-up) _____

Number New Suspects _____

Number New Suspects (%) with recommended smears(2 or 3) _____

Number New Suspects (%) with Positive Smears _____

Number New Suspects (%) with Positive Smears treated _____

(Check Follow-Up Pts: check that month of Fup is indicated _____)

DISTRICT TB REGISTER: QUARTER: _____

Total Number Patients registered _____

(Check addresses in column, smear+ves written in red ink _____)

(Check registration within 7 days of date of treatment _____)

Number not properly classified _____

Number on Retreatment Regimen _____

No.(%) on Retreatment with sputum sent to CRL for C&S _____

Total No.Patients on Guardian/Community Based Rx _____

Total No.Patients on Health Centre Rx _____

Total No.Patients on Hospital Based Rx _____

Total No.Patients where Site of Rx not recorded _____

TB REGISTER-CASE FINDING: QUARTER

Total Number Patients registered _____

New Pulmonary TB _____

New Pulmonary TB: Smear-positive _____

New Pulmonary TB: Smear-negative [sputums indicated] _____

New Pulmonary TB: Smears not done/ unknown _____

New Extrapulmonary TB [EPTB] _____

Smear-positive Pulmonary TB- Relapse _____

Smear-positive Pulmonary TB- Failure/Return after default _____

Other [recurrent smear-ve PTB / EPTB] _____

TB DIAGNOSTIC PRACTICES: QUARTER

No. All Sm+ve PTB Patients with duration cough recorded _____

No.(%) All Sm+ve PTB Patients with cough < 2 months _____

No. All Sm-ve PTB Patients (15 yrs and >) _____

No.(%) All Sm-ve PTB Patients (15 yrs and >) with sputums _____

Central Unit Supervisory visit (on the ward):

No. All Sm-ve PTB Patients (15 yrs and >) _____

No.(%) All Sm-ve PTB Patients with guidelines followed _____

No. All EPTB Patients (15 years and >) _____

No.(%) All EPTB Patients with guidelines followed _____

Weekly TB Ward round conducted _____

COMPARISON OF TB REGISTER WITH TREATMENT CARDS. Qtr

Check 10 treatment cards against register: note inconsistencies.

Number (%) treatment cards fully correct _____

TRANSFER-IN REGISTER and TRANSFER FORMS: QUARTER

(Check: Is T-I Register available?) _____

(Check: Is T-I Register being used?) _____

(Check: Do all patients have registration Nos?) _____

Number of patients in T-I Register _____

(Check: Is there a folder used for Transfer-IN forms?) _____

(Check: Is there a folder used for Transfer-OUT forms?) _____

DRUG-MONITORING DOCUMENT:

(Check on: daily total consumption, amount received, daily balance, pot pill count, differences) _____

(Check on whether a calculator is present) _____

LINKAGE WITH HMIS REGISTER AT DISTRICT LEVEL:

(Check: Has the TBO provided the HMIS staff with data?) _____

TB WARDS:

(Check: Are IEC materials available?) _____

(Check: Is DOTS administered and by whom?) _____

(Check: Is Ward education given, by whom and how often?) _____

PHARMACY: ANTI-TB DRUG STOCKS

| Drug | Amount | Expiry Date |
|------|--------|-------------|
| RH | _____ | _____ |
| PZA | _____ | _____ |
| EH | _____ | _____ |
| E | _____ | _____ |
| H | _____ | _____ |
| S | _____ | _____ |

Comments: _____

TREATMENT OUTCOMES

SMEAR-POSITIVE PATIENTS: YEAR QUARTER

New PTB: No.registered in cohort _____ No.evaluated _____

Number who were cured: _____

Number who were treatment completed: _____

Number who died: _____

Number who failed: _____

Number who defaulted: _____

Number who transferred out: _____

Relapse PTB: No.registered in cohort _____ No.evaluated _____

Number who were cured: _____

Number who were treatment completed: _____

Number who died: _____

Number who failed: _____

Number who defaulted: _____

Number who transferred out: _____

TREATMENT OUTCOMES

SMEAR-NEGATIVE PTB AND EPTB PATIENTS: **YEAR** **QUARTER**

New Smear-ve PTB: No.registered _____ No.evaluated _____

Number who were treatment completed: _____

Number who died: _____

Number who defaulted: _____

Number who transferred out: _____

Number whose outcome was unknown: _____

EPTB: No.registered _____ No.evaluated _____

Number who were treatment completed: _____

Number who died: _____

Number who defaulted: _____

Number who transferred out: _____

Number whose outcome was unknown: _____

NEW SMEAR-POSITIVE PULMONARY TUBERCULOSIS.

