The tuberculosis epidemic is growing larger and more dangerous each year. If we continue to neglect it, future generations will remember this decade as the time when the TB bacilli were allowed to become resistant to the available drugs, and the disease became incurable.

In 1993 the World Health Organisation (WHO) declared TB a global emergency. It was the first time that such an urgent announcement was made. Alarming information was presented on how TB would continue to spread throughout the world, increasingly in multi-drug resistant forms. It was revealed that a cost effective solution to the TB epidemic was available but not being used.

Ever since, much has been done to fight TB. In South Africa, TB was declared a priority disease in 1996. Commitment was pledged by politicians and health managers to improve the TB services rendered in the country, after the findings of an extensive countrywide review conducted by the Department of Health, the WHO and a team of national and international medical experts. This review indicated that the tuberculosis epidemic may be worse in South Africa than in any other country in the world.

The most effective means of controlling TB known to us is a strategy known as Directly Observed Treatment, Short Course (DOTS). This strategy enables tuberculosis patients to complete their treatment and has four proven strengths when compared to previous TB control strategies in South Africa.

- it prevents multi-drug resistant TB from developing
- it is highly successful in curing TB patients
- it quickly makes TB patients non-infectious, and
- it actually costs less than the TB control strategies previously used

This document aims to assist health workers in the successful control of tuberculosis - to ensure a high smear conversion rate of at least 85% at the end of the intensive phase and ultimately cure at least 85% of all new smear positive cases.

Nurses have always played a key role in TB control and their continued contribution is crucial if tuberculosis is to be controlled.

Training of all health care workers in techniques of communication, casefinding and caseholding of tuberculosis patients is the cornerstone of the National Tuberculosis Control Programme (NTCP).
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CHAPTER 1 - TUBERCULOSIS: A WORLD EMERGENCY

1 THE IMPORTANCE OF TB IN THE WORLD

The World Health Organisation (WHO) declared TB a "Global Emergency" in 1993. It stated that "TB is humanity's greatest killer" because TB kills more adults each year than any other infectious disease, including malaria and all tropical diseases.

One third of the world's population is infected by *Mycobacterium tuberculosis* bacilli, the infectious cause of tuberculosis. Eight million new TB cases develop every year, three million people die every year from TB.

Tuberculosis has been declared a priority health issue by the Minister of Health.

2 REASONS WHY TB HAS BECOME AN EPIDEMIC

The major elements are:

2.1 TB is an Airborne Infectious Disease

*Mycobacterium tuberculosis* bacilli are transmitted by the airborne route. There are very few effective measures that will protect individuals from exposure. The large pool of infectious TB cases leads to a high risk of exposure and thus infection in the general population. An infectious case is someone with TB of the lungs who is coughing up the TB bacilli (smear positive).

Small droplets containing TB bacilli are coughed up by infectious pulmonary TB cases. These droplets remain suspended in the air for prolonged periods, and may be inhaled by those in close contact who may develop the disease.

2.2 HIV Infection

"HIV has put TB on the fast track. That means that HIV has greatly accelerated the progression of TB infection to active TB.

HIV is the most powerful risk factor for TB reactivation. HIV attacks the immune system and makes the individual more vulnerable to TB disease.
2.3 Increase in the Population

There is an increase in the world population and people have a higher life expectancy. That means that there are more people who can become infected and hence present with TB.

2.4 Social and Economic Trends

Poverty in the world has increased. In both urban and rural populations in developing countries there is overcrowding, unemployment and poor nutrition. In addition, wars and natural disasters have contributed to the increase in TB.

Increased mobility, migration and urbanisation have increased the risk of infection by presenting opportunities for contact with infectious, untreated pulmonary tuberculosis (PTB) cases.

Economic recession and political disturbances have caused problems in health and social services. In some cases a breakdown of services has led to interrupted TB treatment with serious consequences.

Poverty and overcrowding have always been closely linked with TB, but any healthy person can become infected.

2.5 Poorly Managed TB Control Programme

Poor implementation of the NTCP leads to incomplete and inappropriate TB treatment. This has resulted in an increase in the infectious pool, and is leading to the development of multi-drug resistant TB (MDR TB) with selection of resistant bacteria.

TB, theoretically curable by relatively simple and inexpensive means, can turn into an expensive and potentially incurable MDR disease, which has only a 50%–60% chance of cure.

MDR TB is due to inappropriate and ineffective chemotherapy with:

- single drug regimes
- wrong combinations of drugs
- interrupted treatment
- single drugs added to failing regimens

3 INCIDENCE AND PREVALENCE OF TB

3.1 Annual Incidence Rate

The number of new TB cases that occur per year in a defined population.

- South Africa

In South Africa the TB epidemic has developed into one of the worst in the world. In 1996 78 000 cases were notified, with 3 000 deaths. However, it is estimated by the Medical Research Council (MRC) that real numbers were more like 150 000 new cases with 10 000 deaths and 2 000 MDR TB cases. This rate is equivalent to 20 new cases of TB every hour in SA, with 80% of cases occurring in the 15-49 year age group, and represents one of the highest rates in the world.
• **Worldwide**

Worldwide the annual incidence rate of tuberculosis in 1995 was 8 million cases, with 3 million deaths. Tuberculosis causes more deaths per year than all the other notifiable infectious diseases put together. TB is the major cause of death in HIV-positive patients. One third of the world’s population is already infected with the TB bacillus. Left untreated, one infectious case of TB will infect 10-15 others in a year.

### 3.2 Prevalence Rate of Disease

The prevalence of tuberculosis disease is the number of **new** and **already existent** TB cases at a point in time in a defined population.

### 3.3 Annual Risk of TB Infection (ARI)

The annual risk of *M. tuberculosis* infection is the probability that an individual will become infected with TB in one year. It reflects the extent of transmission of TB bacilli in a community. The possibility of developing TB disease is greatly influenced by socio-economic and certain disease factors, especially HIV infection.

### 4 HISTORY OF TB

#### 4.1 First Era

This era started centuries before Robert Koch's discovery of the TB bacillus as the cause of tuberculosis.

- Epidemic TB has been in the world for many centuries. Proof of TB has been found in the bodies of 4 000 year old mummies.
- No treatment was available. Many superstitions (Royal touch) surrounded the disease.
- Patients with TB were commonly known as having "Consumption" and were stigmatised and isolated in sanatoria, usually high in the mountains, where it was thought that the mountain air and rest offered some hope of cure.
- Some well known people that died of TB included Mozart, the Bronte sisters, Robert Louis Stevenson, DH Lawrence and George Orwell.

#### 4.2 Second Era

This era started with the identification of the causative organism of TB, *Mycobacterium tuberculosis*, in 1882 by Robert Koch. Tuberculosis, then known as Consumption or Phthisis (to waste), was now linked to a specific organism.
Highlights During the Second Era:

- By using the special staining method known as the Ziehl Neelsen (ZN) method the bacilli retain a red stain and resist decolourisation with acid alcohol. Red rods or acid fast bacilli (AFB) can be seen through the microscope.

- It then became possible to culture acid fast bacilli on special culture media.

- The BCG (Bacillus Calmette & Guerin) vaccine was developed from a modified (attenuated) M. bovis bacillus.

- PPD (Purified Protein Derivative) skin tests were introduced as a means of detecting infection with M. tuberculosis. The substance causes an allergic (cell-mediated) reaction in anyone with present or past TB infection.

- Improved socio-economic conditions in Europe caused a dramatic decrease in the burden of disease.

- Anti-tuberculosis drugs were discovered - streptomycin in 1944, INH and PAS between 1946 and 1952 and rifampicin in 1966. These drugs markedly reduced mortality and decreased the transmission of the disease by curing infectious cases.

Negative Effects of this Era:

Massive case finding efforts led to overloading of health services resulting in poorly monitored and inadequately treated TB cases using mono-therapy and irregular treatment regimes.

The result of this was the development of chronic and MDR TB cases

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REMEMBER
A bad TB Control Programme is worse than no programme at all!

4.3 Third Era

This era started with the advent of HIV/AIDS

HIV-associated TB is a serious problem because the disease flourishes when the body's immunity is impaired.

- Reactivation of dormant TB infection increases

- HIV may increase the chances of developing active disease after new infection with M. tuberculosis.

“TB was put onto the ‘fast track’ by HIV infection!” (Dr D Enarson) (IUATLD)

The WHO predicts a fourfold increase in the number of TB cases by the year 2000.
5 WHAT HAPPENED IN SOUTH AFRICA?

There is evidence that tuberculosis was introduced to South Africa by the European colonisers. It was only after 1800 that the disease became established in South Africa on a significant scale.

Since 1919, TB has been a compulsory notifiable medical condition in South Africa and it was also around this time that TB started to take on serious proportions.

Since then the disease has become the principal public health problem and has become an epidemic.

A number of factors have contributed to the South African TB epidemic

**Climate**

In the late nineteenth century tuberculosis sanatoria were established, based on the belief that fresh air and rest could cure tuberculosis. Places with high altitude and sunny, dry climates were favoured like the Karoo (Beaufort West and Matjiesfontein).

In that time an increasing number of tuberculosis sufferers from Europe travelled to South Africa hoping the climate would cure them. They boosted the pool of infectious cases. Karoo towns populated by these people consequently had the highest TB mortality rates in South Africa.

**Mining Industry**

The discovery of gold and diamonds and the resultant flourishing mining industry in the late 1800s was the great stimulus to the increasing incidence of TB in this country. During this period large numbers of skilled mine workers from England and Europe flocked to the South African mines.

Several of them were already infected with TB. Cecil John Rhodes, the mining magnate, came to South Africa suffering from TB.

Conditions in the mines that favoured the spread of tuberculosis were:

- Overcrowding in the mine compounds.
- Poorly ventilated shafts.
- Poor nutrition.
- Physically demanding work with long working hours
- Predisposition to TB in persons who had silicosis
- Due to the migrant labour system, the disease spread to the miners’ families in rural parts of South Africa and neighbouring countries.
Urbanisation

Urbanisation with housing shortages, economic recessions and droughts with subsequent malnutrition have all contributed to the South African tuberculosis epidemic.

Rapid industrial development has stimulated more urban growth with the development of urban slums.

Deteriorating conditions in "locations" and peri-urban slums led to the 1934 Slums Clearing Act

The population removals which followed were associated with a fall in TB rates in the urban centres. However, this was because TB was simply relocated rather than overcome. TB death rates in the Black population continued to rise steeply in the 1940s.

Anti-TB Drugs

The introduction of anti-TB drugs in the 1950s was followed by a sharp decline in the TB mortality rates, but incidence rates and multi-drug resistant cases continued to increase due to a poor TB Control Programme.

HIV Infection and TB

- The strong association between HIV and TB has already caused an increase in the incidence of TB in South Africa.

- Tuberculosis is the principal opportunistic infection and cause of death in patients with AIDS. The result is a rapid deterioration in the TB situation.

After reading this Chapter - you should know:
- How TB is transmitted.
- The relationships between TB, poverty, urbanisation and HIV.
- The danger of a poorly managed TB control programme.

SELF TEST QUESTIONS

1. Why is TB described as a "Global Emergency"?

2. What important developments took place in the history of TB after the discovery of the *M. tuberculosis* bacillus?
List the FIVE underlying causes of the TB epidemic.

Define incidence rate of disease.

What is meant by prevalence of TB in SA?
CHAPTER 2 - THE BASICS OF THE SOUTH AFRICAN NATIONAL TUBERCULOSIS CONTROL PROGRAMME (NTCP)

1 THE MISSION, AIMS AND GOALS OF THE NTCP

1.1 The Mission

The mission of the NTCP is to reduce the incidence of TB and the suffering it causes among the people of South Africa.

1.2 The Aims

- To cure 85% of all new smear positive TB cases.
- To achieve a smear conversion rate of 85% of new smear positive cases and 80% of retreatment cases at the end of the intensive phase of treatment.
- To contain, then reduce, the rising incidence of tuberculosis expected as a result of the HIV epidemic.
- To prevent TB drug resistance.

1.3 The Goals

- To reduce the infectious pool of TB cases. This pool constitutes the source of new infections and maintains the continuous chain of TB transmission.
- To reduce the number of infected persons, who carry a lifelong risk of developing TB disease.
- To undertake disease surveillance and promote appropriate research in TB. In this way we can measure progress, evaluate the programme, identify communities at increased risk, and explore new modes of intervention.
- To promote community awareness and active participation in the control of TB.
- To obtain political commitment for the provision of the necessary resources to control TB.
- To ensure that all health care workers are appropriately trained and supported.

2 THE KEY ASPECTS OF THE NTCP

2.1 A Programme Manual

“The South African Tuberculosis Control Programme Practical Guidelines” provides basic information on the policy, strategy and treatment regimens and must be distributed to all relevant health services. This training manual should also be used.
2.2 A Standardised Recording and Reporting System

The TB clinic register with accompanying documentation, the quarterly reports and the summary of quarterly reports, provide an effective monitoring system and clear definition of new and retreatment cases and treatment outcomes, as well as cohort analysis of TB patients. (See details in Chapter 14).

2.3 A Standardised Training Programme

The aim of the training programme is to ensure that all the health care workers are appropriately trained and motivated in the management of TB patients.

Training of all health workers in case holding and case finding of tuberculosis patients is an essential part of the NTCP.

Special attention should be given to the drug regimens, implementation of the Directly Observed Therapy Short Course (DOTS) strategy, diagnostic protocols and the recording and reporting system.

2.4 Microscopy Services

An accessible and reliable diagnostic TB smear microscopy service within the public health laboratory system is an essential element of an effective NTCP.

A specific requirement is the rapid communication and dissemination of microscopy results within 48 hours, as far as possible.

2.5 Treatment Services

TB management and control should form an integral part of health services. Vertical single purpose programmes have failed to meet the needs of the population as a whole, and have proved to be wasteful of resources.

The concept of a NTCP implemented on a countrywide scale through a network of existing health services, is advocated by the WHO Expert Committee on TB. TB services should be patient-friendly and clinically efficient.

2.6 A Regular Supply of Anti-TB Drugs

An assured supply of all the essential anti-TB drugs is a critical element in TB control. Supplies are obtained at the most favourable prices by the Department of Health and the Provincial and local authorities. The health worker must ensure a constant supply of drugs at every treatment point.
2.7 A Plan For Management

District Health Services should, with the help of Provincial and National TB Services, provide training and support for health care personnel who manage TB as part of comprehensive primary health care.

Appropriate structures, to ensure optimal management of TB at all levels, would include the following:

- National TB staff including a manager, a person responsible for provincial support, a trainer, an advocacy officer and a financial administrator.
- Provincial and district level co-ordinators responsible for TB control.

2.8 A Provincial Strategic Management Plan

Every province should have a 2-5 year strategic plan against tuberculosis, to implement and manage.

2.9 Indicators to Monitor the NTCP

The main indicators of the success of the programme are:

- A high cure rate - 85% or above.
- A high smear conversion rate at the end of the intensive phase - 80% or more
- Low rate of interruption of treatment - 5% or below.
- Low level of acquired drug resistance - less than 1%.

3 REQUIREMENTS OF A WELL MANAGED NTCP:

- Political commitment.
- Secure and constant supply of the correct TB drugs.
- Reliable microscopy services for TB diagnosis.
- Complete recording and reporting of case findings and treatment outcomes.
- Appropriately trained and motivated health workers.

After reading this Chapter - you should be able to:
- Describe the aims of the NTCP.
- Discuss the key aspects of a successful NTCP.
SELF TEST QUESTION

Name the core elements of a well managed NTCP?
1 CHARACTERISTICS OF TUBERCULOSIS BACILLI

These organisms are also known as tubercle bacilli, because they cause lesions called tubercles, or as acid fast bacilli (AFB) because they resist decolourisation with acid alcohol.

1.1 Morphology

- The mycobacterium bacilli are microscopic, thin rods which occur singly or in clusters. They have complex thick waxy cell walls. The consequences of the cell wall structure is that:
  - It protects the bacilli against the host antibodies
  - Commonly used antibiotics (eg penicillin) cannot penetrate this waxy layer, therefore the need for special anti-TB drugs
  - Special staining methods are needed because with the usual staining methods the stain cannot penetrate the waxy layer.

- The bacilli are resistant to some common disinfectants but are destroyed by pasteurisation and heat.
- The bacilli are resistant to drying and can survive for long periods in dried sputum. Once they dry out they are probably no longer infective.

1.2 Staining

The Ziehl Neelson (ZN) staining method is used:

- Sputum Specimens are sterilised, a smear is made on a glass slide and fixed by heating
- The smear is then covered with a red dye and heated
- The red dye is then washed off and an acid alcohol solution is poured on to decolourise the specimen, mycobacteria do not lose the red colour = acid fast (AFB)
- The slide is then covered with a blue dye to give a blue background against which the thin, red mycobacteria are easily identified.

Fluorochrome staining can be done but it needs a special, expensive, fluorescent microscope. In the stain the bacilli shine bright yellow and are easy to see. This is a cost effective method when large numbers of specimens are to be examined.
1.3 Rate of Growth (Multiplication Rate)

In a tuberculosis lesion there are various populations of TB bacilli:
- active, continuously growing bacilli inside cavities
- intermittently active bacilli inside cells e.g. macrophages
- slow growing, semi-dormant bacilli (persisters) which undergo occasional spurts of metabolism
- dormant bacilli which may become active at any time

1.4 Invasive Properties of TB Bacilli

*M. tuberculosis* bacilli are intracellular pathogens that invade macrophages and are able to escape the macrophages' killing mechanisms.

*M. tuberculosis* bacilli are not limited to an intracellular environment which is an acid pH. As the infection progresses the bacilli kill the macrophages. The result is a collection of dead cells in a cheesy (caseous) lesion. This is alkaline and becomes liquid, providing a rich medium for the extracellular growth of TB bacilli. Since anti-TB drugs are not all effective in both acid and alkaline media, several drugs have to be used together.

1.5 Susceptibility to Direct Sunlight

Mycobacteria are susceptible to, and can be inactivated by, sunlight UV light. This is of particular importance in MDR TB units where UV lights are recommended.

2 FACTORS CAUSING REACTIVATION OF DORMANT TB BACILLI

1 HIV

HIV increases reactivation of previous TB infection by suppressing the immune system.

2 Age:

The immune system is not fully developed in the very young, and becomes less effective in old age.

3 Other Diseases:

- Viral infections, e.g. Measles, HIV
- Diabetes
- Malignancies
- Silicosis
4 Malnutrition:
- Marasmus/Kwashiorkor in children
- Chronic alcohol abuse which is associated with malnutrition
- Poor nutrition in any individual

5 Medications:
- Long term cortisone therapy
- Chemotherapy for malignancies/transplants

6 Stress:
Mental or physical stress can cause suppression of the immune system

SOMETHING TO THINK ABOUT
The bad news is that TB bacilli can remain dormant in tissue and persist for many years. Even today Mycobacterium tuberculosis is poorly understood regarding its ability to enter and multiply successfully within its host cell, the macrophage.

Mycobacteria bacilli multiply very slowly (18-20 hours) compared with streptococci which reproduce in twenty minutes. This is one reason why it takes time to culture the TB bacilli. Reactivation of dormant bacilli causes a 10% lifetime risk of developing active disease after primary infection in non-HIV infected individuals. In HIV-positive patients the risk is 10% per year. (It is not known to what extent HIV-associated disease is reactivation of the dormant bacilli already in the body, or the result of new or re-infection). In populations where individuals were infected many years ago, where the annual risk of infection (ART) is now low, disease is more likely to be due to reactivation. This is the situation in Europe and the USA and other developed countries. In populations in countries with a high current ART (1-2%), the organisms are spreading rapidly and disease is more commonly due to re-infection. This is the situation in developing countries.

3 OTHER MYCOBACTERIA WHICH CAN CAUSE DISEASE IN HUMANS

3.1 M. Bovis
This is a pathogen of animals. Humans can become infected most commonly by drinking milk from infected cows. Pasteurisation of milk prevents the transmission of M. bovis to man.

3.2 Non-Tuberculous Mycobacteria (NTM) [Previously called Mycobacteria other than Tuberculosis (MOTT)]
These organisms are a group of environmental mycobacteria (free living in water and soil) and are usually not pathogenic. They are opportunistic in the sense that they will cause disease in immune compromised patients, as in patients with HIV infection. The NTM bacilli are often resistant to the commonly used anti-TB drugs and are, therefore, more difficult to treat. A NTM is not the same as a drug resistant mycobacterium.

The most common NTM’s are:
- M. avium complex
- M. kansasii
- M. scrofulaceum
NTM are not spread from person to person but environmental factors are important for infection. Sputum TB culture is essential to differentiate them from *M. tuberculosis*. The significance of isolation of a NTM is:

- It can cause lung disease if found on more than one sputum culture and if the clinical picture supports the diagnosis.
- Sputum culture may be contaminated with a NTM (false positive).

