Ministry of Public Health and Sanitation

Division of Leprosy, Tuberculosis and Lung Disease

DLTLD Guidelines on management of Leprosy and Tuberculosis

MARCH 2009 VERSION

FOREWORD

Tuberculosis remains a major cause of morbidity and mortality in Kenya. It affects all age groups, but has its greatest toll in the most productive age group of 15 to 44 years. The major factor responsible for the large TB disease burden in Kenya is the concurrent HIV pandemic. Other factors that have contributed to this large TB disease burden include poverty and social deprivation that has led to mushrooming of peri-urban slums, congestion and limited access to general health services. Recently, there have been increasing concerns about the emergence of drug resistant TB, a threat that would pose major challenges in the fight against TB in a resource limited country like Kenya.

To address challenges posed by the tuberculosis epidemic in the face of the HIV epidemic and the socio-economic environment, the Ministry of Public Health and Sanitation through the DLTLD has identified areas for increased support: Strengthening of human resource capacity at all levels of Division of Leprosy, Tuberculosis and Lung Disease (DLTLD) for effective coordination of control activities, decentralisation of control services to the community, strong collaboration between TB and HIV control programs to promote delivery of integrated TB/HIV services, promotion of private–public partnerships to increase the number of non - public providers integrated into the TB service provider network, sustained public health education campaigns to promote early care seeking and adherence to treatment at community level, and health care worker training and support for better TB case management by health care providers.

This guideline is a revision of earlier ones produced in 1994, 2000, 2003 and 2006 and marks yet another step forward for the DLTLD. It includes childhood TB and nutrition for the first time. The immediate short-term goal is to sustain 70/85 target that Kenya recently achieved (detect 70 % of infectious TB and cure 85% of the detected cases) and then sustain and improve this effort over a long time to achieve the Millennium Development Goals (MDGs). These guidelines should be used as technical reference material by all health care workers involved in TB and Leprosy care and can also be used for training of health care workers in conjunction with other training materials.

Although Leprosy is no longer a public health concern in Kenya, the DLTLD has noted a positive growth in cases of about 2% over the last 3 years. The ministry is concerned that this increase coupled with the long incubation period may indicate leprosy resurgence. It is important that mechanisms are put in place to facilitate active contact tracing.

It is my sincere hope that all health care workers will find the revised guidelines useful for successful implementation of tuberculosis and leprosy control activities.

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LIST OF ABBREVIATIONS

AFB	Acid fast bacilli
ARC	AIDS related complex
BCG	Bacille Calmette Guerin
BCP	Blister cell pack
CDC	Centres for Disease Control and Prevention Atlanta Georgia
CIDA	Canadian International Development Agency.
COLS	Clinical Officer Lung and Skin diseases
DOT	Directly Observed Treatment
DOTS	Directly Observed Therapy Short Course
DST	Drug susceptibility Testing
DTLC	District TB & Leprosy Coordinator
GoK	Government of Kenya
KEPI	Kenya Expanded Programme on Immunization
KNCV	Koninklijke Nederlandse Centrale Vereniging voor Tuberculose bestrijding (Royal Netherlands Tuberculosis Association)
MOPHS	Ministry of Public Health and Sanitation
MOTT	Mycobacteria Other Than Tuberculosis
NGO	Non-governmental organization
DLTLD	Division of Leprosy Tuberculosis and Lung Disease
PEPFAR	President's Emergency Plan For AIDS Relief
PHC	Primary health care
PLWHA	People Living With HIV/ Aids.
PTB	Pulmonary Tuberculosis
PTLC	Provincial TB & Leprosy Coordinator.
SCC	Short-Course Chemotherapy
SDP	Service Delivery Point
TB	Tuberculosis
WB	World Bank
WHO	World Health Organisation.
MDR-TB	Multi-Drug Resistant tuberculosis
XDR-TB	Extensively Drug Resistant Tuberculosis
MDGs	Millennium Development Goals
PATH	Program for Appropriate Technology in Health

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PREFACE

Kenya has a large and rising TB disease burden and is ranked 13th among the 22 high burden countries that collectively contribute about 80% of the world's TB cases. The TB case notification rate (CNR) rose from 51 to 338 per 100,000 population between 1987 and 2007. As in the rest of Sub-Saharan Africa, the large increase of TB is attributed primarily to the Human Immunodeficiency Virus (HIV).

Other factors that may be contributing to this include the high poverty levels with consequent socio-economic deprivation. This is evident in urban areas where there has been a phenomenal growth of slums and slum population. The increasingly large urban slum population has led to an increase in the proportion of TB cases notified to the DLTLD from urban areas. For example in 2005, over 35% of all notified TB cases in Kenya were from the five largest urban areas of Nairobi, Mombasa, Kisumu, Nakuru and Eldoret, reinforcing the known fact that poverty and TB are closely related. The implication of this observation is that a general improvement in socioeconomic conditions may be the answer to TB control in the long term. However, case finding and specific chemotherapy are the only methods that are known to have an important and immediate impact on the transmission of TB. The finding of TB cases and the provision of efficacious chemotherapy is the mainstay of TB control activities of DLTLD.

The DLTLD adopted the Directly Observed Therapy Short Course (DOTS) strategy for the control of TB in 1993 and achieved countrywide geographic DOTS coverage in 1997. The country adopted the 1993 World Health Assembly global TB control targets of 70% detection of infectious cases and cure 85% of the detected cases by 2005. The World Health Organization WHO estimates that Kenya attained 70% case detection rate and 85% treatment success rate in 2007. Further, the country has adopted the TB control Millennium Development Goals of halving and beginning to reverse the mortality and prevalence of TB by 2015.

The DLTLD, in line with international trends, has launched several new approaches to increase access to DOTS and truly expand population DOTS coverage. These approaches include community based DOTS (CB-DOTS), Public-Private Mix for DOTS (PPMDOTS), collaboration between TB and HIV control programs and the development of an elaborate advocacy, communication and social mobilization strategy aimed at influencing communities to seek care early when TB symptoms occur and to remain on treatment until this is completed when treatment is initiated.

The Division of Leprosy, Tuberculosis and Lung Disease (DLTLD), previously the National Leprosy and Tuberculosis Programme (NLTP), was launched by the Government of Kenya (GoK) in 1980, combining the hitherto Kenya Tuberculosis Programme which existed since 1956 and several leprosy control projects which were in existence in Western, Coast and Eastern provinces since the early seventies. The DLTLD is mandated to develop policies and guidelines, mobilize political support and resources and carry out activities aimed at controlling both TB and Leprosy so as to eventually remove the threat to public health that these diseases currently pose.

Currently the DLTLD is receiving support from the Government of Kenya, through the Ministry of Public Health and Sanitation and bilateral and multilateral donors and technical agencies such as the Presidential Emergency Plan for AIDS Relief (PEPFAR) through the Centre for Disease Control & Prevention (CDC) and USAID, the WHO, the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) and the

Canadian International Development Agency (CIDA) through the Royal Netherlands Tuberculosis Association (KNCV).

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CHAPTER 1: THE BURDEN AND CONTROL OF TUBERCULOSIS DISEASE IN KENYA

1.1 The burden of tuberculosis in the World, Africa and Kenya

Tuberculosis disease has re-emerged as a major public health problem in the world. It is estimated that a third of the world population is infected with the tubercle bacillus with about nine (9) million people progressing to active tuberculosis disease each year, 2 million of whom die of the disease. The WHO reported that the incidence of TB grew by 1% globally in the year 2003 even though the incidence fell or was stable in five out of six WHO categorized TB regions. In 2003, the African region witnessed a sharp rise in the incidence of TB which was attributed to the high HIV prevalence in the region.

Kenya is one of the 22 high TB burden countries in the world which collectively contribute 80% of the global TB disease burden. Kenya is experiencing a generalized TB epidemic affecting the young economically productive age groups (15-44 year old). In Kenya, more men than women are notified as TB cases. In 2008, a total of 110,251 cases of TB were notified to the Division of Leprosy, Tuberculosis and Lung Disease (DLTLD), which represents a TB case notification rate of 288 per 100,000 population. Since the early nineties, the number of TB cases has increased almost ten times, mainly due to the HIV/AIDS epidemic. People Living with HIV and AIDS (PLWHA) are the major subgroup with increased incidence of tuberculosis. In 1994, a national survey to determine the prevalence of HIV among TB patients found that 40% of them were HIV sero-positive. In 2008, 83% of TB patients were tested for HIV of whom 45% turned out to be HIV positive. Of all patients with TB-HIV co-infection, 94% received co-trimoxazole prophylactic therapy, and 31% were started antiretroviral therapy.

Apart from the HIV epidemic, poor socio-economic status leading to overcrowded slums in the peri-urban areas coupled with poor nutrition and limited access to health services have been identified as contributing factors to the high TB burden. Current data indicates that TB cases occur mostly among the slum dwellers in large cities.

Although the known TB disease burden is large, the WHO estimated that Kenya's TB case detection rate (proportion of incident cases that are diagnosed and treated out of total estimated new cases in the country) was 70% in 2007.

1.2 Tuberculosis control strategies in Kenya – the Stop TB Strategy

Tuberculosis control in Kenya is based on the six elements of the new WHO STOP TB Strategy listed below:

1. Pursuing quality DOTS expansion and enhancement through:
    - Political commitment with increased and sustained financing
    - Case detection through quality assured bacteriology
    - Standardised treatment, with supervision and patient support
    - Effective drug supply and management system
    - Monitoring & evaluation system, and impact measurement
2. Addressing TB-HIV, MDR-TB and other challenges
    - TB/HIV collaborative activities
    - Prevention and control of drug-resistant TB
    - Addressing prisoners, refugees and other risk groups and special situations
3. Contributing to health system strengthening
    - Active participation in efforts to improve human resources, financing, management and service delivery
    - Sharing innovations that strengthen systems, including the Practical Approach to Lung Health
    - Adapting innovations from other fields

4. Involving all care providers
    - Public-private mix approaches
    - International Standards for TB Care
5. Engaging people with TB and affected communities
    - Community participation in TB Care
    - Advocacy, communication and social mobilization
6. Enabling and promoting research
    - Programme-based operational research
    - Research to develop new diagnostics, drugs and vaccines

1.3 The Division of Leprosy, Tuberculosis and Lung Disease (DLTLD)

The responsibility for implementing the WHO STOP TB strategy within the Ministry of Public Health and Sanitation (MOPHS) is vested with the Division of Leprosy, Tuberculosis and Lung Disease. This Division falls under the Department of Disease Prevention and Control.

The Division's Central Unit (CU) has both medical and administrative officers. The main function of the CU is formulation of TB control policies and strategies, resource identification and mobilization, coordination of the procurement and supply chain management for all TB and Leprosy control related commodities, data management, advocacy, and coordination of training and supervision. Tuberculosis control activities are coordinated by Provincial TB and Leprosy Coordinators (PTLCs) and District TB and Leprosy Coordinators (DTLCs) at the provincial and district levels respectively. The TB and Leprosy coordinators are integral members of the Provincial and District Health Management Teams. The delivery of DOTS services is integrated into the general health services provided at health care delivery points.

The DLTLD has about 200 direct technical staff, including staff at the Central, Provincial and District levels. The general health staff consisting of clinicians, nurses, laboratory and public health officers are involved in TB care service delivery. By the end of 2008, TB services were available in 2228 public, NGO and private health care facilities, the majority of which are treatment centres. About nine hundred (900) centres offer smear microscopy services.

CHAPTER 2: INTRODUCTION TO TUBERCULOSIS

2.1 Definitions

Tuberculosis is an infectious disease caused by a bacillus called *Mycobacterium tuberculosis*, an acid-fast rod shaped bacillus. Occasionally *Mycobacterium bovis*, transmitted through contaminated milk and *Mycobacterium africanum* also cause the disease. In rare situations, Mycobacteria other than TB (MOTT) may cause a disease similar to typical TB.

The bacillus is transmitted from person to person through aerosolized droplet nuclei and therefore coughing, which generates infectious droplets, is the most important mode of transmission of TB. The bacillus may also be transmitted by other aerosol generating processes including laughing, talking, sneezing and singing. The most infectious patient is a person with a positive sputum smear.

In the majority of persons infected with the tubercle bacilli, the immune system is able to contain the infection and the bacilli remain dormant for the rest of a person's life and do not lead to disease. Persons who are infected can often be identified by the tuberculin skin test. The most used tuberculin skin test in Kenya is the Mantoux test.

NOTE: The Mantoux test should not be used to diagnose TB disease in Adults. A positive tuberculin skin test (Mantoux) does not indicate disease but confirms infection with the tubercle bacillus. Ref: **WHO/HTM/TB/2006.371*:***

2.2 Risk factors for exposure, infection and disease

To be infected with the tubercle bacillus, a person must be exposed to it in some way. A person's risk of exposure to the bacillus is related to incidence of infectious TB and duration of infectiousness of the index case that person is exposed to and the number of infectious TB cases that he/she interacts with over time. Therefore exposure is likely when there is a high incidence of TB in the community and the population density is high, as it is in urban slums.
During exposure to the bacillus, the risk of infection is related to the extent of exposure to infectious TB. This is determined primarily by the proximity and duration of exposure to the infectious person and the amount of droplet nuclei in the air, determined by the amount of ventilation (dispersion of bacilli) and exposure to sunlight during contact (survival of bacilli). A person is more likely to be infected with the tubercle bacillus if s/he spends long hours with an infectious person who is not on treatment, especially if this contact occurs in a poorly lit and poorly ventilated environment. This highlights the role poverty plays in the transmission of TB and also its influence on disease progress in the event of infection with the tubercles bacillus. TB is airborne and therefore cannot be transmitted by sharing food, cutlery, plates or glasses, as it is often believed.

Note: Poverty, HIV and Tuberculosis are closely interrelated. Poverty reduction will have a significant impact on Tuberculosis incidence while TB control should be an important component of poverty reduction strategies.

