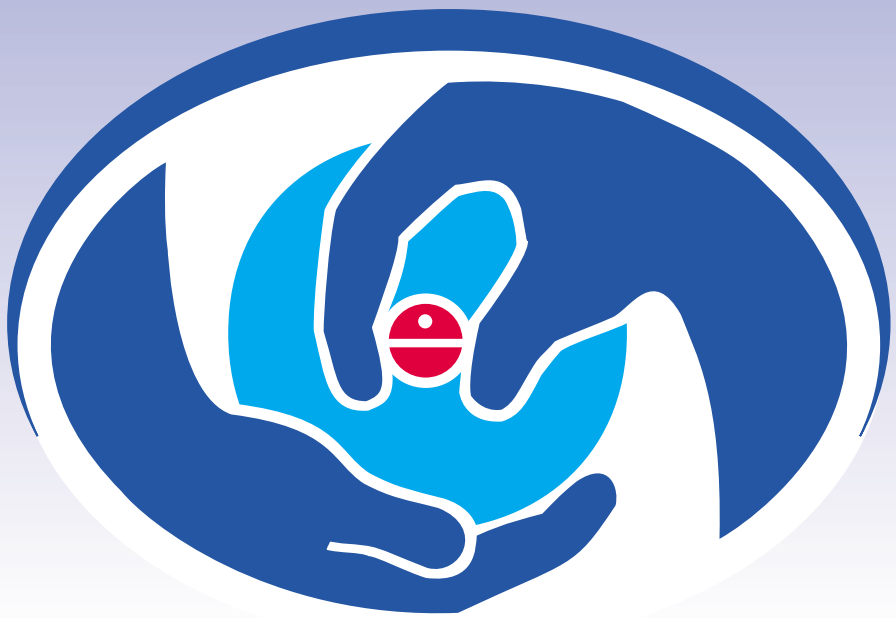
The South African

TUBERCULOSIS
Control Programme

Practical Guidelines

2000



DEPARTMENT OF HEALTH

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LIST OF ABBREVIATIONS

AFB	Acid Fast Bacilli
AIDS	Acquired Immune Deficiency Syndrome
CSF	Cerebrospinal fluid
CT	Computerised tomography
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment Short-course
DTD	Demonstration and Training District
E	Ethambutol
ECG	Electro Cardiogram
HIV	Human Immunodeficiency Virus
INH	Isoniazid
IUATLD	International Union Against Tuberculosis and Lung Disease
IUCD	Intra Uterine Contraceptive Device
MDR TB	Multi drug resistant tuberculosis
NTCP	National TB Control Programme
PGL	Persistent generalised lymphadenopathy
PPD	Purified protein derivative
PTB	Pulmonary Tuberculosis
PZA	Pyrazinamide
R	Rifimpacin
S	Streptomycin
SCC	Short course chemotherapy
WHO	World Health Organisation
ZN Stain	Ziehl - Neelson stain

THE SOUTH AFRICAN TUBERCULOSIS CONTROL PROGRAMME PRACTICAL GUIDELINES 1999 THIRD EDITION

PREFACE

In many parts of South Africa, the cure rate for detected smear-positive cases has not exceeded 50% of all diagnosed smear-positive cases. This is a serious problem.

An important factor contributing to a low cure rate is poor patient compliance in detected cases. Once the symptoms of tuberculosis lessen, patients find it difficult to continue treatment. Incomplete treatment can result in infectious patients with chronic tuberculosis who continue to transmit the infection. It may also lead to the development of drug resistant strains of tuberculosis. Therefore, it is important to increase patient compliance.

Directly Observed Treatment Short-course (DOTS) strategy is the most effective strategy available for controlling TB, developed from the collective best practices, clinical trials and programmatic operations of TB control over the past two decades. DOTS puts the priority on curing infectious patients and its core elements are:

- Sustained TB control activities.
- Sputum smear microscopy to detect the infectious cases among those people attending health care facilities with symptoms of TB, most importantly cough of three week's duration.
- Standardized short-course anti- TB treatment with direct observation of treatment.
- An uninterrupted supply of TB drugs.
- A standardized recording and reporting system which allows assessment of treatment results

Short-course Chemotherapy (SCC) is a combination of potent anti-tuberculosis drugs (isoniazid, rifampicin, pyrazinamide, streptomycin and ethambutol). It has an initial intensive phase of 2-3 months, and a continuation phase of 4-7 more months. Every dose of rifampicin should be observed, at least in the intensive phase of treatment. During the intensive phase, sputum smear-positive patients should convert to sputum smear-negative. A well functioning TB control programme must achieve a smear conversion rate of at least 85% amongst new smear positive cases.

When a patient takes the entire SCC treatment, three main aims of the National Tuberculosis Control Programme (NTCP) will be achieved:

- The patient is cured
- The spread of the disease is stopped
- Multi-drug resistant tuberculosis will be prevented

After a programme achieves a high cure rate, it must also increase the case detection rate. If the NTCP achieves a high cure rate but only detects 10% of cases, it will not control TB. Improving the case detection rate of smear-positive cases, and the cure rate of detected cases are both important.

It is possible to improve the detection of smear-positive cases and to achieve a cure rate of 85% for the detected new smear-positive tuberculosis cases who are treated by general health services.

To do this, the NTCP, with the support of the Department of Health, should implement DOTS, and improve the following aspects of the programme:

- Passive case finding procedures, for example:
  - improve selection of tuberculosis suspects among the population seeking treatment in health units
  - develop microscopy centres within general laboratories that can routinely examine sputum smears for identification of pulmonary smear-positive cases
  - give priority to smear-positive cases
- Drug supply system
- Involve health care workers and mobilize community members to provide directly observed TB treatment
- Recording and reporting system
- Training and supervision of key medical and laboratory staff involved in NTCP activities.

Establishing a good NTCP means making all the above improvements in the existing Programme.

The aim of the NTCP is:

1. To develop policies and guidelines to ensure early detection and effective treatment of TB in South Africa.

2. To manage the strategic implementation of the Directly Observed Treatment Short- course (DOTS) strategy to control TB.

3. To evaluate programme performance and provide technical support for the implementation of national guidelines.

4. Raise national awareness about TB so as to increase early health seeking behaviour of persons with TB symptoms.

CHAPTER 1

INTRODUCTION

1.1 Global epidemiology and burden of disease

About one third of the world's population is infected by *Mycobacterium tuberculosis.* World-wide there are about nine million new cases of TB with three million deaths annually. *Mycobacterium tuberculosis tuberculosis* kills more people than any other single infectious agent. Deaths from TB comprise 25% of all avoidable deaths in developing countries. In Southern Africa the TB epidemic has developed into one of the worst in the world.

1.2 Reasons for global TB burden

The main reasons for the increasing global TB burden are the following:

- poverty and the widening gap between rich and poor in various populations
- poor programme management (inadequate case detection, diagnosis, cure)
- the impact of the HIV pandemic
- population increase

1.3 TB in South Africa

South Africa faces the challenge of implementing effective TB diagnosis and treatment strategies. The incidence rate of TB is well over **200/100 000** and an incidence of 200 is classified by the WHO as a serious epidemic. In addition the HIV /AIDS epidemic continues to escalate making TB management an even bigger challenge.

1.4 National Tuberculosis Control Programme (NTCP)

1.4.1 Overall objectives of the National Tuberculosis Control Programme

- To reduce mortality and morbidity attributable to TB
- To prevent the development of drug resistance
- To ensure accurate measurement and evaluation of programme performance

1.4.2 Short-term objectives of the NTCP

- To achieve smear conversion rates of at least 85% among new smear positive cases and 80% among retreatment cases at the end of the intensive phase of treatment.
- Cure at least 85% of new smear positive cases with short course chemotherapy.

1.4.3 The structure of NTCP

The NTCP has four levels: central unit or national level, provincial level, district level and health unit level, all within the general health services. The central unit level is at the National Department of Health. The central tuberculosis unit plays the role of coordination, facilitation and evaluation of tuberculosis services for the whole country. The provincial level is responsible for implementation and budgeting. The district level is the key level for the management of primary health care and is the most peripheral unit of the health services administration. The health unit level is within a district. It is the level of primary care and includes rural hospitals, health centres, dispensaries and clinics within a district.

This structure may vary to some extent. In some provinces, a regional level has been established between the provincial and district levels.

1.4.5 Core activities at national level

The main function of the national unit is to provide support and technical guidance to the provinces on the following activities:

- Countrywide implementation and expansion of the DOTS strategy
- Training of provincial TB coordinators on all elements of the DOTS strategy
- Supervisory visits to the districts so as to evaluate progress
- Laboratory visits to ensure proper diagnosis and follow up of TB patients
- Ensuring an efficient recording and reporting system for monitoring patients and programme performance.
- Strengthening collaboration between TB and HIV/AIDS programmes to ensure better management of co- infected patients.
- Raise the public's awareness about the seriousness of TB.

1.4.6 NTCP strategy for TB control

To provide standardised short-course chemotherapy (SCC) under direct observation of treatment (DOT) for at least the initial phase of treatment to at least all identified smear-positive TB cases (the sources of infection) so as to ensure high smear conversion rates.

CHAPTER 2

THE DOTS STRATEGY

The National Departmentof Health realised that its TB control efforts had been ineffective and joined it's international counterparts by adopting the DOTS (Directly Observed Treatment, Short-course) strategy to fight the spread of TB. The five key elements of the DOTS strategy are:

- Government commitment to sustained TB control activities.
- Sputum smear microscopy to detect the infectious cases among those people attending health care facilities with symptoms of TB, most importantly cough of three week's duration or more.
- Standardized short-course anti- TB treatment for at least all confirmed sputum smear positive pulmonary TB cases, with direct observation of treatment for at least the initial two months.
- A regular, uninterrupted supply of all essential anti-TB drugs.
- A standardized recording and reporting system which allows assessment of treatment results and overall programme performance.