**REMEMBER**

NTM infection in most people are non-pathogenic. They are identified on TB culture tests. If the individual is not sick, no treatment is needed. NTM infection in HIV-positive people may cause disease and should be treated by a TB specialist.

**After reading this Chapter - you should know:**
- What the TB bacillus looks like.
- Why it is called acid-fast.
- Its growth rate and various growing populations.
- When it is likely to be reactivated.
- Why it is important to protect BCG vaccines from sunlight.

**SELF TEST QUESTIONS**

1. Describe the characteristics of the TB bacillus.

2. What importance has the cell wall of the TB bacillus and its growth rate on treatment?

3. When would we treat NTM infections?

4. List six factors associated with reactivation of TB.
CHAPTER 4 - HOW TB INFECTION DEVELOPS INTO DISEASE

By the end of this Chapter, you should be able to:
- Describe the steps in the development of tuberculosis from exposure to active disease.
- Explain the outcome of untreated TB.
- Describe primary and post primary disease.

1 THE DEVELOPMENT OF TB

1.1 Steps

1.2 Exposure and Transmission

Transmission of *M. tuberculosis* bacilli occurs by airborne spread of infectious droplets.

The source of bacilli is somebody with smear positive pulmonary tuberculosis disease.

Coughing produces tiny infectious droplets. One cough can produce 3 000 infectious droplets.

Transmission generally occurs indoors, where droplet nuclei can stay suspended in the air for hours to be inhaled by others and cause infection.

Ventilation removes droplet nuclei and direct sunlight inactivates tubercle bacilli but they can survive in a dark cool place for several hours.

1.2.1 Period of Infectiousness

As soon as the patient is put onto the correct treatment, that patient becomes rapidly less infectious, because the bacilli become weakened by the anti-TB drugs. Therapy also reduces coughing. After 14 days on appropriate TB treatment there is little risk of transmitting the TB bacilli.

By the time a patient is diagnosed, contacts have already been infected. Little is gained by isolating the patient at this stage.

Patients with MDR TB are a problem as they do not respond to first line anti-TB drugs and stay infectious for long periods of time. There is a benefit in hospitalising them for some time, to reduce possible spread to contacts.

1.3 Risk of Infection

Several factors determine an individual's risk of infection:

- The number of droplet nuclei in contaminated air
- The length of time of exposure
- The individual's susceptibility to infection

The risk of infection of a susceptible individual is therefore high with close, prolonged, indoor exposure to a person with sputum smear positive pulmonary tuberculosis (PTB). An infected person does not necessarily have the disease.
1.3.1 Progression of Infection to Disease

Once infected with *M. tuberculosis*, a person stays infected for many years but the vast majority (90%) of people without HIV infection who are infected with *M. tuberculosis* do not develop disease. The only evidence of infection may be a positive skin test.

Infected persons can develop disease at any time; 10% will develop disease during their lifetimes. The chance of developing disease is greatest within one year of infection and then steadily lessens as time goes by.

Risk of disease: The factors causing for reactivation of dormant TB bacilli are listed on page 14.

BCG immunisation gives up to 80% protection against the progression of TB infection to disease. The main benefit is the protection against the development of TB meningitis and miliary TB in children.

2 PRIMARY TB DISEASE (See also Chapter 12, TB in Children)

This occurs after first exposure to tubercle bacilli.

The inhaled droplet nuclei are so small that they avoid the mucociliary defence of the bronchi and they lodge in the terminal alveoli of the lungs.

Infection begins with multiplication of tubercle bacilli in the lungs. Lymphatics drain the bacilli to the hilar nodes.

During the 2-8 weeks after primary infection a cell mediated hypersensitivity immune response develops and granulomas form around the TB bacilli.

The changes in the lung and related hilar lymphadenopathy are together known as the primary complex. Bacilli may spread in the blood from the primary complex throughout the body.

Ghon focus = calcified peripheral lung lesion plus calcified hilar nodes following a primary TB infection.

After infection the following may happen:

- In most cases the immune response stops the multiplication and spread of bacilli. A positive tuberculin test would be the only evidence of infection.

- Reactivation of an earlier primary lesion:
  A few dormant bacilli may persist and form metastatic foci in places like the lungs, meninges, kidneys vertebræ, glandular tissue. Years later these foci may become active and cause disease in these sites.

- Progression of a primary lung infection:
  The immune response in a few cases is not strong enough to prevent multiplication of bacilli and primary disease occurs within weeks to months. This is more likely after puberty and looks like adult-type TB.
3 POST PRIMARY TB DISEASE (ADULT TB)

Post primary TB disease occurs after a latent period of months or years after the primary infection. It may occur either by reactivation or reinfection.

**Reactivation** means that dormant bacilli persisting in tissues for months or years after primary infection start to multiply. This may be in response to a trigger, such as weakening of the immune system by:

- Infections (HIV, measles, chronic bronchitis)
- Diseases (diabetes, silicosis, malignancies)
- Malnutrition (kwashiorkor, alcohol abuse)
- Immunosuppressive therapy (chemotherapy, long term cortisone)
- Stress
- Old Age

**Reinfection** means a new infection in a person due to new TB organisms entering the body.

3.1 Features of Post Primary TB Disease

- **Pulmonary TB** with
  - cavities
  - upper lobe infiltrates
  - fibrosis
  - progressive pneumonia.
  - pleural effusion

The characteristic chest X-ray (CXR) features of post primary PTB are cavitation leading to lung destruction and upper lobe involvement.

In late stage HIV infection this classical picture is often modified. Adult TB may look like Primary TB (see Chapter 11 on Extrapulmonary TB).

- **Extrapulmonary TB** (see Chapter 6).
4 NATURAL HISTORY OF UNTREATED TB

After five years without treatment, 50% of pulmonary TB patients will have died; 25% will have recovered and 25% will remain ill with chronic, infectious TB.

After reading this Chapter - you should know:
+ How the inhaled TB bacillus develops into full blown TB disease.
+ The difference between primary and post primary TB.
+ The possible outcomes of untreated TB.

SELF TEST QUESTIONS

1 Name the steps in the development of TB disease.

_________________________________________________________________________
_________________________________________________________________________

2 What are the four possible outcomes after primary TB disease?

_________________________________________________________________________
_________________________________________________________________________

3 Discuss the features of post primary TB disease

_________________________________________________________________________
_________________________________________________________________________
CHAPTER 5 - HOW TO DIAGNOSE PULMONARY TUBERCULOSIS

By the end of this Chapter, you should be able to:
- Describe the symptoms associated with PTB.
- Identify suspected PTB cases from their clinical features.
- Describe why (smear) microscopy is the best way of diagnosing PTB.
- Collect sputum specimens and organise transport.
- Interpret microscopy results.
- Know when you should do a sputum culture.
- Know when chest X-rays are indicated.

The Key to this Chapter:

The highest priority for TB control is the identification and cure of infectious cases, i.e. patients with sputum smear positive TB. Therefore, ALL patients with clinical features suspicious of PTB should have a sputum specimen examined by microscopy. Many TB suspects are not in hospital.

Passive case finding is the best way to identify TB patients. It requires that all health workers must think of TB when a patient presents with symptoms associated with TB. These patients must have sputa examinations to look for TB bacilli.

REMEMBER

In most cases a chest X-ray is not essential, although it may be a useful investigation.

TB culture is not used routinely in the diagnosis of PTB.

The tuberculin skin test is routinely used in the work-up of TB in children but is of little value in the diagnosis of pulmonary tuberculosis (PTB) in adults. A positive tuberculin skin test does not by itself distinguish M. tuberculosis infection from tuberculosis disease.

The tuberculin skin test may be negative even if the patient has TB; i.e. in HIV infection, severe malnutrition and miliary TB.

1 HOW TB PRESENTS, HISTORY, SYMPTOMS AND SIGNS

1.1 Clinical History

In the majority of cases the development of tuberculosis is insidious (slow), and the illness progresses over weeks and months. In a small number of cases the disease may develop rapidly leading to death in a short time.

Because it develops slowly the patient very often ignores the symptoms or accepts them as “overwork” “not enough sleep” or “only a smokers cough”. We should inform communities about TB symptoms so that people can present earlier to health facilities.

It is always important to ask a patient with chest symptoms if there was contact with a person with diagnosed TB or if he/she has had TB in the past.
1.2 Symptoms of Pulmonary TB (PTB)

**Respiratory Symptoms**

- **Cough**
  
  Over 90% of patients with PTB develop a cough soon after the onset of the disease. Initially it can be a dry irritating cough but later it may become productive. A cough is not specific to PTB, it is common in smokers and in patients with acute upper and lower respiratory tract infections. However, most acute respiratory infections resolve within 3 weeks.

- **Chest Pain**
  
  A dull nagging pain in the chest due to infiltration in the lung parenchyma, is common. The sharp pleuritic pain due to pleural involvement is less common.

- **Hemoptysis**
  
  This is a late sign and usually indicates advanced disease. It may be profuse or there may be only specks of blood in the sputum.

- **Dyspnoea**
  
  Dyspnoea (shortness of breath) is usually caused by severe lung fibrosis, lung destruction or a tuberculous bronchopneumonia.

- **Frequent Colds**

- **Wheezing**

**Systemic Symptoms**

- **Fever**
  
  Usually a low grade fever that may be remittent or intermittent.

- **Nightsweats**
  
  Cold clammy type of sweating at night

- **Tiredness (Lethargy)**
  
  This is a common symptom in TB patients.

- **Loss of Weight/Loss of Appetite**
  
  Starts early in the disease and becomes worse as the disease progresses.
1.3 Physical Signs of PTB

A physical examination of the patient must always be done. The physical signs in patients with PTB may be non-specific. They often do not help to distinguish PTB from other chest diseases.

- The patient may be **thin and pale**.
- **Body temperature** may be high, slightly raised or normal.
- The **pulse** is usually rapid.
- **Finger clubbing** is associated with extensive lung damage and superinfection with organisms other than TB. It is found in bronchiectasis, lung cancer, empyema and lung abscess.
- **Chest** - very often there are no abnormal signs (especially in **early TB**). **Crackles** are common, there may be **dullness** to percussion or **bronchial breathing** with a localised **wheeze**. There is often **amphoric breathing** over a large cavity. The **trachea** may be pulled over due to **bronchial stenosing**

2 LABORATORY TESTS

The Laboratory is Important in the Tuberculosis Control Programme.

Positive sputum microscopy identifies those patients who are most infectious with the greatest burden of bacilli. Microscopy in a laboratory is essential for the definitive diagnosis of *Mycobacterium tuberculosis*. **Sputum smear microscopy is the most reliable and cost effective way of diagnosing TB**.

The lung is most commonly affected in tuberculosis. Therefore, sputum is the most common specimen submitted to the laboratory when diagnosing TB.

3 SPUTUM COLLECTION, STORAGE AND TRANSPORT

3.1 Sputum Specimen

- A good specimen of sputum is required.
- Saliva is not useful for diagnostic purposes as it is not a secretion of the lungs.
- Early morning specimens are the best.

**Day 1**
Collect an ‘on the spot specimen’, ie. at the time you see the patient when the patient presents to the health facility.

**Day 2**
The patient should produce a specimen first thing in the morning and bring this to the clinic.
3.2 The Sputum Containers

The containers should be the standard plastic specimen bottles which are rigid to avoid crushing when transported. They should be wide mouthed with a tight fitting screw top, to prevent drying out and leakage.

3.3 How to Collect a Good Specimen Safely

Safety precautions are essential as sputum collection results in coughing droplets containing infective bacilli into the air. Health care workers are at risk of becoming infected if they do not take care as described here.

The specimen should be collected under the supervision of a nurse.

Information for the Patient:

- Explain in detail to the patient what is required from why it is necessary to get a good sputum specimen, and what will be done with it.

- Explain to the patient how to produce a good sputum specimen (not saliva) by taking a deep breath, coughing deeply and expectorating the sputum into the container without spilling.

Information for the Nurse/Supervisor:

- Sputum collection should be done in a well ventilated room or outside in the open air (in privacy if possible).

- The supervisor should stand behind the patient during the collection of sputum.

- Use a sterile container, open the container immediately before collection, give to the patient to spit in and close it directly. Make sure that the lid is securely closed.

- Wash hands after handling the sputum specimen.

3.4 Labelling of Sputum Specimens

Correct labelling is essential and will save money and prevent frustration. Label the container first, very clearly with:

- Name of clinic and contact address, name of patient and telephone number.

- Indicate whether the specimen is the first, follow up or end of treatment specimen.
Write clear instructions regarding what investigations are required, e.g.

- TB microscopy, or
- TB culture if TB culture alone is required, or
- TB culture + susceptibility if susceptibility drug tests are required

Date the specimen correctly.

### 3.5 Storage of Sputum Specimens

Place the sputum bottle in a plastic bag to prevent contamination.

Store sputum specimens in a fridge if transport is not immediate. Do not store in a freezer.

Delayed transport and high temperatures lead to overgrowth of other bacteria and make the laboratory procedures more difficult.

### 3.6 Transport of Sputum Specimens

Transport to the laboratory should be as soon as possible and certainly within a few days.

Transport to the laboratory should be in a cooler bag. High temperatures during transit will kill the bacilli and make TB culture tests impossible.

During transport of specimens they should be protected from contact with direct sunlight as this will inactivate the bacilli.

Explain to the driver of the transport vehicle about the reason for transporting the specimens, thereby ensuring that specimens go direct to the laboratory.

### 3.7 Register of Sputum Specimens Sent to the Laboratory

Keep a register of the specimens being sent off. If possible make the driver sign on reception of the sealed containers. The register of specimens sent off to the laboratory can be used to check which results are still outstanding.

**THE MANAGEMENT OF A SPtUM SPECIMEN IS A VERY IMPORTANT PART OF THE NTCP**
4  WHEN TO DO A SPUTUM EXAMINATION

4.1  Sputum TB Microscopy

TWO specimens are taken on THREE separate occasions during the course of treatment of patients with PTB.

- Pretreatment
  When PTB is first suspected (pretreatment) send 2 specimens on consecutive days for TB microscopy.

- During treatment
  Two sputum samples should be submitted for direct microscopy just before the end of the intensive phase of treatment (2 months for new patients and 3 months for retreatment patients).

- At end of treatment
  Two sputum samples should be sent after the completion of 5 months on treatment in new cases, and after 7 months in retreatment cases. (see flow diagram, at the end of this Chapter).

**SOMETHING TO THINK ABOUT**

A microscopy smear needs about 10 000 bacilli per ml of sputum in order for bacilli to be identified or to read as positive.

Patients who have large numbers of organisms in their sputum and who are the most infectious have positive microscopy results.

A patient may have TB bacilli in the sputum but the microscopy is negative if there are fewer than 10 000 bacilli present.

Smear microscopy cannot differentiate live from dead bacilli. A patient who has started on treatment and becomes non-infectious may still have a positive sputum smear for some time because of the presence of dead bacilli.

The laboratory technician must examine at least two samples from each TB suspect and record the results of each sample in a laboratory TB register.

Although microscopy is the standard procedure in the NTCP, false positive and false negative results may occasionally occur. (see 4.3 and 4.4)

4.2  Sputum Reports

The results of the laboratory reports are subject at times to human and material error.

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 disease severity and patient infectivity.
### 4.3 False Positive Results of Sputum Smear Microscopy

A false positive result means that the sputum result is positive but the patient does not have smear positive PTB. This may arise in the following situations:

- Red staining of scratches on the slide
- Accidental transfer of **AFB**s from a positive slide to a negative one, usually in the laboratory
- Contamination of the slide or smear by environmental mycobacteria (NTM)
- Contamination of the sputum with food particles that are acid fast and stain red
- Administrative errors
- Mix up of specimens at clinic level

### 4.4 False Negative Results of Sputum Smear Microscopy

A false negative result means that the sputum result is negative but the patient really does have sputum smear positive PTB.

**Causes of false negative results of sputum smear microscopy:**

<table>
<thead>
<tr>
<th>TYPE OF PROBLEM</th>
<th>EXAMPLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sputum collection and storage</td>
<td>• patient provides inadequate sample</td>
</tr>
<tr>
<td></td>
<td>• sputum stored too long before smear microscopy, with overgrowth of other organisms</td>
</tr>
<tr>
<td>Sputum processing in laboratory</td>
<td>• faulty sampling from specimen</td>
</tr>
<tr>
<td></td>
<td>• faulty smear preparation and staining</td>
</tr>
<tr>
<td>Sputum smear examination</td>
<td>• inadequate time spent on examining the smear</td>
</tr>
<tr>
<td></td>
<td>• inadequate training of laboratory technician</td>
</tr>
<tr>
<td>Administrative errors</td>
<td>• misidentification of patient</td>
</tr>
<tr>
<td></td>
<td>• incorrect labelling of sample</td>
</tr>
<tr>
<td></td>
<td>• mistakes in documentation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No AFB</th>
<th>per 100 oil immersion fields</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 9 AFB</td>
<td>per 100 oil immersion fields</td>
<td>scanty</td>
</tr>
<tr>
<td>10 - 99 AFB</td>
<td>per 100 oil immersion fields</td>
<td>1+</td>
</tr>
<tr>
<td>1 - 10 AFB</td>
<td>per 1 oil immersion field</td>
<td>2++</td>
</tr>
<tr>
<td>&gt;10 AFB</td>
<td>per 1 oil immersion field</td>
<td>3 +++</td>
</tr>
</tbody>
</table>
### 4.5 What to do when a TB Suspect has Negative TB Microscopy

If the sputum microscopy remains negative the patient may not have TB. You should think of the following possibilities:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Pointers to the correct diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congestive cardiac failure</td>
<td>- dyspnoea (shortness of breath)</td>
</tr>
<tr>
<td></td>
<td>- haemoptysis</td>
</tr>
<tr>
<td></td>
<td>- oedema</td>
</tr>
<tr>
<td></td>
<td>- enlarged tender liver</td>
</tr>
<tr>
<td></td>
<td>- CXR showing enlarged heart and pulmonary oedema</td>
</tr>
<tr>
<td>Asthma</td>
<td>- intermittent chest symptoms</td>
</tr>
<tr>
<td></td>
<td>- expiratory wheezes</td>
</tr>
<tr>
<td></td>
<td>- normal CXR</td>
</tr>
<tr>
<td>Chronic obstructive airway disease</td>
<td>- smoking history</td>
</tr>
<tr>
<td></td>
<td>- dyspnoea</td>
</tr>
<tr>
<td></td>
<td>- generalised wheezes</td>
</tr>
<tr>
<td>Purulent Bronchiectasis</td>
<td>- large amounts of purulent sputum</td>
</tr>
<tr>
<td></td>
<td>- clubbing of fingers</td>
</tr>
<tr>
<td>Bronchial carcinoma</td>
<td>- smoking history</td>
</tr>
<tr>
<td></td>
<td>- clubbing of fingers</td>
</tr>
<tr>
<td></td>
<td>- <em>haemoptysis</em></td>
</tr>
<tr>
<td>Bacterial pneumonia</td>
<td>- acute onset</td>
</tr>
<tr>
<td></td>
<td>- responds to antibiotic</td>
</tr>
<tr>
<td></td>
<td>- bacteria can be identified on microscopy and culture</td>
</tr>
<tr>
<td>Lung abscess</td>
<td>- fluid level seen on chest X-ray</td>
</tr>
<tr>
<td></td>
<td>- large amounts of purulent sputum</td>
</tr>
<tr>
<td></td>
<td>- halitosis</td>
</tr>
<tr>
<td>Pneumocystis carinii</td>
<td>- dyspnoea prominent</td>
</tr>
<tr>
<td></td>
<td>- parasite can be identified on microscopy</td>
</tr>
<tr>
<td></td>
<td>- often HIV-positive</td>
</tr>
</tbody>
</table>

**NOTE**

If a Sputum Smear Result is unexpectedly negative, e.g. in a patient who has symptoms of TB and X-ray features suggestive of TB, the negative result may be incorrect. Repeat the sputum microscopy in this case and ask for TB culture as well.
5 TBCULTURE

TB culture is expensive and should not be done routinely.

- Mycobacteria are slow growing bacilli and need special growth media to grow in. The Bactec method (radiometric method using Middlebrook 7812) gives a result within 2-4 weeks, while the Lowenstein Jensen method gives results within ≥6 weeks.

- Culture is more sensitive than direct microscopy. Only 500 bacilli are needed to get a positive growth.

TB culture testing is done:

- to identify patients suspected of having TB who are smear negative, but may be culture positive (in cases of early disease, HIV-associated disease), and

- so that drug susceptibility tests can be done (only possible on cultured organisms).