In the event of infection with the tubercle bacillus, the majority of persons will not develop disease. Those at risk of developing disease include the old and very young children, below five years of age, individuals who are poorly nourished, and those with poor immune defenses. Among the category of persons with poor defenses are people living with HIV/AIDS, diabetics, substance abusers (alcohol, drugs), silicosis and those receiving long term oral steroids or immunosuppressive therapies. Smokers too have an increased risk of developing disease.
The emergence of drug resistant TB strains, including multiple-drug resistant forms, poses a challenge to the control of TB in Kenya

Note: In Kenya the most common risk factor for TB disease is infection with the Human Immunodeficiency Virus (HIV).

A significant proportion of TB cases however do not have any obvious risk factor for disease though unknown genetic factors may play a role.

2.3 Classification of clinical TB

Tuberculosis is classified into two clinical forms namely tuberculosis that involves the lungs (Pulmonary TB or PTB) and tuberculosis outside the lungs (Extra-Pulmonary TB or EPTB). PTB is the most common form accounting for about 80% of the total cases and of public health concern because smear positive cases can transmit the infection. EPTB can involve any part of the body (except nails, hair and teeth) such as the lymph nodes, urinary tract (kidney, ureters, and bladder), the genital system (ovary, fallopian tubes, uterus, testes, epididymis), skeletal system (bone, joints), the nervous system (brain, meninges, spinal cord), the skin, the eye, the gastro-intestinal system and serosal membranes (peritoneum, pleura, pericardium).
When untreated, tuberculosis is a disease with a high mortality rate. The current treatment regimens achieve a very high cure rate (almost 100 %) provided the patient receives the correct drug regimen at the correct dosage and the treatment is adhered to fully until completion.

Tuberculosis patients are categorised as follows:

1. **Category 1- New cases (**patients who have never been treated before or used anti-TB drugs for less than one month)
    a. Sputum smear positive PTB
    b. Sputum smear negative with extensive parenchymal involvement
    c. Severe forms of EPTB (Meningitis, milliary, pericarditis, genitourinary, peritonitis, spinal)

2. **Category 2 – Previously treated sputum smear positive PTB**

Relapses, failures and returnees after default (also called smear positive re-treatment cases). These patients are at increased risk of having drug resistant TB, especially retreatment failures.

3. **Category 3** New less severe
    a. Sputum smear negative PTB
    b. Extra-pulmonary TB

4. **Category 4**
    Chronic and MDR-TB

Note: All pulmonary TB re-treatment cases should have sputum TB culture and drug susceptibility testing to exclude drug resistance and especially multi-drug resistant TB.

2.4. Case Definition

Pulmonary tuberculosis, sputum smear positive (PTB+)

- Two or more initial sputum smear examinations positive for acid fast bacilli (AFB), or
- One sputum smear examination positive for AFB plus radiographic abnormalities consistent with active pulmonary tuberculosis as determined by a clinician, or
- One sputum smear positive for AFB plus sputum culture positive for mycobacteria tuberculosis

[Revised case definition of sputum smear positive TB (WHO 2008): ***A TB suspect with at least one acid –fast bacillus in at least one sputum smear examination in countries with a well functioning External Quality Assurance (EQA) system****]*

Pulmonary tuberculosis, sputum smear negative (PTB-)
About 50% of PTB patients will have negative sputum smears for AFBs. A diagnosis of smear negative PTB should be made in patients with:

Sputum smear negative (PTB-)

- A cough of longer than two weeks
- At least two sputum specimens are negative for AFB (including at least one early- morning specimen), and
- Radiographic abnormalities are consistent with active pulmonary tuberculosis, and
- The patient has not responded to a course of broad-spectrum antibiotics excluding fluoroquinolones

This definition of smear negative PTB therefore implies that the diagnosis can not be made, if sputum smears and a chest x-ray are not done.

Extra-pulmonary tuberculosis (ETB)
This is a case of tuberculosis involving organs other than the lungs: e.g. pleura, lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, meninges, etc.
Diagnosis should be based on:

Extra-pulmonary tuberculosis

- One culture positive specimen, or
- Histology, or
- Clinical evidence consistent with active extra-pulmonary tuberculosis

A patient diagnosed with both pulmonary and extra-pulmonary tuberculosis should be classified and registered as a case of pulmonary tuberculosis.

CHAPTER 3: DIAGNOSIS OF PULMONARY TB IN ADULTS

3.1 Symptoms

Pulmonary TB is the most common clinical form of TB. Over 80% of all TB occurs in the lungs. Pulmonary TB should be suspected in any person presenting with a cough of more than two weeks duration. The cough may be associated with production of sputum that may be blood stained. Other symptoms that often accompany the cough include fevers, night sweats, loss of weight, chest pain and shortness of breath.

None of the symptoms of TB are specific to this disease and therefore all persons presenting with a cough for more than two weeks should be evaluated for TB with sputum smears unless there is another obvious cause of the cough.

All persons presenting with a cough for longer than two weeks should be evaluated for TB with sputum smears unless there is another obvious cause of the cough.

Physical signs are also not specific but every patient with suspected TB should be carefully examined especially for the presence of obvious signs of HIV/AIDS.

3.2 Sputum smear examination

Patients suspected to have PTB should have two sputum samples collected and microscopically examined for Acid Fast Bacilli (AFB) before they can be called a smear negative PTB case.

The recommended sputum collection procedure is the Spot - Morning, in which a first sputum sample is collected at the time the patient presents and a second sample is collected in the early morning the following day. This strategy enables two sputum samples to be collected within a 24-hour period. The results should also be available within the same time frame allowing infectious cases of TB to be rapidly identified and placed on treatment within 24 hours.

A specimen collected under the supervision of a member of the health team is likely to be better than a specimen collected without supervision. One needs to explain to the patient that saliva is not the same as sputum. Patients usually co-operate better if they are out of sight of other patients at the time of sputum collection. Patients who have had some food shortly before sputum collection should be asked to rinse their mouths with water first.

It is important to observe a few basic principles before sputum collection to improve the quality of care of TB patients and these should be observed by all care givers irrespective of seniority or status. These include:

- All patients requested to submit a sputum sample should have brief explanation of the reason for sputum collection.
- A laboratory request form should be filled properly.
- The patient's name and number should be clearly written on the **side** of the sputum container.
- The patient should produce the sputum **outside**, in an open space away from other people.

3.2.1 Process of sputum collection

- Ask the patient to cough deeply (demonstration is usually more effective than words).
- Ensure that no one is standing in front of a patient trying to produce sputum.
- Avoid contaminating the outside of the sputum container. If the outside is contaminated, discard the container and repeat the collection process with a fresh one.
- If the specimen is not suitable (e.g. if the quantity is insufficient or if it contains saliva), ask the patient to repeat the cough process until a sufficient amount of sputum has been obtained (3 to 5 ml).

3.2.2 After collecting the sputum specimen

- Place the lid on the sputum container and close it firmly.
- Wash your hands with soap and water.
- Preferably store the sputum specimens in a cool and dark place, such as a cupboard or refrigerator, that can be locked and which is used solely for this purpose, more so if the specimen is for culture.
- Send the specimens to the laboratory as soon as possible (in any case, the specimen should arrive at the laboratory as soon as possible but within 1 day of collection).
- Accompany each specimen with a properly completed laboratory request form.

3.3 Sputum culture examination

In general sputum TB culture and DST should be reserved for the evaluation of all PTB patients, who have failed initial or re-treatment, relapsed or are returning to treatment after a period of default because these patients may have drug resistant TB bacilli.

3.4 Chest X-ray

The chest x-ray may aid the diagnosis of PTB but it should not be used as the sole means of establishing a TB diagnosis.

All patients with chest x-ray features suggestive of PTB should have sputum specimens submitted for microbiological examination. It is a major error to diagnose TB on the basis of a chest x-ray and fail to examine sputum.

The radiographic features that usually suggest PTB include upper zone patchy shadows especially when these show evidence of cavitations and scarring (fibrosis). In HIV infected persons the radiological picture is more often atypical with the lower or mid-zone shadows and the presence of hilar or mediastinal lymph node enlargement being relatively common. Miliary mottling and pleural and/or pericardial effusion, which strictly speaking is not PTB, are also common radiographic features in HIV infected persons.

3.5 Tuberculin skin test

The tuberculin skin test (Mantoux) should not be used to diagnose TB in adults.

This test only indicates that the person has previously been infected with the TB bacillus. Similarly, most serological tests are not able to distinguish infection from current active disease and therefore should not be used to diagnose PTB.

3.6 ESR and other tests

The erythrocyte sedimentation rate (ESR) is usually elevated in active TB, but this test is not sensitive or specific enough to be of value in the diagnosis of PTB.

Nucleic acid detection tests including Polymerase Chain Reaction (PCR) may have a reasonable sensitivity and specificity for TB but are usually expensive and have not been adequately studied in resource limited settings.

3.7 Differential diagnosis of PTB.

In a person presenting with a chronic cough and negative sputum smears, other diagnoses must always be considered. These include atypical pneumonias (caused by unusual pathogens such as fungi including ***Pneumocytis jirovecii)***, lung abscess, lung cancer, heart failure, sarcoidosis and bronchiectasis. These alternative diagnoses require careful history taking, physical examination and various tests including chest computed tomographic (CT) scan which may not be easily accessible to the majority of PTB suspects. When the diagnosis of TB is in doubt, the patient should be referred to the next level for appropriate evaluation.

3.8 Complications of PTB

3.8.1 Haemoptysis

Coughing up of blood (haemoptysis) may be a symptom of TB and in most cases the amount of blood coughed out is small. After the treatment of TB, haemoptysis is usually a symptom of post TB bronchiectasis and in most cases it is precipitated by an infection in the bronchiectatic cavities. Recurrent haemoptysis in a patient who was previously treated for TB may also be a symptom of aspergilloma (fungal ball) in a bronchiectatic lesion or post TB cavitary lesion. Haemoptysis is a frightening symptom to most patients and when it occurs, patients should be reassured and sedated with a low dose of chlorpromazine at 25 mg twice daily. A course of broad spectrum antibiotics is indicated in those patients with post TB bronchiectasis. If the bleeding is severe and life threatening, patients should be admitted to hospital for more specialized treatment which may include surgery (to remove a bronchiectatic lung segment or lobe or an aspergilloma).

3.8.2 Spontaneous pneumothorax

This is usually as a result of rupture of a pleural based TB cavity. It is often associated with formation of pus in the pleural space (empyema) leading to a pyopneumothorax. The patient will present with shortness of breath and usually some chest pain. This complication requires insertion of a chest tube with underwater drainage of the air and pus or other surgical intervention. Therefore patients with a pneumothorax with or without pus should be admitted to hospital for appropriate management.

3.8.3 Bronchiectasis

Patients with this complication may cough out copious amounts of sputum which periodically is coloured, blood stained or foul smelling. This classical presentation of bronchiectasis is becoming less common with the widespread use of antibiotics. In those patients with upper lobe bronchiectatic lesions there may be no sputum production as a result of gravitation facilitated spontaneous drainage (dry bronchiectasis). The optimal management of post TB bronchiectasis will depend on the extent and severity of disease. Infective exacerbations will require antibiotic therapy which may be given when needed, cyclically or continuously depending on the frequency of exacerbations. Several antibiotics may be used including broad spectrum antibiotics like amoxycillin-clavulanate. Metronidazole or clindamycin should be added or used when anaerobic infection is suspected and an anti-pseudomonal antibiotic like ciprofloxacin should be used when colonization with *Pseudomonas* is suspected or proved. The hallmark of management of productive bronchiectasis is chest physiotherapy, typically postural drainage and other manoeuvres aimed at improving drainage of respiratory secretions.

3.8.4 Fibrosis of the lungs

This is sequelae of extensive tuberculous disease and only symptomatic therapy is possible. In severe terminal cases, long term oxygen therapy may be required. These patients should be referred to a hospital for review.

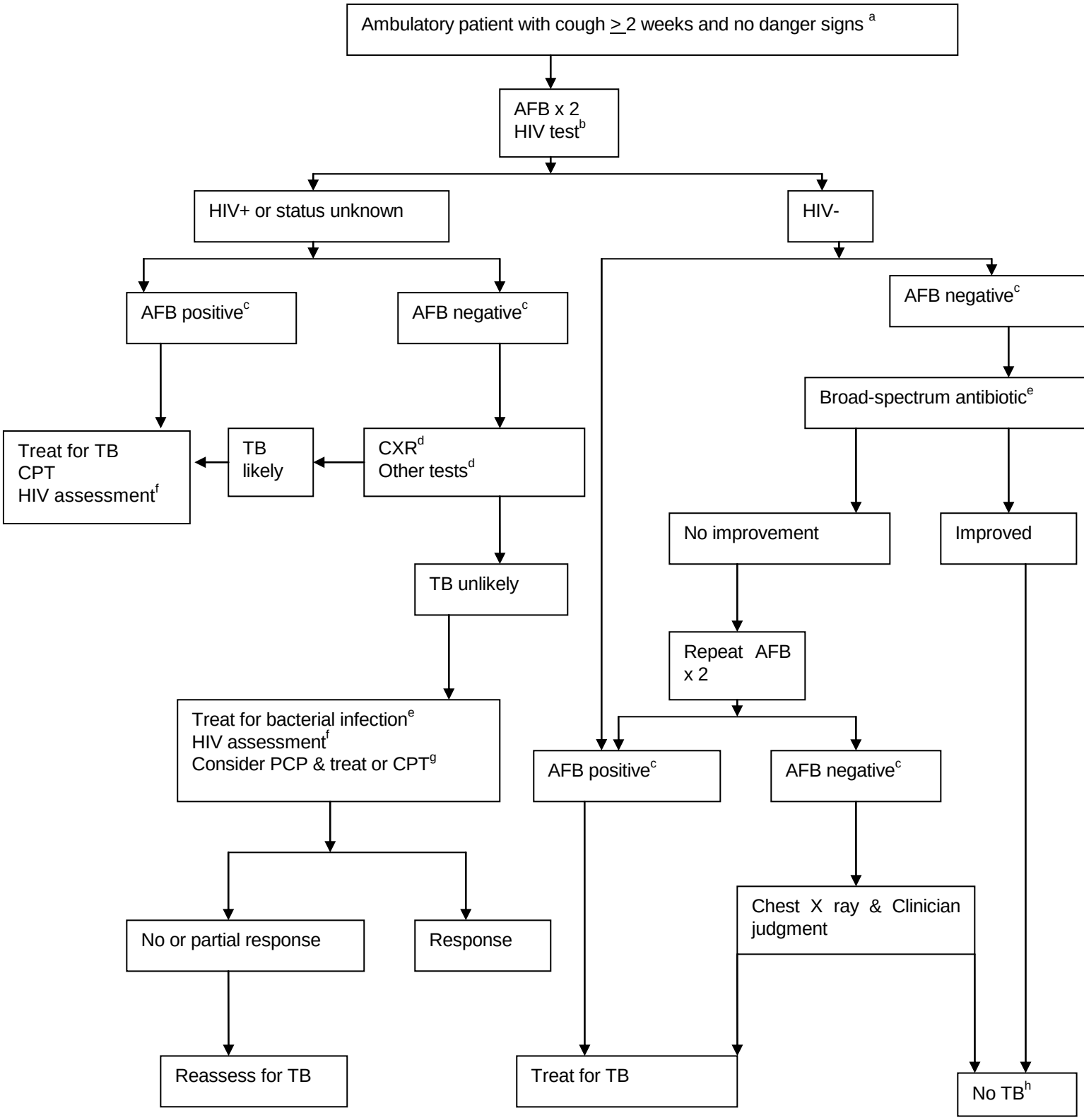
3.8.5 Lung abscess

A lung abscess may occur in a patient with extensive damage to the lungs after tuberculosis. Antibiotic treatment is given and the choice of antibiotic may be aided by the results of a sputum culture-sensitivity test. Surgical intervention may also be necessary. Patients who require surgical intervention should be referred appropriately.