What is DOTS? DOTS is the only globally recognised strategy for effective TB control. The DOTS strategy ensures that infectious TB patients are identified and cured using standardized drug combinations. Treatment supporters observe patients as they swallow their drugs daily.

This strategy has proven to be a powerful solution to many TB epidemics in a variety of settings such as Tanzania , Botswana, India, Nepal and New York City. It is more than a curative strategy. It is also a preventive strategy because it concentrates on curing infectious patients so as to stop TB in its tracks. The DOTS strategy is embedded in the following principles.

2.1 Government Commitment

The support of the national and provincial Heads of the Department of Health has significantly helped South Africa to implement the DOTS strategy. This support is essential because DOTS requires significant changes of approach and tends to challenge old practices. Although the strategy offers the least expensive way of tackling TB, often it requires substantial redirection of funds and this cannot happen without the political commitment and support of key decision makers.

Directly Observed Treatment Short-course as a global initiative, is a breakthrough that is increasingly providing solutions to the control of the TB epidemic in South Africa. However, it is a new strategy and as such may seem at first complicated and confusing. This merely shows the need to effectively and adequately reorientate our resources and train health staff and treatment supporters to this strategy. This means that each one of us from all sectors has a major role to play. TB is everywhere and as such effective TB control should be practised everywhere. Good TB control is part of good district development.

2.2 Identifying Infectious Patients

TB is a bacterial disease and bacterial tools should be used to manage it. The TB Control programme is moving away from chest x-rays as a primary method of diagnosis. A crucial element of DOTS is to use microscopes to ensure that infectious TB is reliably and cost -effectively diagnosed. The first priority and the key issue in the new programme is to cure infectious patients at the very first attempt to slow down the epidemic.

The over use of x -rays is discouraged as the primary means to confirm the diagnosis of TB because it does not tell whether a patient is infectious, and it is difficult to distinguish between active TB and other lung diseases or scarring. This leads to over diagnosis so that health workers could be treating many patients that do not have active TB and are not sick with TB. More importantly, the TB epidemic in South Africa is approaching uncontrollable levels and energies should be concentrated on curing infectious TB patients to stop the spread of this disease. Only bacteriology identifies infectious patients.

2.3 Direct Observation of Treatment

The implementation of DOTS ensures that every TB patient should have the support of another person to ensure that they swallow their medication daily. The treatment supporter does not have to be a professional health worker, but can be any responsible member of the community. Employers, colleagues and community members can act as treatment supporters. Using family members is often problematic but has been successful in exceptional cases. This person should know the signs and symptoms of TB, side effects of TB drugs and the importance of taking TB medication regularly for the patient. They should also motivate and empower patients and their families and provide them with a better understanding of TB and the importance of cure.

Treatment supporters are best recruited as part of a community based system which is reviewed annually and its results documented. Treatment supporters should work closely with local health authorities.

Because of the length of time, the patient has to take treatment, completing TB treatment is a special challenge and requires an unyielding sense of commitment. This may be easy to sustain while the patient feels sick. However, after a few weeks of taking treatment, patients often feel better and see no reason for continuing their treatment. It is thus essential for health workers or treatment supporters to be supportive and use the initial period to bond with the patient. This will enable them to build a strong relationship in which the patient believes and trusts advice given by the treatment supporter.

2.4 Standardized Drug Combinations

A daily dose of a powerful combination of medications is administered to TB patients for five days a week. Combination tablets simplify treatment and ensure that drugs are not given separately and therefore decrease the risk of drug resistance.

2.5 Reliable Reporting System

A reliable recording and reporting system is necessary in order to monitor progress. Sputum results should also be recorded to document smear conversion. This gives an accurate measurement of performance and one can identify areas which need support.

The First Step to Filling the Country with DOTS:

Setting up Demonstration and Training Districts (DTDs) in 1997 was one of the first crucial steps in the implementation of the DOTS strategy. In South Africa at least one Demonstration and Training area was identified in each province where all the elements of DOTS would be adopted in the management of TB services. Initially these areas would receive the necessary resources and support to ensure that they function well. When these districts demonstrate success in implementing DOTS they can be used as examples and training points to expand DOTS provincially and country-wide.

CHAPTER 3

HOW TB INFECTION DEVELOPS

3.1 What is tuberculosis?

Tuberculosis is an infectious disease caused by micro-organism, a bacilli called *Mycobacterium tuberculosis* which usually enters the body by inhalation through the lungs. They spread from the initial location in the lungs to other parts of the body via the blood stream, the lymphatic system, via the airways or by direct extension to other organs.

- Pulmonary tuberculosis is the infectious and common form of the disease, occurring in over 80% of cases.
- Extra-pulmonary tuberculosis is a result of the spread of tuberculosis to other organs, most commonly pleura, lymph nodes, spine, joints, genito-urinary tract, nervous system or abdomen. Tuberculosis may affect any part of the body.

3.2 How does tuberculosis develop?

Tuberculosis develops in the human body in two stages. The first stage occurs when an individual breathes in TB bacilli and becomes infected (tuberculosis infection) but the immune system contains the infection. The second stage is when the infected individual develops the disease (tuberculosis).

3.3 How are tuberculosis micro-organisms spread?

The infectiousness of a case of tuberculosis is determined by the concentration of micro-organisms within the lungs and their spread into the air surrounding the patient who has tuberculosis. When a TB patient with active pulmonary TB coughs or spits he or she will produce small droplets that contain TB bacilli. Anyone who inhales this air with droplets can then be infected and may later develop TB disease.

The most infectious cases are those with a positive smear by microscopy (smear positive cases). Those in whom micro-organisms cannot be seen directly under the microscope (smear negative cases) are very much less infectious. Extra-pulmonary cases are almost never infectious, unless they have pulmonary tuberculosis as well.

3.4 How does the disease appear

Among those who do become infected, most (90%) will never become ill with tuberculosis unless their immunity is seriously compromised for example by malnutrition, stress, HIV, cancer and diabetes. The micro-organisms remain dormant within the body and their presence is indicated only by a significant size of induration in reaction to a tuberculin skin test. BCG immunisation gives up to 80% protection against the progression of TB infection to disease. However, the main benefit of BCG is the protection against the development of the serious forms of TB (TB meningitis, miliary TB) in children.

CHAPTER 4

DIAGNOSING TB

4.1 How is Tuberculosis Diagnosed?

4.1 When is tuberculosis likely to be present?

The most common symptoms of pulmonary tuberculosis are:

- persistent cough for 3 weeks or more; every patient presenting to a health facility with this symptom should be designated a “tuberculosis suspect”;
- sputum production which may be blood-stained
- shortness of breath, and chest pain;
- loss of appetite and loss of weight
- a general feeling of illness (malaise)
- tiredness and loss of motivation;
- night sweats and fever.

A patient presenting with these symptoms who is, or was in contact with a person with infectious tuberculosis is more likely to be suffering from tuberculosis. Symptoms of extra-pulmonary tuberculosis depend on the organ involved. Chest pain from tuberculosis pleurisy, enlarged lymph nodes and sharp angular deformity of the spine are the most frequent signs of extra-pulmonary tuberculosis.

4.2 How is Diagnosis of Tuberculosis Confirmed?

4.2.1 What is the value of bacteriology?

In all instances, individuals identified as tuberculosis patients must have an examination of their sputum performed to determine whether or not they are infectious cases of tuberculosis, prior to the commencement of their treatment. The examination consists of microscopic examination of a specimen which has been spread on a slide and stained by the Ziehl-Neelsen method (smear microscopy). If micro-organisms (commonly referred to as acid-fast bacilli, or AFB) are detected by this method then the patient is said to have smear positive tuberculosis. It is important to carry out smear microscopy because it correctly and efficiently identifies the cases which are infectious and therefore have the highest priority for care.

4.2.2 Sputum collection, labelling, storage and transport

At least two sputum specimens should be taken from a TB suspect.

First specimen

At the first interview with the patient a “spot specimen” is collected; this specimen is obtained on the spot, after coughing and clearing the back of the throat and should be under the supervision of a health worker.

Second specimen

The patient is then given a sputum container for the collection of an early morning specimen, which should be on the next day.

Third specimen

When the patient returns to the clinic to deliver the second sputum, a third sputum should be collected on the spot.

4.2.3 Sputum labelling

Correct labelling is essential and will save time and prevent errors.

Label the container first, very clearly with:

- Name of clinic/hospital
- Name of patient and clinic/hospital number
- Indicate whether the specimen is pretreatment, follow-up or end of treatment specimen
- Write clear instructions regarding what investigations are required
- Write the appearance of the sputum (eg mucoid, lumpy, green, offensive, etc)
- Date the specimen clearly

Note
The container should always be labelled as the lids may get mixed up.

4.2.4 Sputum collection

This is an extremely important procedure

- Let the person rinse mouth with water
- Explain the steps fully and slowly
- Ask the patient to be very careful to direct the sputum into the container not to contaminate the outside
- Demonstrate a deep cough from the bottom of the chest, beginning with deep breathing
- Supervise the collection, but do not stand in front of the patient
- Do it in a well ventilated area or outside without others watching
- Give the patient the container without the lid
- Hold the lid yourself, ready to replace it immediately
- Make sure that the lid is securely closed, by pressing the centre of the lid down until a click is heard
- Wash hands after handling the sputum specimen
- The person must be encouraged to produce a specimen after deep coughing even if this is saliva

4.2.5 Sputum storage

- Place the sputum bottle in a plastic bag if possible to prevent contamination
- Store sputum specimen in a fridge if transport is not available immediately. Do not store in a freezer
- Send away as soon as possible
- Record the date on which the specimen has been sent to the laboratory

4.2.6 Transportation of sputum specimens

- Transportation of specimens to the laboratory should be in a cooler bag. High temperatures during transit will kill bacilli
- During transportation of specimens they should be protected from contact with direct sunlight
- Explain to the driver about the reasons for transporting the specimens, thereby ensuring that specimens go direct to the laboratory.