You should only ask for culture from:

- patients who remain smear positive at the end of the intensive phase of treatment (2 or 3 months) and at the end of a full course of treatment (failed treatment). They should be asked to bring in a sputum sample on a Monday morning (thereby ensuring that the bacilli are more viable for culture as the patient has not had treatment for 48 hours);

- patients who have had TB treatment in the past and are starting another course (re-treatment cases); and

- patients who have had close contact with a known MDR TB case as these patients are markers for MDR TB.

6 CHEST X-RAYS

Too much reliance on chest X-rays in the diagnosis of PTB results in unnecessary treatment, because the chest X-ray is not a reliable indicator of active PTB disease. An effective NTCP concentrates on sputum positive patients.

No radiographic picture is absolutely typical of tuberculosis. Many diseases mimic TB on chest X-rays and this may lead to incorrect diagnosis of PTB. X-rays may show lung fibrosis or destruction due to previous TB and this may also lead to unnecessary treatment. Where X-ray facilities are available, a chest X-ray may be helpful but it is not essential for diagnosing TB nor for recording improvement.

Cure can only be established by negative sputum smears at the end of a treatment course.
6.1 Indications for Chest X-Ray

When the sputum results are positive:

- Suspected complications, e.g., a breathless patient needing specific treatment, c.g., pneumothorax or pleural effusion.
- Frequent or severe haemoptysis (to exclude malignancy, bronchiectasis)
- To help in diagnosing other lung diseases.
- Only one of the two pretreatment smears is positive. (In this case an abnormal chest X-ray is a necessary additional criterion for the diagnosis of PTB).

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.

Indications for X-ray 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 has not been satisfactory. X-rays should not be done routinely on every case at the end of treatment.

6.2 X-Ray Patterns (see page 32)

<table>
<thead>
<tr>
<th>Classical Pattern</th>
<th>Atypical Pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilateral upper lobe infiltrates</td>
<td>Interstitial infiltrates (especially lower zones)</td>
</tr>
<tr>
<td>Cavitation</td>
<td>No cavitation</td>
</tr>
<tr>
<td>Pulmonary fibrosis and shrinkage</td>
<td>No abnormalities</td>
</tr>
</tbody>
</table>

Remember:
The table above shows the so called “classical” and “atypical” patterns:
- The classical pattern is more common in HIV-negative patients.
- The atypical pattern is more common in the patients who have more advanced HIV-infection (see Chapter 11).
6.3 Differential Diagnosis of Chest X-Ray Findings

X-ray changes are not specific to TB. Here is a short list of other possibilities you should think of when looking at a chest X-ray:

<table>
<thead>
<tr>
<th>Chest X-Ray Finding</th>
<th>Differential Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavitation</td>
<td>Bacterial pneumonia</td>
</tr>
<tr>
<td></td>
<td>Lung abscess</td>
</tr>
<tr>
<td></td>
<td>Fungal infections</td>
</tr>
<tr>
<td></td>
<td>Bronchial carcinoma</td>
</tr>
<tr>
<td>Unilateral infiltrations</td>
<td>Pneumonia bronchial carcinoma</td>
</tr>
<tr>
<td>Bilateral infiltrations</td>
<td>Bronchopneumonia</td>
</tr>
<tr>
<td></td>
<td>Occupational lung disease</td>
</tr>
<tr>
<td></td>
<td>Connective tissue disorders</td>
</tr>
<tr>
<td></td>
<td>Sarcoidosis</td>
</tr>
<tr>
<td></td>
<td>Pulmonary oedema</td>
</tr>
<tr>
<td>Mediastinal Lymphadenopathy</td>
<td>Lymphoma</td>
</tr>
<tr>
<td></td>
<td>Bronchial carcinoma</td>
</tr>
<tr>
<td></td>
<td>Sarcoidosis</td>
</tr>
</tbody>
</table>

6.4 Describing Chest X-Ray Abnormalities in Tuberculosis

Apply a simplified range of terms to the abnormality(ies):

- Is the distribution unilateral or bilateral?
- Is/are the abnormality(ies) in the apex, upper, middle or lower zones?
6.5 Chest X-Ray abnormalities in TB:

Are they diffuse, **many** or nodular (**<5 mm**)?

Is there fibrosis (well marked, scattered or clustered, streaks, lines or bands) which may include calcification (dense white patches, usually small)?

Is there consolidation, lobar or patchy (like pneumonia or broncho-pneumonia)?

Are the shadows pleural (mainly spreading down the outside of the lungfield, or in the costophrenic angle, or obscuring most of the lung field)?

Are there cavities, single or multiple?

Is there extensive lung destruction (little 'normal' looking lung, but large cavities, maybe running together into large spaces) and fibrosis (thick bands in and around the rest)?

Are there single or multiple opacities (rounded large shadows, sometimes called coin shadows or canon balls)?

Is there lung contraction (shown by deviation of the trachea, or by shifting upwards of the hilum, or a general shrinkage of one lung with shift of the mediastinum)?

Is the shadows pleural (mainly spreading down the outside of the lungfield, or in the costophrenic angle, or obscuring most of the lung field)?
PULMONARY TB - NEW ADULT PATIENTS - DIAGNOSIS

NOTE
- Collect sputum (not saliva)
- Store specimen in a cool place in a sealed container
- Label specimen clearly with patient name, TB register number, clinic, hospital, "TB specimen"

DAY 1 - Take sputum for microscopy (AFB)

DAY 2 - Take sputum for microscopy (AFB)
early in the morning if possible

Both smears positive

One smear positive

Both smears negative

Do chest X-ray

Compatible with TB

Normal

Compatible with TB

Normal

Take 2 sputa

1 smear, 1 culture

Smear or culture positive

Smear and culture negative

Reassess diagnosis

TREAT AS NEW PATIENT

FOLLOW-UP

Treatment as for New Adults - Intensive Phase - first 2 months (Regimen 1)

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 report Continuation Phase

Treatment - as for Continuation Phase last 4 months (Regimen 1)

Susceptible

Resistant

Refer to TB medical officer

Continuation phase

5 months - take 2 sputa

Both negative and clinically well

One or both positive

Register as a failure and re-register as a re-treatment patient

Do culture and susceptibility

Susceptible

Resistant

Refer to TB medical officer

6 months - stop treatment and register as cured
PULMONARY TB - RETREATMENT ADULT PATIENTS - DIAGNOSIS

DAY 1 - Take sputum for microscopy (AFB)

DAY 2 - Take 2 sputa early in the morning, 1 smear 'culture and susceptibility

- Both smears positive
- One smear positive
- Both smears negative

- Do chest X-ray

Compatible with TB

- Reassess diagnosis

- Smear or culture positive
- Smear and culture negative

TREAT AS RETREATMENT PATIENT

- Susceptible
- Resistant

Refer to TB Medical Officer

- Both negative
- One or both positive

Do culture and susceptibility and start Continuation phase

- Susceptible
- Refer to TB Medical Officer

Continuation phase

Treatment as for Continuation Phase - last 5 months (Regimen 2)

7 months - take 2 sputa

- Both negative and critically well
- One or both positive

Registered as a failure and refer to TB medical officer

- 2 months - stop treatment and register as cured

NOTE
- collect sputum (not saliva)
- store specimen in a cool place in a sealed container
- label specimen clearly with patient name, TB register number, clinic/hospital
- "TB specimen"

How to Diagnose Pulmonary Tuberculosis
7 TESTS NOT USEFUL IN THE DIAGNOSIS OF TB IN ADULTS

There is no place for “trial of treatment” as a means of diagnosing PTB. If PTB is suspected even with negative sputum smears and culture, the patient should be referred to the TB medical officer for a decision on diagnosis.

In South Africa the tuberculin test (TINE\textregistered\textsuperscript{M} or Mantoux) should not be used for the routine diagnosis of TB in adults.

PCR (polymerase chain reaction) and \textit{ELISA} tests are expensive new tests which are not yet useful for the routine diagnosis of TB.

\begin{itemize}
  \item Patients with TB have had a cough for more than 3 weeks, experienced weight loss and tiredness.
  \item Sputum smear microscopy identifies the infectious cases who are a priority for treatment.
  \item Two good sputum specimens must reach a laboratory as soon as possible after collection and results returned within 48 hours if possible.
  \item TB culture is only used under certain conditions, but not for routine investigation of a new patient.
  \item PTB cannot be diagnosed from CXR. X-rays can be helpful if one or two smears are negative in a patient suspected of having TB.
\end{itemize}

SELF TEST QUESTIONS

1. List three respiratory and three systemic symptoms of PTB.

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

2. How can a good specimen of sputum be collected from a patient without putting the health worker at risk of infection?

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

3. What are the possible causes of negative sputum smears in a patient who has PTB?

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
4 When is a CXR indicated? (a) at the beginning of treatment; and (b) at the end of treatment?

_________________________________________________________________________

_________________________________________________________________________

5 When is a TB culture necessary?

_________________________________________________________________________
## CHAPTER 6 - EXTRAPULMONARY TUBERCULOSIS

By the end of this Chapter, you should be able to:
- Know how to diagnose extrapulmonary TB
- Describe the clinical features of some important forms of extrapulmonary TB.

Patients usually present with systemic features like fever, night sweats, weight loss and local features which reflect the site of the disease.

### 1 AN OVERVIEW OF EXTRAPULMONARY TB

<table>
<thead>
<tr>
<th>Type of Disease</th>
<th>Clinical Features</th>
<th>Diagnosis</th>
<th>Differential Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphadenopathy</td>
<td>Common in cervical nodes, Matted together, May cause chronic sinuses</td>
<td>Aspiration biopsy and histology</td>
<td>PGL (persistent generalised lymphadenopathy) in HIV, Carcinoma, Sarciodosis</td>
</tr>
<tr>
<td>Miliary TB</td>
<td>Sick patient, Fever, Weight loss, Hepatosplenomegaly, Tubercles in the choroid of the eye</td>
<td>Chest X-ray, Pancreatic, Pancytopenia, Bacteriemia in sputum, CSF, Bone marrow or liver biopsy</td>
<td>AIDS, Septicaema, Disseminated carcinoma</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>Chest pain, Breathlessness, Mediastinal shift, Decreased breath sounds, Stony dullness on percussion</td>
<td>Chest X-ray, Aspiration of straw coloured fluid (raised ADA), Pleural biopsy</td>
<td>Malignancy, Post pneumonic effusion, Pulmonary embolism</td>
</tr>
<tr>
<td>Pericardial effusion</td>
<td>Cardiovascular features (see page 42), Pericardial friction rub</td>
<td>Chest X-ray shows a large globular heart, ECG: ST and T wave changes</td>
<td>Cardiomyopathy</td>
</tr>
<tr>
<td>Ascites (due to peritoneal TB and GIT TB)</td>
<td>Weight loss, Abdominal mass, ascites, Fistulae may develop, Diarrhoea</td>
<td>Chest X-ray (to exclude PTB), Ascitic tap, Peritoneal biopsy, Barium X-ray (in suspected malignancy)</td>
<td>Malignancy, Liver disease</td>
</tr>
<tr>
<td>TB meningitis</td>
<td>Irritability, Fever, Weight loss, Headache, Decreasing consciousness, Neck stiffness, Fits</td>
<td>CSF microscopic and chemical examination, NB Prompt: diagnosis vital!</td>
<td>Acute meningitis</td>
</tr>
<tr>
<td>Type of Disease</td>
<td>Clinical Features</td>
<td>Diagnosis</td>
<td>Differential Diagnosis</td>
</tr>
<tr>
<td>----------------</td>
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<td>------------------------</td>
</tr>
<tr>
<td>TB spine</td>
<td>Back pain</td>
<td>X-ray</td>
<td>Secondary malignancy</td>
</tr>
<tr>
<td></td>
<td>Psoas abscess</td>
<td>CT-scan</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spinal cord</td>
<td>biopsy</td>
<td></td>
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<tr>
<td></td>
<td>compression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB bone</td>
<td>Chronic osteomyelitis</td>
<td>X-ray</td>
<td>Malignancy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>biopsy</td>
<td></td>
</tr>
<tr>
<td>Hepatic TB</td>
<td>Hepatomegaly</td>
<td>Ultrasound</td>
<td>amoebic abscess</td>
</tr>
<tr>
<td></td>
<td></td>
<td>biopsy</td>
<td></td>
</tr>
<tr>
<td>Renal TB</td>
<td>Frequency</td>
<td>Sterile</td>
<td>Bilharzia</td>
</tr>
<tr>
<td></td>
<td>Dysuria</td>
<td>pyuria</td>
<td>Carcinoma</td>
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<td></td>
<td>Haematuria</td>
<td>urine</td>
<td>Nephritis</td>
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<tr>
<td></td>
<td>Loin pain</td>
<td>culture</td>
<td></td>
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<tr>
<td></td>
<td>Oedema</td>
<td>for TB</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>IV pyelogram</td>
<td></td>
</tr>
<tr>
<td>Adrenal glands</td>
<td>Hypo-adrenalinism</td>
<td>Ultrasound</td>
<td>Malignancy</td>
</tr>
<tr>
<td></td>
<td>features:</td>
<td>X-ray</td>
<td></td>
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<tr>
<td></td>
<td>Hypotension,</td>
<td>shows</td>
<td></td>
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<tr>
<td></td>
<td>raised urea,</td>
<td>calcifications</td>
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<td></td>
<td>low serum sodium</td>
<td></td>
<td></td>
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<tr>
<td>Upper respiratory tract TB</td>
<td>Hoarseness</td>
<td>Laryngoscopy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pain in ear</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Pain on swallowing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female genital</td>
<td>Infertility</td>
<td>Pelvic</td>
<td>Sexually transmitted</td>
</tr>
<tr>
<td></td>
<td>Pelvic infection</td>
<td>examination</td>
<td>diseases (STD)</td>
</tr>
<tr>
<td></td>
<td>Ectopic pregnancy</td>
<td>X-rays of</td>
<td>Malignancy</td>
</tr>
<tr>
<td>Male genital tract</td>
<td>Epididymitis</td>
<td>Tissue biopsy</td>
<td></td>
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<tr>
<td></td>
<td>local pain</td>
<td>X-ray</td>
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<td></td>
<td></td>
<td>kidney</td>
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<td></td>
<td></td>
<td>urine for</td>
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<td></td>
<td></td>
<td>TB culture</td>
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</tr>
</tbody>
</table>

2 ADDITIONAL FEATURES OF SOME FORMS OF EXTRAPULMONARY TB

2.1 Tuberculous Meningitis

TB Meningitis is a life threatening disease with serious consequences if not treated promptly. The complications of TB meningitis often cause mental retardation and physical handicaps. Patients may lose their ability to lead independent lives.

Routes of spread of TB to the meninges include the following:

- Blood borne
- From rupture of a cerebral tuberculoma into the subarachnoidal space

Clinical Features

- There is a gradual onset and progression of headache and decreased consciousness.
- Examination often reveals neck stiffness and a positive Kernig's sign.
- Cranial nerve palsy results from exudates around the base of the brain.
- Tuberculomas and vascular occlusion may cause focal neurological deficits and seizures
- Obstructive hydrocephalus may develop
- Spinal meningeal involvement as well as the meningitis itself, may cause paraplegia.
Diagnosis

The diagnosis is made from clinical features and cerebrospinal fluid (CSF) examination. In most cases of clinically suspected TB meningitis, lumbar puncture is safe.

Treatment

- Hospitalisation is always indicated initially.
- Intensive phase of treatment with four drugs for TWO months (Regimen 1):
- Continuation phase for SEVEN months
- Cortisone should be added to the treatment regimen and prescribed by a medical officer

Differential Diagnosis

The table below shows the differential diagnosis of TB meningitis, with typical CSF abnormal findings. A normal CSF does not exclude disease in HIV-positive patients.

<table>
<thead>
<tr>
<th>Disease</th>
<th>CSF White cells</th>
<th>Protein</th>
<th>Glucose</th>
<th>Microscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tuberculosis meningitis</strong></td>
<td>Elevated PMN</td>
<td>Increased</td>
<td>Decreased</td>
<td>AFB (in some cases)</td>
</tr>
<tr>
<td></td>
<td>(PMN raised initially)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cryptococcal meningitis</strong></td>
<td>Elevated PMN</td>
<td>Increased</td>
<td>Decreased</td>
<td>Positive India ink staining</td>
</tr>
<tr>
<td><strong>Partially treated bacterial meningitis</strong></td>
<td>Elevated both PMN and L</td>
<td>Increased</td>
<td>Decreased</td>
<td>Bacteria on Gram stain (rarely)</td>
</tr>
<tr>
<td><strong>Viral meningitis</strong></td>
<td>Elevated PMN</td>
<td>Increased</td>
<td>Normal (low in mumps or H.simplic)</td>
<td></td>
</tr>
<tr>
<td><strong>Secondary syphilis</strong></td>
<td>Elevated PMN</td>
<td>Increased</td>
<td>Normal</td>
<td></td>
</tr>
</tbody>
</table>

**RARE CAUSES**

<table>
<thead>
<tr>
<th>Disease</th>
<th>CSF White cells</th>
<th>Protein</th>
<th>Glucose</th>
<th>Microscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Late stage trypanosomiasis</strong></td>
<td>Elevated PMN</td>
<td>Increased</td>
<td>Decreased</td>
<td>Mobile trypanosomes</td>
</tr>
<tr>
<td><strong>Tumour (carcinoma/lymphoma)</strong></td>
<td>Elevated PMN</td>
<td>Increased</td>
<td>Decreased</td>
<td>Cytology shows malignant cells</td>
</tr>
<tr>
<td><strong>Leptospirosis</strong></td>
<td>Elevated PMN</td>
<td>Increased</td>
<td>Decreased</td>
<td>Leptospires</td>
</tr>
<tr>
<td><strong>Amoebic meningitis</strong></td>
<td>Elevated PMN</td>
<td>Increased</td>
<td>Decreased</td>
<td>Amoebae</td>
</tr>
</tbody>
</table>

**NOTE:** TB Culture of CSF is important for diagnosis.

- ≥ greaterthan
- PMN - polymorphonuclear leucocytes
- L - Lymphocytes
- *common differential diagnosis
2.2 Tuberculous Lymphadenopathy

The lymph nodes most commonly involved are the cervical nodes. The usual course of lymph node disease is as follows:

- Firm, discrete nodes + fluctuating nodes, matted together + Skin breakdown + Abscesses
- Chronic sinuses → Heal with scarring

In severe immunocompromised patients, tuberculous lymphadenopathy may resemble acute pyogenic lymphadenitis. Persistent Generalised Lymphadenopathy (PGL) is a feature of HIV infection which develops in 50% of HIV-positive individuals.

Diagnosis

The possibility of TB should always be suspected in cases of lymphadenopathy. The diagnosis can usually be made from other clinical features of TB. If you suspect TB in a patient with enlarged lymph nodes, refer to a doctor who may need to aspirate. All aspirates must be sent for microscopy and culture. This will be positive for AFB in 70% of cases of TB lymph nodes. Routine biopsy for histology is only done if the diagnosis is still in doubt.

Treatment

TWO months intensive phase, FOUR months continuation phase (Regimen 1)

2.3 Miliary Tuberculosis

Miliary TB results from widespread blood borne dissemination of TB bacilli. This is either the consequences of a recent primary infection or the erosion of a tuberculous lesion into a blood vessel.

Clinical Features

The patient presents with systemic features (fever, weight loss etc.). He may have hepatosplenomegaly and tubercles in the choroid of the eyes. Miliary TB is a common cause of terminal illness in HIV-positive patients.

Diagnosis

- Sputum smear microscopy is usually negative
- Chest X-ray shows diffuse, uniformly distributed, small miliary shadows. "Miliary" means "like small millet seeds".
- Fever present for more than 10 days.
- Blood count may show a pancytopenia.
- Liver function tests may be abnormal.
- Confirmation of the diagnosis is sometimes possible from culture of sputum, CSF, bone marrow, or biopsy, i.e., liver, showing typical tubercles on histology.

Treatment

TWO months intensive phase, SEVEN months continuation phase (Regimen 1).
2.4 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.

Diagnosis

Patients usually have systemic and local features.

Microscopy of the aspirates from tuberculous serous effusions rarely shows AFB because the fluid forms as an inflammatory reaction to TB lesions in the serous membrane.

TB culture, even if available, is of no immediate help. A culture result takes six weeks.

The aspirate is usually an exudate, i.e. the protein content is more than 30 g/l.

In populations with a high prevalence of HIV, TB is the commonest cause of an exudative serous effusion.