3.8.6 Aspergilloma

This complication arises from the colonization of tuberculous cavities or bronchiectatic lesions with the fungus, Aspergilus fumigatus. Characteristically aspergillomas present with recurrent or persistent haemoptysis which may or may not be accompanied by systemic symptoms like malaise and fever. The diagnosis should be suspected when a patient previously treated for TB presents with recurrent haemoptysis and is found to have a shadow with an air crescent (halo) around it. The diagnosis is supported by the finding of high levels of specific immunoglobulin G against Aspergillus in blood. The only effective treatment is surgical removal of the aspergilloma.

3.9. Algorithm for Diagnosis of Pulmonary Tuberculosis



[a] The danger signs include any one of: respiratory rate > 30/minute, fever > 39 °C, pulse rate > 120/min and unable to walk unaided.

[b] Remember the national guidelines for HIV testing in clinical settings recommend an opt out approach.

[c] AFB-positive is defined at least one positive and AFB-negative as two or more negative smears.

[d] The other tests may include repeat AFB, Culture etc, which should be done at the same time wherever possible.

[e] A course of antibiotics (except fluoroquinolones) to cover both typical and atypical bacteria should be considered

[f] HIV assessment includes HIV clinical staging, CD4 count if available and referral for comprehensive HIV care.

[g] Assess for PCP and treat those with it. Those without should be put on CPT

[h] Investigate further or refer

CHAPTER 4: DIAGNOSIS OF EXTRA-PULMONARY TB IN ADULTS

The presentation and diagnostic approach to extra-pulmonary TB will depend on the site of disease. A detailed description of all forms of EPTB is beyond the scope of this guide. However the most common forms of TB and the diagnostic approaches are briefly described below:

4.1 Tuberculous pleural effusion and empyema

Involvement of the pleura in TB may occur soon after infection (primary disease in children and young adults), or may be the result of reactivated disease in older persons. A tuberculous cavity in the lung that is close to the pleura may rupture into the pleura allowing its involvement in the disease process. In these circumstances there is usually formation of pus in the pleural space (empyema) and if air has also leaked into the pleural space, the resulting condition is called pyopneumothorax. When the pyopneumothorax is communicating with a bronchus, a bronchopleural fistula is created.

Tuberculous pleural effusion usually presents with local chest symptoms including chest pain and breathlessness. Many patients also have a cough and systemic symptoms including fever and night sweats. When examined the trachea and the point of maximum cardiac impulse (apex beat) may be found to have shifted away from the side of the effusion. Percussion of the chest reveals “stony” dullness and breath sounds are reduced on the side of the effusion. It is advisable to obtain a chest x-ray to confirm the presence of the effusion, and if expertise exists, to perform a diagnostic pleural aspiration which at the minimum will distinguish pus (empyema) from “usual” effusion.

Where facilities exist, aspirated pleural fluid should be sent to the laboratory for biochemical tests (sugar, protein, and lactic dehydrogenase), cell count, cytology and microbiological tests including smears and cultures for tubercle bacilli. Although a pleural biopsy may improve the confidence with which the diagnosis of TB is made by demonstrating granulomatous inflammation on histology or a positive Ziehl Nielsen (ZN) stain or a positive TB culture, it is rarely required in young patients below the age of 40 years. Older patients and especially those with a significant smoking history may have other diagnoses and in these patients it is advisable to perform a pleural biopsy using an Abraham’s needle.

4.2 Tuberculous pericardial effusion

Tuberculous pericardial effusion may present with a variety of symptoms including chest pain, shortness of breath, a cough, leg swelling and fever. The patient with a pericardial effusion will usually have a high pulse rate (tachycardia) and may have a low blood pressure, impalpable apex beat, quiet heart sounds and signs of heart failure including an enlarged liver, ascites and leg edema. A chest x-ray is always required and usually shows a large globular heart. Where feasible, patients suspected to have a pericardial effusion should be referred to a heart specialist for confirmation of the diagnosis using echocardiography. A pericardial tap (pericardiocentesis) for diagnostic purposes is rarely carried out but this procedure may be life saving if there are signs of cardiac compression (tamponade). This procedure must be done by technically qualified and experienced health care workers only.

4.3 Tuberculous lymphadenopathy

Tuberculous lymphadenopathy most commonly involves the cervical (neck) nodes but any other lymph node group may be involved. The lymph nodes enlarge and are usually painless and initially firm and discrete. As the disease progresses the nodes become fluctuant and matted together and then they break down with sinus formation and pus discharge. The presence of unilateral fluctuant nodes or draining nodes often without much pain or fever is usually due to TB and in this situation a formal node biopsy may not be necessary. However when an alternative diagnosis is being considered, for example Kaposi’s sarcoma, lymphoma and cancer then a node biopsy should be obtained.

4.4 Tuberculous meningitis

This disease is often difficult to diagnose and requires a very high index of clinical suspicion. The onset of the disease is usually gradual with a progressive headache and vomiting with eventual neck stiffness. The presence of a thick exudate at the base of the brain leads to cranial nerve palsies while involvement of the arteries of the brain can lead to convulsions, loss of speech or loss of power in one or more limbs. If not diagnosed and treated, TB meningitis leads to a gradual change in the level of consciousness and eventually could end in coma and death. The diagnosis of tuberculous meningitis rests on clinical suspicion and examination of cerebrospinal fluid obtained following a lumbar puncture. In some situations it may be advisable to obtain a brain CT scan, if available, to exclude space occupying lesions and raised intracranial pressure before performing a lumbar puncture. In TB meningitis the brain CT scan may show basal enhancement. In the presence of raised intracranial pressure a lumbar puncture may cause fatal brain herniation through the foramen magnum. By the time the diagnosis of TB meningitis is made the CSF is usually clear or may be opalescent or xanthochromic. The CSF should be left to stand to see if spider webs formation occurs. Usually the CSF has a high cell count (mainly lymphocytes), low sugar and high protein. The ZN stain is rarely positive (less than 10%) while TB culture improves the yield only slightly.

4.5 TB encephalitis including tuberculoma

The clinical presentation is similar to that of other space occupying brain lesions and includes headaches, vomiting, convulsions, limb weakness, and cranial nerve palsies. Brain CT scans are useful in demonstrating lesions. A variety of radiological appearances may be seen to some extent reflecting the stage of the evolving granulomatous inflammation. Thus there may be low attenuation areas (edema formation), high attenuation areas, contrast enhancement and calcification (organization). Often it is difficult to confirm the diagnosis of brain TB and most patients are treated on an empiric basis.

4.6 Intestinal TB including ascites

Tuberculous ascites presents with progressive vague abdominal pain, abdominal distension, and vague abdominal mass with a doughy feeling, fever, wasting and diarrhea that may alternate with constipation. A health care worker with reasonable clinical skills should be able to diagnose ascites. However the diagnosis of TB as the cause of the ascites is often presumptive after exclusion of other causes which include heart, liver, kidney diseases or abdominal malignancies.

4.7 Miliary TB

Miliary TB usually presents with gradual onset of fever, malaise, night sweats, wasting and other constitutional symptoms but very little respiratory ones. There may be a large liver and/ or spleen. Whenever miliary TB is suspected, the eyes should be examined, where feasible, for choroidal tubercles. The chest x-ray shows multiple, small millet sized nodular shadows. The diagnosis is rarely confirmed but where facilities are available the cultures of blood and CSF, and liver biopsies and blood may be positive for the tubercle bacilli.

4.8 TB of the bones and joints

The commonest sites include the Vertebrae- thoracolumbar region, large joints especially hip and knee joints. It is also associated with Gibbus deformity and paraparesis/paraplegia.
Diagnostic approach:

- X-ray examination
- Athrocentesis with M. tuberculosis culture
- Synovial biopsy

CHAPTER 5: DIAGNOSIS OF TUBERCULOSIS IN CHILDREN

5.1 The burden of childhood TB

A child is defined as any individual who is under 15 years of age. Of the 9 million new cases of TB that occur in the world every year, it is estimated that nearly one million cases (11%) occur in children less than 15 years of age. Seventy-five percent of these childhood cases occur in the 22 high TB-burdened countries, of which Kenya is one, that together account for 80% of the world's estimated incident TB cases. In Kenya, TB in children below the age of 15 years accounts for about 10% all cases notified to the DLTLD every year.

5.2 Pathogenesis and risk factors

5.2.1 Pathogenesis of childhood TB

Infection with *M. tuberculosis* usually results from inhalation of infected droplets produced by someone who has active pulmonary TB disease and is coughing. The source of infection of most children is an infectious adult in their close environment (usually the household). This exposure leads to the development of a primary parenchymal lesion (Ghon focus) in the lung with spread to the regional lymph node(s). In the majority of cases, the resulting cell-mediated immunity will contain the disease process at this stage. Risk of progression to disease is increased when primary infection occurs before adolescence (less than 10 years of age), particularly in the very young (0 – 4 years) and in immunocompromised children. Progression to disease occurs by extension of the primary focus with or without cavitation, effects of pathological processes caused by lymph node enlargement or lymphatic and/or haematogenous spread of the infection. In children, the majority of TB is pulmonary and fewer cases are extra-pulmonary.

5.2.2 Risk factors for TB

- A history of contact with an adult with smear-positive TB, especially household members,
- under 5 years,
- HIV infection and
- Severe malnutrition)

5.3 Types of TB in Children

5.3.1 Pulmonary TB

The diagnosis of PTB in children remains a major challenge primarily because the majority of children with TB are not able to expectorate and provide lower respiratory tract specimens for microbiological investigations.
The key elements to a successful diagnosis of PTB in children include:

- Careful history taking (including history of TB contact and symptoms consistent with TB
- Clinical examination (especially growth monitoring))
- Smear microscopy
- Tuberculin skin testing (TST)
- Chest radiography
- HIV testing

In the majority of cases the clinical diagnosis of PTB in children will be straightforward, if the clinician pays attention to **clinical details** aided by the chest x-ray, tuberculin skin test, and sputum smear microscopy where feasible and HIV testing. Although bacteriological confirmation of disease in children may be difficult, older children should be encouraged to give sputum samples. In most immune competent children, TB presents with symptoms of a chronic disease after they have been in contact with an infectious source case. Infection with *Mycobacterium tuberculosis* can often be demonstrated by a tuberculin skin test (though due to interactions with prior BCG vaccination, TST may not always yield a definite result) and chest radiograph changes typical of TB.

5.3.1.1 The signs and symptoms of PTB in children

TB should be suspected in any child who presents with the following:

- Chronic unremitting cough for more than two weeks.
- Physical signs suggestive of TB (e.g. fever of greater than 38^0C for two or more weeks, failure to gain weight or weight loss (growth faltering)
- A positive tuberculin skin test
- Suggestive chest X-ray

Presence of 3 or more of the above strongly suggests TB.

The most common symptoms of TB in children are chronic unremitting cough for more than two weeks, fever of greater than 38^0C for two or more weeks after other common causes like malaria has been excluded, and persisting weight loss or failure to gain weight, even after treatment for malnutrition. There may be no signs in the lung that are specific for TB, but Pulmonary TB should be considered in any child presenting with suspected **pneumonia** unresponsive to appropriate antibiotic treatment.

5.3.1.2 Definition of TB contact

A close contact is defined as a person living in the same household or someone who is in frequent contact with the child and has or has had smear-positive PTB. Source cases that are sputum smear-negative but culture positive are also infectious, but to a much lesser degree.

All children (especially those under 5 years of age) who have been in close contact with a source case must be screened for TB**. **After TB is diagnosed in a child or adolescent, an effort should be made to detect the adult source case(s), especially the undiagnosed household case. If a child presents with infectious TB, then childhood contacts must be sought and screened as one would for any smear-positive source case. Children should be regarded as infectious if they are sputum smear-positive or have a cavity visible on the chest radiograph.

5.3.1.3 Specimens for bacteriologic tests

Specimens should be collected for bacteriologic examination from all children suspected to have PTB. Appropriate specimens include sputum (spontaneous or induced), and gastric aspirates
The common ways of obtaining these specimens include:

Spontaneous Sputum Expectoration
In children above 5 years of age, sputum should be collected and sent for smear microscopy and culture (where available). Sputum is difficult to obtain from children under five years of age; however some may be obtained by sputum induction. Young children tend to have paucibacillary disease, which may render a relatively higher proportion smear negative. However, culture increases the ability to identify the bacilli. Yields are higher in older children above five years of age, adolescents, and in children with severe TB disease.