4.2.7 The management of a sputum specimen is a very important part of the NTCP

Note
Every work day, a responsible person should check the sputum register to see which results are outstanding and then contact the laboratory to find out where the results are.

Close cooperation with the laboratory will produce quick results, resulting in sputum positive patients being started on the correct treatment as soon as possible.

The target of the NTCP is to ensure a sputum turn around time of at least 48 hours.

*** Sputum turn around time refers to time from taking a specimen from the patient to receiving the results at the health facility.**

4.3 Sputum Results

The results of the laboratory reports are subject at times to human and material error. Some of the errors are: clerical errors, reagents problems, bad quality of specimens, process errors and lack of quality control. A laboratory result which does not tie up with other clinical information must be interpreted with care. The number of bacilli (AFB) seen in a smear reflects the patients infectivity.

The laboratory must record the number of bacilli seen on each smear as follows:

Number of bacilli seen on a smear		
No AFB	per 100 oil immersion fields	0
1-9 AFB	per 100 oil immersion fields	scanty
10-99 AFB	per 100 oil immersion fields	1+
1-10 AFB	per 1 oil immersion field	2++
>10 AFB	per 1 oil immersion field	3+++

4.4 When to do a Sputum Examination

Two specimens are taken on three separate occasions during the course of treatment of patients with PTB.

4.4.1 Pretreatment
When PTB is first suspected; send 2 specimens on consecutive days for TB microscopy.

4.4.2 During treatment
Two specimens should be sent for microscopy just before the end of intensive phase of treatment (after 2 months of treatment for new patients and after 3 months for retreatment patients).

4.4.3 At the end of treatment
Two specimens should be sent after the completion of 5 months of treatment for new patients and after 7 months for retreatment cases.

4.5 Monitoring Progress in Adult Pulmonary TB

During TB treatment, all pulmonary TB patients should be monitored by sputum smear microscopy, only in some cases, sputum culture and susceptibility testing is necessary.

4.5.1 New patients

4.5.1.1 Sputum microscopy after 2 months of treatment

- At 2 months, send 2 sputum samples for smear microscopy for all new patients.
- If both smears are negative, then start the continuation phase of treatment (see “Treatment of TB - New Adult Patients” Regimen 1).
- If one or both of the 2 month smears is positive, then give a third month of intensive phase treatment.

4.5.1.2 Sputum investigations at 3 months

- Send 2 sputum samples for smear microscopy at 3 months only if one or both of the 2 month smears was positive.
- If both 3 month smears are negative, then the continuation phase of treatment should be given for 3 months (not 4 months) so that a total of 6 months of treatmen is given.
- If one or both of the smears is still positive, then a sputum sample should be sent for TB culture and susceptibility and the continuation phase should be started. This is to ensure that the patient is still sensitive to normal TB drugs.
- If the TB bacilli are susceptible to all anti-TB drugs then the continuation phase should be continued.
- If the TB bacilli are resistant to any of the anti-TB drugs, then the patient should be referred to the provincial lung/MDR TB clinics.

4.5.1.3 Sputum investigations at 5 months

- Send 2 sputa for smear microscopy for all new patients (preferably early morning specimen).
- If both smears are negative and the patient is clinically well continue treatment until 6 months and register the patient as cured.
- If one or both of the 5 month smears is positive, then register the patient as a treatment failure, send sputum for culture and susceptibility, re-register the patient as a retreatment patient and start the retreatment regimen (see “Treatment of TB - Retreatment Adult Patients” Regimen 2).

4.6 Retreatment Patients

4.6.1 Sputum investigations at 3 months

- Send 2 sputa for smear microscopy at 3 months for all retreatment patients.
- If both smears are negative, start continuation phase (see “Treatment of TB - Retreatment Adult Patients”).
- If one or both smears are positive, send sputum for culture and susceptibility and start continuation phase.
- If the TB bacilli are susceptible to all anti-TB drugs, continue continuation phase.
- If the TB bacilli are resistant to any of the anti-TB drugs, refer to a higher level.

4.6.2 Sputum investigations at 7 months

- Send 2 sputa for smear microscopy at 7 months for all retreatment patients.
- If both smears are negative, continue treatment until 8 months and register the patient as cured.
- If one or both of the smears are positive, register the patient as a treatment failure and refer to a medical officer.

There is no place for “trial of TB treatment”. If the patient has 2 negative sputum samples, then provide a 7 day course of broad-spectrum antibiotics. Reassess the patient after the course of anti-biotics especially the patient who continues to cough after a course of antibiotics. If you still suspect TB, then do a chest x-ray. But remember that no chest x-ray pattern is absolutely typical of TB.

4.7 Chest x-rays

While chest x-rays are quick and convenient, reliance on chest x-rays as the primary source for confirmation of diagnosis results in unnecessary treatment. X-rays are necessary in suspects who cannot produce sputum and must be interpreted in the light of their history and clinical findings. Many diseases mimic TB on chest x-ray and this may lead to incorrect diagnosis. X-rays may show lung fibrosis or destruction due to old TB and this may also lead to over diagnosing of pulmonary TB.

4.7.1 Indications for chest x-ray

4.7.1.1 When the sputum results are positive

- Suspected complications, e.g. a breathless patient needing specific treatment (pneumothorax or pleural effusion).
- Frequent or severe haemoptysis
- To help in diagnosing other lung diseases
- Only one of the two pretreatment smears is positive

4.7.1.2 When the sputum results are negative

If you clinically still suspect TB despite negative smears, the patient should have a chest x-ray to help make a decision regarding diagnosis and treatment.

4.7.1.3 During and at the end of treatment

It is only necessary to do x-rays during and at the end of treatment if there are specific clinical reasons and the progress is not satisfactory.

4.8 TB Culture

TB culture and sensitivity is an expensive, slow and misleading diagnostic technique. It is unsuitable for case detection in routine programme operation. It should only be done:

- on patients who have had TB treatment in the past (interrupters, failures or relapses)
- when drug susceptibility testing is indicated.
- for patients who remain positive at the end of intensive phase of treatment and/or at the end of treatment.
- for patients, who have two negative smears and initially have had a course of antibiotics but TB is still suspected.

4.9 Tuberculin Test

The tuberculin test has limited value in clinical work, especially where TB is common.
The tuberculin test measures the body's immune system response to an injection of tuberculin purified protein derivative (PPD).

- The Mantoux test injects a known amount of PPD between layers of skin (intradermally) - ensure that the injection goes into and not under the skin. Measure the reaction to the test at the site of injection 48-72 hours later.
- Tine/Mono tests use instruments which are impregnated with PPD and need only to be pressed into the skin of the forearm. The area of induration is measured 72 hours later.
- Measure the diameter of the reaction at widest point of the raised, thickened area for the Mantoux and Monotests, record the results in millimetres.
- To help measure accurately, mark the edges of the duration at the widest point with a pen and measure the exact distance between the two points.

4.9.1 What does a positive tuberculin skin test mean?

- A positive test indicates infection with TB, but not necessarily TB disease.
- In a child under 5 years a strongly positive skin test indicates recent (6 weeks or more) infection which is a risk factor for progression to disease. In the presence of other features, i.e. history TB contact, signs and symptoms of TB and x-ray changes, a positive tuberculin skin test is suggestive of TB disease in children.
- A positive reaction occurs after previous BCG immunisation and should remain positive for several years thereafter. This reaction is usually weaker than the reaction to natural infection with M. tuberculosis.
- A positive reaction is only one piece of evidence in favour of the diagnosis.
- Because of increased risk, children under the age of 5 years who have a positive skin test should be put into chemoprophylaxis (RH) for three months.

Interpreting Skin Test Results:

Tuberculin Test	Previous BCG	No previous BCG	HIV+
Mantoux	15 mm or more	10 mm or more	more 4 mm
Monotest	8 mm or more	4 mm or more	uncertain
TINE test	blistering and confluent swelling	ring of induration	uncertain

4.9.2 What does a negative tuberculin skin test mean?

- A negative tuberculin skin test does not exclude TB.
- Various conditions may cause a negative reaction even if a child has TB. If the chest x-ray is suspicious of TB and the skin test is negative, TB can be diagnosed in children.
- Conditions which may suppress the tuberculin skin test and give a false negative result include: HIV infection, malnutrition, severe viral infections (eg, measles, chicken pox), cancer, immunosuppressive drugs (eg, steroids), severe disseminated TB.

CHAPTER 5

TB CASE DEFINITIONS

5.1 Standard Case Definitions

5.1.1 New case
A patient who has never had treatment for TB or who has taken anti-tuberculosis drugs for less than four weeks.

5.1.2 Relapse
A patient who has been declared cured of any form of TB in the past, after one full course of chemotherapy, and has become sputum smear-positive.

5.1.3 Treatment failure
A patient who, while on treatment, remained or became again smear-positive five months or later after commencing treatment. It is also a patient who was initially smear-negative before starting treatment and became smear-positive after the second month of treatment.

5.1.4 Treatment after interruption
A patient who returns to treatment after having interrupted treatment for two months or more, and returned to the health service smear-positive (sometimes smear-negative but still with active TB as judged on clinical and radiological assessment).

5.1.5 Chronic case
Same as treatment failure.

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

5.2 Reasons for having Standard Case Definitions

- to standardise patient registration and case notification
- to evaluate the trend in the proportions of new smear-positive cases and smear-positive relapse and other retreatment cases
- to allocate cases to standardised treatment categories
- for cohort analysis which allows valid comparisons
- to be able to accurately measure progress

5.3 Why Match Treatment to Standardised Category?

- to allow priority to be given to infectious cases
- to avoid under-treatment of sputum smear-positive cases and therefore to prevent acquired resistance
- to increase cost-effective use of resources and to minimise side-effects for patients by avoiding unnecessary over-treatment

5.4 What Determines Case Definitions?

- site of TB disease
- bacteriology (result of sputum smear)
- history of previous treatment of TB

5.4.1 Site of TB disease: pulmonary or extra-pulmonary

- Pulmonary TB refers to disease involving the lung parenchyma. Therefore tuberculosis intrathoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, constitute a case of extra-pulmonary TB.
- A patient with both pulmonary and extra-pulmonary TB constitutes a case of pulmonary TB.
- The case definition of an extra-pulmonary case with several sites affected depends on the site representing the most severe form of disease.