2.4.1 Tuberculous Pleural Effusion

Typical clinical features are systemic and local:
- chest pain
- breathlessness
- tracheal and mediastinal shift away from the side of the effusion
- decreased chest movement
- stony dullness

Chest X-ray shows unilateral or bilateral, uniform, white opacity, with a concave upper border.

Diagnosis

A pleural aspiration will show that:
- the fluid is an exudate (protein content is >30 g/l);
- it is usually straw coloured occasionally blood stained
- the white cell count is high with predominantly lymphocytes (1000 - 2500 per mm$^3$);
- the Adenosine Deaminase (ADA) is raised > 30 U/L (this is a measure of the lymphocyte count)

If the fluid is bloody, you should exclude carcinoma. If the fluid contains pus, it indicates an empyema.

A closed pleural biopsy can be done by a medical officer with an Abrams needle for histological diagnosis. The yield is about 75% positive for TB. This is the best way to confirm the diagnosis.

Treatment

TWO months intensive phase, FOUR months continuation phase (Regimen 1).
2.4.2 Tuberculous Pericardial Effusion

Diagnosis

The diagnosis usually rests on suggestive clinical features and investigations (ECG, chest X-ray):

Cardiovascular signs and symptoms:
- Chest pains
- Shortness of breath
- Cough
- Dizziness and weakness
- Leg swelling
- Tachycardia
- Low blood pressure
- Raised jugular venous pressure
- Impalpable apex beat, 3rd heart sound
- Pericardial friction rub

Chest X-ray:
- Large globular heart
- Clear lung fields
- Pleural effusion

ECG:
- Tachycardia
- Flattening of ST and T waves
- Low voltage QRS complexes

Treatment

TWO months intensive phase, FOUR months continuation phase (Regimen 1). Corticosteroids can be added. Treatment with steroids and anti-TB drugs without pericardiocentesis (tap), usually results in satisfactory resolution of tuberculous pericardial effusion. In cases of cardiac tamponade the effusion should be aspirated.

A possible outcome of a TB pericardial effusion is the development of constrictive pericarditis. All patients with pericardial effusion should be referred to a specialist centre.

2.4.3 Tuberculous Ascites (TB peritonitis)

Ascites results from peritoneal TB. Routes of spread of TB to the peritoneum include the following:

- From tuberculous mesenteric lymph nodes.
- From intestinal T
- Blood borne

Clinical Features

- Patients present with systemic features, ascites, and abdominal pain
- There may be palpable abdominal masses
- Fistulae may develop between bowel, bladder and abdominal wall
- Bowel obstruction may occur
Investigations
- Always do a diagnostic ascitic tap. The aspirated fluid is straw coloured, turbid or blood stained
- Do a chest X-ray to look for PTB

Diagnosis
TB culture and raised ADA on aspirated fluid. In doubtful cases a peritoneal biopsy can be helpful.

Treatment
TWO months intensive phase, FOUR months continuation phase (Regimen 1)

2.5 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 also 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 the disc between two vertebrae usually becomes involved and as the disease progresses an abscess may form and track down to other sites i.e. psoas abscess.

Clinical Features
- Pain and swelling locally, sometimes an obvious lump or bend of the spine (a gibbus)
- Stiff back
- Reluctance to bend the back
- A child that refuses to walk
- Abscess
- Paralysis or weakness of the lower limbs due to pressure on the spinal cord.

Diagnosis
- X-rays of the spine
- Clinical features
- Blood tests to exclude other pyogenic infections
- Biopsy (if possible) for microscopy and culture

Treatment
TWO months intensive phase, SEVEN months continuation phase (Regimen 1)

A well fitted orthopaedic brace is sometimes needed to immobilising 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.

After reading this Chapter - you should know:
- How to recognise the symptoms of meningitis and how to act upon them.
- How to manage a pleural effusion.
- When you should consider the diagnosis of a pericardial effusion.
SELF TEST QUESTIONS

1. How would you diagnose meningitis?

A patient in your hospital ward suddenly complains of tingling in his feet and weakness of both legs. What diagnosis should you think of and what investigations must be done?
CHAPTER 7 - HOW TO TREAT TUBERCULOSIS

The Key to this Chapter:

The key to controlling the spread of TB in a community is to treat smear positive patients as soon as possible and to cure them at the first attempt as they are the source of the infection.

For treatment to be effective it is crucial that correct drugs are given for the correct period of time and that standardised treatment regimens are used for all cases. This will cure nearly all patients and will prevent the emergence of MDR TB.

1 THE AIMS OF TB TREATMENT

- To cure at least 85% of all sputum smear positive PTB patients, with the least interference to their lives, otherwise they will not continue with their treatment. It is very important that the intensive phase of TB treatment (2 months in new patients) is strictly supervised.
- To prevent death in seriously ill patients.
- To prevent extensive damage to the lungs with the consequent complications of disability.
- To avoid relapse of the disease by treating for the correct duration.
- To prevent the development of resistant tubercle bacilli (acquired resistance) that can then be transmitted to other people and thus increase the difficult problem of MDR TB.
- To protect families and the communities from infection by treating the source of bacilli - the smear positive patients.

2 STANDARDISED TB CASE DEFINITIONS AND TREATMENT CATEGORIES

REMEMBER
- The diagnosis of TB means that a patient has TB.
- A case definition tells us more about the type of TB the patient has. We define TB cases in a standardised way. This means that when we talk about a certain type of TB, we are all talking about the same thing.
- It is important to answer this question before starting treatment.

ON MAKING THE DIAGNOSIS OF TB, YOU MUST ALSO DECIDE ON THE TB CASE DEFINITION!
2.1 Reasons for Having Case Definitions

- to determine the correct treatment regimen (new or retreatment)
- for recording and reporting purposes
- to identify priority cases (sputum smear positive PTB) so we can target resources on priority cases

What determines a case definition?

- result of the sputum smear (smear positive or negative)
- previous TB treatment (new or retreatment)
- the site of TB (pulmonary or extrapulmonary)

NOTE:
Always ask a TB patient if he/she has ever had TB treatment before.

2.2 Case Definitions by Site and Result of Sputum Smear

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 or culture positive and clinically ill

Smear Negative PTB Case

- At least 2 sputum smears negative for AFBs.
- Chest X-ray abnormalities consistent with active TB. In most cases, the patient will have had treatment with a broad spectrum antibiotic with no response.

Extrapulmonary TB

There is clinical and/or histological evidence consistent with active TB

The following are some of the forms of extrapulmonary TB:
- Pleural effusion (the pleura is outside the lung)
- Hilar adenopathy
- Miliary TB (TB is widespread throughout the body and not limited to the lungs)

2.3 Case Definitions by Treatment

New TB Case

Decide whether a patient is a new patient i.e. has never been treated before or has been treated for less than 4 weeks before.
Retreatment TB Case

A retreatment case can be ONE of the following four categories

- Relapse after previous cure (RC). A sputum smear positive PTB who received treatment and was declared cured (sputum became negative) **AND** has now developed sputum smear positive PTB again.

- Relapse after previously completed treatment (RT), **but** no proof of sputum conversion to negative

- Retreatment after treatment failure (RF). A PTB patient who is still sputum smear positive at the end of the treatment period.

- Retreatment after treatment interruption (RI). A TB patient who interrupted the treatment for more than 10 days during the intensive phase of treatment **OR** who interrupted treatment for a total of more than one month during the continuation phase.

3 PRINCIPLES OF TB TREATMENT

Effective anti-TB drug treatment means properly applied Short Course Chemotherapy

- Keep strictly to the correct dose and the duration of treatment
- Cure of the **new** PTB patients depends on taking Regimen 1 for 6 months
- Cure of **treatment** PTB patients depends on taking Regimen 2 for 8 months

**Treat with combination drugs.** Combined tablets are the best as they improve patient compliance.

**Patient must take treatment 5 days a week, Monday to Friday.** No treatment is necessary on Saturday and Sunday. In hospitals, treatment is given for seven days a week. Intermittent therapy (3 times a week), if used, may be given in the continuation phase only.

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

**NOTE**

Sputum negative patients. There will be occasions when clinical and radiological findings make a diagnosis of active pulmonary tuberculosis highly probable although the sputum smears are negative. Sometimes treatment can be withheld until results of culture are known. If not, the decision to give TB treatment must be taken by an experienced clinician, and a full course of TB drugs given as for a new case.

In Summary: Criteria for Starting TB Treatment

- 2 positive sputum smears
- 1 positive sputum smear and an abnormal chest X-ray
- 1 positive sputum smear and one or more positive sputum culture
- 1 positive sputum culture and an abnormal chest X-ray
- Sick patient with 1 positive smear or positive culture.
3.1 Reasons for using Several Anti-TB Drugs

Different Populations of TB Bacilli (see Chapter 3)

In a tuberculous lesion there are various populations of bacilli:

- metabolically active
- intermediately active
- semi dormant bacilli (persisters) which undergo occasional spurts of metabolism
- dormant bacilli which may become active

Different anti-TB drugs act against different populations of bacilli

Bacilli may occur Extracellularly or Intracellularly.

The pH in the intercellular spaces is usually neutral or alkaline, whereas it is acid intracellularly. Some TB drugs act best in an acid environment, others better in a more alkaline pH.

REMEMBER
It is necessary to take anti-TB drug treatment for long periods because it is difficult to kill the semi dormant TB bacilli.

4 THE ESSENTIAL ANTI-TB DRUGS

Isoniazid (INH) (H). Acts in both alkaline and acid media (mainly alkaline) on both intracellular and extracellular bacilli, and predominately on rapid and intermediate growing bacilli, with a limited action on slow growers. Action commences after 24 hours of administration. Isoniazid is bactericidal with a high potency, kills more than 90% of the total population of TB bacilli during the first few days of treatment.

Rifampicin (R). Acts in both alkaline and acid media, on both intracellular and extracellular bacilli, and on all bacterial populations including dormant bacilli. Action commences within one hour of intake. Because it is bactericidal with a high potency, rifampicin is the most effective sterilising anti-TB drug and makes short course chemotherapy possible.

Pyrazinamide (PZA) (Z) Acts only in an acid medium, on intracellular bacilli only (inside macrophages) and mainly on slow growing bacilli. Achieves its sterilising action with 2-3 months. It is bactericidal with a low potency.

Ethambutol (E). Acts in both alkaline and acid media, on all bacterial populations. Minimises the emergence of drug resistance. Ethambutol is bacteriostatic with a low potency.

Streptomycin (S). Acts only in an alkaline medium mainly on extracellular bacilli and on rapidly growing bacilli. Streptomycin is bactericidal with a low potency.

It is clear from the above that various drugs must be used in the correct combination.

Sterilising Action: This means killing all the bacilli. The persisters (dormant bacilli) are the hardest to kill. The aim of killing all the bacilli is to prevent relapse.

SOMETHING TO THINK ABOUT
Preventing Drug Resistance:
Consider a population of TB bacilli never previously exposed to anti-TB drugs. There will be a few naturally occurring drug resistant mutant bacilli. Faced with only 1 or 2 anti-TB drugs or drugs given haphazardly, these drug resistant mutant bacilli will grow and replace the drug sensitive bacilli. This is why multiple drugs must be given on a daily basis.
5  **STANDARDISED TB TREATMENT REGIMENS**

5.1 Reasons for Standardised TB Treatment Regimens:

- To treat patients with regimens with proven effectiveness
- To prevent the development of multi-drug resistance
- To enable all health care workers to manage TB patients with the same regimens
- To ensure continuity and prevent confusion when a patient is transferred to another clinic

**REMEMBER**

The treatment regimens each consist of an intensive and continuation phase, totaling 6 months in new patients, 8 months in retreatment patients.

Treatment should be given 5 days a week and when in hospital, the patient should receive treatment for 7 days a week.

Intermittent therapy, if used, can be given during the continuation phase only.

During the intensive phase of treatment there is a rapid killing of TB bacilli. The patient becomes practically non-infectious within 2 weeks, provided there is no drug resistance. The symptoms improve and the vast majority of patients (80-90%) with sputum smear positive TB become sputum smear negative within 2 months of treatment.

Directly Observed Therapy (DOTS) is essential during the intensive phase of treatment to ensure that the patient takes every single dose. DOTS is also necessary during the continuation phase of treatment when rifampicin is part of the regimen. To retain its high potency against TB, rifampicin has to be protected.

During the continuation phase of treatment fewer drugs are necessary, but they must be taken for a longer period of time to eliminate the remaining TB bacilli.

The weight of the patient, when determining the dosage, refers to patient weight BEFORE treatment for ALL regimens. It should be adjusted accordingly after the intensive phase.

5.2 Regimens for TB Treatment

**NOTE**

Always refer to the treatment regimens as described in the current National TB guidelines. These will be updated regularly.

**Regimen 1: New Adult TB patient (smear or culture positive and extrapulmonary TB)**

A patient who has never been treated before or who has previously been treated for less than 4 weeks. Weights refer to weights before treatment, dosage according to weight. Intensive phase of treatment for 2 months and then continuation phase for 4 months.

Exceptions to duration of treatment for new patients:

Patients with TBM, miliary and bone TB should have 9 months of treatment.

**Regimen 2: Retreatment Adult TB patients**

A patient who has had a previous course of treatment (failure, relapse or previous interruption) intensive phase of treatment for 3 months, then continuation phase for 5 months.
6 SIDE EFFECTS OF THE MAIN ANTI-TB DRUGS AND THEIR MANAGEMENT

6.1 Isoniazid (H)

Adverse effects:
- Peripheral neuropathy (tingling and numbness of the hands and feet).
- Hepatitis, more often in patients older than 35 years (rare).
- Generalised skin rash (occurs rarely).
- Fever.
- Joint pains.

Management:
- Mild itching: continue drug treatment, reassure the patient, give calamine lotion and if necessary antihistamine.
- Fever and generalised skin rash: stop all drugs, give antihistamine.
- Neuropathy: give 1C mg - 25 mg of pyridoxine, daily.
- Drug induced hepatitis: stop anti-TB treatment, do liver function tests. If there is a loss of appetite, jaundice and liver enlargement, do not give treatment for at least 1 week or until the liver functions have returned to normal. In most patients INH can usually be given later without the return of hepatitis. Refer the patient to a doctor before starting anti-TB drugs again.

REMEMBER
A severely ill patient may die without anti-TB drugs. In this case, treat the patient with 2 of the least hepatotoxic drugs, streptomycin and ethambutol. When the hepatitis resolves, restart usual anti-TB treatment.

NOTE
Isoniazid inhibits breakdown of drugs given for epilepsy (phenytoin and carbamazepine). Dosages of these drugs may need to be REDUCED during the treatment period.

6.2 Rifampicin (R)

Adverse effects:
- Gastro-intestinal: nausea, anorexia and mild abdominal pain, diarrhoea occurs less frequently.
- Cutaneous reactions: mild flushing and itchiness of the skin.
- Hepatitis: which is uncommon unless the patient has a history of liver disease or alcoholism.
- Serious side effects like influenza syndrome and shock may occur in patients who take the medicine intermittently instead of daily. Stop the treatment and refer the patient to the TB medical officer.

NOTE
Warn patient that rifampicin colours the urine, sweat and tears pink (urine looks orange-pink).
- Rifampicin stimulates liver enzymes which may then break down other drugs more rapidly than normal, e.g. oral anticoagulants (warfarin), oral diabetics drugs, digoxin, phenobarbitone and other anti-epileptics. Refer the patient to a doctor for adjustment (increased) dosages of these drugs.
- Contraception: The dose of contraceptives should be increased in patients on rifampicin. Depo provera 150 mg should be given 8 weekly instead of 12 weekly. Nu-Isterate 200 mg should be given 6 weekly instead of 8 weekly. Combined oral contraceptives with at least 0.05 mg of ethinyloestradiol should be prescribed. The pill free interval should be shortened from 7 to 4 days. IUCDs may be recommended.

Warn the patient that the effect of rifampicin may last up to 2 months after the treatment is stopped.
6.3 Streptomycin (S)

Adverse effects:

- Cutaneous hypersensitivity, rash and fever.
- Ototoxicity (damage to eighth cranial nerve). Damage to the vestibular (balancing) apparatus is shown by dizziness, sometimes with vomiting. Unsteadiness is more marked in the dark.
- Deafness.
- Anaphylaxis. Streptomycin injection may be followed by tingling around the mouth, nausea and occasionally by sudden collapse. Treat as for any anaphylactic reaction and do not give streptomycin again.
- Deafness in unborn children. Streptomycin should be avoided during pregnancy because it crosses the placenta.
- Do not give to patients with existing renal disease as it will impair renal function more. Older people (>65 years) have reduced renal function and should not be given streptomycin.

Management:

- Skin reactions: treat as for allergic skin reactions.
- Damage to vestibular apparatus: treatment must be stopped immediately,
- Ringing in the ears or loss of hearing: if the drug is stopped immediately, the symptoms will usually clear over weeks, if not, the damage will be permanent.

NOTE
Do not give streptomycin to patients above 65 years, to pregnant women or to young children.

6.4 Ethambutol (E)

Adverse effects:

- Progressive loss of vision caused by retrobulbar neuritis, usually manifests first as loss of colour vision and usually presents after the patient has been on treatment for at least two months. This is usually caused by excessive doses of ethambutol.
  - Skin rash.
  - Joint pains.
  - Peripheral neuropathy.

Management:

- If the patient complains about visual disturbance, stop treatment immediately.
- Skin rashes and joint pains usually respond to symptomatic treatment.

NOTE
Never give ethambutol to children under the age of 8 years who are unable to tell you that they are losing their sight.
When you start the patient on treatment warn him about possible changes in vision. If he notices failing eyesight, he must stop the treatment immediately and report to the clinic.
6.5 Pyrazinamide (PZA)

Adverse effects:

<table>
<thead>
<tr>
<th>SIDE EFFECTS</th>
<th>Drug(s); Probably Responsible</th>
<th>MANAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>anorexia, nausea, abdominal pain</td>
<td>rifampicin</td>
<td>give tablets last thing at night</td>
</tr>
<tr>
<td>joint pains</td>
<td>pyrazinamide</td>
<td>aspirin</td>
</tr>
<tr>
<td>burning sensation in feet</td>
<td>isoniazid</td>
<td>pyridoxine 25 mg daily</td>
</tr>
<tr>
<td>orange urine</td>
<td>rifampicin</td>
<td>reassurance</td>
</tr>
<tr>
<td><strong>Major</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>skin itching (anaphylactic reaction)</td>
<td>streptomycin</td>
<td>stop streptomycin, treat as for hypersensitivity reaction (see page 53)</td>
</tr>
<tr>
<td>deafness (no wax on eardrum)</td>
<td>streptomycin</td>
<td>stop streptomycin</td>
</tr>
<tr>
<td>dizziness (vertigo and nystagmus)</td>
<td>streptomycin</td>
<td>stop streptomycin if severe</td>
</tr>
<tr>
<td>jaundice (other causes excluded)</td>
<td>most anti-TB drugs</td>
<td>stop all anti-TB drugs until jaundice resolves, then re-introduce one by one</td>
</tr>
<tr>
<td>vomiting and confusion (suspected drug-induced pre-icteric hepatitis)</td>
<td>most anti-TB drugs</td>
<td>stop anti-TB drugs, urgent liver function tests</td>
</tr>
<tr>
<td>visual impairment</td>
<td>ethambutol</td>
<td>stop ethambutol</td>
</tr>
<tr>
<td>generalised reaction, including shock and purpura</td>
<td>rifampicin</td>
<td>stop rifampicin</td>
</tr>
</tbody>
</table>
TB TREATMENT: QUESTIONS AND ANSWERS

Q Why use 4 drugs in the intensive (initial) phase?
A Use of less than FOUR drugs runs the risk of selecting out drug resistant mutants. This happens especially in patients with high bacillary loads, e.g. cavitating pulmonary PTB. A 4 drug regimen decreases the risk of drug resistance, treatment failure, and relapse.

Q Why use pyrazinamide in the intensive (initial) phase only?
A Pyrazinamide has its maximum sterilising effect within the first 2 months of treatment. There is little benefit from longer use.

Q How can resistance be prevented?
A The best way is to have a good NTCP, with guidelines on treatment regimens and to ensure directly observed therapy (DOTS). It is also important to use methods of drug administration which will avoid the danger of the use of rifampicin alone. Whenever possible fixed dose combination tablets of anti-TB drugs should be supplied.