Sputum induction
Sputum induction can safely and effectively be performed in children of all ages, and the bacteriologic yields are better than for gastric aspirates. However this procedure cannot be performed in the absence of a nebulizer and preferably an ultrasonic nebulizer. Because it is an aerosol generating procedure, there is potential danger of transmission of TB to health care workers and therefore it should be done only in health care environments where adequate measures for prevention of transmission of infectious aerosols are in place.

Gastric aspirates
Early morning gastric aspiration using a nasogastric feeding tube can be performed in young children who are unable or unwilling to expectorate sputum. These gastric aspirates should be sent for smear microscopy and mycobacterial culture.

5.3.1.4 The Chest radiograph in children with PTB

The commonest picture is that of persistent **opacification** in the lung together with enlarged and usually unilateral mediastinal lymph glands. A **miliary** pattern of opacification in HIV non-infected children is highly suggestive of TB. Patients with persistent opacification which does not improve after an adequate course of broad spectrum antibiotics should be considered TB suspects and appropriately investigated or treated for the disease. Adolescent patients with PTB have chest radiographic changes which are similar to adult patients with **apical infiltrates** and/or **cavity formation** being the most common forms of presentation.

Although chest radiography is useful in the diagnosis of TB in children, chest radiographs may be difficult to read in children under the age of five years, who have malnutrition and/or HIV infection. These x-rays should preferably be read and reported by a radiologist or other health care worker with adequate knowledge and skill to do so.

5.3.1.5 The tuberculin skin test (Mantoux) in childhood TB

A mantoux test should be regarded as positive if:

- there is ≥ 5 mm diameter of induration in high-risk children (including HIV-infected, and severely malnourished children, i.e. those with clinical evidence of marasmus or kwashiorkor)
- there is ≥ 10mm diameter of induration in all other children (whether they have received a Bacilli Calmette – Guerin (BCG) vaccination or not).

A positive TST (Mantoux) indicates that the child has been infected with TB but does not necessarily indicate disease. In severe malnutrition or HIV infection, the Mantoux test may be negative (false negative due to diminished ability to mount an immune response) despite the presence of TB infection.

Tuberculin skin tests are useful in HIV infected children especially to identify those with dual HIV/TB infection and as an aid in the diagnosis of TB, although the percentage positive will be lower than in non-infected children.

A negative TST (Mantoux) never rules out diagnosis of TB in a child.

When a decision is made to treat a child for TB, full treatment instead of "trial treatment" should be offered.

5.3.1.6 Other specialized tests

Other Tests including computerized chest tomography, bronchoscopy, serological and Nucleic Acid Amplification (e.g. PCR) assays, and Gamma Interferon release tests are generally not recommended for the routine diagnosis of TB in children. Gamma Interferon release tests such as Ellispot, has high specificity but low sensitivity for identification of mycobacterial antigen in children.

5.3.2 Extra pulmonary TB in Children

TB can affect any organ of the body. Of the extra-pulmonary forms of TB that occur in children, miliary and tuberculous meningitis carry the highest risk of death. The most common forms of extra-pulmonary TB and the practical approach to diagnosis are shown in the table below:

Practical approaches in EPTB

Category	**Practical approach to diagnosis**
Lymph nodes (cervical most common)	Node biopsy/Fine needle aspiration
Miliary	Chest X-ray and lumbar puncture
Meningitis	Lumbar puncture and CSF examination, CT scan
Pleural effusion	Chest X-ray, pleural tap
Peritoneal TB	Abdominal ultrasound and ascitic tap
Osteoarticular	X-ray, joint tap or synovial biopsy

The following physical signs and conditions are highly suggestive of extra pulmonary TB in children:

- The presence of a gibbus, especially of recent onset, is highly suggestive of spinal TB
- Non-painful enlarged cervical lymphadenopathy with fistula formation
- Meningitis not responding to treatment, with a sub-acute onset or raised intracranial pressure
- Pleural effusion
- Pericardial effusion
- Distended abdomen with ascites
- Non-painful enlarged joints
- Signs of tuberculin hypersensitivity: phlyctenular conjunctivitis, erythema nodosum

5.4 HIV in Childhood TB

Children who are HIV infected may be at increased risk of developing TB just like adults. The diagnosis of TB in HIV-infected children is more complex, as many HIV-related lung diseases can easily be confused with TB. It is possible that a significant proportion of HIV infected children with pulmonary disease and treated as TB do not in fact have TB.

As in adults, all children with TB should be offered HIV testing and counselling in accordance with the published guidelines for HIV testing in children.

5.5 Summary on the Diagnosis of TB in Children

The presence of three or more of the following in children should strongly suggest a diagnosis of TB:

- Chronic symptoms suggestive of TB
- Physical signs highly suggestive of TB
- A positive mantoux skin test
- Chest x-ray suggestive of TB

Diagnostic approaches have been developed to facilitate diagnosis. These include Pediatric TB score charts which are in two parts.

Pediatric TB score chart: 1

Feature/ Score	**0**	**1**	**3**
Duration of Illness	< 2 weeks	2 – 4 weeks	> 4 weeks
Nutritional status (Weight for age)	> 80%	60 – 80%	< 60%
Family History of TB	None	Reported	Confirmed SM+ve

Pediatric TB score chart: 2

Positive tuberculin test	3
Enlarged painless lymph nodes, sinus present	3
Night sweats, unexplained fever	2
Malnutrition not improving after treatment	3
Angle deformity of spine	4
Firm, non-fluid, non-traumatic swelling of joint	3
Unexplained abdominal swelling or ascites	3
Change of temperament, fits, or coma	3
Abnormal X-ray	2

When total score for section 1 and 2 together is 7 or more, then treat as TB.

If a child does not fulfill the above summarized diagnostic criteria, and fails to respond to appropriate antibiotic treatment, and the clinician has a high index of suspicion of TB in the child, treatment for TB should be considered. Once a decision is made to initiate anti-TB therapy, the full course of treatment should be given.

CHAPTER 6: TREATMENT OF TB IN ADULTS AND CHILDREN

6.1. What the Patient Should Know

- It is the responsibility of the health staff to continuously educate patients with TB, their relatives and treatment supporters about the disease.
- It is essential to obtain the patient's co-operation during the whole treatment period.
- An understanding, sympathetic and concerned attitude on the part of the health staff is essential for getting the message across.
- To attain a high cure rate and to prevent default, health education should be provided every time the patient receives care from the health care provider.
- Infection prevention measures like hand capping and opening windows at home should be addressed.

At diagnosis the patient needs to know:

- Tuberculosis is an infectious disease, which is transmitted from one person to another through coughing, sneezing etc.
- The patient may have infected other people who may also develop tuberculosis. He/she should therefore, be asked to encourage other people with whom they been is in close contact with to undergo screening for TB.
- Infection prevention measures like hand capping, opening windows at home, proper lighting, and benefits of spending most of their time in open air.
- Tuberculosis drugs are available and free of charge at any government health facility, most mission hospitals and some private health facilities.
- Each patient has his/her own patient pack. Therefore the availability of drugs for the complete treatment period is guaranteed for the patient. The patient should be shown his/her patient pack; this will also create a sense of ownership and responsibility in the patient.
- Patients will be required to come and swallow their drugs from the clinic daily under Direct Observation of the health worker. Where circumstances may not allow, a treatment supporter will be required do the Direct Observation on behalf of and report to the health worker (DOT).
- Once treatment with these drugs is initiated the symptoms of tuberculosis disease will disappear quickly, but the drugs still need to be continued daily until the end of the prescribed treatment period. Failure to comply with this treatment requirement may cause the disease to start again, with the possibility that drug resistance may have developed which would make treatment with the same drugs inadequate. This could occasion a greater risk for the health of the patient and that of his or her close contacts.
- Side effects may include urine discoloration by Rifampicin, skin reactions by Isoniazid, blurring of vision etc.
- The type of regimen, the exact number and type of tablets that the patients will take.
- How long the intensive phase and the continuation phase will take, where and when the drugs will be administered.
- Women should be informed that Rifampicin containing regimen interacts with oral contraceptives and hence additional contraceptive measures need to be taken if necessary.
- A sputum-smear examination is required at certain intervals to monitor the progress towards cure. Explain to the patient when the examination will be required.
- HIV testing offers an opportunity for further treatment, care and support especially to those who are HIV positive. For those who are HIV negative it offers them an opportunity to know their HIV status and how to prevent HIV infection.

After the start of treatment:

- Encourage contacts (e.g. household members especially children under 5 years of age, PLHWA) to come for TB screening.
- Patients are requested to inform the staff at the clinic when they intend to travel. An adequate supply of drugs can then be given to cater for the period they are away from their local area.
- Patients are requested to inform the staff at the clinic when they intend to move to another area. The clinic staff will then write a transfer letter and give advice as to where they can continue treatment.
- Alcohol is injurious to the liver. Anti-TB drugs also may be toxic to the liver. Therefore the

combination of alcohol and anti-TB drugs may lead to a greater risk of hepatic reactions. It is advisable therefore to encourage patients on anti-TB treatment to reduce the amount of alcohol taken if it cannot be entirely avoided.

- Tobacco smoking is injurious to body organs too and should be strongly discouraged in patients receiving TB treatment.
- There is no known contraindication to sexual intercourse during treatment with anti-TB drugs.

At the end of treatment:

Tuberculosis disease may occur again. The patient should therefore report immediately to the health care provider when similar symptoms recur.

6.2 The aims of treatment:

- Prevent suffering and death from TB
- Prevent long term complications or sequel of TB
- Prevent relapse of the disease
- Prevent transmission of the infection
- Prevent the development of resistant tubercle bacilli

It is important to remember that treatment of tuberculosis benefits both the community as a whole and the individual patient; thus, any public health program or private provider undertaking to treat a patient with tuberculosis is assuming a public health function that includes not only prescribing an appropriate regimen but also ensuring adherence to the regimen until treatment is completed.

Tuberculosis treatment involves the use of multiple drugs taken in combination. This is done to prevent the emergence of drug resistance to any of the drugs. When single drugs are used (monotherapy) the tubercle bacilli quickly develop resistance to the drug used. Therefore anti-TB drugs should always be used in combination and currently most anti-TB drugs are available as tablets containing multiple drugs in Fixed Dose Combinations (FDC). There are currently five primary drugs used to treat TB: Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), Ethambutol (E), and Streptomycin (S).

Please note that Thiacetazone is no longer used for TB treatment in Kenya. This is because of the high HIV prevalence among TB patients and the attendant high incidence of cutaneous adverse reactions including Steven-Johnson syndrome.

In the first two months of treatment, four drugs (RHZE) are used to rapidly reduce the number of tubercle bacilli (bacillary load) in the body. This phase is called the Intensive phase of anti-TB treatment. After two months two drugs are used for 4-6 months (RH or EH) and this phase is called the Continuation Phase of anti-TB treatment.

Anti-TB drugs should be taken in the right combinations and doses, and the correct schedules for the appropriate duration. To promote total adherence to treatment, an individualized patient centered approach should be developed.

A patient centered approach to facilitate adherence to treatment including Direct Observation of Treatment (DOT) should be promoted. DOT should be provided using a treatment supporter who is acceptable and accountable to the patient and to the health system, for example a friend, family member, community or health care worker. The DOT may take place at home, workplace, health facility or other convenient place agreeable to the patient, the treatment supporter and the health care system.

6.3 Treatment regimen for new adult TB patients

All patients who have not been on TB therapy previously should have a two month initial phase of treatment consisting of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol followed by a continuation phase of ethambutol and isoniazid for six months or Isoniazid and Rifampicin for four months.

Fixed Dose Combinations (FDC)
FDC tabs contain two or more medicines within the same tablet or capsule.
Advantages include:

- Reduced risk of resistance developing to the drugs in the event of missed doses
- Fewer medication errors
- Fewer prescription errors

Disadvantages include:

- Reduced bioavailability of some drugs, particularly Rifampicin
- Flexibility in obtaining an optimal dose of some agents such as pyrazinamide
- Excluding a drug which causes strong adverse events

NB: Only those FDC's that have been proven to provide unaltered bioavailability of the component drugs should be used.

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The treatment regimen for new adult category 1 and 3 TB patients (see 2.3) is:

2RHZE/6EH or 2RHZE/4RH *which is offered through* ***WEEKLY*** *drug collection during the intensive phase and* ***TWO*** *weekly (RH) or* ***monthly*** *(EH) during the continuation phase****.***

Since most defaults happen in the first two months of treatment, weekly drug collection during the intensive phase is particularly important to identify potential defaulters.

Table 6.1 Treatment regiment for new adult TB patient

Abbreviation of the regimen	2RHZE/6EH or 2RHZE/4RH	
Phase	Intensive Phase	Continuation Phase
Duration	Daily treatment with appropriate patient support, including DOT, for two months	Daily treatment with appropriate treatment support, including DOT, for four or six months.
Drugs used	Rifampicin (R) + Isoniazid (H)+ Pyrazinamide (Z) + Ethambutol (E)	Ethambutol (E) and Isoniazid (H), 6 months. or Rifampicin (R) and Isoniazid (H), 4 months.

6.4 Treatment regimen for TB patients who relapsed, failed or returned after default

For patients who have previously been treated for TB for more than one month including those who have relapsed after successful previous treatment, or those who defaulted from previous treatment or failed previous treatment, with sputum smears remaining positive at 4/5, 6/8 months (Category 2 patients) the regimen used is two months of SRHZE followed by one month of RHZE and then five months of RHE. This regimen is abbreviated 2SRHZE/1RHZE/5RHE. Patients in this category should have their sputum collected and sent for culture and DST.

The treatment regimen for Category 2 (retreatment TB patients) is:

2SRHZE/1RHZE/5RHE

The intensive phase is therefore 3 months with daily injections of Streptomycin and swallowing of RHZE in the first two months and weekly drug collections in the third month, followed by 5 months of continuation phase with two weekly drug collections. DOT throughout has to be guaranteed.

Patients in this category should have their sputum collected and sent for culture and DST to the Central Reference Laboratory before the start of treatment.

Failures of this retreatment regimen are likely to be patients with multi-drug resistant TB.