DATE _____

COHORT ANALYSIS OF TREATMENT OUTCOME:

| Cohort No. | No. | Sm-ve | Sm Not Done | Died | Sm+ve | Default | Transfer | TOTAL Quarter: | Reported |
|-------------------|----------------------|---------------|--------------------|-------------|--------------|----------------|-----------------|-----------------------|-----------------|
| (Cure) | (Rx Complete) | (Fail) | Out | | | | | | |

TB REGISTER:

2months _____

5months _____

8months _____

QUARTERLY REPORT:

2months _____

5months _____

8months _____

RELAPSE SMEAR-POSITIVE PULMONARY TUBERCULOSIS.

DATE _____

COHORT ANALYSIS OF TREATMENT OUTCOME:

| Cohort No. (Cure) (Rx Complete) | Sm-ve (Fail) | Sm Not Done Out | Died | Sm+ve | Default | Transfer | TOTAL Quarter: | Reported |
|--|-------------------------------|----------------------------------|-------------|--------------|----------------|-----------------|-----------------------|-----------------|
|--|-------------------------------|----------------------------------|-------------|--------------|----------------|-----------------|-----------------------|-----------------|

TB REGISTER:

2months _____

5months _____

8months _____

QUARTERLY REPORT:

2months _____

5months _____

8months _____

SMEAR-NEGATIVE AND EPTB TUBERCULOSIS.

DATE _____

COHORT ANALYSIS OF TREATMENT OUTCOME AT END OF TREATMENT:

| Cohort | No.cases | Treatment | Died | Default | Transfer | Unknown | TOTAL |
|-----------------|-----------------|------------------|-------------|----------------|-----------------|----------------|--------------|
| Quarter: | Reported | Complete | | Out | | | |

SMEAR-NEGATIVE PTB:

_____ : _____

EXTRA-PULMONARY TB:

_____ : _____

DRUG SUPERVISION FROM TB REGISTER: NEW REGIMENS.

QUARTER: _____

**1.1. Number of all new patients on IP: tablets of RH used
(includes all sm+ve, sm-ve and EPTB - adults and children)**

Count number on SCC in same quarter _____

Count number on SCC in previous quarter _____

Add these two numbers together and divide by 2 _____

Multiply the number by 96 (1.1) _____

1.2. Number of patients on Retreatment (ReRX IP): tablets of RH

Count number on ReRX in same quarter _____

Count number on ReRX in previous quarter _____

Add these two numbers together and divide by 2 _____

Multiply the number by 270 (1.2.) _____

1.3. Number of patients on TB Meningitis Rx (CP): tablets of RH

Count number with TB Meningitis in previous 2 quarters _____

Multiply the number by 270 (1.4.) _____

1.4. Number of patients on ReRx (CP): tablets RH used

Count number with Relapse TB in previous 2 quarters _____

Multiply the number by 108 (1.5.) _____

Add 1.1., 1.2., 1.3.and 1.4 = Approx RH tablets used

2. PHARMACY LEDGER CARDS:

2.1. Number RH tablets issued during quarter _____

2.2. Number Pyrazinamide tablets issued during quarter _____

2.3. Imbalance two drugs _____

HEALTH FACILITY:

DATE:

DTO:

VISIT CONDUCTED BY:

MAJOR COMMENTS AND ACTION TO BE TAKEN:

ONE COPY FOR DTO: _____

ONE COPY FOR FILE: _____

DTO TO WRITE TO CENTRAL UNIT, TB PROGRAMME, ON VALUE OF SUPERVISORY VISIT.