Q What are the indications for steroid treatment in TB?
A Steroids may be given, by medical officers only, in addition to anti-TB drugs in the following cases:

- TB meningitis
- TB pericarditis, with effusion or constriction
- TB pleural effusion (when large with severe symptoms)
- Hypoadrenalism due to TB of the adrenal glands
- TB laryngitis with life threatening airway obstruction
- Severe hypersensitivity reactions to anti-TB drugs
- Renal tract TB to prevent ureteric scarring
- Massive lymph node enlargement with pressure effects

The daily dosage will vary according to the site and severity of the TB i.e.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Prednisone treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB meningitis</td>
<td>60 mg daily for 1-4 weeks</td>
</tr>
<tr>
<td>TB pericarditis</td>
<td>60 mg daily for 1-4 weeks</td>
</tr>
<tr>
<td></td>
<td>30 mg daily for 5-8 weeks then decrease over several weeks</td>
</tr>
<tr>
<td>TB pleural effusion</td>
<td>40 mg daily for 1-2 weeks</td>
</tr>
<tr>
<td>TB lymphadenitis</td>
<td>40 mg daily for 1-4 weeks</td>
</tr>
</tbody>
</table>

Hypersensitivity reaction:

In a severe skin reaction (exfoliative dermatitis or toxic epidermal necrolysis) use:

- IV fluids
- IV hydrocortisone (100-200 mg) daily (if unable to swallow)
- Then oral prednisolone 60 mg daily until there is improvement and dose can be reduced and gradually stopped within 1 to 2 weeks
- This should be prescribed by a medical officer only
8 MANAGEMENT OF TB IN PREGNANCY

A patient with tuberculosis should be advised not to become pregnant while she is on TB treatment. Rifampicin stimulates liver enzymes which may breakdown other drugs more rapidly than normal. Those on the contraceptive pill and on rifampicin should take extra precautions against pregnancy (see page 50).

If a pregnant patient presents with tuberculosis, all drugs recommended in the standard regimens are safe, with the exception of streptomycin. Give pyridoxine with isoniazid to avoid the small risk of damaging the infant's nervous system. Daily dose of pyridoxine should NOT exceed 25 mg daily.

TB drugs that should NOT be given, are the following:

- streptomycin (or related drugs capreomycin, kanamycin) or ofloxacin. All these may cause deafness in the infant.
- ethionamide and prothionamide (drugs used for MDR TB should not be given because they can cause abnormalities of development in the foetus).

9 HOSPITAL ADMISSION AND DISCHARGE CRITERIA FOR TB PATIENTS

As a rule, most TB patients can be managed as outpatients at a TB clinic. TB patients who are critically ill and who require continuous supervision by a medical officer and nursing staff should be stabilised at the nearest general hospital unless a TB hospital in the area is able to provide adequate acute medical care.

TB patients should be referred to a hospital (either district or a TB hospital if there is one in the area), when the following applies:

9.1 Hospital Admission Criteria

1 Pulmonary TB patients with positive sputum microscopy and with one or more of the following:

- dyspnoea
- haemoptysis
- fever more than 38°C
- severe emaciation (weight at least 15% less than expected for height)

2 Retreatment Pulmonary TB Patients

All retreatment TB patients should be hospitalised for the duration of the daily streptomycin injections (2 months), unless daily outpatient treatment at a clinic can be arranged.

3 Extrapulmonary TB Patients. This includes:

- TB meningitis
- TB pericarditis
- Miliary TB
- TB spine
- TB peritonitis
4 Multi-drug Resistant TB. MDR patients should be admitted ONLY to hospitals which are able to provide appropriate treatment.

5 Patients with the following associated disease should be considered for admission depending on their clinical condition:

- Cardiac failure and/or cor pulmonale
- Chronic lung sepsis
- Diabetes mellitis
- Epilepsy
- Severe hypertension
- Liver disease
- Psychiatric illness

6 Patients with complications of TB:

- Pneumothorax
- Lung abscess
- Large pleural effusion
- Haemoptysis
- Weakness of the legs

7 Adverse Drug Reactions. The following adverse drug reactions should be referred for medical attention in a hospital:

- hepatitis jaundice
- persistent vomiting
- severe rash

8 Children. Children who have extensive TB:

- miliary
- TB meningitis
- and/or with very large lymph nodes in the neck.
- those not improving on TB treatment

9 Lack of Community Care. Patients for whom a clinic is inaccessible (they live too far from the clinic) with inadequate community support, can be hospitalised. Attempts must first be made to arrange DOTS in the community.

10 Adherence Problems. TB patients who are at risk of adherence (compliance) especially:

- alcohol or drug dependent patients;
- previous treatment interrupters; and
- patients who refuse therapy, can be admitted until the health care team, the patient and the family feel confident that outpatient care and treatment can be monitored. In other patients where supervised treatment cannot be arranged in the community, hospitalisation should be considered at least for the intensive phase.

11 Breast Fed Babies. Breast fed babies of mothers in hospital with TB should be admitted as lodger babies.

12 HIV-infected TB Patients. The decision to admit HIV-infected TB patients should be made in the same way as for any other TB patient.
9.2 Hospital Discharge Criteria

Discharge planning should start within two weeks after the patient has been admitted to a hospital. It should include recruitment of a treatment supporter, health education of the patient, communication with the patient’s chosen outpatient clinic and with his employers via a social worker.

Clinical Criteria. A patient should not routinely be kept in hospital for a specific period of time. Each patient should be assessed individually and should be discharged as soon as the following apply:

- The patient is medically stable
  - no dyspnoea at rest or on exertion
  - shows adequate weight gain
- Afebrile
- No haemoptysis
- Sputum has become negative for AFB (in cases where DOTS cannot be ensured)
- Able to care for himself or if somebody in the family or community will take care of him
- Willing and able to go to a local clinic or a community supporter for treatment.

HIV-infected TB Patients. The decision to discharge a HIV-infected TB patient should be made in the same way as for any other TB patient.

Nutritional Support. No patient should be kept in hospital for nutritional support only. Outpatient nutritional support should be arranged for patients with inadequate access to food at home.

Extrapulmonary TB Patients. These patients should be discharged from hospital when the TB medical officer with the health team have decided that the patient on clinical grounds is fit for discharge.

MDR TB Patients. MDR patients should have THREE negative sputum cultures taken one month apart and be assessed by a MDR specialist prior to discharge.

NOTE

Communication should be established with the relevant TB clinics to inform them about discharges. A discharge form (GW 20/14) should be sent to the relevant clinic unless the patient is taken to the clinic. This will prevent patients being ‘lost’ between hospital and clinic.

10 TREATMENT OUTCOMES

Cured: A patient who is smear negative at, or one month prior to, the completion of treatment and on at least one previous occasion.

Treatment completed: A patient who has completed treatment but in whom smear results are not available on at least two occasions prior to the completion of treatment.

Treatment failure: A patient who has completed 6 months of tuberculosis treatment and who is still sputum smear or culture positive at the end of 6 months (8 months retreatment).

Treatment interrupted: A patient who has not taken TB drugs for 2 months or longer over the 6 month treatment period.

Transferred out: A patient who has moved to another clinic, hospital or district

Not tuberculosis: A patient who has been initially diagnosed as having tuberculosis and who has commenced tuberculosis treatment but was later found not to suffer from tuberculosis.

Died: Indicate if patient died from tuberculosis or from another cause.
SELF TEST QUESTIONS

You are working in a peri-urban TB clinic as a Professional Nurse. A young male patient with PTB presents to you after he interrupted treatment for 2 months. In total he has been on TB treatment for 10 weeks taken irregularly. He had difficulty in attending the clinic as he has to go to school and the clinic is too far away from school, he claims.

Discuss in detail how would you manage this patient under the following headings:

1. What treatment regimen should he be put on and for how long?

2. Should you send away sputum for TB culture and sensitivity? If yes, why?


4. Could the school act as a treatment supporter? Discuss

5. After recommencing TB treatment he complains of mild nausea, itchy skin and red urine. How would you manage these complaints? Which drug(s) could be responsible?
CHAPTER 8 - MULTI-DRUG RESISTANT TUBERCULOSIS (MDR TB)

1 WHAT IS MULTI-DRUG RESISTANT TUBERCULOSIS?

Multi-drug resistant TB (MDR TB) refers to resistance to both INH and rifampicin without resistance to other drugs. It means that these drugs have little or no effect against the TB bacilli causing disease in a patient.

MDR TB is very difficult to cure. The drugs that have to be used are very expensive. Estimations are that in South Africa 2 000 people developed MDR TB in 1996. This translates to, more or less, 1% of new patients and 4% of retreatment cases. The cost of medicine alone for one MDR patient for the duration of treatment (up to 24 months) is nearly R50 000.

It is clear that prevention of MDR TB is of the utmost importance. This can only be achieved if the National Tuberculosis Control Programme is properly implemented.

How Resistance Develops

Natural Resistance; Resistant Mutants. In any population of mycobacteria there will be a small number of bacilli which are naturally resistant. If only one drug is given, or if drugs are taken irregularly, the sensitive bacilli will be destroyed but the resistant bacilli will multiply. This is the reason why monotherapy (single drug therapy) should never be given and why drugs must never be taken irregularly. The advantage of the combination tablets, in the South African regimens, is that multi-drug therapy is given to all patients.

Types of resistance (from history of TB):

- Primary Resistance. This happens when there is NO history of previous treatment for TB. In patients that do not disclose the fact that they have been on treatment before, this will be referred to as Initial Resistance.

- Acquired or Secondary Resistance. This is resistance in patients with a previous history of treatment for TB. This is caused by:
  - incorrect treatment prescribed, e.g. monotherapy
  - when two or more drugs have been prescribed but the patient's bacilli were resistant to them
  - the patient failed to take his drugs properly every day or stopped treatment before the prescribed time

REMEMBER

When a MDR TB patient is diagnosed, active case finding of contacts should be done. If some of these patients are found to be sputum positive, they should then also submit sputum specimens for culture and susceptibility to ensure that they are treated with the correct drugs in case they are MDR TB cases.
2 HOW TO DIAGNOSE MDR TB

Multi-drug resistant TB is diagnosed by susceptibility results on TB cultures. Cultures must be done if the direct smear microscopy is still positive at the end of the intensive phase (2/3 months) of treatment or at the end of the continuation phase of treatment (5 months).

For other patients who do not improve clinically after 2 months on treatment, or if their condition deteriorates even on treatment, a sputum specimen should be sent for culture and susceptibility.

3 PREVENTION OF MDR TB

Start the patient on an adequate initial regimen. This will ensure a high smear conversion rate. The health worker or doctor should be very sure that the patient is not a retreatment case before he is placed on Regimen 1. Single drug regimens should be avoided at all times.

Identify and manage patient non-adherence by the provision of DOTS and other adherence promoting strategies. MDR TB develops when the patient takes treatment irregularly.

The health worker has the responsibility to prevent poor adherence by organising DOTS and by monitoring adherence. Then MDR TB will not happen.

Obtain drug susceptibility tests when indicated. Proper supervision and implementation of the NTCP will lead to early detection of MDR TB patients.

Sputum should be sent for TB culture and susceptibility (as explained under 2 above).

These procedures must be emphasised at all training sessions and monitored during supervisory visits.

Modify the regimen according to the results of the susceptibility tests. Expensive tests are useless if the patient is not then referred to a competent clinician to manage the MDR TB patient at a MDR TB unit. There the importance of supervised therapy is even greater than before. Patients should be hospitalised. Under no circumstances should the patient be allowed to carry on spreading MDR TB bacilli.

SOMETHING TO THINK ABOUT

The MDR TB patients should be indicated as such in the register so that cross references can be made with subsequent MDR TB cases being entered in the register. It is necessary to keep track of the spread of multi-drug resistance in a specific district.

NOTE

• No patient should ever be placed on a trial therapy or on monotherapy.

• The main message that should be conveyed to health workers, treatment supporters and patients alike is that MDR TB can be prevented if there is strict adherence to the treatment regimen. The message should also be conveyed that TB can become incurable if there is non-adherence and that everyone who comes into contact with this patient will be at risk for MDR TB.
4 PRINCIPLES OF THERAPY FOR MDR TB

- If the laboratory reports resistance to INH and rifampicin (or more anti-TB drugs), the patient must be referred to a MDR TB unit where he/she can be treated by clinicians experienced in managing MDR TB patients.

- Treatment of patients with MDR TB is very expensive (at least twenty times more than usual TB treatment), and has to be continued for a long period of time (12-18 months or more). The chances of cure are at best only 50%.

- Counselling of patients is important to offer emotional support, to educate about prevention of spread and to ensure that patients are given the best chance of cure.

- Patients whose treatment has failed after a first course of anti-TB treatment should be put onto the retreatment regimen for 8 months. This includes patients with resistance to a single drug.

- There are two acceptable approaches to the selection of treatment regimen in MDR TB patients. Approach 1 involves a standard treatment regimen irrespective of susceptibility results. Approach 2 involves a tailor-made regimen for each patient based on susceptibility results.

- Irrespective of the approach used, patients should receive 5 drugs during a 4 month intensive phase followed by 3 drugs during a continuation phase of between 12 and 18 months.

- Patients with MDR TB are best treated in hospital, at least until 3 consecutive monthly sputa are culture negative.

Drugs used in the treatment of MDR TB are chosen from the following list below. They are ranked from a higher profile of efficacy to lower. These drugs must be used for MDR TB only. They offer no benefit in treating patients with organisms sensitive to drugs of the standard regimens. In many instances they are less effective and more toxic. They should only be prescribed by medical officers.

- Aminoglycosides; Streptomycin, Kanamycin or Amikacin
- Thiomides, i.e Ethionamide
- Pyrazinamide
- Ofloxacin
- Ethambutol
- Cycloserine or Terizadone
- PAS acid

After reading this Chapter - you should know:
- How resistance develops and how to prevent MDR TB.
- The importance of susceptibility and culture tests and when to use them.
- What to do when you have diagnosed a MDR TB patient.
SELF TEST QUESTIONS

A newly diagnosed TB patient has positive sputum at the end of the intensive phase. He runs his own undertaking business and travels all over the country. Susceptibility tests show that he is resistant to INH and RMP. After intensive questioning he admits to having had TB before.

Two years ago he received treatment for PTB at a local clinic but admits to taking his medication irregularly due to his business activities.

Explain fully how you would manage this patient, with regard to:

1. His business.

2. Treatment regimen

3. Cause of his MDR TB and type of resistance

4. How would you ensure that he takes his treatment for 18 months?

5. Family contacts.
CHAPTER 9 - DIRECTLY OBSERVED TREATMENT SHORT COURSE (DOTS)

By the end of this Chapter, you should be able to:
- Describe what DOTS is.
- Know why DOTS is important in controlling TB.
- Determine who can be a treatment supporter.

1 WHAT IS DOTS?

DOTS is the name (Directly Observed Treatment Short Course) for a comprehensive strategy which primary health services around the world are using to detect and cure TB patients.

It means that someone supports the patient by actually observing that the pills are taken on a daily (or 3 times a week) basis. DOTS is the best way to help patients take all their treatment.

It depends on FOUR elements:

D DIRECTLY: The first priority of the NTCP must be to direct resources towards detecting sick, infectious TB cases, so they can be cured.

O OBSERVED: Patients must be observed swallowing each dose of their medicines by a health care worker or a trained volunteer (treatment supporter). They must be monitored throughout their treatment to ensure cure.

T TREATMENT: TB patients must be provided with correct TREATMENT.

S SHORT COURSE: The correct combination and dosage of anti-TB medicines - known as short course - must be used for the right length of time.

Governments must support the DOTS strategy if they want to control TB.

Why is DOTS Important?

DOTS is a solution to the poor-adherence problem with the low cure and treatment completion rates.

By using DOTS a high sputum conversion and cure rate can be achieved. This is the aim of the NTCP.

2 REASONS TO USE DOTS:

1 It cures the patient.

No other TB control strategy has consistently demonstrated such high cure rates. The cure rates can be as high as 95% even in poor countries with few resources. Without DOTS the cure rates are very low - 40% and lower.
2 It prevents new infections.

DOTS stops the TB bacilli at the source by curing the infectious patient. If not cured, a patient can infect on average 10 - 15 family members, friends and co-workers each year.

3 It prevents MDR TB

The uninterrupted treatment observed through DOTS is the best way of preventing TB bacilli develop resistance. MDR TB is caused by taking anti-TB drugs irregularly.

In the past this happened frequently. Coughing and other symptoms improve after treatment for a few weeks, which can result in patients discontinuing their treatment or in taking it irregularly, one of the main causes of MDR TB.

4 It is cost effective.

Community based DOTS is cheaper than the cost of hospitalising patients for all or some of their course of treatment.

In 1998 the cost of medicine for the standardised treatment regimens in our country is estimated to be as follows:

- Regimen 1 for New Patients (6 months)...................... R 300
- Regimen 2 for Retreatment Patients (8 months).......... R 589
- Standard regimen for MDR TB (24 months)............. R 46 400

It is clear that MDR TB should be prevented at all cost. The only known effective way is through DOTS.

5 It is community based.

DOTS does not require expensive hospitalisation nor technology and a new health structure. The TB control programme can be easily integrated in an existing primary health care system.

6 It extends the lives of AIDS patients by making it easier for them to be cured.

By treating and curing TB in HIV-positive patients, many years can be added to their lives.

7 It protects the workforce.

DOTS with supporters in the workplace means that TB patients can continue working.

Nearly 80% of TB patients are in their most productive years of life. Without the DOTS strategy to cure patients the TB epidemic will continue to burden the workforce. Previously self-sustaining families will be reduced to beggars or welfare recipients.

8 It stimulates economies.

The DOTS strategy assists the economies of developing countries by allowing patients to continue working with a DOTS supporter. Studies in India and Thailand have shown that a small investment in the DOTS strategy can save their economies billions in US dollars. In South Africa we can save many millions by using DOTS.
9 It is effective.

DOTS strategy was pioneered 16 years ago. It has been successfully implemented under various conditions in Tanzania, China, Bangladesh, New York City and Peru. Currently nearly 70 countries worldwide have implemented DOTS with good results. In 1996 approximately ONE MILLION TB patients were treated with DOTS support.

DOTS makes it the responsibility of the health system and the community as well as the patient, to ensure that treatment is taken regularly and that treatment is completed. Community involvement in TB will be discussed in the next chapter.

3 QUESTION AND ANSWERS ABOUT DOTS

We suggest this section could be used in training sessions to discuss DOTS issues.

Q Does DOTS prevent people from getting TB?
A DOTS is effective because it is also a preventive strategy. Curing infective patients is the best way of preventing the spread of TB. General and specific measures have a role in prevention, but DOTS, which helps to cure patients, is the most cost effective of them all.

Q Why do we need to observe treatment?
A The problem is that TB treatment must be taken for a long time, at least 6 months. Few people on their own manage to take all their medicines for the correct period of time. DOTS is necessary to ensure that treatment is not interrupted or stopped prematurely. Patients feel better, forget to take or simply stop their medicine. They might move to other places and lose interest in taking their treatment. Other factors may contribute to the problem, e.g.:
- getting a new job, or changing jobs
- alcohol abuse
- patients cannot afford the cost of reaching health facilities
- health facilities far from the patient

It is in the interest of the whole community to ensure that an infectious TB patient is cured.

By the DOTS strategy we are supporting patients to take the correct treatment for the correct period of time. It also helps the health worker to monitor patients’ progress and ensure cure.

Q How is DOTS implemented?
A DOTS is administered by health workers, employers, volunteers, concerned community members, family members, teachers, church members, or traditional leaders. TB patients visit their treatment supporter or local clinic daily from Monday to Friday (or 3 times per week if the intermittent regimen is used) to take their medicine.

When the patient is too sick to visit a supporter or if they live in a remote place with no reliable supporter available, or when he has to receive injections, the patient will probably have to be hospitalised for treatment.
Q How do we introduce the patient to observed therapy?

A The responsibility of the health worker does not end with the prescription of the correct regimen of treatment. The success of the DOTS strategy also depends on a patient taking treatment exactly as prescribed. During the initial consultation the health worker and the patient should make a complete analysis of the situation and possible problems that can influence adherence to treatment.

The whole process of DOTS has to be explained carefully to the patient so that he/she gains insight into, and becomes an active partner in treatment and cure.

The patient and the health worker will then decide whether the patient will receive treatment at the clinic or whether a community-based treatment supporter will be needed.

The health worker (usually a nurse) should take time and ensure that the patient understands:

- how the disease is spread
- that TB is curable
- that MDR TB may develop if treatment is not taken correctly
- must avoid the temptation to stop treatment

Q Who observes treatment and who can be a treatment supporter?

A A health worker can be a supporter, but there are many other possible supporters:

- a relative or family member who lives with the patient
- a neighbour or friend who lives near the patient
- a teacher at school if the patient is a scholar or teacher
- an employer or somebody at the workplace designated to be the treatment supporter
- a member or employee of a NGO or community based organisation (CBO)
- a traditional healer that is trusted by the patient
- a private medical practitioner

Q What is expected of the treatment supporter?