Table 6.2 Treatment regime for retreatment patients

Abbreviation of the regimen	2SRHZE / 1RHZE / 5RHE		
Phase	Intensive Phase		Continuation Phase
Duration	Daily treatment with appropriate patient support for two months	Daily treatment with appropriate patient support for one month	Daily treatment with appropriate patient support for five months
Drugs used	Streptomycin (S) + Ethambutol (E) + Rifampicin (R) + Isoniazid (H)+ Pyrazinamide (Z)	Ethambutol (E) + Rifampicin (R) +Isoniazid (H)+ Pyrazinamide (Z)	Ethambutol (E) +Rifampicin (R)+ Isoniazid (H)

Note: Patients who are pregnant must never be given streptomycin due to risk of vestibulo-cochlear damage to the fetus. Patients over 64 years of age should not be given more than 0.75mg of Streptomycin.

6.5 Treatment dosages for adults

Table 6.3 Treatment dosages for adults

Drug Dosages		Pre-treatment weight		
Drug	Formulation	Over 54 kg	40-54 kg	30-39 kg
Streptomycin	i.m injection	1 g	0.75 g	0.50 g
Rifampicin 150 mg + Isoniazid 75 mg + Pyrazinamide 400 mg + Ethambutol 275 mg	4-FDC tablet RHZE	4	3	2
Rifampicin 150 mg + Isoniazid 75 mg + Pyrazinamide 400 mg	3-FDC tablet RHZ	4	3	2
Rifampicin 150 mg + Isoniazid 75mg	2-FDC tablet RH	4	3	2
Rifampicin 150, Isoniazid 75 and Ethambutol 275 (RHE)	Tablet RHE	4	3	2
Isoniazid 150 mg and Ethambutol 400 mg	Tablet EH	2	2	2

The re-treatment drugs are provided in 4 FDC (RHZE) to be taken with Streptomycin in the first two months and alone in the third month followed by a 3 FDC of RHE for the five months continuation phase.

Patients on TB treatment should be monitored for:

1. Clinical outcomes:

- Weight gain

- Resolution of symptoms and signs

2. Bacteriologic response - follow-up sputum smears for all smear positive patients:

- Patient treatment on EH – follow up sputum smears at 2, 5 and 8 months

- Patient treatment on RH – follow up sputum smears at 2, 5 and 6 months

- Patient treatment on retreatment – follow up sputum smears at 3, 5 and 8 months.

Patients who still have a positive smear at the end of the intensive phase should have the intensive phase extended for one month only. Sputum smears need to be done at the end of the third month at which point the patient should be switched to the continuation phase.

Patients who still have a positive smear at month 5 should be considered to have failed initial treatment and switched to the re-treatment regimen (2SRHZE/1RHZE/5RHE). A sputum sample needs to be collected and sent for culture and drug sensitivity testing to the CRL. The medications given, the bacteriologic and clinical response should be all recorded in the patient record card and the TB treatment register.

6.6 TB patient treatment packs

In the public health care sector, TB treatment is now provided in individualized patient packs. Patient packs will also be available to private health care providers irrespective of the source of drugs (GoK or otherwise). Before allocating a pack to a patient determine where the patient will actually receive his or her treatment.

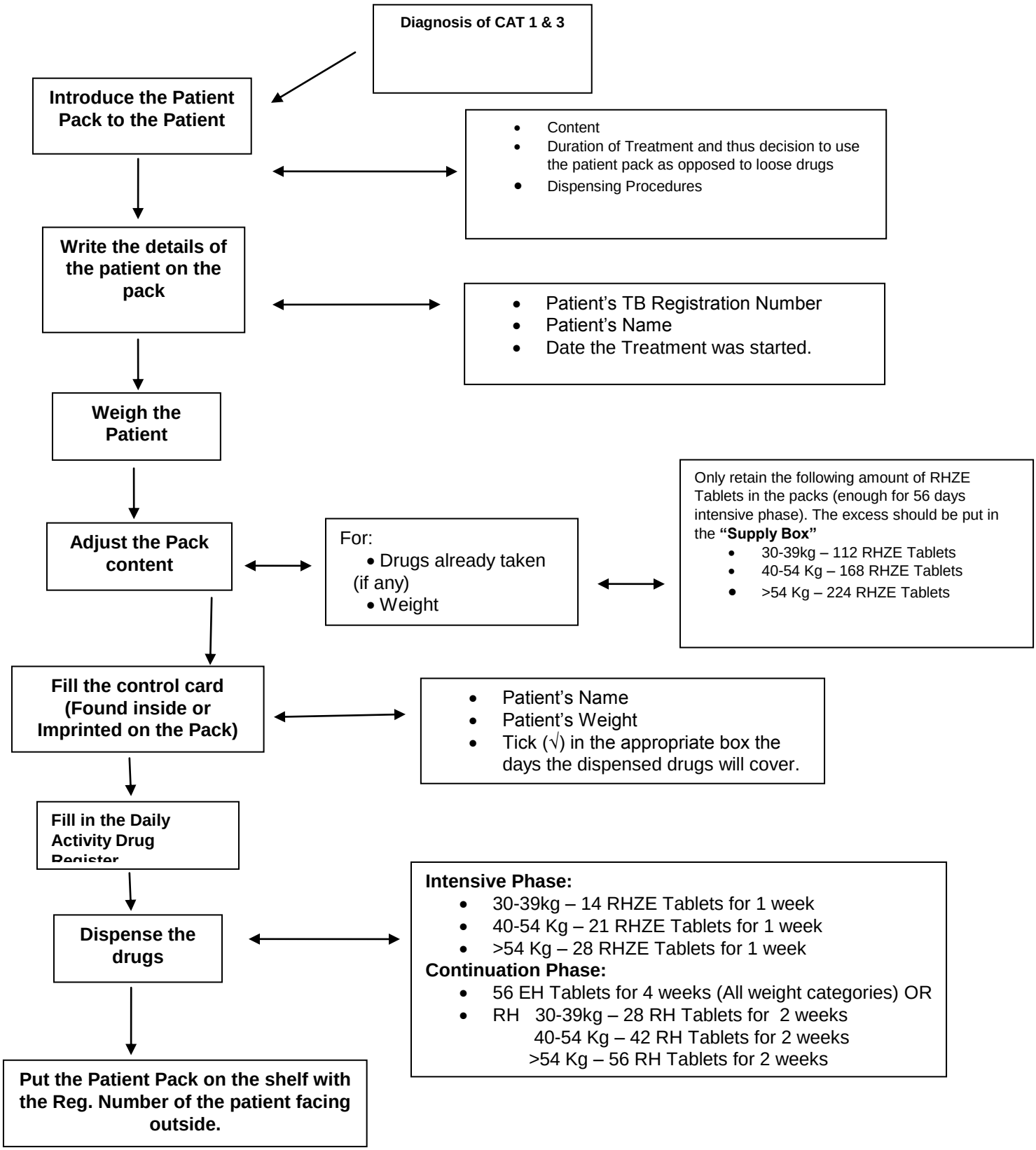
One patient pack is for one patient only and should be labeled with the name of that patient and his/her registration number. The patient should be introduced to "his/her"pack so he/she understands that the full treatment is available to him/her.

The patient packs should remain in the health facility and appropriate doses taken out or added to the pack for the recommended duration of treatment. Adjustment in doses should be made at the beginning of treatment according to the instructions in the patient packs.

Tablets not needed due to reduced dosages should be put into a separate supply box which can be dispensed to patients who are referred or are in transit to other facilities. Patients being transferred out to another health facility should not be given their pack to move with.

All patient information together with the clinical notes should be entered into the patient's TB treatment record card (and the patient appointment card). Relevant information should thereafter be entered in the treatment register with all entries filled in.

Handling & Dispensing of Tuberculosis Patient Packs



NOTE: Contents of Patient Packs for those who die or "Lost to follow up" should be put in the Supply Box and the Daily Activity Drug Register filled to update the Supply Box information.

Subsequent visits will entail weighing, filling control card and dispensing drugs.

6.7 TB treatment in mobile populations

In Kenya, about 10% of all registered tuberculosis patients live in the arid and semi-arid areas, and patient support and follow-up of treatment is difficult due to the scarcity of health facilities and the mobile life style of the patient. However the DLTLD has now standardized treatment all over the country and the same regimens are now used in patients treated in the TB manyattas.

6.8 Treatment of TB in pregnancy

In general, pregnancy should be avoided during anti-TB treatment. ***However when it occurs, termination of pregnancy should not be recommended***. Like most drugs, anti-TB drugs have not been specifically studied in pregnancy. There is always some risk of teratogenicity with any drugs especially when the drug is given in the first trimester. There have been no significant reports that anti-TB drugs pose a greater than usual risk of teratogenicity and therefore all pregnant women with active TB should be treated with a full complement of anti-TB drugs. It is useful to give Pyridoxine with Isoniazid to avoid the small risk of damaging the infant's nervous system. **Streptomycin should not be used in pregnancy because it may cause deafness in the infant.** When treating drug resistant TB the aminoglycosides (Kanamycin, Amikacin and Capreomycin) and the thioamides (Ethionamide and Prothionamide) should not be used in pregnancy because of associated ototoxity**.**

6.9 Treatment of Tuberculosis in children

Children usually have paucibacillary disease (low organism numbers), as cavitating disease is relatively rare (about 6% or less) at less than 13 years of age and the majority of the organisms in adult-type disease are found in the cavities. On the other hand, children more often than adults develop extra-pulmonary TB (EPTB), and severe, disseminated TB (e.g. miliary TB and TB meningitis) is especially found in the < 3 year olds. Both the bacillary load and the type of disease may influence treatment regimens.

Treatment outcomes in children are generally good, even in the young and immune compromised who are at higher risk of disease progression and dissemination, provided treatment is started promptly to decrease morbidity and mortality.

The management of all children with TB should be in line with the DOTS strategy, including daily directly-observed treatment. The principles of TB treatment are similar to those in adults. As in adults anti-tuberculosis treatment is divided into two phases: an intensive phase and a continuation phase. The intensive phase uses at least three drugs (RHZ) while the continuation phase utilizes usually two drugs (RH). The drug regimen and doses for children are summarized in the tables below:

6.9.1 Treatment regimen for category 1 and 3 tuberculosis patients younger than 15 years

The recommended regimen for all forms of TB in children in Kenya is 2RHZ/4RH. Recently children friendly formulations have been introduced.

Treatment regimen for children

Abbreviation of the regimen	2 RHZ	4RH
Phase	Intensive Phase	Continuation Phase
Duration	Daily treatment with appropriate patient support for two months	Daily treatment with appropriate patient support for four months

6.9.2 Anti-tuberculosis drug dosages for children

Table 6.4 Anti-TB drug dosages for children

Drug	**Daily recommended dosage in mg/kg (range)**	**Maximum daily dose**
Isoniazid	5 (4-6)	300mg
Rifampicin	10 (8-12)	600mg
Pyrazinamide	25 (20-30)	-
Ethambutol*	20 (15-25)	Not to exceed 25mg/kg
Streptomycin	15 (12-18)	-

Table 6.5 Tablet Dosage Guide for children

Drug Dosages		Pre-treatment weight				
Drug	Formulation	<10 kg	10 – 14 kg	15 – 19 kg	20 – 24kg	25 – 29 kg
Fixed Dosage Combination (No of tablets per dose per day – Paediatric dispersible FDC						
Rifampicin 60 mg + Isoniazid 30mg + Pyrazinamide 150 mg +	3-FDC tablet (RHZ)	1	2	3	4	5
Rifampicin 60 mg + Isoniazid 30 mg	2-FDC tablet (RH)	1	2	3	4	5

Where pediatric dispersible FDC are not available, adult formulations can be used as below:

	No of tablets to give	
Patient Weight	**Rifampicin 150mg + Isoniazid 75mg + Pyrazinamide 400mg**	**Rifampicin 150mg + Isoniazid 75mg**
<10 kg	¼	¼
10 – 14 kg	½	½
15 – 19 kg	1	1
20 – 24kg	1 ½	1 ½
25 – 29kg	2	2

**WHO states that current evidence indicates Ethambutol is safe in children, when given at dosages of below 25mg/kg (with risk of optic neuritis below 0.05%). Although there is evidence that Ethambutol is safe in children, it is reasonable to limit the use of this drug to children who are able to indicate when*

visual problems occur (over the age of 3 years). Children who must be given this drug for whatever reason should not be denied this treatment on the basis of risk of ocular toxicity (*Ethambutol efficacy and toxicity. Literature review and recommendations for daily and intermittent dosage in children*. Geneva, World Health Organization, 2006
(WHO/HTM/TB/2006.365).

6.9.3 Management of Severe forms of TB in children: TB meningitis, and Miliary TB

TB meningitis and miliary TB are more common in young children and are associated with high rates of death and disability. Children with these severe forms of TB should be:

- Hospitalized for initial management, until their clinical status has stabilized
- Managed with 4 anti-TB drugs during intensive phase of treatment, and upper end of recommended dose ranges should be used.
- Given corticosteroids, prednisone 2mg/kg for 4 weeks, after which the dose should be slowly reduced over 1-2 weeks before stopping.
- If initial response to therapy is poor, consider extending the full treatment regimen to 9-12 months.
- If initial response to therapy is poor, consider using 3 drugs throughout the continuation phase of treatment (RHZ).

6.9.4 Corticosteroids in childhood TB

Corticosteroids should be used for the management of certain types of TB where scar formation may lead to serious consequences. These include TB meningitis, lymphobronchial TB (causing respiratory obstruction), TB pericarditis and genitourinary TB. The drug most frequently used is prednisone, in a dosage of 2mg/kg/day for 4 weeks. The dose should then be slowly reduced (tapered off) over 1-2 weeks before stopping.

6.9.5 Administering treatment and ensuring adherence

Children, their parents, and other family members should be educated about TB and the importance of completing treatment. Where possible, someone other than the child's parent or immediate family should observe or administer treatment. Fixed dose combinations (FDCs) should be used at all times to improve simplicity and adherence. Child-friendly formulations, such as soluble tablets or powder, or suspensions, should be used where available and if of proven quality. Treatment adherence should be recorded in the patient appointment card, facility record card and the TB register.