5.4.2 Case definitions by site and result of smear

5.4.2.1 Smear positive PTB case

- There are at least 2 sputum smears positive for AFBs or
- 1 sputum smear positive for AFBs and chest x-ray abnormalities consistent with active TB or culture positive TB, or
- 1 sputum smear and clinically ill.

It is advisable that even if the first specimen is positive pre-treatment, another specimen should be taken. This will reduce the chances of a false-positive result as administrative errors may occur.

5.4.2.2 Smear negative PTB case

- At least 2 sputum smears are negative for AFBs.
- Chest x-ray abnormalities are consistent with active TB.

Note
A patient with 2 negative smears and with a suspicious chest x-ray should be given a trial of broad-spectrum antibiotics for at least 7 days, then re-assessed.

5.5 History of Previous Treatment: treatment after interruption, treatment failure, relapse

It is important to define a case according to whether or not the patient has previously received anti-TB treatment for the following purposes:

- the identification of patients at increased risk of acquired drug resistance and the prescription of appropriate treatment;
- epidemiological monitoring.

5.6 Recording Treatment Outcome in Smear-positive TB Patients

5.6.1 Cure
Patient who is smear-negative at, or one month prior to, the completion of treatment and on at least one previous occasion.

5.6.2 Treatment completed
Patient who has completed treatment but without proof of cure.

5.6.3 Treatment failure
Patient who remains or becomes again smear-positive at five months or later during treatment.

5.6.4 Died
Patient who dies for any reason during the course of TB treatment.

5.6.5 Treatment interrupted
Patient whose treatment was interrupted for two months or more.

5.6.6 Transfer out
Patient who has been transferred to another reporting unit (eg district) and for whom the treatment outcome is not known.

CHAPTER 6

EXTRA-PULMONARY TUBERCULOSIS

Extra-pulmonary tuberculosis covers all forms of tuberculosis in which the disease process occurs outside the lungs. Many forms of extra-pulmonary tuberculosis originate from lymphatic or haematogenic spread of mycobacteria from a primary focus in the lung. Diagnosis of extra-pulmonary TB is often difficult, so diagnosis may be presumptive after excluding other conditions.
The most common types of extra-pulmonary tuberculosis are:

- TB meningitis
- TB lymphadenitis
- Miliary tuberculosis
- Tuberculous serous effusions
- Pleural effusion
- Tuberculous empyema
- Tuberculous pericardial effusion
- Ascites
- TB of the bones

6.1 TB Meningitis

TB meningitis is life threatening with serious complications if not treated promptly.

- Patients present with gradual onset of headache and decreased consciousness.
- Examination reveals neck stiffness and positive Kernig's sign (flex one of the patient's legs at hip and knee with the patient lying on back, and then straighten the knee - resistance to straightening the knee and pain in the low back and posterior thigh suggest meningeal inflammation).
- Diagnosis rests on clinical grounds and lumbar puncture to examine cerebrospinal fluid (CSF)(elevated CSF white cells with predominance of lymphocytes, increased protein, decreased glucose and sometimes the presence of acid-fast bacilli).
- Always exclude cryptococcal meningitis by cryptococcal antigen test, if possible - if cryptococcal antigen test is not available do CSF microscopy (India ink stain) and, if available, fungal culture.
- Patients with TB meningitis should be hospitalised.

6.2 Tuberculous Lymphadenopathy

- Persistent generalized lymphadenopathy (PGL) develops in up to 80% of HIV- infected individuals and requires no treatment - in PGL, lymph nodes are non- tender, <2 cm in size and symmetrical.
- Lymph node disease, including tuberculous lymphadenopathy, should be suspected if lymph nodes are tender, painful, nonsymmetrical, matted, flactuant, rapidly growing or associated with fever, night sweats or weight loss.
- If clinical features suggest a cause of lymphadenopathy other than PGL, refer to a doctor who will do a needle (18G or 19G) aspirate of the lymph node (TB is diagnosed if the aspirated material is caseated and a smear of the aspirate reveals acid-fast bacilli).
- If no diagnosis is made after a needle aspirate, a lymph node biopsy should be done.
- Tuberculosis may also cause mediastinal or intra-abdominal lymphadenopathy which may be detected by x-ray, ultrasound or computerised axial tomography (CT scan) - this may be treated empirically, unless the nodes are accessible to aspiration at a tertiary health facility (at tertiary centres, aspiration may be guided by CT scan, fluoroscopy or ultrasound).

6.3 Miliary TB

Miliary TB results from widespread blood borne dissemination of TB bacilli.

- Miliary TB is an under-diagnosed cause of end stage wasting in HIV-positive individuals.
- Patients present with fever, night sweats and weight loss and may have an enlarged liver and spleen (hepatosplenomegaly).
- Chest x-ray shows diffuse, uniformly distributed, small miliary nodules ("miliary" means "like small millet seeds").
- Full blood count may show pancytopenia (this may also be seen as a result of HIV).
- Bacterial confirmation of the diagnosis is sometimes possible from sputum, CSF or bone marrow.

6.4 Tuberculous Serous Effusions

Inflammatory tuberculous effusions may occur in any of the serous cavities of the body, i.e. pleural, pericardial or peritoneal cavities. They are a common form of TB in HIV- positive patients.

- Patients usually have systemic and local features.
- Microscopy of the aspirates from tuberculous serous effusions rarely show AFB because the fluid forms as an inflammatory reaction to TB lesions in the serous membrane.
- TB culture is of no immediate help because a culture result takes three weeks.
- The aspirate is an exudate (the protein content is more than 30g/L). A biochemistry lab is not required to diagnose an exudate: let the aspirated fluid stand for a while - if it clots, it is an exudate.
- In populations with a high prevalence of HIV, TB is the commonest cause of an exudative serous effusion.

6.5 Tuberculous Pleural Effusion

- Typical clinical features are chest pains, breathlessness, tracheal and mediastinal shift away from the side of the effusion and decreased chest movement.
- Chest x-ray shows unilateral, uniform white opacity, often with a concave upper border.
- Diagnosis is done by pleural aspiration: the fluid is an exudate and is usually straw coloured and the white cell count is high [1 000 - 2 500 per mm3].
- If facilities are available, a closed pleural biopsy can be done with an Abrams needle for histological diagnosis - the yield is about 75% positive for TB.
- Differential diagnosis includes malignancy, post-pneumonic effusion and pulmonary embolism.

Note
In a hospital or clinic serving a population with a high prevalence of TB you should treat a patient with a unilateral exudative pleural effusion with anti-TB drugs.

6.6 Tuberculous Empyema

- The physical signs are the same as those of a pleural effusion
- If pleural aspiration reveals pus, it indicates an empyema - send the pus to the laboratory for examination for TB, Gram stain and bacterial culture - the main differential diagnosis is bacterial empyema.
- A succussion splash is a splashing sound heard with the stethoscope while shaking the patient's chest - if heard, it indicates a pyopneumothorax (pus and air in the pleural space) - after chest x-ray confirmation, insert a chest drain with underwater seal.

6.7 Tuberculous Pericardial Effusion

- Diagnosis usually rests on suggestive systemic features and ultrasound.
- Cardiovascular symptoms include: chest pain, shortness of breath, cough, dizziness and weakness due to low cardiac output, leg swelling, right hypochondrial pain (liver congestion), abdominal swelling (ascites).
- Cardiovascular signs include: tachycardia, low blood pressure/pulsus paradoxus, raised jugular venous pressure, impalpable apex beat, distant heart sounds, pericardial friction rub, signs of right-sided heart failure (eg, hepatosplenomegaly, ascites, oedema).
- Chest x-ray may show a large globular heart, clear lung fields, pleural effusion.
- ECG may show tachycardia, flattening of ST and T waves, low voltage QRS complexes.
- Treatment is the same as for all types of TB (see “Treatment of TB”) but corticosteroids can be added. Treatment without pericardiocentesis usually results in resolution of tuberculous pericardial effusion.
- In cases of cardiac tamponade the effusion should be aspirated by a specialist.

Note
In high TB/HIV prevalent populations, TB is the most likely treatable cause of pericardial effusion. It may be safer for the patient to start presumptive anti-TB treatment than to undergo diagnostic pericardiocentesis.

6.8 Tuberculous Ascites (TB peritonitis)

- Clinical features include systemic features and ascites; there may be palpable abdominal masses (mesenteric lymph nodes); bowel obstruction may develop from adhesion of nodes to bowel; and fistulae may develop between bowel, bladder and abdominal wall.
- Always do a diagnostic ascitic tap - the aspirated fluid is usually straw coloured, but is occasionally turbid or blood stained - the fluid is an exudate, usually with more than 300 white cells per mm3 - white cells are predominantly lymphocytes (polymorphs predominate in spontaneous bacterial peritonitis which is a common complication of cirrhosis).
- Investigate for pulmonary TB .
- Diagnosis is usually presumptive - in doubtful cases, a peritoneal biopsy may be considered at a hospital if a mini-laparotomy or laparoscopy can be performed.

6.9 Tuberculosis of Bones and Joints

When primary TB occurs during childhood bacilli often spread to the vertebrae and ends of long bones where disease may develop either then or months or years later. The infection may spread locally causing an arthritis. The bones and joints most commonly affected are those that bear weight.