A The nurse responsible for the patient must explain to the supporter exactly what is required. This is best done by visiting the supporter at home or work, or the supporter may be able to visit the clinic. During this session an agreement should be reached that:

- the treatment supporter will accept the responsibility for DOTS
- the patient will cooperate fully
- the nurse will be there as backup and support for both the treatment supporter and the patient

This means that:

- the TB medicine will be supplied to the treatment supporter or to the patient by the nurse
- the supporter will meet the patient from Monday to Friday for DOTS
- the supporter will sign the card each time the patient has taken the medicine
- the supporter will immediately contact the nurse if the patient has serious side effects, if the patient is non-adherent or if the patient’s condition deteriorates
Q How can we prevent patients from stopping their treatment?

A Always be kind and friendly. Do not be in a rush to explain the disease to the patient, bearing in mind local beliefs about tuberculosis.

The nurse should equip both the patient and the treatment supporter with core knowledge about the disease, the treatment and especially the signs and symptoms of suspected TB, so that other people in the family and in the community can be referred to the clinic if necessary.

CORE INFORMATION THAT THE PATIENT WILL NEED:

- TB is an infectious disease.
- Early symptoms and signs of TB.
- It is curable if treatment is taken for 6 months in a new patient, 8 months in a retreatment case.
- If treatment is interrupted for more than 4 weeks it will have to be restarted all over again, this time treatment will be 8 months including 2 months of injections.
- A TB patient is unlikely to infect others once on treatment.
- Patients should avoid smoking tobacco or dagga or drinking alcohol while on treatment.
- If the patient is moving to another area, the nurse should be informed.
- The green card is the passport to TB treatment at any local authority or provincial clinic anywhere in the country.
- Patients must practice good hygiene by covering their nose and mouth with tissues or toilet paper when coughing or sneezing. (This can be disposed of in a flush toilet or pit latrine or can be burnt.) They must never spit into the air.

Inform the patient about possible side effects of the drugs and what to do if they should have any.

What the TB pills look like and how many and how often they must be taken. Always check on left-over pills at follow-up visits. This will assist the health worker/nurse in knowing if the patient has taken the treatment regularly. If the nurse has little time to spend with patients, she can get a kind and knowledgeable health worker to assist her.

Q Is it important for health workers to spend time organising DOTS?

A Few things have such a significant impact on health in the community as DOTS. Without DOTS the cure rate of TB is less than 50%, with DOTS it can be as high as 85%. This means time and money spent wisely. A trained treatment supporter can also take over from the nurse and thus decrease her workload (see Chapter 10).
Q Is DOTS also implemented in hospital?

A Observed treatment also applies to hospital treatment. No patient will be cured if the medicine is left in the locker, hidden under the pillow or discarded in the toilet or dustbin.

The nurse handing out the medicine should ensure that the pills are swallowed. A good way of ensuring that this happens, is to get the patient to talk.

Q If patients attend a clinic for DOTS, how can a clinic nurse or health worker identify patients that did not attend the clinic for treatment that day?

A Have two drawers or boxes for the clinic cards, one in-box and one out-box. The cards of the patients that have received their treatment will be signed and placed in the out-box. The ones remaining in the in-box each day are the patients that have not attended.

In a small clinic a hand written list of names attached to calendar days can be used. The patients that have attended the clinic can then be ticked off on the list.

This system can also be applied to sputum collection, treatment collection days for treatment supporters etc.

Q Can private practitioners supervise a TB patient's treatment?

A Yes, but the practitioner should:

- adhere to the prescribed standard regimen and the DOTS strategy
- obtain the drugs (free of charge) from the clinic and then supply them free of charge to the patient
- supply relevant particulars on each patient to the district TB centre
- keep the patient's TB record open to audit by the relevant TB coordinator
- adhere to the practice of sputum tests at the end of the initial phase of treatment and at completion of treatment, or refer the patient to the clinic for sputum monitoring

SELF TEST QUESTIONS

1 What would you tell a TB patient that wants to go to his GP for treatment?

__________________________________________________________________________

__________________________________________________________________________

2 Why is DOTS the best way of giving treatment to a TB patient?

__________________________________________________________________________

__________________________________________________________________________
CHAPTER 10 - COMMUNITY INVOLVEMENT IN TB CONTROL

The cooperation of many role players, acting together in the interests of the tuberculosis patients is essential for a successful NTCP.

National and Provincial health departments have adopted the primary health care approach which promotes community involvement at all levels of health care. Involvement includes that of non-government organisations (NGOs), community-based organisations (CBOs), business and employer sectors, cured tuberculosis patients, any interest groups, as well as other government departments.

Management and control of tuberculosis must be a shared responsibility.

1 COMMUNITY BASED DOTS

DOTS is the tuberculosis management strategy that brings treatment closer to patients. It makes it easier for patients to access treatment without travelling long distances and waiting long hours. This is achieved when treatment points (clinics and health centres) are close to communities and when community-based supporters are appointed to help patients.

2 TREATMENT SUPPORTERS

DOTS should be available at many points within a community, including at homes, in the neighbourhood, at workplaces, shops, churches, NGOs, businesses, as well as health facilities.

Supporters can be family members, neighbours, priests, traditional healers, shopkeepers, friends, employers, colleagues at work, health workers, or in fact any person who is motivated to help a patient with tuberculosis to complete his treatment and who knows how to do this.

2.1 Characteristics of a Supporter

A supporter needs:

- an interest in and concern for the health and welfare of his/her community
- to be responsible, compassionate and caring to patients with tuberculosis
- to live in the district that he/she serves
- to be accepted and respected by the patients to be supported and the community
- to maintain confidentiality on patients' details
2.2 Patients’ Introduction to DOTS

The first meeting of a patient with a supporter is very important. It occurs at a time when the patient is sick, sensitive, possibly confused and frightened and needs information and encouragement. Health workers and supporters must spend time with patients in order to:

- establish trusting and caring relationships
- arrange convenient times for treatment
- inform, educate, support and encourage patients that tuberculosis is curable, that cure needs good treatment adherence and that the supporter is there to help

2.3 Role and Duties of Treatment Supporters Regarding DOTS

Each treatment supporter must:

- look after the patient’s drugs carefully, storing them in a safe place
- observe the patient actually swallowing the tablets on a daily basis (or three times a week if the intermittent regimen is used)
- continue until the patient has had a full course: for new patients - 6 months, for retreatment patients - 8 months
- record every time the tablets are taken by ticking the appropriate square in the patient tuberculosis (green) card (GW 29:15)
- provide constant support and encouragement for the patient
- refer any problems to the health worker responsible
- remind the patient about sputum tests at 2 and 5-6 months (new patients) or 3 and 8 months (retreatment patients)
- if possible, visit the patient at home if he/she misses any treatment, and tell the health worker responsible that the patient has missed treatment
- educate the community in general about tuberculosis and its treatment
- discuss local beliefs about tuberculosis and encourage people to attend health facilities
- identify any people with suspected tuberculosis and refer them to a health facility
2.4 Role and Duties of Health Workers Regarding DOTS

For each patient referred to a community based supporter, the health workers should:

- discuss a treatment supporter who is acceptable and accessible to the patient
- visit or communicate with that supporter to explain the supporter’s role and to explain basic facts about tuberculosis and the treatment
- explain exactly how to give the drugs and how to observe the patient swallowing the tablets with water and to make sure they have been swallowed by then asking the patient to talk
- explain that the patient should be referred to the health facility if there are any problems
- explain how to tick the patient treatment (green) card every time the tablets are taken
- provide regular supplies of drugs to the supporter
- provide ongoing support and advice to patient and supporter both at regular visits and at other visits
- trace any patient who has missed visits to the supporter or to the health facility
- organise change in treatment support or transfer, if the patient leaves the area or work, temporarily or permanently.

2.5 What is Expected of Tuberculosis Patients

- swallow each dose of TB medication and complete the full course of treatment
- report side effects and any other problems to the treatment supporter or health worker
- attend the clinic for appointments and provide sputum specimens at 2 and 5-6 months (new patients), 3 and 7-8 months (retreatment patients)
- inform health workers or treatment supporters if going on leave, leaving work, or unable to receive TB treatment for any reason

3 THE WORKPLACE - SPECIAL CONSIDERATIONS

Employers can play a big part in patient care and support by organising or facilitating DOTS in the workplace.

They need to be informed and educated, as any other community member, about the disease and the treatment and especially about the need that the patient has to remain employed if he/she is fit to work.

DOTS in the workplace can be done by an employer, manager or supervisor or by a colleague with the help of a health worker from the health facility responsible for the patient.

Role of the employers:

Employers have a special role in:

- support and facilitation of DOTS at work
- allowing time off for employee supporters to meet health workers to discuss their role as supporters
- allow time off for employee patients to visit the health facility for regular checks
- if possible, providing a private space where the patient can receive treatment from the work supporter
- understanding that employees with tuberculosis should be helped and encouraged as much as possible, and not be dismissed.
The involvement of employers in this system is beneficial because they will not lose valuable, experienced and trained employees. These employees will not infect other employees. If employees are healthy, business will flourish and the relationship between employees and employers will improve. If workers see that the company cares about their health and welfare, they in turn will care more about the company and ultimately be much more productive.

If employers are interested in providing DOTS in their respective companies, they can contact their local clinic or health authorities, their District or Provincial TB Coordinators.

However, if an employee is suspected of having TB, he/she should be allowed to take leave in order to be diagnosed and treated. Once patients have taken treatment for at least TWO weeks, they are unlikely to be infectious. Medical doctors or health workers can then assess them to see if they are fit to return to work. At this time, most patients can return to work without putting their co-workers at risk, as long as they take their treatment regularly. They can continue to work as any other employee.

4 COMMUNITY INVOLVEMENT MODEL

This is an idea of how health workers can set up ways of involving communities in helping TB patients. Community involvement models are often simple and flexible in order to accommodate various styles of management and situations. The model below can be adapted to suit local settings and it encourages creative thinking and a problem solving approach in the implementation of the DOTS strategy. This is a basic model that can be used by health workers and managers when involving community based organisations, non governmental organisations and the business sectors. The community involvement model has four phases:

- community entry
- planning and needs assessment
- implementation
- evaluation

4.1 Phase One

Community Entry and Establishing a Community TB Committee

It is the duty of the District TB Coordinators to enter into an agreement with the local health authorities before involving community members. Authorities will include the hospital health centre, staff, community health forums or health committees. Members of the health authority should be informed about TB and the DOTS strategy.

The District Coordinator should know the district and its boundaries, the population, different organisations operating in the district and the infrastructure and resources.

A meeting should be set up with all stakeholders including representatives of different community based organisations, non governmental organisations, health forums, political structures, chiefs, and other key people in the area. The meeting will help in establishing trust and friendship between health services and the communities.

The main aim of the meeting is to gain entrance into the community. Those attending the meeting should be briefed on the TB problem and the DOTS strategy. The District TB Coordinator should request collaboration and cooperation from the representatives of different organisations. Community members should be invited to a Workshop to establish a community based TB working committee whose responsibility should be directed at coordinating all DOTS activities in the community.
The workshop should be conducted democratically with the District TB Coordinator as facilitator. Committee members could consist of a community member, a health care provider, a CBO representative, an NGO representative, TB patients and others, depending on the needs of the community. The District Coordinator, community members and the TB working committee should decide how useful and effective this group has been.

4.2 Phase Two

Planning and Needs Assessment

The TB working committee and other stakeholders should develop a working plan for identification and prioritisation of needs. These may be recruiting treatment supporters, training, their training and motivation and the involvement of NGOs. Solutions for every problem need to be identified. For example, if there is a need for financial resources, contacting potential donors may be one of the solutions.

Management of problems should be structured as goals and objectives. For example, if training is a goal, specific objectives may be identification of trainees, training manuals, trainers, venue etc. These objectives will help in achieving the goal.

Targets should be set for each specific objective to be carried out. Each activity should have its own time frame and responsibilities must be allocated to individuals according to their abilities and available resources.

The TB working committee should take responsibility for the work plan which deals with:

- coordination and monitoring and supervision of the supporter DOTS system
- community information and education about tuberculosis
- feedback to health workers about the District TB Control Programme

4.3 Phase Three

Implementation

The community TB committee should keep the district community informed about activities. Seeking community opinion and advice will bring about a sense of ownership and a sustainable TB Control Programme at district level.

Treatment supporters should be identified, trained and start providing DOTS both in the communities and at work. Supporters, health workers, employees, NGOs must work together.

Provision of DOTS at community level need to be monitored constantly by the District Coordinator so that adherence is good and cure rates reach 85%. Monitoring also helps to identify problems so that solutions can be found.
4.4 Phase Four

Evaluation

An evaluation process should be conducted to measure achievements of community involvement. Methods include asking patients, supporters, employers, health workers, community groups, individuals and organisations about their knowledge of tuberculosis and the control programme, problems experienced or observed, and constraints in achieving the objectives of patient cure.

After reading this Chapter, you should be able to:

- Explain the responsibilities of treatment supporters, health workers, employers and patients.
- Set up the process of community involvement.

SELF TEST QUESTIONS

1 List the ways you would implement DOTS in the workplace?

2 Discuss the four phases of the community involvement model?
1 ASSOCIATION OF TB AND HIV

In 1997 it was estimated that one third of 30 million people infected with HIV worldwide were co-infected with TB. HIV destroys the immune system so that TB infection already present, flares up as TB disease. TB is an AIDS defining illness. The presence of TB causes HIV infection to develop more rapidly into full-blown AIDS.

Risk of TB in HIV-Infected Compared with Non HIV-Infected Persons

A person who is infected with TB (with a positive skin test for TB) but not with HIV, has a 10% lifetime risk of developing TB disease.

A person infected with TB (positive skin test for TB), who is also infected with HIV, has a 10% risk every year of developing TB disease. If, for example, that person has 5 years of co-infection, he or she has about a 50% risk of developing TB ($5 \times 10\%$).

2 PATTERNS OF HIV-RELATED TB

In early HIV infection, TB disease is similar to that in persons without HIV.

Later, as the HIV infection progresses, the CD4 lymphocyte count (a measure of a working immune system) drops and the TB presents differently. The table below shows the stages of TB.

<table>
<thead>
<tr>
<th>Features of PTB</th>
<th>Early HIV Infection</th>
<th>Late HIV Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical picture</td>
<td>Often resembles post primary PTB</td>
<td>Often resembles primary PTB</td>
</tr>
<tr>
<td>Sputum smear results</td>
<td>Often positive</td>
<td>Often negative</td>
</tr>
<tr>
<td>Chest X-ray</td>
<td>Often cavities and/or infiltrations Often upper lobe</td>
<td>Often infiltrates with no cavities. Pleural or pericardial effusion without mediastinal glands, may affect any part of the lung</td>
</tr>
<tr>
<td>Tuberculin test (children)</td>
<td>Often positive</td>
<td>Often negative</td>
</tr>
</tbody>
</table>

REMEMBER
Disseminated (miliary) and extrapulmonary TB are more common in HIV-infected persons, but pulmonary TB is still the most common presentation overall.
3 HOW TO DIAGNOSE PULMONARY TB IN AN HIV-INFECTED PERSON

Any patient with a history suggestive of TB and symptoms and signs of TB (as discussed in Chapter 5) should be investigated for TB, irrespective of whether they are HIV-positive or not.

The cornerstone of diagnosis remains sputum microscopy. In the later stage of HIV infection, the smear may be negative. If TB is suspected in a smear negative patient, do a TB culture. An X-ray may be useful to confirm TB. If there is still no confirmation of TB, refer to a TB medical officer for assessment.

4 HOW TO RECOGNISE OTHER HIV-RELATED PULMONARY DISEASES

Several diseases in HIV-positive patients may present with cough, fever and sometimes X-ray signs. If the patient has had a cough for 3 weeks or longer you MUST send sputum for AFB. Three other common pulmonary diseases are:

- Acute Bacterial Pneumonia

  Acute bacterial pneumonia is common in HIV-positive patients. Pneumonia usually has an acute onset with a shorter history than PTB. The most common causative organism in adults is *Streptococcus pneumonia* which can be treated with a broad spectrum antibiotic such as penicillin/amoxicillin or cotrimoxazole.

- Kaposi's Sarcoma

  Kaposi's Sarcoma usually presents with purple nodules on the skin and mucous membranes. The X-ray may show a nodular or diffuse infiltrate.

- Pneumocystis Carinii Pneumonia (PCP)

  The patient usually presents with a dry cough and severe dyspnoea with a high respiratory rate (whereas TB presents with a purulent, productive cough). The X-ray features are often normal or show a bilateral diffuse interstitial shadowing. TB and PCP often occur together.

  The definitive diagnosis of PCP depends on finding microscopic cysts in the sputum. These investigations are not always available at local clinics. The diagnosis should then rest on clinical and X-ray features and exclusion of TB. The condition progresses rapidly and can be fatal, so it is best to start treatment on clinical features as soon as possible. A medical doctor should assess the patient and start on high dose cotrimoxazole, i.e. 4 single strength tablets 6 hourly for 2 weeks if PCP is clinically suspected.
The common forms of extrapulmonary TB associated with HIV are the following:

- lymphadenopathy
- pleural effusions
- pericardial disease
- TB meningitis
- miliary TB
- abdominal TB (including liver TB)

**Persistent Generalised Lymphadenopathy (PGL)**

PGL is a feature of HIV infection which develops in up to 50% of HIV-infected persons. There is no specific treatment. The diagnostic criteria for PGL are lymph nodes larger than:

- 1 cm diameter;
- in 2 or more extra inguinal sites; and
- for 3 or more months duration.

The nodes are non-tender, symmetrical and often involve the posterior cervical nodes. PGL may slowly regress during the course of HIV infection and may disappear before the onset of AIDS. To make a diagnosis a patient with lymphadenopathy must be referred to a doctor for aspiration and possibly biopsy (see page 40).

**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 more common in HIV-positive patients.

Approach to diagnosing TB from a serous aspirate (see page 41).
6 CLINICAL CLUES OF HIV INFECTION IN TB PATIENTS

Certain clinical features are more common in HIV-positive patients than in HIV-negative patients. The table below gives an indication when you should suspect HIV infection in TB patients.

<table>
<thead>
<tr>
<th>Past History</th>
<th>Symptoms</th>
<th>Signs</th>
</tr>
</thead>
<tbody>
<tr>
<td>- sexually transmitted disease (STD) t with HIV</td>
<td>- weight loss (10 kg or 20% of original weight)</td>
<td>- generalised lymphadenopathy</td>
</tr>
<tr>
<td>- herpes zoster (shingles)</td>
<td>- diarrhoea (1 month or more)</td>
<td>- oral candidiasis</td>
</tr>
<tr>
<td>- burning sensation of feet (nonspecific)</td>
<td>- night sweats</td>
<td>- oral hairy leukoplakia</td>
</tr>
<tr>
<td>- persistent painful genital ulceration</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

The link between HIV and TB is becoming more and more well known to members of the public. It may be in the interest of all TB patients to offer counselling and voluntary HIV testing for the following reasons:

- The patient may want to know his HIV status
- Better diagnosis and management of HIV-related illnesses
- Management of any drug reactions
- Increased condom use and decreased HIV transmission

Confidential counselling is essential before and after HIV testing. Trained counsellors should be available to all those that are being tested.

7 HIV INFECTION IN CHILDREN WITH TB

HIV infection in children may show in many ways. The clinical signs are often non-specific and the diagnosis of HIV in young children is often very difficult.

**REMEMBER**
Parents often provide the only clues to possible infection with HIV in children. Sometimes parents will tell you when they are HIV-positive.
The list below shows some suspicious clinical signs associated with HIV infection in children:

- weight loss or abnormally slow growth
- chronic diarrhoea (1 month or more)
- prolonged fever (1 month)
- generalised lymph node enlargement
- oropharyngeal candidiasis
- recurrent common infections, e.g. ear/throat
- persistent cough
- generalised rash
- neurological problems
- delay in development
- bilateral parotid gland enlargement
- enlarged spleen
- enlarged liver
- recurrent abscesses
- meningitis
- recurrent herpes simplex

NOTE
In children under 18 months, the diagnosis of HIV infection rests on clinical features in the baby and a positive HIV test in the mother. Circulating antibodies from the mother may still be present in the baby and hence the HIV test on the baby’s blood will be unreliable.

8 TREATMENT OF TB IN HIV-POSITIVE PATIENTS

Anti-TB drug treatment is the same for HIV-positive and HIV-negative TB patients.

- **The same drugs are used for the same duration.**

  - Thiacetazone should not be used in a HIV-positive patient as it may cause severe skin reactions that may be potentially fatal.

  - Take extra care when administering streptomycin injections to prevent possible needlestick injuries and cross infection.