6.9.6 Follow-up of children on TB treatment

Ideally, each child should be clinically assessed at 2 weeks after treatment initiation, at the end of intensive phase, and every month until treatment completion. The assessment should include, at a minimum, a symptom assessment, an assessment of adherence, inquiry about any adverse events, and weight measurement. Medication dosages should be adjusted to account for any weight gain. Adherence should be assessed by reviewing the treatment card. A follow-up sputum smear for microscopy at 2 months should be obtained for any child who was smear-positive at diagnosis. Follow-up chest radiographs are not routinely required in children, particularly as many children will have a slow radiological response to treatment. A child who is not responding to TB treatment should be referred for further assessment and management.

6.9.7 Case recording and reporting for childhood TB

All children between 0-4 and 5-14 years diagnosed and treated for TB should be recorded in the TB facility register, quarterly case finding/cohort reports and standard treatment outcomes reported.

6.9.8 Paradoxical Reactions in childhood TB

A temporary exacerbation of symptoms, signs or radiographic manifestations sometimes may occur after beginning anti-tuberculosis therapy. This can simulate worsening disease, with fever, increased size of lymph nodes or tuberculoma, but is usually the result of immune reconstitution brought about by improved nutritional status or the anti-tuberculosis treatment itself. Anti-tuberculosis treatment should be continued and in the majority of cases oral corticosteroids should be added.

6.9.9 Anti-TB drug adverse events in children.

Adverse events are much less common in children than in adults. The most important adverse event is the development of hepatotoxicity, which can be caused by any of the anti-TB drugs. The management of anti-TB drug adverse events is similar to that in adults.

6.9.10 Childhood re-treatment Cases

In childhood TB cases where anti-tuberculosis treatment fails or a relapse occurs, every effort should be made to find the most likely cause for the failure of treatment or relapse. Failure of treatment in confirmed TB is more likely to be due to drug resistant TB. Therefore all children who fail first line anti-TB treatment should as far as feasible have specimens submitted to a laboratory for mycobacterial culture and Drug Susceptibility Testing (DST). While results are awaited the child should be placed on the 2SRHZ (E)/1RHZ (E)/5RH (E) regimen.

6.10. Prevention of TB in children: BCG and IPT

6.10.1 BCG vaccination

It is generally accepted that after effective BCG vaccination there is protection against the more severe types of TB such as military and tuberculosis meningitis, which are most common in young children. Therefore in Kenya it is recommended that this vaccine be given to all children at birth or first contact with the health care system except in children with full blown AIDS.
In general, BCG vaccination is safe. However a small number of children develop reactions which include local abscesses, secondary bacterial infections, supportive adenitis and very rarely disseminated BCG disease. Those who develop BCG disease should be treated using a first line regimen.

6.10.2 Preventing TB in children in contact with smear positive PTB

When a patient is diagnosed with smear-positive pulmonary tuberculosis, all children in that household should be screened for evidence of active TB (see chapter 6). Those found with TB disease should be put on treatment. Children below 5years without TB disease should be put on Isoniazid 5mg/kg daily for six (6) months. If active TB disease develops during the 6 month period, prophylaxis should be stopped, and switched to full anti-TB treatment using the standard regimen.

6.11 Nutritional support for TB patients

6.11.1 Nutritional needs in Tuberculosis

Tuberculosis is a chronic wasting disease characterized by high prolonged fevers. During this period when the body temperatures are beyond 37 degrees several metabolic changes occur in the bodies, which are proportional to the increased body temperatures. Some of these changes are:-

- There's a 13% increase in basal metabolic rate (BMR) change with every 1 degree Celsius rise in body temperature.

- The adipose and glycogen stores normally decrease due to the increase in energy expenditure.
- There's is reduced absorption of minerals, vitamins, proteins and increase in nitrogen breakdown hence low immunity.
- Due to the high fevers there is loss of body fluids as a result of excessive sweating and urination during the acute phase .The increase in urine production is to remove nitrogenous waste.
- Due to loss of appetite and anorexia during illness there is reduced food intake hence depletion of the body stores.
- Mal absorption due to the high metabolic rate leading to malnutrition and wasting

Nutrition requirements for patients with tuberculosis include

Energy

Most patients with chronic tuberculosis are malnourished, energy needs are increased in order to minimize weight loss and achieve a desirable weight. An additional 300- 500 kcals (35 -40 kcals per ideal body weight) this also helps in protein sparing.

Proteins

An intake of 1.2- 1.5 gm of protein per kg body weight is required to generate serum albumin levels per day, due to tissue wasting and repair of worn out tissues.

Fats/ oils

These should provide 25-30% or less of the total energy requirements of an individual.

Vitamins and minerals

The body should be provided with liberal amounts of the vitamins and minerals. In TB conversion of beta carotene to rational is affected in the intestinal mucosa. The client should be supplemented with Vit A (every six months or as per the National Vit A supplementation schedule) and encouraged to eat vitamin A rich foods.

Patients on Isoniazid should ideally be supplemented with 10mg of pyridoxine B6 daily since the drug inhibits its absorption. Additional amounts of vitamin C is recommended in the diet to facilitate healing of lesions.

Other antioxidants (Vit A,C,E, folic acid, zinc and selenium) Neutralize free radicals (ROS) and prevent the production of peroxides from lipids.

Water

At least 8 glasses or more of safe clean water should be consumed per day. The water helps regulate temperatures, improve blood circulation and helps flush out toxins.

Fiber

Low fiber diet is recommended.

6.11.2 Nutritional assessment

This forms the basis of nutrition support and care.

It's important to carry out nutrition assessment to all patients on tuberculosis therapy in order to plan and determine the type of intervention early before clients develop complications. Monitoring is required regularly.

Anthropometric tools

- Standio-meter / Height meter rule
- Weighing scale
- Length/height board
- Infant scale
- Height – weight combo scale
- Child MUAC tape
- Adults MUAC tape

Common nutritional indices

Body Mass Index (BMI)

- Body Mass Index BMI) is an anthropometric index of weight and height that is defined as body weight in kilograms divided by height in meters squared (Keys et al., 1972).

Body Mass Index (BMI) calculated as follows:

The weight in (Kg) divided the square of height in meters. i.e.,

$$BMI = \frac{\text{weight (kg)}}{(\text{Height- in meters})^2}$$

BMI useful for both adults and children

BMI	Nutrition Status	Interpretation
Below 17	Moderate severe malnutrition	High risk of illness and death
17 to < 18.5	Mild malnutrition	High risk of illness
≥ 18.5 – 25	Normal	
> 25.0 – 29.9	Over weight	Risk of diabetes and heart disease
30.0 and Above	Obese	High risk of diabetes and heart disease.

MUAC for adults, children and lactating mothers

Stunting, wasting and underweight for children

6.11.3 Recommendations for Nutritional support

The aim is to correct and prevent malnutrition.

Decision Matrix

Is a point of reference for health service providers to enhance best practices. It includes – Assessment, Diagnosis, Interventions, follow up and referrals.

6.11.3.1 TB clinical presentations, nutrition implications and interventions

Clinical presentation	Nutritional implication	Intervention
Fever	Increased Basal metabolic rate	Increase energy intake through consumption of small, frequent energy dense meals and high fluid intake.
Skin lesions	Increased demand for vitamins C, A, Zinc,	Increase intake of the vitamins A, C, Zinc.
Constipation/flatulence	Compromised dietary intake & digestion.	Dietary modification -High fibre diet with restriction of gas forming foods.
Loss of appetite	Compromised dietary intake	Counsel on small frequent nutritious meals, use of favorite foods and spices.
Wasting	Compromised Health, nutrition and immune status.	-Follow guidelines on management of malnutrition.
peripheral neuropathy	Increased demand for **B-complex vitamins**	Prescribe pyridoxine 10mg OD. In the absence of pyridoxine, supplement with B-com. Vit.
Failure to thrive	Compromised Health, nutrition and immune status.	-Promote exclusive breastfeeding -Follow IYCF guidelines. -Assess the child for OTP or SFP. -Vit.A supplementation as per the national schedule.

6.11.3.2 Food / nutrient based intervention for TB patients

Without malnutrition or with mild malnutrition.
Provide nutrition education and counseling on good nutrition practices (CNP), follow-up and closely monitor.

Moderate Malnutrition
Provide nutrition education and counseling
Enroll into Food by Prescription Supplementary feeding programme
Regular monitoring and follow-up.

Severe acute malnutrition without complications.
Enroll into Food by Prescription Out - patient therapeutic feeding programme (OTP).
Provide nutrition education and counseling
Close monitoring and follow-up (weekly).

Severe acute malnutrition with complications.
Admit for IP stabilization and management of severe malnutrition.
Close monitoring and follow-up (Daily).

4.4.3 Other Interventions
Regular de-worming
Vitamin A supplementation as per national schedule.
Targeted multiple micro nutrient supplementations.
Health and Nutrition education and counseling**.**

CHAPTER 7: ANTI-TB DRUG ADVERSE EVENTS OF FIRST LINE DRUGS

While most patients treated for TB experience no problems with the treatment a few patients may have significant side effects which can threaten life or interfere with the quality of life. All health care workers managing cases of TB should be familiar with the common side effects of anti-TB drugs and how to manage these side effects.

Table 7.1 Anti-TB common side effects.

Drug	Common side effects
Isoniazid	Peripheral neuropathy and hepatitis
Rifampicin	GI disturbance: nausea, vomiting, anorexia Hepatitis Red coloration of body fluids
Pyrazinamide	Joint pains and hepatitis
Streptomycin	Auditory and vestibular damage Damage to the kidney
Ethambutol	Optic neuritis

Any of these drugs may cause a skin rash. TB patients who are also HIV infected have more common and severe side effects.

7.1 Management of skin rash

The initial symptom of a cutaneous hypersensitivity reaction is often an itchy skin (pruritis). If there is no obvious rash, the skin itch should be treated with an antihistamine without withdrawing the drugs while monitoring the patient closely. If a severe reaction develops with a maculopapular erythematous blistering rash with ulceration of mucous membrane (Stevens-Johnson syndrome) with or without a generalized systemic disturbance, the anti-TB drugs should be stopped and where necessary the patient should be referred to the next level of health care for appropriate treatment of this major side-effect. Treatment for TB should be withheld until the rash resolves.
Thereafter anti-TB drugs should be reintroduced one at a time (single drugs), beginning with the least likely drug to have caused the rash and starting with low doses. This is best done by a clinician familiar with the drug challenge protocols. If on challenge the patient is found to react to an essential anti-TB drug (for example H or R) attempts at desensitization should be made and once again this must be done by a clinician familiar with the desensitization protocols.

7.2 Management of peripheral neuropathy

The most common cause of this side effect in TB treatment is Isoniazid. Peripheral neuropathy is more common in HIV infected patients, diabetics, alcoholics and sufficiently malnourished patients. To prevent peripheral neuropathy in these patients pyridoxine at 25 mg/ day should be co-prescribed with anti-TB drugs. Peripheral neuropathy is usually sensory and is recognized by the presence of pain, numbness and paraesthesias (pins and needles) in the hands and feet. When these symptoms occur the dose of pyridoxine should be increased to 100 mg/day.

7.3 Management of hepatitis

The key suspect drugs with regard to anti-TB drug related Hepatitis are Isoniazid, Pyrazinamide and Rifampicin. Hepatitis is recognized by the presence of malaise, nausea, vomiting, anorexia, fever, abdominal pain, hepatomegally and jaundice. When hepatitis occurs the anti-TB drugs should be stopped until the jaundice resolves. Strangely most patients can restart treatment after the jaundice resolves without a recurrence. It is advisable to refer patients with hepatitis to a specialist clinician, especially when the hepatitis is severe.

7.4 Management of gastrointestinal side effects

Anorexia, nausea and vomiting are very common in patients who commence anti-TB treatment. These side effects are usually not life threatening and resolve with time. However they may interfere with food and drug intake and compromise the patient's quality of life. The appearance of these side effects may lead to non- or poor adherence to treatment. These symptoms may be mitigated by taking the anti-TB drug with meals. Often an anti-emetic drug may be required. It is rare that anti-TB drugs need to be withdrawn. If vomiting is intractable, the patient should be referred to a specialist clinician.

7.5 Management of impaired vision

Impaired vision is a rare adverse effect associated with Ethambutol. If suspected, the drug should be withdrawn and the patient immediately referred to an eye specialist for assessment. If this adverse event is confirmed to be related to Ethambutol, the patients should not be given this drug ever again.

7.6 Management of vestibule-cochlear toxicity

This adverse effect, vestibular-cochlear toxicity, is usually due to Streptomycin. It is often, though not always, dose dependent. When the symptoms of vestibule-cochlear toxicity occur, the dose of Streptomycin should be checked and reduced if possible. If the dose cannot be reduced or the symptoms do not improve with dose reduction, Streptomycin should be stopped and not be given again.

7.7 Drug-Drug Interactions

Rifampicin is a potent hepatic enzyme inducer and therefore when co-administered it may lead to reduced drug levels for the following: **oral contraceptives, anticonvulsants, anti retroviral drugs** (e.g. Lopinavir/Ritonavir and Nevirapine) etc. Patients on Rifampicin should have their doses adjusted including for oral contraceptives or alternatives like condom used.

CHAPTER 8: TUBERCULOSIS AND HIV

8.1 HIV and TB interactions

HIV pandemic has been the main factor behind the re-emergence of TB in Kenya and in many countries affected by the HIV scourge. There has been an increase in TB incidence with the HIV epidemic. HIV influences TB in several ways. The virus is the most potent known risk factor for reactivation of dormant infection. HIV positive individuals infected with the tubercle bacilli have a 5-10% annual risk of developing active TB disease while HIV negative persons have only a 5-10% risk of developing TB disease over their life time. HIV increases the rate of progression of new TB infections to disease and also increases the risk of recurrence of previously successfully treated disease. Current data shows that on average 48% of TB patients in Kenya screened for HIV (79% of notified cases) are infected with this virus (DLTLD Annual Report 2007).
HIV infected TB patients are more likely to develop other acute infections and be hospitalized while receiving TB treatment. Some of these infections include bacteremic Streptococcal pneumonia, Non-typhoid Salmonella septicemia and others. Additionally HIV infected TB patients are more likely to die while receiving TB treatment than TB patients who are not HIV infected. Increasing TB cases among PLWHA enhances the risk of TB transmission in the community regardless of their HIV status.