- The spine is most frequently affected, then the hip, the knee and the bones of the foot.
- In the spine, TB starts in the intervertebral disc, spreads along the ligaments and involves the adjacent vertebral bodies.
- Clinical features of spinal TB include: pain and swelling locally, sometimes an obvious lump or bend of the spine, stiff back, reluctance to bend the back, a child that refuses to walk, paralysis or weakness of the lower limbs due to pressure on the spinal cord.
- X-rays of the spine show disc space narrowing and erosion of the adjacent vertebral bodies
- A well fitted orthopaedic brace is sometimes needed to immobilise the affected area.
- Surgical treatment is necessary if there is compression of the spinal cord and the patient has weakness or paraplegia of the lower limbs - these patients should be referred to a specialist urgently.

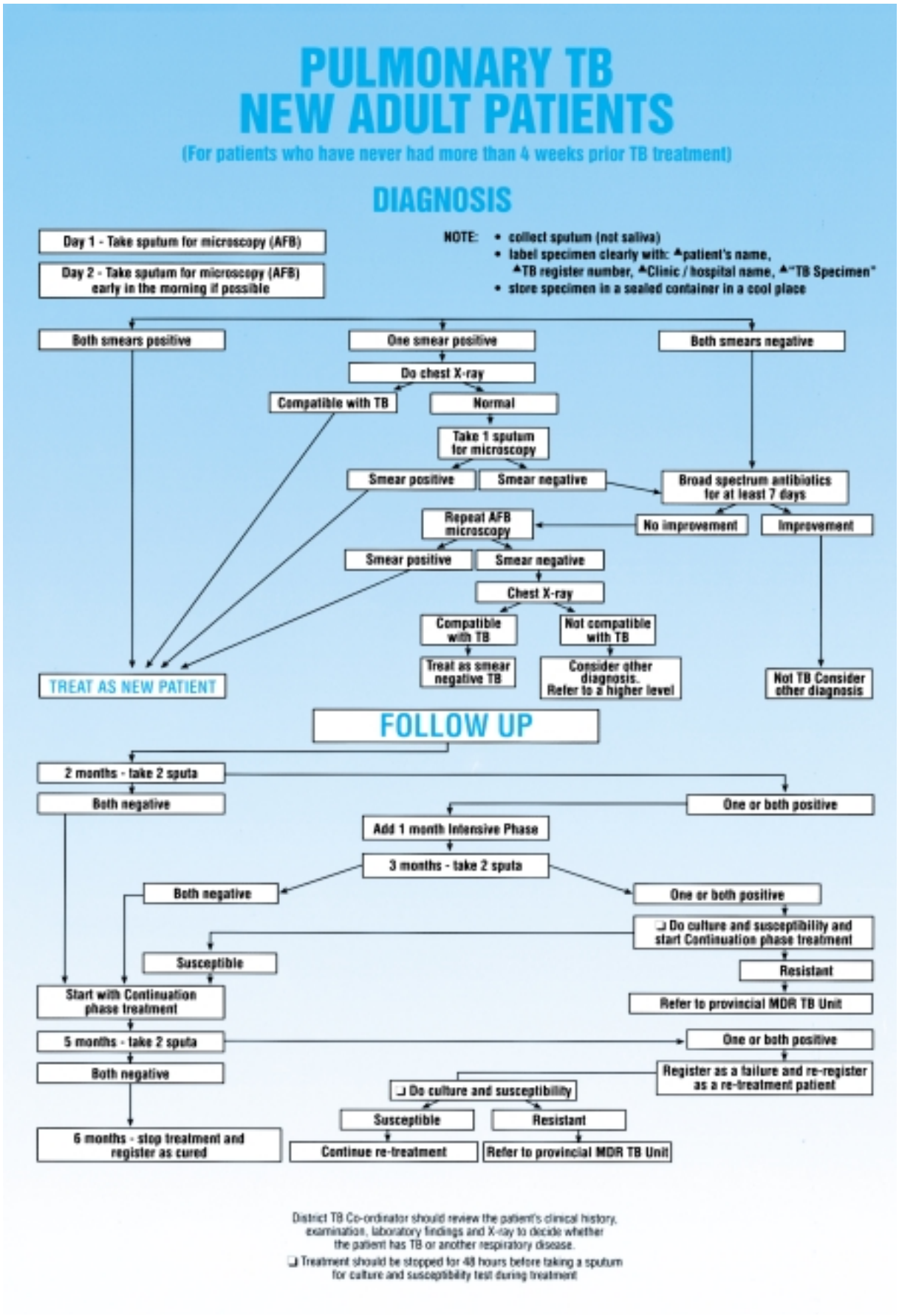
Note
Patients with extra-pulmonary TB should be treated with regimen one. (See 8.1 on page 27)

6.10 Severity of TB Disease

The following forms of extra-pulmonary TB are classified as severe: meningitis, miliary, pericarditis, peritonitis, bilateral or extensive pleural effusion, spinal, intestinal, genito-urinary.

Note
Some authorities recommend a 7 month continuation phase (7 HR) for patients with severe forms of extra-pulmonary TB.

The following forms of extra-pulmonary TB are classified as less severe: lymph node, pleural effusion (unilateral), bone (excluding spine), peripheral joint, skin.


PULMONARY TB
NEW ADULT PATIENTS
(For patients who have never had more than 4 weeks prior TB treatment)
DIAGNOSIS
Day 1 - Take sputum for microscopy (AFB)
Day 2 - Take sputum for microscopy (AFB) early in the morning if possible
NOTE:
• collect sputum (not saliva)
• label specimen clearly with: ▲patient's name, ▲TB register number, ▲Clinic / hospital name, ▲"TB Specimen"
• store specimen in a sealed container in a cool place
Both smears positive
One smear positive
Both smears negative
Do chest X-ray
Compatible with TB
Normal
Take 1 sputum for microscopy
Smear positive
Smear negative
Broad spectrum antibiotics for at least 7 days
No improvement
Improvement
Repeat AFB microscopy
Smear positive
Smear negative
Chest X-ray
Compatible with TB
Not compatible with TB
Treat as smear negative TB
Consider other diagnosis. Refer to a higher level
TREAT AS NEW PATIENT
Not TB Consider other diagnosis
FOLLOW UP
2 months - take 2 sputa
Both negative
One or both positive
Add 1 month Intensive Phase
3 months - take 2 sputa
Both negative
One or both positive
❑ Do culture and susceptibility and start Continuation phase treatment
Susceptible
Resistant
Refer to provincial MDR TB Unit
Start with Continuation phase treatment
5 months - take 2 sputa
Both negative
One or both positive
Register as a failure and re-register as a re-treatment patient
❑ Do culture and susceptibility
Susceptible
Resistant
6 months - stop treatment and register as cured
Continue re-treatment
Refer to provincial MDR TB Unit
District TB Co-ordinator should review the patient's clinical history, examination, laboratory findings and X-ray to decide whether the patient has TB or another respiratory disease.
❑ Treatment should be stopped for 48 hours before taking a sputum for culture and susceptibility test during treatment

CHAPTER 8

PRINCIPLES OF TREATMENT

The key to stop the spread of TB in a community is to start treating patients who are coughing up living TB bacilli as soon as possible. For treatment to be effective, it is crucial that correct drugs are given for the correct period of time.

8.1 The Essential Anti-TB Drugs

There are three main properties of anti-TB drugs: bactericidal, sterilizing and the ability to prevent resistance. The anti-TB drugs possess these properties to different extents. Isoniazid and Rifampicin are the most powerful bactericidal drugs, active against all populations of TB bacilli. Pyrazinamide and streptomycin are also bactericidal against certain populations of TB bacilli. Pyrazinamide is active in an acid environment against TB bacilli inside macrophages. Streptomycin is active against rapidly multiplying extracellular bacilli. Ethambutol is bacteriostatic.

8.2 Irregular Attendance

8.2.1 In the intensive phase

- Up to 10 missed doses, in total may be accepted, but must be added on to the end of the intensive phase.
- If more than 10 doses, are missed, the patient should be started on a standardized TB re-treatment regimen.

8.2.2 In the Continuation phase

When more than two months of treatment, in total, is missed:

- If sputum is smear negative, complete the continuation phase;
- If sputum is smear positive begin retreatment.

8.3 Retreatment Patients

Retreatment patients are more likely to develop multi-drug resistance and so should, if at all possible, be hospitalised for their initial 2 months of treatment. Initial culture and susceptibility testing should be done on every retreatment patient. Hospitalising these patients may also facilitate giving daily streptomycin injection.

CHAPTER 9

INITIATION OF TREATMENT

NB: Dosages of treatment five times per week in the intensive phase. For continuation phase treatment can be given five times or three times a week. Ensure that you give the correct doses.

9.1 (Regimen1) New adult patients

New smear positive and other serious pulmonary and extra pulmonary tuberculosis.

2 Months Initial Phase (treatment given 5 times a week)	**Patient under 50 kg**	**Patient over 50kg**
Combination tablet RHZE 120/60/300/200 mg*	4 tabs	5 tabs

4 Months Continuation phase (treatment given 5 times a week)	**Patient under 50 kg**	**Patient over 50kg**
Combination tablet RH 150/100 mg	3 tabs	
Combination tablet RH 300/150 mg		2 tabs

If conditions do not allow for giving treatment 5 times a week, treatment can also be given 3 times a week.