  - New patients are treated with Regimen 1

  - Reactivation or re-infection is treated with the retreatment Regimen 2

The recurrence of TB in HIV-positive cases after completion of treatment is higher than in HIV-negative cases. The reasons for this are:

- true relapse - reactivation of persistent bacilli not killed by the anti-TB drugs

- re-infection - due to re-exposure to a NEW source of infection

Non-tuberculous Mycobacteria (NTM) are usually non-pathogenic but in HIV-positive patients may cause disease and should be treated. They can only be identified on culture tests. A HIV-positive patient with NTM on culture should be referred to a specialist (see page 15).
9 **FREQUENT SIDE EFFECTS OF ANTI-TB DRUGS**

TB-HIV co-infected patients have more frequent side effects to anti-TB drugs. Skin rash is the most common reaction and is often accompanied by fever. Mucous membrane involvement is common. This may be caused by rifampicin or streptomycin.

Gastro-intestinal disturbances and hepatitis may require change in treatment. There may be an increased risk of rifampicin-associated anaphylactic shock and thrombocytopenia.

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**SELF TEST QUESTIONS**

A young man of 28 years who is HIV-positive presents to the TB clinic with a 2 month history of cough and weight loss. Two sputum samples were taken, both negative for acid fast bacilli.

1 What would your next step be in trying to make a diagnosis of TB?

2 What else may this patient have?

3 If a decision is made that this patient has TB (based on clinical and X-ray evidence), what TB treatment should he get?

4 What will you do if he remains sputum positive after 2 months and keeps on losing weight?
1 HOW TB INFECTION AND DISEASE DEVELOP IN CHILDREN

- In healthy, asymptomatic children infected with TB the only evidence of infection may be a positive tuberculin skin test. These children do not have TB disease. Abnormalities may be seen on chest X-ray (The Ghon focus is a calcified lesion usually situated at the outer edge of the lung).

- The vast majority of children infected with *M. tuberculosis* do not develop TB disease.

- As in adults, the child inhales infected droplet nuclei from a person with sputum positive pulmonary TB. The bacilli are carried through the air passages to just under the surface of the lung where they remain and multiply. Some bacilli are carried to the lymph nodes.

- The body's defence system causes a reaction both in the lungs and in the lymph nodes. This is called the Primary Complex.

<table>
<thead>
<tr>
<th>Primary Tuberculosis Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB disease in children is usually primary and occurs under certain conditions.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post Primary TB Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>The TB bacilli can lie dormant for years, but they can be reactivated at any time causing post primary TB disease, usually in adults.</td>
</tr>
</tbody>
</table>

1.2 Risk of Progression of TB Infection to Primary TB Disease in Children Depends on:

- **The Age when a Child is Infected**

  The younger the child, the greater the risk of spread of the TB bacilli to other parts of the body. Children under the age of two years are especially at risk of developing serious TB disease.

  The incidence of miliary TB, TB meningitis, TB of the spine and TB of the lymph nodes is the highest in children younger than five years.

- **HIV Infection**

  A child with HIV infection, as with adults, is more prone to develop TB disease.
• Nutritional Status

Poorly nourished children are at greatest risk of developing severe PTB with cavitation in the lungs (like adult TB) and miliary TB (disseminated TB) as their immune systems do not function very well.

Severe worm infestation can cause malnutrition and likewise lower the body's immune defence.

• Other infections particularly measles and whooping cough in children

• **How recent the infection**

A child recently infected is at greater risk of TB disease.

• **BCG immunisation**

BCG is a weak vaccine that does not prevent TB disease totally. It protects children to a large extent from developing TBM and miliary TB.

### 1.3 Outcome of Primary Infection

**Asymptomatic**

In a healthy individual the body's defence (immune system) stops the TB bacilli from multiplying to cause disease.

The immune system of a young child is less developed than that of an adult, but it is usually able to prevent the spread of disease within the lung itself, causing less cavitation. These bacilli usually become dormant.

Asymptomatic disease does not require treatment. If disease develops, as listed below, treatment is required.

**Miliary TB or TB Meningitis**

Less than 1% of children infected with TB develop miliary TB or TB meningitis, the two main causes of death from TB in children, but the incidence is much higher in children under the age of two. Chemoprophylaxis is particularly important in very young children who are in close contact with an adult smear positive PTB (see Chapter 13 for details on chemoprophylaxis).

**Pulmonary Disease**

This usually presents with enlarged hilar and mediastinal glands or pleural effusion in children. Cavitation (post primary disease) occurs rarely, and only if immunity is poor.

**TB Spine and other extra-pulmonary forms**

Also occur in children (see later in this Chapter)
2 TRANSMISSION OF TB TO CHILDREN

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

TB in children usually represent between 5-15% of all TB cases. The frequency of children with TB in a given population depends on the following:

- The number of infectious cases in the population (pool of infection)
- the intensity of transmission, e.g. the extent or length of exposure to infectious droplet nuclei
- The age structure of the population, e.g. the proportion of children under five in the population

Children rarely have sputum smear positive TB, so they are rarely infectious. TB in children is due to failure to control pulmonary TB in adults.

3 AN APPROACH TO DIAGNOSIS OF PTB IN CHILDREN

It is easy to over diagnose TB in children but it is also easy to miss it. We need to assess carefully all the evidence before making the diagnosis. Bacteriological confirmation of TB in children is usually not possible. Under the age of ten years, children with PTB rarely cough up sputum. They usually swallow their sputum. Gastric aspiration and laryngeal swabs are sometimes used to identify swallowed organisms in the diagnosis of PTB in children.

The diagnosis of TB in children revolves around:

- the clinical features
- tuberculin skin test
- chest X-ray
- history of contact with a sputum positive PTB case

3.1 Clinical Symptoms and Signs of TB in Children

In children the symptoms and signs of TB are non specific, so careful history taking and physical examination are very important.
General 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 is the most common symptom. An audible wheeze which does not respond to bronchodilators is suggestive of airway compression, which is the result of enlarged intra-thoracic glands.

- TB should be suspected in children with 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

- Steady high fever

- Rapid pulse

- Vomiting and diarrhoea

- Cyanosis (blueness of the lips)

Specific symptoms and signs vary according to the site of infection (See also Chapter 6)

- TB Meningitis (TBM)

Tuberculosis meningitis affects the brain and central nervous system. It causes fever, irritability - usually of long standing, headaches, vomiting, stiffness of the neck, increasing drowsiness. Diagnosis can be confirmed by a lumbar puncture.

- Miliary TB

TB disease is widespread in the lungs, various organs, bones and brain.
• **Pulmonary TB**

Children do not always have dramatic symptoms. They may complain of chest pain, there may be a persistent cough or a wheeze for two weeks or longer not responding to treatment.

There may be evidence of a pleural effusion and hilar glands with a broadened mediastinum on chest X-ray.

• **TB Bones**

TB can present in the spine, hips, knees and other bones. This will present with swelling of the joints, unwillingness to walk or delayed walking, a limp when walking, unwillingness to bend the spine, and weakness in an arm or leg.

• **TB Lymph Glands**

Painless swelling of the lymph nodes usually in the neck.

• **TB Abdomen**

The abdomen is less commonly affected but there may be abdominal swelling due to TB peritonitis with ascites or enlarged abdominal lymph glands.

3.2 Detection and Diagnostic Tools (including Skin testing and X-Ray)

**Tuberculin Skin Test**

The basis of the tuberculin skin test is the injection into the skin of PPD (purified protein derivative). This is an extract of tuberculin material.

**Principles of Tuberculin skin testing**

- It measures the body’s reaction to tuberculin protein.
- It is a useful indicator of infection in young children,
- It is easy to perform and interpret (TINE or MONO test are PPD impregnated tools and Mantoux is an intradermal injection).

**Methods of the Tuberculin skin test**

- **Mantoux Test**

  Inject a known amount of PPD between the 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 Test**

  The instruments 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.
What does a POSITIVE Tuberculin Skin Test mean?

A positive test indicates infection with TB, but not necessarily TB disease.

In a young child a strongly positive skin test would indicate recent (6 weeks or more) infection. This 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.

A positive reaction occurs after previous BCG immunisation and should remain positive for several years thereafter. This reaction is usually a weaker reaction than the reaction to natural infection with *M. tuberculosis* unless there is recent new infection with TB.

A positive reaction is only one piece of evidence in favour of the diagnosis.

Positive results of skin test:

<table>
<thead>
<tr>
<th>Tuberculin Test</th>
<th>Previous BCG</th>
<th>No previous BCG</th>
<th>HIV+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mantoux</td>
<td>≥ 15 mm or more</td>
<td>≥ 10 mm or more</td>
<td>4 mm or more</td>
</tr>
<tr>
<td><strong>Mantoux/Mantoux</strong></td>
<td>8 mm or more</td>
<td>4 mm or more</td>
<td>uncertain</td>
</tr>
<tr>
<td>TINE test</td>
<td>blistering and confluent swelling</td>
<td>ring of induration</td>
<td>uncertain</td>
</tr>
</tbody>
</table>

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 typical of TB and the skin test is negative, TB can be diagnosed.

**Conditions which may suppress the tuberculin skin test** (give a false negative result)

- HIV infection and other severe viral infections, i.e. measles
- Malnutrition
- Immunosuppressivedrugs, e.g. steroids and patients on cancer treatment
- Severe disseminated TB
Chest Radiography (X-ray)

X-rays are expensive and usually only available in hospitals. Changes on X-rays are often non-specific. It is undesirable to diagnose TB from X-rays alone. Many diseases can look like TB on X-ray.

The most common X-ray signs in children with TB 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-ray can be helpful but results depend on the quality of the X-ray and the expertise of the doctor who reads it. X-ray changes are non-specific.

Family History

A family member with smear positive TB and living in the same household as a young child, increases the likelihood of the child being infected.

4 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.
- 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 (see Chapter 11)

Differential Diagnosis of PTB in HIV-Infected Children

- Bacterial pneumonia
- Pneumocystis carinii pneumonia
- Viral pneumonia
- Pulmonary lymphoma
- Fungal lung disease

REMEMBER

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.
5 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 (adapted from the WHO book HIV/TB† for the diagnosis of childhood TB.

**SCORE SHEET FOR TB IN CHILDREN (A score of 7 or more indicates a high likelihood of TB)**

<table>
<thead>
<tr>
<th>Feature</th>
<th>C</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GENERAL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weeks of illness</td>
<td>&lt; 2</td>
<td>2-4</td>
<td>&gt; 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nutrition (% weight for age)</td>
<td>&gt; 60%</td>
<td>60-80%</td>
<td>&lt; 60%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family history of TB</td>
<td>None</td>
<td>reported by family</td>
<td>proved sputum positive</td>
<td>positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuberculin test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malnutrition</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexplained fever and night sweats</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LOCAL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal mass or swelling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CNS signs, Abnormal CSF</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angle deformity of spine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Name of Child:..................
Date:................................. Completed by:.................................

(≥ = more than; ≤ = less than.)
How to apply the 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.

<table>
<thead>
<tr>
<th>FEATURE</th>
<th>SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family history of TB</td>
<td>2</td>
</tr>
<tr>
<td>Tuberculin Test</td>
<td>2</td>
</tr>
<tr>
<td>Unexplained fever, no response to treatment</td>
<td>2</td>
</tr>
<tr>
<td>Lymph nodes</td>
<td>3</td>
</tr>
<tr>
<td>TOTAL</td>
<td>8</td>
</tr>
</tbody>
</table>

*Any score of 7 or more is suggestive of TB.*

6 PREVENTION OF TB IN CHILDREN

- BCG vaccination
- Chemoprophylaxis of child contacts of infectious adults
- Full immunisation programme (measles and whooping cough predispose to TB)
- A good NTCP

See Chapter 13 on Prevention of TB

7 SOME FURTHER ISSUES IN CHILDHOOD TB

7.1 Children Who Should be Hospitalised

Any child with the following diagnosis:

- TB meningitis
- Miliary TB
- Airway obstruction with an audible wheeze
- Extensive lung disease with cavities
- TB pericarditis
- A severely malnourished child

The duration of hospitalisation will depend on the response to treatment

7.2 Response to TB Treatment

- The child gains weight and the TB symptoms disappear.
- Fever can take two weeks or more to subside.
- A child who is on treatment but does not improve may have some other disease and should be reassessed.
- X-ray changes, especially hilar and mediastinal adenopathy, may remain unchanged for 18 months, or longer, despite a satisfactory response to treatment.

7.3 A Baby Born to a Mother with Active PTB

- The baby should have treatment for THREE months starting immediately after birth with INH and rifampicin (see TB Guidelines for dosage)
- BCG immunisation should be done three days after the TB treatment is completed.

7.4 A Child with TB Cervical Adenitis (Swollen Glands in the Neck)

- Even if the neck glands are hard and matted together children should be treated for six months and no more.
- It might be advisable to add steroid therapy for a few weeks to prevent ulceration and obstruction of the airways.
- Hilar adenopathy can take 2 years to disappear. A six month course of anti-TB treatment is sufficient.

After reading this Chapter, you should know:

- How TB disease develops in a child.
- Why TB control in adults will decrease the number of TB cases in childhood.
- How TB is diagnosed in children.
- How HIV can affect the diagnosis of TB in children.
- The symptoms and signs associated with:
  - Pulmonary TB
  - TB meningitis
SELF TEST QUESTIONS

1. Why was the score system for the diagnosis of TB in children developed?

2. List conditions which make the tuberculin skin test negative in children.

3. When would you hospitalise a child with TB?

A young mother presents to the local clinic with an eight month old crying baby. She complains that the baby has been crying for the last two days, has been reluctant to breast feed and often vomited after feeding.

- What other information would you ask for if you suspect TB meningitis?

- What will you look for when examining this baby? How would you confirm the diagnosis of TBM?
CHAPTER 13 - PREVENTION OF TB, THE HEALTH CARE SETTING AND PROTECTION OF HEALTH WORKERS

1 GENERAL PREVENTIVE MEASURES

TB is caused by organisms that spread from people with smear positive disease. Therefore, the most important way to prevent it is to stop the spread by curing all smear positive patients (or at least 85% of them).

We also know that TB spreads more easily in communities where there is overcrowding and malnutrition. These are associated with poverty. The declining incidence of TB in Europe over the last 100 years, was due to improvement in socio economic circumstances (jobs, better housing, more education, access to good food). So it is important that health workers join hands with communities to campaign for improvement in living conditions. In addition there must be a good NTCP to reduce the TB incidence.

Measles, whooping cough and other common debilitating diseases predispose to TB, especially in children. Cigarette smoking, high alcohol intake, uncontrolled diabetes, leukaemia, silicosis are important associated factors in adults. All of these factors (including HIV infection) undermine immunity, so that the TB organism can flourish. General health promotion and good general preventive health programmes are essential, e.g. immunisation and good patient care.

2 BCG IMMUNISATION

BCG stands for Bacillus Calmette-Guerin. BCG is made from M. bovis which has lost its virulence after many years of growth in the laboratory. It is a live vaccine. BCG stimulates the body's own immunity so that when the TB bacilli enter the body, the infection is usually controlled.

How well does BCG work?

The efficacy of BCG immunisation to prevent pulmonary TB is uncertain. Trials have measured the preventive efficacy to be between 0 and 80%. If a person has been immunised with BCG in the past, there is no evidence to show that re-immunisation will provide increased protection against pulmonary TB.

BCG can cause local side effects such as erythema, induration and tenderness at the site of vaccination as well as regional lymphadenopathy which can persist for 3 months or longer. Local serious or long term reactions are rare. BCG should not be given to individuals with AIDS because it may cause disseminated BCG infection.

BCG can protect up to 80% of young children if it is given before they are infected with TB. It seems that it is especially useful against miliary TB and TB meningitis.
BCG should be given to all infants as a routine

BCG is given in all countries where there is high prevalence of TB. In South Africa it is part of the Expanded Programme of Immunisation (EPI) and is given to all children at birth. If there is no record of BCG or a BCG scar, it must be given to children up to the age of 1 year. (BCG is no longer repeated again at three months and at school entry).

If an infant is on prophylactic TB treatment, as a contact of an infectious mother, BCG should only be given three days after the treatment is completed as the drugs will kill the vaccine if given at the same time.

Method of giving BCG

In South Africa we use the multiple puncture method (Japanese tool).

BCG in children with HIV infection and with AIDS

Children with AIDS disease should not be given BCG. The lack of immunity can cause disseminated disease. However, HIV-infected children without symptoms should receive BCG.

3 RISK GROUPS

In some developed countries, any person infected with TB, i.e. anyone with a positive skin test, is put on preventive treatment for TB. This is to prevent progression to disease.

In countries like South Africa, with a high prevalence of TB, a high proportion of adults are infected and thus would have positive skin tests. Preventive treatment is neither feasible nor cost effective (it costs more to give preventive treatment to all these persons than to treat those who develop TB).

3.1 Specific Risk Groups

Specific groups at risk for TB disease are young age and HIV infection. Each of these two groups will be considered.

- Young Age (less than 5 years)

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 a 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.

Small children in contact with household members, domestic workers, child minders or nursery school teachers with smear positive TB should be put on preventive treatment.
HIV Infection

We have seen how HIV infection increases the risk of developing TB disease and accelerates the progression of HIV infection to AIDS. (see Chapter 11).

If HIV-positive persons who are infected with TB, i.e. have positive TB skin tests, are given TB preventive treatment, there is evidence that TB disease can be prevented.

However, the following issues are important:

- We have to identify the HIV-positive individuals

- We would have a large numbers of people for preventive treatment. Strict adherence to treatment of such people is of the utmost importance to prevent drug resistance.

- Preventive therapy should only be used in settings where it is possible to exclude active TB cases and to ensure appropriate monitoring and follow up. For further details refer to the TB/HIV guidelines for TB preventative treatment to HIV-infected persons.

4 THE HEALTH CARE SETTING

4.1 The TB Ward and the Clinic

It has become necessary to give attention to the control of transmission of tuberculosis in health care settings, following the nosocomial (hospital) outbreaks of multi-drug resistant tuberculosis in the USA in association with HIV infection.

A joint statement by the WHO Tuberculosis Programme and the IJATLC includes guidelines on the identification and isolation of infectious tuberculosis patients, environmental control and protection of health care workers and others. These guidelines are applicable to all TB patients and health workers whether or not multi-drug resistant tuberculosis is present.

The initial phase of treatment must be supported through DOTS. This might necessitate hospitalisation of patients. Unless certain precautions are taken by hospital and clinic staff, TB can be transmitted to health workers.
4.2 Core Elements of Effective TB Prevention

Identification and Treatment of Infectious Tuberculosis Patients

The best way of interrupting the chain of tuberculosis transmission is by rapid diagnosis and treatment of infectious pulmonary TB patients.

The most infectious tuberculosis patients are those with sputum positive pulmonary disease. Sputum negative pulmonary TB patients are much less infectious, and those with extrapulmonary TB are essentially not infectious.

Ventilation

Good ventilation is one of the most effective environmental measures to reduce tuberculosis transmission. Tuberculosis wards with doors closed and windows open to the outside are ideal. Exhaust fans are useful for moving air from wards and isolation rooms to the outside.

Difficulty may arise in areas with cold winters when windows are kept closed. In these situations it is important that air flow from tuberculosis wards and isolation rooms are not directed into other parts of the hospital. Fans to the outside may be useful.

Collection of Sputum

Areas where sputum specimens are collected must be well ventilated. Health workers need to take special care that patients do not cough directly onto them (see Chapter 5).

Outpatient clinics which screen for suspected tuberculosis cases should also be well ventilated. Sputum specimens should be collected in an area separate from the waiting room, outdoors or in a well ventilated room.

Laboratories processing sputum specimens from tuberculosis suspects should follow published guidelines to minimize tuberculosis transmission to laboratory workers.

Ultraviolet Light / Direct Sunlight

Some authorities have recommended that ultraviolet lights be installed in areas where tuberculosis transmission is likely to happen, or in wards where TB patients (especially MDR TB patients) are treated. The installation and maintenance is expensive and requires expert supervision, as it can be potentially harmful if incorrectly installed.
4.3 Protection of the Health Worker

**BCG Immunisation**

If a health worker who works with TB patients has not received BCG immunisation in the past, counselling could be offered on the possible benefits and risks of BCG as described earlier in this chapter. If the health worker is interested in receiving BCG immunisation, then a tuberculin skin test should be done. If the skin test is negative, then BCG could be administered.

**Education and Orientation**

Health care workers need to be educated about tuberculosis. Health staff who know that they are HIV-positive should avoid working with tuberculosis patients.