8.1.1 HIV and TB interactions:

HIV infection results in:

- Reactivation of dormant TB infection
- Rapid progression of new infections to TB disease
- Recurrence of TB disease after successful treatment
- Increased risk of other acute infectious illnesses
- Increased risk of death
- Increased risk of adverse reactions to anti-TB drugs
- Increases stigma to the two diseases

8.1.2 TB disease:

- Causes rapid progression of HIV disease. TB is one of the most common opportunistic infection among PLWHA in high TB burden countries.
- Is the leading cause of HIV-related morbidity.
- TB is also one of the leading causes of mortality: one-third of all AIDS related deaths are due to TB.

8.2 TB/HIV collaborative activities:

The close association between TB and HIV makes it imperative to develop strategies for the delivery of combined TB and HIV services in what is commonly referred to as TB/HIV collaborative activities. These activities are aimed at coordination of TB and HIV programmes at all levels, reducing the burden of TB among persons living with HIV / AIDS (PLWHA) and reducing the burden of HIV in TB patients.

The key TB/HIV collaborative activities include:

8.3. Screening of persons found to be HIV positive at HIV testing sites for TB

All persons found to be HIV positive at HIV testing sites including VCT centers, STI clinics, PMTCT sites etc should be screened for TB and referred to the nearest TB diagnostic centres. This is more critical in clients who have a cough, fever, weight loss, or have lymph node enlargement. All HIV infected individuals should be screened for TB at initial enrollment into HIV care and at each clinical/ follow-up appointment. This process of intensified case finding (ICF) through screening for certain signs and symptoms associated with tuberculosis infection is aimed at early identification of TB suspects and diagnosis of tuberculosis and prompt treatment of the disease among the PLWHA and possibly among their household contacts.

8.3.1 Rationale for Intensified Case Finding among PLWHA

TB rates are higher in HIV infected populations than in the general population. TB is often the first opportunistic infection in PLWHA. It is the leading killer of HIV infected individuals in Sub –Saharan Africa. TB may also accelerate progression of HIV infection to full blown AIDS. For these reasons TB – ICF among PLWHA is an essential intervention required to reduce the burden of TB in HIV infected individuals. Ideally TB-ICF should be carried out at all HIV testing and/or treatment sites including Outpatient Departments where HIV Diagnostic Testing and Counseling (DTC) for all persons presenting with any HIV defining illness should be encouraged, VCT, PMTCT,CCC and Hospital wards caring for medical and pediatric patients . TB –ICF is intended to identify persons with TB who may benefit from early treatment to increase chances of survival, quality of life and reduce transmission of TB in the community. TB-ICF may be coupled with TB Preventive Therapy (usually Isoniazid Preventive Therapy (IPT) by identifying HIV infected persons who are suitable candidates for this intervention.

8.3.2 TB-ICF Sites

8.3.2.1 TB- ICF at Health Care Settings (Out Patient Departments, Hospital Medical and Pediatric Wards)

There is data that suggests that health care providers contribute significantly to TB diagnostic delays, often a lot longer than patient related diagnostic delays. Therefore, there is need to develop ICF approaches aimed at reducing provider related TB diagnostic delays when persons who may have TB present at health care providing sites. The proposed approach is to promote HIV testing for all persons presenting at outpatients departments with HIV defining illness and also in hospital medical and pediatric wards and to include TB screening, (using the symptom questionnaire below) as part of the medical evaluation of all those patients who are also HIV infected. With the use of rapid HIV tests it should be possible to rapidly identify HIV infected sick persons who must then be screened appropriately to exclude active TB.

8.3.2.2TB-ICF at congregate settings (Prisons)

Those who are confined to jails and other similar settings have a higher incidence of TB. It is important that Kenya strengthens its effort at TB-ICF within these settings. The approaches that have been developed by the NLTP in collaboration with CDC and the Prisons Department should be vigorously pursued. All new inmates should be screened for TB using the developed TB screening tools. Those diagnosed with TB should be offered DTC and placed on treatment as soon as possible.

8.3.2.3TB-ICF approaches at pharmacies and drug stores

There is some data that suggests that a significant proportion of TB patients will have self medicated for a long period with pharmaceutical products obtained from pharmacies and drug shops prior to the TB diagnosis. Targeting pharmacies and drug shops for TB-ICF is likely to result in early TB case detection and may improve TB CDR. Pharmacists need to use the new TB screening tool to screen all coughers and refer those suspected to have TB to the nearest health facility for diagnosis.

8.3.2.4TB-ICF at Community Level

TB patients come from the communities (in the broader sense of this word) that we all come from. Therefore well informed and empowered communities are essential for TB care and prevention. The approaches developed by the NLTP and partners for communication and Social Mobilization will be essential for TB-ICF at community level and must be vigorously pursued.

8.3.2.4TB-ICF at HIV testing or Care sites: The screening tools

TB-ICF may take all manner of complexity depending on the site of HIV testing (integrated vs. stand alone), skills of health care personnel and the availability of various screening tools and tests. However, the screening tool that can be made available to all is the screening questionnaire. It is proposed that this basic screening tool should be available at all HIV testing and / or care sites. The questionnaire is designed to identify symptomatic HIV infected persons who are TB suspects.

8.3.2.5TB-*ICF:* Symptom Questionnaire in Adults PLWHA

Symptom	YES	NO
1. Cough (of any duration)?		
2. Blood stained sputum?		
3. Night sweats >2 weeks		
4. Fever?		
5. Weight loss?		
6. Chest pain?		
7. Breathlessness?		
8. History of previous TB treatment?		
9. History of close contact with a person confirmed to have TB?		
10. Swellings in the neck, armpits or elsewhere?		

8.3.2.6TB-*ICF at HIV testing or Care sites*: the symptom questionnaire for children living with HIV

Symptom	YES	NO
1. Cough: (of any duration)?		
2. Blood stained sputum?		
3. Night sweats >2 weeks		
4. Fever? Of any duration?		
5. Weight loss?		
6. Chest pain?		
7. Fast Breathing?		
8. History of previous TB treatment?		
9. History of close contact with a person confirmed to have TB?		
11. Swellings in the neck, armpits or elsewhere?		
12: Diarrhea for more than two weeks?		
13. Failure to thrive?		

- If **"Yes"** to question one: Do sputum test and carry out clinical evaluation of the patient using the algorithm of diagnosing PTB below.

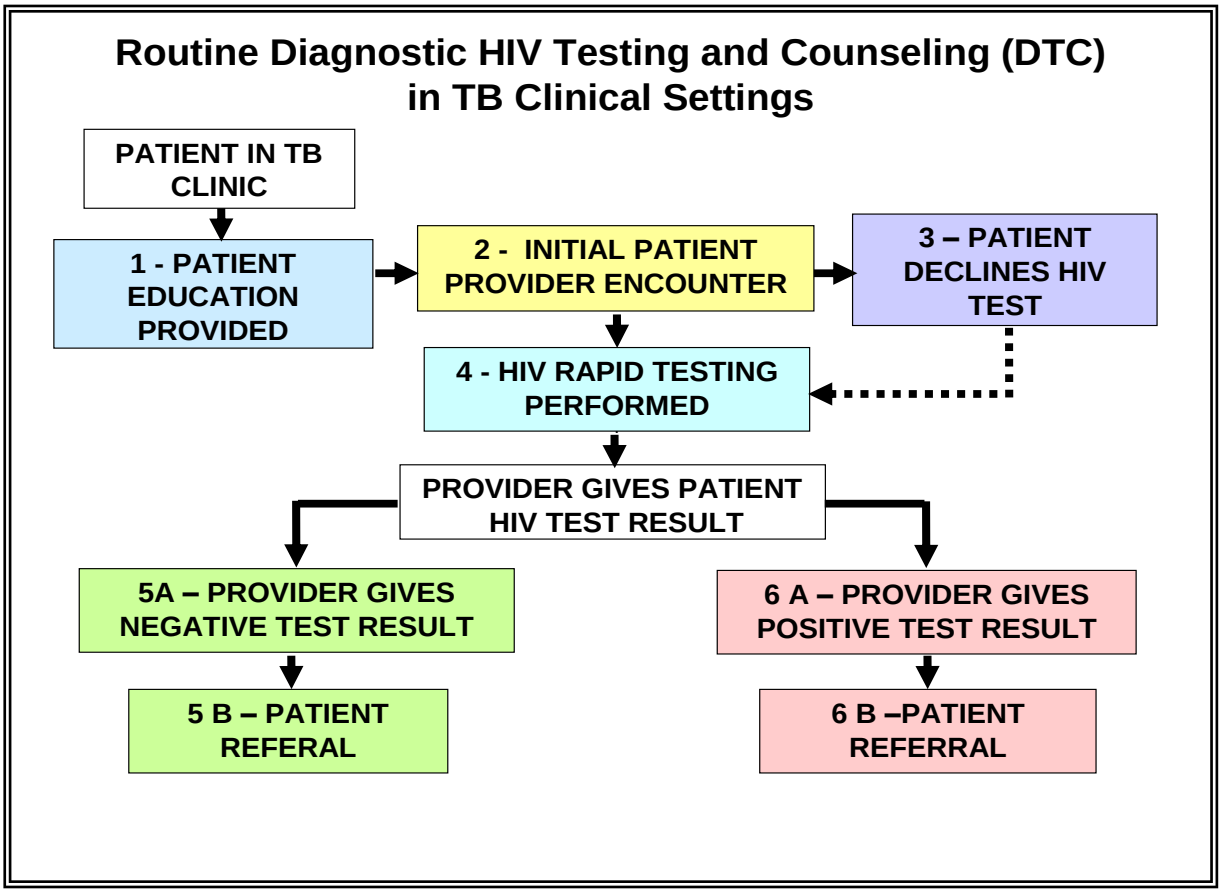
- If **"No"** to question 1 and **"Yes"** to any other question; continue investigating for TB according to clinical signs. Refer when necessary.

- If **"No"** to all questions: Stop investigation for TB and repeat intensive detection during the next medical visit.

8.4 Screening of TB patients for HIV through Diagnostic Testing and Counselling/PITC

Because of the relationship between TB and HIV and the high prevalence of HIV among TB patients in Kenya, **ALL *TB patients should be offered HIV testing and counseling through the process of Diagnostic Testing and Counseling (DTC/PITC). The DLTLD with partners have developed protocol DTC script shown below on DTC.***

DTC protocol script.



Diagnostic Testing and Counseling/PITC is the process of preparing patients for an HIV test within health care settings. The underlying principle is that clinicians have a duty to provide patients who come with signs and symptoms of HIV related illnesses with an accurate and a complete diagnosis, and with appropriate advice about management of this condition.

Note: It is considered substandard care not to offer HIV diagnostic testing and counseling to patients presenting with an illness that may be HIV related including TB.

The emphasis is on the patient knowing his/her patient's HIV status as a way of improving treatment outcomes. Benefits of knowing one's HIV status include prevention of HIV infection, treatment and prevention of HIV related opportunistic infections, getting life-prolonging ARV drugs and access to psychological and social support.

When carrying out DTC the health care worker should ensure that the patient fully understands the purpose and benefits of testing during the pre-test counseling. The patient should also be informed of the disadvantages of declining the HIV test including the missed opportunities for treatment and prevention of opportunistic infections. The health care worker should be able to respond to the patient's questions and concerns; and very importantly, the patient should know that he or she has a right to decline the test (opt-out). For those who decline the test the health care worker should try and identify the barriers to testing to try and solve them. All patients who decline the test should be encouraged to think about returning for the test during the course of TB treatment.

Before giving the results the health care worker should provide post-test counseling with emphasis on interventions that can be provided. Post test counseling should include the following:

Those who test negative:

- Should be informed about couple discordance and be encouraged to refer their partners for testing.
- Should be motivated to maintain non-risky behavior so as to avoid acquisition of HIV infection.

Those who are positive:

This group of patients may require more intense counseling and support to cope with the positive result and may benefit from referral to a formal counselor. The basic post counseling session should include:

An empathic disclosure of the positive result and:

- A discussion with the patient about the care available and referral to a Comprehensive Care Clinic as soon as possible.
- A discussion on disclosure of result to the partner and partner referral for a HIV test
- Nutritional advise
- A discussion on positive living
- Referral to post-test clubs or any other support groups for psychosocial support

Note: Always be on the look out for other Opportunistic Infections (OIs) and treat or refer the patient accordingly.

8.5 Provision of Cotrimoxazole preventive therapy

Cotrimoxazole Preventive Therapy (CPT) has been shown to provide reduced mortality among TB patients with HIV infection. CPT should therefore be provided to all TB/HIV co-infected individuals (Unless contra-indicated). **The adult dose is 960 mg once daily** (two tablets for the single strength tablets or one tablet for the double strength tablets). Patients given Co-trimoxazole should be monitored for side effects which include skin rashes and gastrointestinal disturbances. Minor skin reactions may be managed with an antihistamine e.g. chlorpheniramine while minor gastrointestinal reactions can be managed with metoclopramide. Co-trimoxazole should be withdrawn whenever moderate to severe reactions occur. HIV infected patients should be made to understand that treatment with Co-trimoxazole is life long.

*8.6 Provision of Anti-Retroviral Therapy (ART)**

Tuberculosis patients with HIV infection should be offered ARVs or referred to ART centers at the earliest possible opportunity. Referral forms for this purpose are available. All TB/HIV co-infected patients should be assessed for ART. Start ART ***during*** the course of TB treatment in TB/HIV co-infected patients who qualify for ART. Many HIV infected TB patients will initiate ART after the intensive phase of TB treatment. Priority should always be given to TB treatment in these co-infected patients.

Dual treatment of TB/HIV co-infection is complicated by:

- Drug interactions involving rifampicin with NNRTIs and PIs.
- Overlapping toxicities e.g. INH and d4T that both cause peripheral neuropathy.
- High pill burden of combined ARV and anti-TB drugs.

ART management of TB patients should be in accordance with the current National ART Guidelines.