4 Months Continuation phase (treatment given 3 times a week)	**Patient under 50 kg**	**Patient over 50kg**
Combination tablet RH 150/100 mg	3 tabs	
H 100 mg	1 tab	
Combination tablet RH 300/150 mg		2 tabs
H 300 mg		1 tab

R=rifampicin: H=isoniazid (INH): Z=pyrazinamide: E=ethambutol: S=streptomycin
***Ethambutol 225 mg in combination is also acceptable**

9.2 (Regimen 2) Retreatment adult cases

smear positive retreatment cases (failure, relapse and return after interruption)

2 months Initial Phase (treatment given 5 times a week)	**Patient under 50 kg**	**Patient over 50 kg**
RHZE 120/60/300/200 mg*	4 tabs	5 tabs
streptomycin	750 mg	1000 mg
3rd month (five times a week)	**Patient under 50 kg**	**Patient over 50 kg**
RHZE	4 tabs	5 tabs

R=rifampicin: H=isoniazid (INH): Z=pyrazinamide: E=ethambutol: S=streptomycin
***Ethambutol 225 mg in combination is also acceptable**

5 months Continuation Phase (5 times a week)	**Patient under 50 kg**	**Patient over 50 kg**
RH 150/100 mg	3 tabs	
E 400 mg	2 tabs	
RH 300/150 mg		2 tabs
E 400 mg		3 tabs

Note
Streptomycin should be reduced to 750 mg per day to those older than 45 years and not be given to those over 65 years. It should also not be given during pregnancy.
*** Ethambutol 225 mg in combination is also acceptable**

5 months Continuation Phase (3 times a week)	**Patient under 50 kg**	**Patient over 50 kg**
RH 150/100 mg	3 tabs	
H 100 mg	1 tab	
E 400 mg	2 tabs	
RH 300/150 mg		2 tabs
H 300 mg		1 tab
E 400 mg		4 tabs

9.3 (Regimen 3) Children with Tuberculosis

Pretreatment body weight	**2 months initial phase** (treatment given 5 times a week) RHZ 60/30/150 mg	**4 months continuation phase** (treatment given 5 times a week) RH 60/30 mg
3-4 Kg	1/2 tab	1/2 tab
5-7 Kg	1 tab	1 tab
8-9 Kg	1 1/2 tabs	1 1/2 tabs
10-14 Kg	2 tabs	2 tabs
15 -19 Kg	3 tabs	3 tabs
20 - 24 Kg	4 tabs	4 tabs
25 - 29 Kg	5 tabs	5 tabs
30 - 35 Kg	6 tabs	6 tabs

R = rifampicin: H = isoniazid Z = pyrazinamide

If conditions do not allow for giving treatment 5 times a week, treatment can also be given 3 times a week.

Pretreatment body weight	**2 months initial phase** (treatment given 5 times a week) RHZ 60/30/150 mg	**4 months continuation phase** (treatment given 3 times a week) RH 60/60 mg
3-4 Kg	1/2 tab	1/2 tab
5-7 Kg	1 tab	1 tab
8-9 Kg	1 1/2 tabs	1 1/2 tabs
10-14 Kg	2 tabs	2 tabs
15-19 Kg	3 tabs	3 tabs
20-24 Kg	4 tabs	4 tabs
25-29 Kg	5 tabs	5 tabs
30 -35 Kg	6 tabs	6 tabs

Note
Refer to weights before treatment for all regimens

All children with severe forms of tuberculosis (TB-bone, meningitis, spine, peritonitis, miliary TB) should **be referred** to hospital for management. Guidelines for management of such cases are different and longer.

9.4 Chemoprophylaxis

Active case-finding is recommended for all children under the age of 5 years. Such children in close household contact with a smear positive case of pulmonary TB or who are tuberculin skin test positive (see 11.3) should be given prophylaxis. The correct regimen to give as prophylaxis to a well child under 5 is 5mg of isoniazid per kg for 6 months.
Routine chemoprophylaxis of those older than 5 years is not recommended.

CHAPTER 10

MANAGEMENT OF SIDE EFFECTS

Side Effects *Minor*	**Drug(s) Probably Responsible**	**Management** *Continue treatment*
anorexia, nausea, abdominal pain	rifampicin	give tablets last thing at night
joint pain	pyrazinamide	aspirin
burning sensation in feet	isoniazid	piridoxine 25 mg daily
orange/red urine	rifampicin	reassurance
Major		
skin itching/rash anaphylactic reaction	streptomycin	If a patient experiences any of these major side effects the drugs responsible should be immediately stopped and the patient referred to a specialist physician for an examination
deafness	streptomycin	
dizziness	streptomycin	
jaundice	most anti-TB drugs	
vomiting and confusion	most anti-TB drugs	
visual impairment	ethambutol	
generalised reaction, including shock and purpura	rifampicin	

Note

- **Streptomycin should not be used in pregnancy or for patients over 65 years of age.**
- **Ethambutol should not be given to children under 8 years of age.**
- **Rifampicin reduces the efficacy of oral and injectable contraceptives. It is very important when introducing new patients to treatment to:**
  - **ask about contraception**
  - **explain the problem**
  - **if necessary, alter the oral and injectable contraceptive or suggest an IUCD.**
- **Ask patients about other drugs they may be taking and check that there is no cross reaction. Get expert advice if necessary.**

CHAPTER 11

TB IN CHILDREN

11.1 Transmission of TB in children

The source of TB infection in a child is usually an adult (often a family member) with sputum positive PTB. When children are infected, family members and other close contacts should be investigated to find the source of disease.

Note
A good NTCP is the best way to prevent TB in children. The highest priority in TB control is to cure the infectious cases.

The diagnosis of TB in children can be difficult.

- It is easy to over-diagnose TB in children but it is also easy to miss it.
- Bacteriological confirmation of pulmonary TB in children is usually not possible because under the age of ten years, children with pulmonary TB rarely cough up sputum.
- Children usually swallow their sputum - gastric aspiration and laryngeal swabs may be used to identify swallowed organisms in the diagnosis of pulmonary TB in children, although this is not currently recommended.
- The diagnosis of TB in children revolves around: the clinical features, tuberculin skin test, chest x-ray and a history of contact with a sputum positive pulmonary TB case.

11.2 Clinical Features

- Decrease in weight, loss of appetite and failure to thrive without any obvious explanation. The “Road to Health” card can help to identify these children. Growth percentiles remaining the same or decreasing for two or more months must be investigated. If no cause is obvious, then TB should be suspected.
- Cough for more than two weeks and chest pain.
- An audible wheeze which does not respond to bronchodilators is suggestive of airway compression which is the result of enlarged intra-thoracic glands.
- Repeated respiratory tract infections which do not respond to treatment.
- Painless swelling of the lymph nodes - enlarged matted glands in the neck commonly occur.
- Two or more episodes of fever without any obvious cause such as malaria or acute respiratory infection.
- Non-specific signs include: steady high fever, rapid pulse, vomiting and diarrhoea, cyanosis (blueness of the lips).
- The two forms of TB which are most dangerous to children are: TB meningitis and miliary TB (see “Diagnosis of TB Meningitis in Children” and “Diagnosis of Extra-pulmonary TB”).

11.3 Tuberculin Skin Test

- The tuberculin skin test measures the body’s immune response to an injection of tuberculin purified protein derivative (PPD). (See Tuberculin skin test in Chapter 14, Section 4.9.)

11.4 Chest Radiography

Changes on x-rays are often non-specific, so TB should not be diagnosed from x-rays alone.
The most common x-ray signs are:

- A broad mediastinum due to enlarged hilar or mediastinal glands - the enlarged hilar glands may compress the airway and cause obstruction and lobar collapse.
- Miliary infiltrations in the lungs.
- Pleural effusions which usually occur in children older than six years.
- X-rays can be helpful but results depend on the quality of the x-ray and the expertise of the doctor who reads it.

11.5 Contact History

- A history of close contact (family member, person living in the same household, friend, caretaker) with a person who has smear positive TB increases the likelihood of the child being infected with TB.

11.6 The Impact of HIV on the Diagnosis of TB in Children

HIV makes the diagnosis of TB in children even **more difficult** for the following reasons:

- Several HIV-related respiratory diseases, including TB may have similar symptoms.
- Weight loss is a common problem in HIV-positive children due to chronic diarrhoea.
- The interpretation of the tuberculin skin test is even more unreliable than usual: an immunocompromised child may have a negative tuberculin skin test despite having TB.
- The radiological features of TB in HIV positive children with TB are often atypical.
- Differential diagnosis of pulmonary TB in HIV-infected children: bacterial pneumonia, viral pneumonia, fungal lung disease, pneumocystis carinii pneumonia, pulmonary lymphoma.
- If you are unsure of the diagnosis, treat the child with antibiotics for 5-7 days and repeat the chest x-ray after two weeks.

11.7 A Score System for the Diagnosis of TB in Children

A score system is one way of trying to improve the diagnosis of childhood TB by the careful and systematic collection of diagnostic information. A score system is there to help you in your clinical judgement. The table below shows a score chart for the diagnosis of childhood TB:

SCORE SHEET FOR TB IN CHILDREN

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

Feature	0	1	2	3	4	Score
GENERAL						
Weeks of illness	< 2	2 - 4		> 4		
Nutrition [% weight for age]	> 80%	60-80%		< 60%		
Family history of TB	None	reported by family		proved sputum positive		
Tuberculin test				positive		
Malnutrition				not improving after 4 weeks		
Unexplained fever			No response to treatment			
LOCAL						
				Lymph nodes		
				Joint or bone swelling		
				Abdominal mass or ascites		
				CNS signs, Abnormal CSF		
					Angle deformity of spine	
TOTAL						

Name of Child . . . . . .

Date . . . . . Completed by . . . . . .

[> = more than; < = less than.]

How to apply/read score system

Example: Score the following patient for TB:

A young child has weight loss (weight < 60% for age) with no family member with TB, skin test is not available, has bouts of unexplained fever with no response to antibiotic and positive lymph nodes in the neck.

FEATURE	SCORE
Weight less than 60%	3
Family history of TB	0
Tuberculin Test	0
Unexplained fever, no response to treatment	2
Lymph nodes	3
TOTAL	8

Any score of 7 or more is suggestive of TB!

Treatment of TB in Children - refer to the treatment regimens in Chapter 9, Regimen 3.

11.8 Diagnosis of TB Meningitis in Children - How do I diagnose TB meningitis in children?

TB meningitis is a very serious form of TB in children. Complications include obstruction of cerebrospinal fluid (CSF) flow, hydrocephalus, inappropriate antidiuretic hormone secretion, hemi- or quadriplegia, convulsions, deafness, blindness and mental retardation.