Infectious PTB patients with uncontrolled coughing who are being transported to other areas of the hospital, e.g. the radiology department, should wear masks, if available. For maximal efficiency masks should be tight fitting and filter particles 1-5 microns, i.e., the size of infectious droplet nuclei. These masks are expensive and probably cannot be used routinely.

Other masks, such as surgical masks, which prevent larger particles from being aerosolised as patients cough or sneeze, may have some protective effect. Surgical masks, however, do not prevent inhalation of infectious droplet nuclei and cannot be relied on for full protection. They are thus not indicated for staff and visitors.

Health workers should be encouraged to eat well, stay fit, restrict their alcohol consumption and **not** smoke cigarettes.

**Staff Surveillance**

**ON EMPLOYMENT**

On employment, a standardised questionnaire should be completed by each new employee. This should include questions on:

- BCG immunisation
- past TB infection
- previous contact with TB
- underlying medical conditions which affect immunity

A tuberculin skin test should be done to detect past infection, together with a baseline chest X-ray. If it is negative a BCG should be given (see page 93).

Voluntary HIV counselling and testing should be offered, after explaining the increased risk of TB to an HIV-positive person. HIV-positive staff should be advised to avoid contact with TB patients and should be given responsibilities which limit their exposure to TB patients.

Most importantly, health workers should be instructed to seek care if they develop symptoms of TB.

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**NOTE**

- If a staff member should develop tuberculosis the Provincial TB Coordinator should be notified.
MONITORING
Serial tuberculin testing is not currently recommended in South Africa because of the high prevalence of TB infection in South Africa. An estimated 60% of adults would have positive tuberculin tests. Additionally more than 90% of children in South Africa are immunised with BCG which makes the interpretation of tuberculin skin test difficult.

The only situation in which tuberculin testing should be considered is in a HIV-positive health worker in settings where decisions for provision of TB preventive therapy are based on tuberculin results.

Regular questionnaires on symptoms of TB and regular weighing every six months to detect unexplained weight loss should also be considered.

Annual chest X-ray screening is not recommended

POST EMPLOYMENT

Tuberculin skin tests may be done on termination of employment. If the test is positive, and the pre-employment test was negative, and if the health worker subsequently gets sick with TB, the worker is eligible for compensation according to the Compensation for Occupational Injuries and Diseases Act.

A chest X-ray may be done to compare with the pre-employment chest X-ray.

SELF TEST QUESTIONS

1  To whom is BCG routinely given?

__________________________________________________________________________________

2  Name 2 groups at special risk of developing TB.

__________________________________________________________________________________
3 Discuss the policy in South Africa for preventive treatment of TB skin test positive HIV-infected individuals.

4 How can health workers protect themselves from TB from smear positive patients in their care.
CHAPTER 14 - RECORD KEEPING IN THE NTCP

1 THE RECORDS AND REPORTS

- Patient Treatment Card (GW20/15) - green pocket size card kept by the patient as a passport to TB treatment - it records the patient's smear results, treatment regimens and adherence. Attendance at clinics or hospitals and/or at supporters is recorded as ticks.

- Patient Clinic/Hospital Card (GW20/12) - blue folder kept by the health facility to record the same information as the Patient Treatment Card and used to monitor adherence and clinical progress.

- Tuberculosis Register (GW20/11) - large blue register completed and kept by the health facility responsible for treatment used to document patient's name, address, category and smear results, treatment outcomes and adherence.

- Patient Transfer Form (GW20/14) - pink form sent to the referral health facility to which patients are referred to ensure continuity of care.

- Sputum Request Form (GW20/13) - white form sent by health facility to laboratory.

- Tuberculosis Laboratory Register - to be used by the District TB Coordinator to ensure that all smear positive cases detected in the laboratory are enrolled on treatment (still to be developed).

- Quarterly Reports on Case Finding and Treatment Outcomes (GW16) - Large green register which is completed quarterly. The case finding refers to "patients found" in the last quarter, and the outcome report refers to those who started treatment 12-15 months earlier and have now completed treatment.

- Summary Report on Programme Management - (still to be developed)
  
  Part A - District Level
  Part B - Provincial Level
  Part C - National Level

2 THE PURPOSE OF THE RECORD SYSTEM

The recording and reporting system provides information to manage the National Tuberculosis Control Programme (NTCP) at all levels (national, provincial and district). Accurate record keeping of each patient, by maintaining up to date patient cards and registers and reporting data to the central unit quarterly, is essential for the proper management of the programme.

The accurate completion of the referral form is important, ensuring that patient details are available to the health workers to whom the patients are referred.

Standardised case definitions, disease classifications, treatment regimens and definitions for treatment outcomes have been incorporated into the recording and reporting system.
3 TUBERCULOSIS REGISTER AND QUARTERLY REPORTS

In South Africa, the Tuberculosis Register is kept at the health facility (clinic or hospital) where tuberculosis treatment is given. This health facility is also responsible for completing the Quarterly Reports and sending them to the District TB Coordinator.

The District TB Coordinator checks the Quarterly Reports and uses them to complete the Summary Quarterly Reports which are sent to the Regional or Provincial TB Coordinator.

The Provincial TB Coordinator should check the Summary Quarterly Reports before submitting them to the person responsible for data entry into TBSYS (the computer software programme for TB information) in the Provincial and National Health Information sections. The data is used to generate standardised provincial and national reports.

Feedback of analysed information to the peripheral levels is very important to ensure quality of data collection and to motivate TB Coordinators and health care staff.

Supervisors at all levels of the programme have access to the information they need to manage the TB programme because of decentralised record keeping and quarterly analysis of data by district and province.

REMEMBER
The Tuberculosis Register should be maintained at the District Level, the most peripheral unit of the Health Services. The District Level is the key level for the management of Primary Health Care. Collecting information quarterly allows for analysis of groups of patient data for given clinics, hospitals, districts, regions or a whole province.

4 INDICATORS MEASURED BY THE RECORDING SYSTEM

The routine records and reports for the NTCP indicate whether patient oriented activities such as case finding, diagnosis and treatment are being performed. They should also indicate whether planned programme management activities, such as training and expansion of the revised NTCP strategy into new districts, are being accomplished.

Using indicators is a way to measure the achievement of patient oriented activities and programme management activities.

On the next few pages are several indicators which are examined regularly by all NTCP Programmes. These include indicators for:

- Case finding
- Case holding (monitoring)
- Treatment outcome
- Management
4.1 Case Finding Indicators

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>DESCRIPTION</th>
<th>CALCULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteriological coverage</td>
<td>The proportion of pulmonary tuberculosis patients who have a documented sputum examination at the time of diagnosis. (The aim of the NTCP is 100% coverage).</td>
<td>For one quarter: The number of pulmonary TB patients with pretreatment bacteriology divided by the number of pulmonary TB patients registered</td>
</tr>
<tr>
<td>Case detection rate of new pulmonary smear positive cases</td>
<td>The number of new pulmonary smear positive cases detected, as a percentage of the estimate of new smear positive cases. (Case finding)</td>
<td>For a defined population: The number of new smear positive cases registered in one year divided by the number of new smear positive cases estimated to occur during the year</td>
</tr>
<tr>
<td>Proportion of pulmonary cases that are smear positive</td>
<td>The number of smear positive cases as a percentage of all registered pulmonary TB cases (should be 65% or more)</td>
<td>For one quarter: The number of smear positive pulmonary TB cases (new and retreatment) registered divided by the total number of all pulmonary cases (new and retreatment) registered</td>
</tr>
<tr>
<td>Ratio of new smear positive cases to new smear negative and extra pulmonary cases</td>
<td>The number of new smear positive cases compared with the number of new smear negative cases and extra pulmonary cases combined. (Should be approximately 1:1)</td>
<td>For one quarter: The number of new smear positive cases registered compared with the total number of new smear negative cases and extra pulmonary cases registered</td>
</tr>
<tr>
<td>Reported case incidence rate (per 100,000 population)</td>
<td>The number of newly detected smear positive cases (or all new cases) per 100,000 population. (Important for programme planning, e.g. to estimate drug needs)</td>
<td>For a specified area: The number of new smear positive cases (or all new cases) divided by Total Population x 100,000</td>
</tr>
</tbody>
</table>

**SOMETHING TO THINK ABOUT**

As the transmission of TB decreases, the incidence of disease in young people falls. The incidence rate in older people does not fall as rapidly, because many of them were infected years or decades earlier. In a successful TB Control Programme, the peak incidence gradually moves from young people to old people.
### 4.2 Case Monitoring Indicator

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>DESCRIPTION</th>
<th>CALCULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smear conversion rate during treatment (at 2 months new cases; 3 months retreatment cases)</td>
<td>The new smear positive cases who convert from smear positive to smear negative after 2 (3) months of treatment as a proportion of all smear positive cases. (For new smear positives should be at least 85% and at least 80% for retreatment cases).</td>
<td>For one quarter: The number of smear positive cases (new or retreatment) which are smear negative at 2 (3) months of treatment divided by the number of smear positive cases (new or retreatment) at the start of treatment.</td>
</tr>
</tbody>
</table>

**NOTE**

For new smear positive cases, check sputum at 2 months. For any not converted at 2 months, check again at 3 months. For retreatment cases check at 3 months.

### 4.3 Treatment Outcome Indicators

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>DESCRIPTION</th>
<th>CALCULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>For new smear positive cases</td>
<td>Rates of: cure, completion rates, interruption, failure, death, transfer</td>
<td>For each quarter: The number of new smear positive cases having each outcome divided by the number of all new smear positive cases with all known outcomes (excluding those &quot;transferred out&quot; and &quot;not TB&quot;).</td>
</tr>
<tr>
<td></td>
<td>See definition of treatment outcomes on page 56. (Cure rates of new pulmonary smear positive cases should be at least 85%).</td>
<td></td>
</tr>
</tbody>
</table>
4.4 Management Indicators

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>DESCRIPTION</th>
<th>CALCULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation</td>
<td>Proportion of districts implementing the revised NTCP strategy in each province</td>
<td>For each Province: The number of districts involved in implementing the revised NTCP strategy divided by all the districts in the province</td>
</tr>
<tr>
<td>Supervisory Visits</td>
<td>Proportion of supervisory visits planned that are done.</td>
<td>Number of supervisory visits conducted divided by number of planned supervisory visits</td>
</tr>
<tr>
<td>Reporting rate</td>
<td>Proportion of all districts that submit quarterly reports.</td>
<td>The number of quarterly reports completed by the districts divided by number of total districts</td>
</tr>
<tr>
<td>Drug Use</td>
<td>Proportion of the drugs used compared to estimated drug supply usage for a quarter.</td>
<td>Number of drugs and supplies used divided by estimate of drugs and supplies needed</td>
</tr>
<tr>
<td>Laboratory Quality Control</td>
<td>Proportion of microscopy sputum specimen slides submitted for quality control that are accurately reported on.</td>
<td>Number of slides correctly reported divided by the sample of slides sent to check for quality control</td>
</tr>
</tbody>
</table>

NOTE
The Tuberculosis Register Manual (yellow booklet) gives a full description of existing reports and directions on how to complete them (except for the Summary Quarterly report).

5 IMPLEMENTING THE RECORDING AND REPORTING SYSTEM

Every district which is implementing the NTCP should be using the recording and reporting system.

District Tuberculosis Coordinators (DTCs) and health workers need training on how to complete the new records and reports. Difficulties that health workers have in completing the forms, or that the DTCs have with reviewing the Tuberculosis Registers and completing the Summary Quarterly Reports, should be attended to timeously. Extra time on job training should be given to help solve these difficulties.

Notification

When the revised recording and reporting system was introduced, a decision was taken to continue the old notification system for TB. The main reason for using both systems is to retain the ability of the notification system to provide information for evaluation about tuberculosis in the country while the new system is becoming firmly established.

There is a column in the Register for the date of notification to remind health workers to notify TB patients.
TRAINING EXERCISE

Examples of all the different registers should be distributed to the trainees. Each report or register should be discussed in detail and trainees should be shown how to fill in each card.

SELF TEST EXERCISE

In a given quarter (3 month period), 360 new smear positive patients were registered, 250 were cured (smear negative after 6 months' treatment).

1  Calculate the new smear positive cure rate.

2  Comment on this cure rate.
CHAPTER 15 - PATIENT CENTREDNESS

By the end of this Chapter, you should be able to:
- Describe what patient centred care means and why it is important in the NTCP.
- Explain why the integration of health services is necessary for a good NTCP.
- Describe the role of the community health nurse in patient care.
- List and discuss characteristics that will improve patient adherence.

1 PATIENT CENTRED CARE AND ADHERENCE

Treatment cure for TB patients needs adherence to a fairly long course of treatment (6 or 8 months). Patient adherence to treatment depends on many factors. Health workers must always try to see the situation from the patient’s perspective and must recognise and understand patients’ rights, their needs, physical and social circumstances and realise the importance of the rights of patients, their needs, wishes and circumstances.

An important factor in treatment cure is the relationship between the patient, the carers, the health worker and the supporters.

Patient centred care is linked directly to adherence to treatment.

Carers should explain sympathetically the importance of completing treatment. Feelings, expectations and potential barriers/problems should be freely discussed when treatment is started.

Patients are often able to predict their own adherence taking their lifestyle, habits and past experience into account. If at all possible, the same health worker should listen to the patient, monitor, encourage and provide feedback on progress. This is the best way to develop and maintain the effective bond which ensures treatment success.

Health workers are responsible for making health facilities for tuberculosis patients accessible (within reach) and acceptable. Poor adherence is usually a result of health service inadequacies. However, there are factors that health workers must consider so they can find solutions with their patients. These include:

- alcohol and substance abuse
- poverty
- physical and mental disability
- being a teenager
- casual employment
- lack of a fixed address
- previous history of poor adherence

Many of these factors are outside the patient’s control and here the health worker will have to find resources to address the problems and really try to help the patient.

REMEMBER
The most important factors in patient adherence to treatment are health service related. Individual patient factors are less important.
2 HEALTH SERVICE MANAGEMENT

An integrated primary health care service will promote a patient centred approach. Health services are responsible for providing the service infrastructure, i.e. accessible clinics, good services, short waiting times, enough drugs, efficient records and trained, motivated staff so that a good NTCP can be delivered.

- **Integration of Tuberculosis Control into Primary Health Care**

Integration of NTCP activities within the primary health care system offers opportunities to improve case finding and case holding. This means improving skills of health workers at peripheral health units so they can diagnose and manage common health problems. All health workers should know about TB and be able to manage it. A good NTCP can be implemented and maintained by:

- encouraging sick people to attend health facilities
- early diagnosis of patients with TB
- treatment of patients with TB of district clinics
- education of communities about health in general and TB and its treatment.

- **Management**

In order to maintain high standards of care of health workers, a well organised management (support) system at district, provincial and national level is essential. This will provide training, supervision and support to staff and will ensure adequate supplies of required drugs, equipment and will set up laboratory networks and referral systems.

3 SUPPORTED TREATMENT (DOTS)

Once TB is diagnosed and patients are registered, health workers must ensure that the correct treatment is given.

This should be arranged so that drug taking will be uninterrupted. It must therefore be as convenient to patients as possible, particularly once their presenting symptoms have been relieved and they feel better and so have less motivation to continue therapy.

Health education alone is not sufficient to motivate patients to take their full course of treatment. **At least during the initial intensive phase of therapy, and as far as possible for the total duration of treatment, drug taking should be supported** (see Chapter 9 on DOTS for details).

Health workers must monitor the attendance of patients on DOTS and record this on the patient clinic cards.

Community and non-government organisations can provide help in identifying patients and encouraging adherence to treatment.

The best way to help a patient who is taking treatment irregularly is to visit him/her at home to discuss the treatment and the problems being experienced. An important responsibility of health workers is the careful referral of any patient who is being transferred to another district.
4 THE ROLE OF THE COMMUNITY HEALTH NURSE IN A PATIENT CENTRED APPROACH

The functions of the community based nurse who serves as patient care co-ordinator include:

- facilitating continuous patient care between health care resources
- making sure health services are accessible
- helping other health workers plan for individual, group and community needs

Patients will expect the nurse to resolve their problems, and to assist in making services available. In addition, patients expect high quality service, skill and knowledge, sound judgement and a reasonable effort on the part of the nurse.

As the patient carer, the nurse must establish communication networks with local government officials, social services agencies, business organisations and NGOs and the media.

As a collaborator the nurse is involved with multi-professional relationships in the health team which aims at helping the patient and mobilising community involvement.

5 KEY ASPECTS OF PATIENT CENTRED CARE

- **Courteousness**

  Nurses should always show respect and consideration for others, be friendly and encouraging. They should be genuinely concerned with the well being of their patients and have an attitude that will make patients feel accepted and welcome at health facilities.

- **Communication**

  A communicative nurse (or health worker) will convey knowledge and information about tuberculosis to the patient, and 

  This two way communication is necessary to ensure a longstanding relationship, which is important to prevent interruption of treatment.

  The more informed patients are about TB, the more they will be motivated to complete treatment.

  Patients should be counselled in their own language to ensure that they understand.

- **Continuity**

  Patients should be followed up by the same members of staff, if this is possible.

  This does not imply that only one person in a health facility should be responsible for TB care.

  There should not be a breakdown in patient care when a specific nurse is not on duty.
patients should always be introduced to other staff members in a health facility. This creates a sense of belonging that will make them want to complete their treatment and be cured.

The recording and reporting system should be so complete that another health worker will know what the patient's situation is when studying the records.

The principle of the team approach should be introduced in such a way that the patient will feel at ease with any member of the team.

- Consistency

All the messages and information given to the patient must be consistent and clear - the same message from all health workers.

This is only possible if a standard training programme is followed throughout the country and if all the staff in a health facility is updated on the latest practices and information regarding the NTCP.

- Client Orientated

The nurse must listen to the patient's feelings about their illness and the problems this will cause.

Patients can often foresee their adherence problems.

It is useful to discuss barriers to treatment with them, so solutions can be found and help them to find solutions. No measures must be enforced, otherwise the patients may not be seen at the health facility again.

In an attempt to overcome some of the problems the nurse may have to implement her advocacy role to plead the case of the patient, e.g., to encourage the employer not to dismiss the patient but to assist with supervising his treatment (this should always be done with the patient's knowledge and agreement).

During the 6 or 8 months of the patient's treatment, there may be periods of stress between the patient and the nurse, e.g., when the patient's treatment schedule changes from the intensive phase to the continuation phase.

At this stage it is possible that the patient is feeling so much better that he does not want to continue treatment. Then the nurse will have to rely on the relationship of trust she has developed over the past two months with the patient, so that she can convince him of the necessity to continue his treatment until the end.

If the relationship has not been patient centred, the advice may be disregarded and the patient may discontinue treatment.
• Clearly Contracted

There should be a mutual agreement between each patient and nurse to work together towards the patient's cure. The patient should be aware that all treatment and procedures of the NTCP are free of charge.

• Conveniency

The planning of the patient's management should suit his needs and circumstances as far as possible.

There should be as short a time as possible spent waiting in clinics. Appointments should be arranged at convenient times for those patients that have to get back to work or attend to domestic duties.

Clinic hours should be extended, if possible, to facilitate management of patients that leave home early and return late.

• Contact Maintenance

The commitment of the staff, the management of the service and the record keeping should be of a high standard so that if a patient does not attend as expected, it will be noted immediately and responded to.

In this way it will be possible to decrease the number of patients that interrupt their treatment.

This will ultimately decrease the number of retreatment cases and the development of MDR TB

Patient follow-up requires that the health worker has access to transport or is able to communicate with their patients.

• Caring

A bond should develop between the health worker and patient with concern for each individual.

The nurse should see the cure of every TB patient as a challenge. In curing TB she/he will prevent spread to other members of the community and health staff.

A caring relationship with the patient will ensure that the health worker responds timely to their needs, so that patients complete their treatment.

• Cleanliness

A neat, tidy and organised clinic will promote regular attendance and therefore healing.

The minimum health requirements of a clinic should be a well ventilated room with proper waste disposal, sanitation and clean water supply.

The nurse should liaise with district management and other departments and agencies to assist in improving the conditions at the clinic and the surrounding environment.
Companionship

Loneliness and despair are two well known companions of patients with a debilitating disease that requires long term therapy such as TB.

The treatment supporter is a vital link to give emotional support and encouragement to the patient to enable them to overcome these feelings.

Co-operative

The NTCP can only be implemented successfully in co-operation with organisations in the district; governmental, non-governmental (NGOs); and private.

The support of community members and organisations such as SANTA should be used.

A co-ordinated approach will help to reach the NTCP goals.

SELF TEST QUESTION

List and discuss the 12 care characteristics that are important to improving patient adherence to TB treatment.
FURTHER READINGS ON TUBERCULOSIS

BOOKS


JOURNAL ARTICLES


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