GRADED 1 = VERY BAD -----> 5 = EXCELLENT
(Central Unit to record during district supervisory visit)

GRADING _____

FORM 18:

DTO SUPERVISORY CHECK LIST

Health Centre _____ **Date:** _____

MA/ENM in charge: write Name _____

Who is in charge of TB activities? _____

Is he/she present? _____

TB Treatment Cards: (record number at health centre =

Have all the sputum's been taken on time? _____

Have all laboratory results been entered? _____

Have all weight been done _____

If a defaulter, what action has been taken? _____

Is anyone a transfer out? _____

If treatment completed, take card back to hospital _____

TB Register: (take to health centre during visit)

Are all patients registered (check with cards)?

Are all results entered? _____

Has treatment outcome been properly entered? _____

Enter dates of treatment outcome _____

Did any patient not report after discharge from hospital? _____

Are there any Transfer Ins _____

If any Transfer Ins, have they been registered in Dist. TB Reg. _____

Record all Transfer Ins/Outs for DTO meeting _____

Other

Are laboratory forms properly completed? _____

Are there enough sputum containers/sputum request forms? _____

Are there enough TB drugs? _____

Is there any sputum to take back to hospital laboratory? _____

In-service training done (mention topic) _____

FORM 19:

TUBERCULOSIS LABORATORY QUARTERLY REPORT

YEAR: 20

NAME OF LABORATORY: _____ NAME OF RESPONSIBLE MICROSCOPIST _____

SIGNATURE _____ DATE _____

QUARTER _____ (Months) _____

1. Total Number of TB cases registered _____
2. Number of TB suspects registered _____
3. Number of New TB suspects who are sputum smear-positive _____
4. Number of New TB suspects who have 3 sputum smear-positive _____
5. Number of TB suspects whose category (i.e. New or follow-up is known) _____
6. Number of follow-up cases (2 months, 5 months and 7 months) registered _____
7. Number of follow-up cases (5 months and 7 months) who are sputum smear-positive _____

PLEASE MAKE 2 COPIES: KEEP ONE AND GIVE ONE TO THE REGIONAL TB OFFICER

“ 1st quarter = Jan – Mar: 2nd quarter = Apr – Jun: 3rd quarter = Jul – Sep: 4th quarter = Oct – Dec”

FORM 20 a:

TB DOT MONITORING FORM FOR GUARDIAN USE: Regimen

Name of patient:

TB Registration No.

Name of Guardian: DOT Centre:

| TABLET | DATE DAY | MON | TUE | WED | THU | FRI | SAT | SUN | | | | | | | MON | TUE | WED | THU | FRI | SAT | SUN |
|---------------------------|----------|-----|-----|-----|-----|-----|-----|-----|--|--|--|--|--|--|-----|-----|-----|-----|-----|-----|-----|
| RH Pink aang'ono | | | | | | | | | | | | | | | | | | | | | |
| RHZE PAKETI YOFIRA aakulu | | | | | | | | | | | | | | | | | | | | | |
| E Paketi yofiira aang'ono | | | | | | | | | | | | | | | | | | | | | |

| TABLET | DATE DAY | MON | TUE | WED | THU | FRI | SAT | SUN | | | | | | |
|-------------------------------|----------|-----|-----|-----|-----|-----|-----|-----|--|--|--|--|--|--|
| RH aang'ono Paketi yobiliwira | | | | | | | | | | | | | | |
| RHE Paketi ya khofi | | | | | | | | | | | | | | |

REMARKS:.....

FORM 20 b:

TB DOT MONITORING FORM FOR CHILDREN: Regimen

Name of patient:

TB Registration No.

Name of Guardian: DOT Centre:

| TABLET | DATE DAY | MON | TUE | WED | THU | FRI | SAT | SUN | MON | TUE | WED | THU | FRI | SAT | SUN |
|-----------------------|----------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| RHZ Paketi ya blue | | | | | | | | | | | | | | | |
| E Paketi yofiira | | | | | | | | | | | | | | | |
| RH Paketi ya kuda | | | | | | | | | | | | | | | |

| TABLET | DATE DAY | MON | TUE | WED | THU | FRI | SAT | SUN | MON | TUE | WED | THU | FRI | SAT | SUN |
|----------------------------------|----------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| RH aang'ono Paketi yobiliwira | | | | | | | | | | | | | | | |

REMARKS:.....