11.8.1 Symptoms

- headache
- irritability
- drowsiness
- convulsions
- weight loss

11.8.2 History

- contact with a TB patient

11.8.3 Physical signs

- signs of meningeal irritation (neck pain and resistance to neck flexion)
- cranial nerve palsies
- altered level of consciousness

11.8.4 Investigations

- lumbar puncture (CSF findings: raised protein, low glucose, low chloride, lymphocytes predominate, gram stain negative - acid fast bacilli are seldom found)
- Mantoux test positive (see above)
- chest x-ray may be abnormal (see above)

11.9 Treatment of TB Meningitis in Children - How do I treat TB meningitis in children?

Note
TB meningitis is a very serious form of TB and should not be treated at primary health care facility but should be urgently referred to a tertiary level.

Tuberculous Meningitis		
	Management	**Comments**
Non-drug treatment	Monitor neurological status on a regular basis. Attend to nutritional status. Nasogastric feeding is usually needed initially.	All patients need physiotherapy and occupational therapy.
Drug treatment 3-month initial phase	Rifampicin + isoniazid + Pyrazinamide + ethionamide Rifampicin,oral,20mg/Kg/24 hrs as a single dose. Isoniazid,oral,20mg/Kg/24 hrs as a single dose. Pyrazinamide,oral,40mg hrs as a single dose; maximum 2g per 24 hrs. Ethionamide,oral,20mg/Kg/24 hrs as a single dose; maximum 1g per 24 hrs.	
6-month continuation phase	Discontinue pyrazinamide. Continue with rifampicin, isoniazid and ethionamide using the doses above. Treatment is then given once daily for 5 days per week.	
Steroids	Prednisone, oral, 2-4mg/Kg/24 hrs in 3 divided doses for 4-6 weeks. Then taper to stop over 14 - 21 days.	
Hydrocephalus	acetazolamide oral, 100 mg/Kg/24 hrs in 3 divided doses; maximum 1g/day. AND Furosemide,oral, 1-2 mg/Kg/24 hrs as a single daily dose for at least 4-6 weeks.	Refer non-communicating hydrocephalus for ventriculo-peritoneal shunt
Convulsions	Diazepam, slow IV, 0.2-0.3 mg/Kg, to control acute seizures. Maintenance: Phenobarbital, oral, 5-10mg/Kg/24 hrs in 2 divided doses, until the patient is free of convulsions for 14 days. Taper to stop over 1 week	
Raised Intracranial pressure cerebral oedema	Elevate head of bed Maintain Paco2 at 28-30 mmHg; intubate and ventilate if necessary. Mannitol, IV, 1g/Kg administered over 1 hour. (Do not repeat) Furosemide, IV, 1mg/Kg. (Do not repeat) Avoid fluid overload. Limit total daily fluid intake (IV + oral) not to exceed the maintenance requirements for age.	Treat severe cerebral oedema/increased intracranial pressure if there is and acute deterioration of the level of consciousness.

11.10 Treatment of Complications in Children - How do I treat complications in children?

In patients with large hilar and mediastinal glands causing potentially life threatening airway compression effects like wheezing and lobar collapse as well as patients with symptomatic pleural effusions:

- Prednisone 2-4 mg/kg/24 hours orally in 3 divided doses for 4-6 weeks can be added to the anti-TB drugs - taper to stop over 2 weeks.

11.11 Contact tracing - What contact tracing should I do?

Contacts are people who live in the same house as a TB patient who was smear positive. Contacts are at risk of becoming infected with TB.

- Patients should be advised to bring any contacts under 5 years old to the clinic for assessment.
- Patients should tell contacts who are older than 5 years old to come to the clinic if they develop TB symptoms.
- Contacts under 5 years should be put on TB prophylaxis for a period of 3 months
- A visit to the patient's home may be useful to establish a relationship, understand circumstances and reinforce early signs and symptoms to all family members

11.12 Prophylaxis for healthy child contacts who are under 5 years old

Children under the age of 5 years are at high risk of being infected with TB and of developing TB disease. Their immune systems are not fully developed and their infection is likely to be recent. Children under two years of age are at high risk of developing serious forms of TB.

A young child who lives with a smear positive TB family member is at special risk and can be protected with a course of preventive prophylactic TB treatment.

That is why all child contacts under 5 years of age of smear positive patients are put on prophylactic treatment. A child contact is a well child, with no symptoms. If the child is sick, that is a different matter and the sickness must be diagnosed and treated accordingly.

The correct regimen to give as prophylaxis to a well child under 5 is 5mg of isoniazid per kg for 6 months. Currently the combination tablet 60/30 can be used as an alternative but is not strongly recommended.

CHAPTER 12

TB AND HIV/AIDS

For detailed information on TB/HIV/AIDS, please refer to “Tuberculosis and HIV/AIDS Clinical Guidelines”.

12.1 How is tuberculosis affected by HIV?

Human Immunodeficiency virus (HIV) infection is spread most commonly by sexual intercourse, through blood products, injuries with hollow needles and from mother to child. 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 deadly diseases to which persons without HIV infection would not usually be susceptible. When HIV infection is accompanied by “opportunistic” diseases, the effected person is said to have the “acquired immunodeficiency syndrome” (AIDS).

12.2 Interaction of TB and HIV/AIDS

- TB is a common cause of death in people living with HIV/AIDS.
- TB is caused by Mycobacterium tuberculosis, also known as TB bacilli.
- HIV, by attacking the immune system, makes a person who is infected with TB bacilli more likely to get sick with TB.
- In the absence of HIV infection, only about 5% of people infected with TB bacilli get sick with TB during their lifetime. In people who are co-infected with HIV and TB, about 50% may become ill with TB
- About 40% of TB patients in South Africa are infected with HIV and this proportion is increasing rapidly with time.
- TB can occur at any time, but often occurs early in the course of HIV disease.
- TB probably accelerates the progression of HIV disease.
- **TB can be cured,** whether a patient is infected with HIV or not, using Directly Observed Treatment, Short-Course (DOTS), with the same drugs for the same amount of time.

12.3 Diagnosis of HIV in TB Patients - When should I suspect HIV co-infection in TB patients

12.3.1 Symptoms

Symptoms suggestive of HIV infection are:

- weight loss
- diarrhoea (>1 month)
- pain on swallowing (suggests oesophageal candida)
- burning sensation of feet (suggests peripheral sensory neuropathy)

12.3.2 History

History suggestive of HIV infection include:

- herpes Zoster (shingles)
- recurrent pneumonia
- bacteraemia
- sexual partner with HIV infection
- sexually transmitted infection

12.3.3 Physical signs

Physical signs suggestive of HIV infection include:

- oral thrush
- oral hairy leukoplakia
- extensive herpes of Zoster (shingles)
- scar of herpes Zoster
- Kaposi's sarcoma
- Pruritic papular rash
- symmetrical generalised lymphadenopathy
- persistent painful genital ulceration

12.4 Investigations

HIV infection should be suspected if, during the course of other investigations the following results are found:

- unexplained anaemia, leucopenia or thrombocytopenia
- bacteraemia

The definitive diagnosis of HIV infection rests on a positive HIV test.

12.5 HIV Counselling and Testing

12.5.1 HIV counselling and testing - When should I offer HIV counselling and testing?

All TB patients in South Africa should receive HIV information and education. There should be emphasis on the benefits of knowing whether they are HIV positive. Given that about 40% of TB patients in South Africa are infected with HIV, HIV counselling and testing should be offered to all TB patients, if the following conditions are met:

- Testing is voluntary.
- Counselling is provided by trained counsellors (not necessarily nurses).
- Pre-test counselling is provided to enable the patient to make an informed decision to have the test or not. The main issues for discussion are assessments of the following: the patient's likelihood of having acquired HIV infection; the patient's knowledge about HIV; the patient's ability to cope with the result.
- Post-test counselling is provided to discuss the result, share information, provide support and encourage safe sexual behaviour.
- Continuing clinical and counselling support is available for patients who are HIV-positive.

The potential benefits of HIV counselling and testing are:

- Improved health status through good nutritional advice and early access to prevention/treat ment for HIV-related illness (eg, TB preventive therapy).
- Ability to plan for HIV-related illness and death.
- Emotional support and better ability to cope with HIV-related anxiety.
- Awareness of safer options for reproduction and infant feeding.
- Motivation to initiate and maintain safer sexual and drug-related behaviours.

12.6 TB Preventive Therapy

TB preventive therapy has been proven to prevent TB in HIV-positive patients who have positive tuberculin skin tests and who are not already sick with TB. TB disease can be prevented in 60% of such people by offering Isoniazid prophylaxis for 6 months.
In these individuals, TB preventive therapy decreases the risk of TB disease and should be part of a package of care for people living with HIV/AIDS.
TB preventive therapy will not be offered initially in all public health services. It will be piloted in HIV/TB pilot districts and may be considered in occupational health services (including mines), in prison health services, and for health workers.

Note
To get more information about TB preventive therapy and how it should be administered contact the TB coordinator in your province. (See list in chapter 15)

CHAPTER 13

MULTI-DRUG RESISTANT TUBERCULOSIS

The emergence of multi-drug resistant (MDR) TB is the most serious aspect of the TB epidemic. Multi-drug resistant TB refers to TB which is resistant to at least isoniazid and rifampicin. MDR TB is difficult and expensive to treat. Currently, the cure rate of MDR TB patients is less than 50%.
It is therefore essential to prevent the development of MDR TB. As with other forms of drug resistance, MDR TB is a largely man-made problem, being the consequence of human error in any of the following:

- prescription of chemotherapy
- management of drug supply
- patient management
- patient adherence.

13.1 Most Common Medical Errors Leading to the Selection of Resistant Bacilli

- prescription of inadequate chemotherapy
- adding one extra drug in the case of treatment failure, and often adding a further drug when the patient relapses after amounts to monotherapy.

13.2 Most Common Errors Observed in the Management of Drug Supply

- frequent or prolonged shortages of anti-tuberculosis drugs due to poor management; especially when rifampicin is available as a single drug
- use of drugs of unproven bioavailability

13.3 Poor Management Practices

successive monotherapies and selection of Resistant Bacilli:

- health care workers not ensuring a good relationship is built from the start. (Not taking time for patient problems and supporting a problem solving approach so as to establish a relationship where the patient trusts advice given by the health care worker.)
- patients' lack of knowledge (due to lack of information about TB and treatment of the disease or due to inadequate explanation before starting treatment).

13.4 Prevention, Diagnosis and Management of MDR TB

13.4.1 Prevention:

- MDR TB can be prevented by treating TB patients with appropriate TB regimens (see "Treatment of TB")
- ensuring patient adherence to treatment by providing DOT (see "Directly Observed Treatment in Chapter 2 section 2.3")

13.4.2 When to suspect MDR TB

- Retreatment patients who remain sputum smear positive after three months' of intensive therapy
- Treatment failure and interruption cases
- Close contacts of MDR tuberculosis cases

13.4.3 Diagnosing MDR TB

- MDR TB is only diagnosed by TB culture and susceptibility testing.

13.4.4 Management of MDR TB

- Refer MDR TB patients to an MDR TB unit where experienced clinicians can treat the patient according to the "Guidelines for the Management of Drug-resistant Tuberculosis Patients in South Africa" which are available from the Department of Health. If you are unsure of which facility is designated as an MDR TB unit in your province, contact your Provincial TB Coordinator. (See contact list in Chapter 15)

13.4.4.1 Management of MDR TB should be characterised by :

- rational drug susceptibility testing of specimens from MDR tuberculosis patients
- provision of a social worker for counselling and support
- provision of key nursing staff to provide continuity during the treatment period
- direct observation of treatment throughout the course
- keeping updated registers
- monitoring compliance
- developing measures for rapid recall if patients interrupt their treatment
- increasing education and motivation of patients
- tracing and evaluating contacts rapidly.

13.4.4.2 MDR TB contact management

Contact management for MDR TB should be the same as in contacts of pulmonary TB. There is no evidence to support giving such contacts MDR TB drugs as chemoprophylaxis. Early diagnosis before there is a lung damage and correct treatment is the best way to improve outcomes of those infected with ordinary or MDR TB

CHAPTER 14

GUIDELINES ON TACKLING TB AT WORK

14.1 Introduction

Employers can make a huge difference to employees, to the community at large, and most importantly, to their own businesses, by providing DOTS in the workplace. (See Chapter 2 for the DOTS strategy). Providing TB treatment in the workplace will encourage working people with TB to start treatment early on and stay with it, which will cure them and prevent TB spread. This will encourage others not to hide their TB status but to report early on.

A high proportion of TB patients are able to return to their work within at least two weeks of starting TB treatment. Thus employers need to know how to tackle TB in the workplace. These guidelines will help show employers, supervisors and occupational health workers how to manage TB in their work-places.

14.2 What Does Providing DOTS in the Workplace Mean?

The most important element of the DOTS strategy is the treatment supporter, who observes a TB patient swallowing each dose of TB medication for the entire 6 to 8 months of treatment. Anyone who is dependable and accountable to the health system can be a treatment supporter. Treatment supporters can be health workers, managers, co - workers, peer educators, community members, teachers, shop keepers and family members. A treatment supporter should be chosen by the TB patient in consultation with a health worker.

For people with TB who work, it is often most convenient to receive their TB treatment at the workplace. The increased convenience of receiving TB treatment at work makes it more likely for the person to complete their TB treatment and be cured. Because people who are on correct TB treatment don't infect other employees, providing DOTS in the workplace prevents the spread of TB.

14.3 How will I Know if an Employee has TB?

Employers and employees should be taught the symptoms of TB and should be encouraged to go to a clinic to have their sputum examined if they develop TB symptoms.

The symptoms of TB are:

- cough for more than 3 weeks
- chest pain
- loss of appetite and weight
- night sweats
- tiredness and weakness
- coughing up blood

Education about TB should also include the following:

- TB patients on appropriate treatment are not infectious
- TB patients can continue working and can receive TB treatment from a treatment supporter in the workplace

HIV may be a factor, however:

- TB can be cured as easily in HIV-infected people as in people who are not HIV infected
- HIV increases the risk of developing TB, but not all HIV-infected people have TB and not all people with TB are HIV-infected
- Treating TB gives people who are HIV positive an extra few years of life

Educational materials, such as posters and pamphlets about TB, are available from the Department of Health (see Resources in Chapter 15).

14.4 How is TB Diagnosed?

A person with symptoms of TB should go to a clinic or hospital for examination. The person will cough up material known as sputum, and spit it into a small bottle. The sputum will be examined under a microscope. If TB germs are discovered, the person should be started on TB treatment. Chest x-rays and sputum cultures may also be used for diagnosis of TB.

14.5 What Should I do if my Employee is Diagnosed with TB?

People diagnosed with TB should be given at least two weeks of sick leave to allow them to begin their treatment and make an initial recovery. After two weeks of treatment, the person should be reassessed by a health worker to determine if s/he can return to work. At this time, most TB patients can return to work without putting their co-workers at risk, as long as they take their treatment regularly. TB patients on correct TB treatment will not infect other people.

14.6 How do I Set up DOTS in my Workplace?

DOTS in the workplace should be set up by an employer, manager, or supervisor in consultation with a health worker at the nearest clinic which treats TB. If you are interested in providing DOTS in the workplace, contact the clinic, your local health authority, your Provincial TB Coordinator or the NTCP (see list of Resources in Chapter 15).

If a TB patient chooses a treatment supporter in the workplace, the supporter should work closely with the health worker at the local clinic.

The health worker will do the following:

- explain to the treatment supporter how to give the correct doses of TB drugs, to refer the patient to the clinic if they develop side effects, and to fill in the Patient Treatment Card
- provide monthly supplies of drugs and review the Patient Treatment Card to make sure that treatment is going smoothly
- provide ongoing support to the patient and treatment supporter and follow up all problems and concerns
- trace the patient and ensure appropriate treatment supervision if the patient resigns, goes on leave, or is absent from work for any reason

The treatment supporter will do the following:

- observe the TB patient as s/he swallows the daily dose of medication
- liaise with health worker to ensure an uninterrupted supply of TB drugs
- advise the patient to attend the clinic if side-effects develop, and remind the patient of clinic appointments
- check off the appropriate box on the Patient Treatment Card each time a dose of TB drugs is taken
- support and motivate the patient to complete treatment
- visit the patient or inform the health worker on the second day if the patient did not show up to receive treatment
- inform the health worker if the patient resigns, goes on leave, is absent from work or is unable to receive TB treatment for any reason

The TB patient will do the following:

- swallow each dose of TB medication, report side effects and any other problems promptly to the supporter or health worker and attend the clinic for appointments
- inform the health worker or supporter if resigning, going on leave, absent from work or unable to receive TB treatment for any reason

The employer has the following responsibilities:

- support and encourage DOTS in the workplace
- allow time off for employees to meet with health workers about how to provide DOTS in the workplace
- allow time off for employees to go to clinic
- attempt to provide a private space where a TB patient can receive TB treatment

14.7 What's in it for me?

TB patients who are left untreated may infect many other workers in the company. However, if they get treated according to the DOTS strategy, they will rapidly be uninfectious. You, as an employer, will not lose your valuable, trained employees due to TB, nor will your employees infect others around them. DOTS is therefore a cost-effective, win-win proposition for employers and employees alike. Additionally, your business will get much better performance from healthy workers, and your relationship with your employees will improve. If your workers see that their company cares about them, they in turn will care more about their company, and ultimately be much more productive. Working together, we can stop the spread of TB in South Africa, and reduce the economic toll this disease is taking on the country.

CHAPTER 15

RESOURCES

15.1 National and Provincial Level Contact Numbers

National level

Position	Telephone	Fax
NTCP Manager	(012) 312 0106	(012) 326 4365
TB/HIV Technical Advisor	(012) 312 0124	(012) 326 4365
Patient Centred Care	(012) 312 0100	(012) 326 4365
Workplace Programmes	(012) 312 0100	(012) 326 4365
Advocacy Officer	(012) 312 0113	(012) 326 4365
Training	(012) 312 0101	(012) 326 4365
Laboratory Coordinator	(012) 312 0112	(012) 326 4365
Administration	(012) 312 0107/8/9	(012) 326 4365

Provincial level

Province	Telephone	Fax
Eastern Cape	(082) 491 5484	(040) 635 0072
Free State	(051) 403 3853	(051) 403 3851
Gauteng	(011) 355 3408	(011) 355 3381
Kwazulu-Natal	(033) 395 2596	(033) 342 1714
Mpumalanga	(082) 822 6044	(013) 293 0520
Northern Cape	(053) 830 0600	(053) 833 3814
Northern Province	(0152) 290 9124	(0152) 291 2925
North West	(018) 462 2731	(018) 462 3737
Western Cape	(021)483 2270	(021) 483 2264

Available TB Publications

TB Educational materials are available free of charge from the National Tuberculosis Control Programme (NTCP) in the National Department of Health:

Manual

- TB Practical Guidelines
- TB Training Manual

Posters

- Symptoms of TB: available in Afrikaans, English, Northern Sotho, Southern Sotho, Xhosa and Zulu.
- Patient Centred care helps cure TB with DOTS : available only in English.

Pamphlets

- “Everything you should know about tuberculosis (TB)”: available in Afrikaans, English, Sotho, Tswana, Xhosa and Zulu.

Booklets

- “TB in South Africa - The People’s Plague”- 1997: available in English.
- “Strides and Struggles In TB Control” - 1998: available in English
- “Faces of TB” - 1999: available in English

TB educational materials endorsed by the NTCP which can be bought from other organizations:

Comics

- “Choices about smoking - Your health and TB” - a Soul City publication - purchase from Jacana Education Tel:(011)648 1157.
- “TB can be Cured” - a story of a soccer star who gets TB and is cured - purchase from Solidarity Health Publications, PO Box 260, Eikenhof 1872, Tel:(011) 900 1754.