When to start ART in HIV/TB co-infected patients

1. Adults and Adolescents

CD4 COUNT	TREATMENT RECOMMENDATION
NOT available	Start anti-TB treatment Start ART as soon as practicable, preferably in the continuation phase. If EPTB[1] start ART in the intensive phase where feasible
CD4 <100/mm^3	Start anti-TB treatment Start ART as soon as possible
CD4 count 100-350/mm^3	Start anti-TB treatment Start ART after intensive phase of TB treatment
CD4 count >350/mm^3	Treat TB. Defer ART and follow up patient

[1]EPTB = Extra-pulmonary TB other than TB lymphadenitis

2. Children

Child's Clinical And /Or Immunological Condition	Treatment Recommendation
Stable but ART is needed	Complete first 2 months of anti-TB treatment. Start ART in Continuation phase
Advanced HIV Disease; likely to succumb if ART delayed	Start Anti-TB treatment Start ART in the intensive phase as soon as feasible

CHOICE OF ARV DRUGS IN TB/HIV CO-INFECTED ARV-NAÏVE PATIENTS

Patient Category	Rifampicin-Based TB Treatment (Intensive Phase Or Entire TB Regimen)	Non Rifampicin-Based Continuation Phase
Adults & Adolescents	AZT or D4T + 3TC + EFV[1]	AZT or D4T + 3TC + NVP
Pregnant Women	AZT + 3TC + ABC[2] at any gestation OR AZT or D4T + 3TC + EFV[1] if ≥ 12 weeks gestation	AZT or D4T + 3TC + NVP
Children age below 3 years or weight < 10kg	AZT[4] + 3TC + ABC[2,3]	N/A
Children age above 3 years and weight > 10kg	AZT[4] + 3TC + EFV	N/A

AZT = Zidovudine; D4T= Stavudine; 3TC= Lamivudine; EFV= Efavirenz; NVP= Nevirapine; ABC = Abacavir;

[1] Do a pregnancy test in all pre-menopausal women prior to initiation of EFV. EFV should not be given to women at risk of pregnancy unless effective contraception is used, or in those in the first trimester of pregnancy. For women who commence EFV in the 2nd trimester, if treatment with EFV is to continue post partum, effective contraception should be provided.

[2]Patients who are started on triple nucleoside regimen should be changed to a standard regimen once the TB treatment is complete.

[3]Children who failed prophylaxis (exposed to SDNVP) with TB and who also need ART as well should

be started on the triple nucleoside therapy and changed to PI-based regimen once anti-TB treatment completed.

Choice of ART if patient develops TB while on a successful 1st Line ART

- For adults and adolescents, if on NVP switch to EFV.
- For pregnant women on NVP-based ART
    - If in the first trimester switch NVP to ABC; once TB treatment is complete switch ABC back to NVP.
    - If in the second or third trimester, switch NVP to EFV.
- For Children
    - If on NVP switch to ABC (if < 3 years or < 10kg bwt) or EFV (if above 3 years and/or > 10kg bwt). Once the child completes anti-TB treatment, they should revert back to the national first-line regimen (switch from ABC back to NVP).

Where dual treatment is difficult and is likely to affect adherence to either the TB or the ARV treatment, or where toxicity of dual treatment is a problem, consider delaying/interrupting ART. Start/resume after completion of anti-TB therapy.

8.7 Isoniazid Preventive Therapy (IPT)

There is good evidence that TB preventive therapy using a six to nine months course of 5 mg/kg bodyweight isoniazid daily prevents the development of active TB in HIV infected persons. This beneficial effect may last up to two years after the course of treatment. It is critical however to ensure that active TB is confidently ruled out to avoid inadvertent mono-therapy with Isoniazid in those patients with undiagnosed TB, which would only serve to generate resistance to this drug. Suitable persons for Isoniazid TB preventive therapy include:

1. HIV infected individuals who are asymptomatic of TB.

It is necessary to carry out a thorough history and physical examination to ensure that the patient has no TB. While assessing the patients, ensure that there is no:

- Fever in the past month
- History of unexplained weight lost.
- History of persistent diarrhea
- Palpable lymph glands
- Palpable liver or spleen
- Clinical or biochemical evidence of liver disease
- Abnormal chest x-ray

2. Children

- Children born to mothers who have smear positive TB. If the mother has not been on TB treatment and is sputum smear negative prior to child delivery.
- Child contacts of infectious TB (Refer to Section 7.9.2)

Because the screening of HIV infected persons for active TB may be clinically challenging, the DLTLD recommends that Isoniazid TB Preventive Therapy in Kenya be limited to controlled settings where thorough screening and follow up of patients can be ensured. Isoniazid TB Preventive Therapy may therefore be offered in congregate settings, for example prisons, among health care workers and in industrial medical clinics where client follow up and monitoring may be relatively easy.

Patient Assessment for IPT

Assess Suitability for IPT

- Symptoms? (fever, weight loss, cough and failure to thrive in children)
- CXR abnormal?[1]
- Sputum (repeat x3) for AFB positive (in adults and older children with cough)?[2]
- Treated for TB in the preceding 2 years?

IF ANSWER TO ANY OF THE ABOVE IS "YES" THE PATIENT IS NOT SUITABLE FOR IPT.

Which patients could receive IPT if suitable as per above criteria?

- **All** children < 5 years exposed to "open" PTB in a close contact, with a negative TB screen should be given IPT regardless of HIV sero-status as a minimum standard of care
- **All** HIV positive patients in whom TB has been excluded

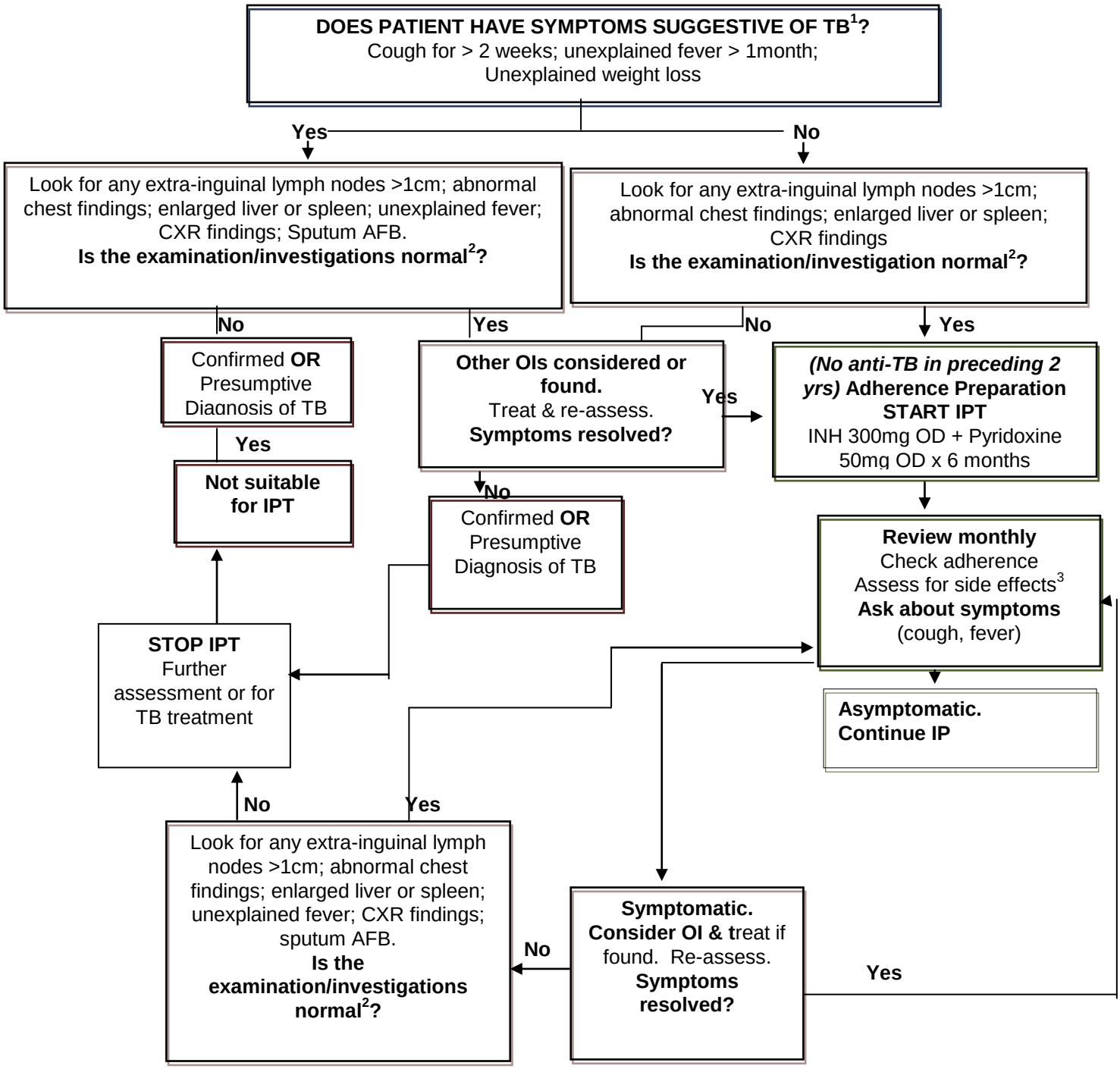
[1] These patients should be investigated for active TB; [2] these patients should be treated for PTB

Dose of Isoniazid for IPT

Child: 5-10mg/kg/day (max 300mg OD) for 6 months

Adult/ Adolescent: INH 300 mg OD + Pyridoxine 50 mg OD for 6 months

ISONIAZID PREVENTIVE THERAPY (IPT) FOR PLWHA AND CLWHA - Algorithm



***Currently the use of routine IPT in HIV infected pts is not routinely recommended in Kenya.** [1]HIV+ pts may not have typical symptoms associated with TB as in HIV negative population; extrapulmonary TB (EPTB) is more common especially in severely immunocompromised pts & may present with prolonged fever alone. [2] Review of symptoms & examination of sick pts should not be restricted to the areas listed here. [3]INH-associated side effects include peripheral neuropathy and hepatitis. Pts on IPT should be assessed for TB whenever they are ill.

CHAPTER 9: DRUG RESISTANT TB IN KENYA

9.1 Magnitude of Drug Resistant TB in Kenya

Multi-Drug resistance TB in Kenya had been rare. In 1993-94 Kenya participated in the global anti-TB drug resistance survey coordinated by the WHO and of the participating countries; it was the only one that reported no multi-drug resistant TB. The Isoniazid mono-resistance was however reported to be 5% and 10% for primary and combined resistance respectively. For Streptomycin, a combined resistance of 2% was reported. No resistance to Rifampicin was reported. At that point Rifampicin was not widely in use. SCC was started in the country in 1993.
The country has been offering drug resistance surveillance for all PTB retreatment cases. Results from this routine MDR surveillance on retreatment shows confirmed 249 MDR-TB cases as of end of 2007.

9.2 Development of drug resistance

The major reasons for the development of drug resistance is

1) Non-adherence:
Patient failure to adhere to complete course of prescribed TB treatment contributes emergence of drug resistance. Causes of non adherence are multifactorial such as inadequate access due distance, implied cost, poor health education, displacement of persons due hunger, wars and migration.

2) Poor quality medicines. With the liberalization of the pharmaceutical sector in Kenya coupled with a weak post marketing surveillance regime, there may be poor quality anti-TB drugs circulating in the country. The bioavailability of Rifampicin can easily be compromised by poor quality FDC.

3) Misuse of mainstay anti-TB drug treatment for treatment of other ailments.

4) Due to inadequate monitoring of TB treatment in the private health care sector, there may be wide-spread use of regimens other than the standard treatment regimen, use of low quality drugs, and patient non-adherence due to lack of supervision.

5) Drug stock outs leading to treatment interruptions

6) Kenya is a recipient of large population of displaced persons (refugees) from the surrounding countries where there has been ongoing civil strife. TB control in these countries has been greatly affected leading a high possibility of emergence of TB drug resistance.

7) High virulence strains of Mycobacterium TB.

9.3 Basic approaches to avoid TB drug resistance in the community

The main task of a TB control programme is to reduce transmission of TB through early detection and effective treatment of infectious patients without creating drug resistance. Treatment for MDR-TB is complex, expensive, takes long with severe side effects and poor treatment outcomes.
The basic approaches for prevention includes

1. Implementation of good DOTS programme
2. Good history taking to choose proper regimen (Cat I or Cat II)
3. Use of recommended standard treatment regimens (6 to 8 months)
4. Use of Fixed Dose Combinations (FDC) and avoid adding a single drug to a failing regimen
5. Advocate for free treatment of all TB cases
6. Strict Supervision of treatment (DOT) for rifampicin based regimens
7. Improve TB care in private sector.

9.4 Classification of drug resistance

Drug Resistance is classified in two ways:

1) Based on exposure as

   - **Primary resistance** - if there was definitely no previous treatment.
   - **Initial resistance** - when previous treatment cannot definitely be excluded.
   - **Acquired resistance** - if there is a definite history of previous treatment.

2) Based on the type of resistance expressed by the TB bacilli as

- **Mono-resistant TB-** TB which is resistant *in vitro* to exactly one anti-TB drug.
- **Poly resistant TB-** TB which is resistant *in vitro* to more than one anti-TB drug except both Rifampicin and Isoniazid.
- **Multi-Drug Resistant (MDR) TB** - resistance to both Rifampicin and Isoniazid
- **Extensively Drug Resistant (XDR) TB-** is MDR TB with further resistance to at least Rifampicin and Isoniazid, a fluoroquinolone and one or more of the following injectable drugs: Kanamycin, Amikacin and Capreomycin. (XDR-TB task force October 2004)

9.5 Management of drug resistant TB

The management of drug resistant TB through the principles of DOTS has been mainstreamed into routine TB control activities. The objective is to strengthen anti-TB drug surveillance system for early detection of drug resistant TB and to provide drug treatment to those detected to have drug resistant TB.
DLTLD is encouraging the routine collection of sputum specimens from all TB re-treatment cases and submission of these to the Central Reference TB Laboratory to carry out TB cultures and DST. The DLTLD has established quality assurance and quality control systems for all laboratories offering sputum smear microscopy, culture and DST for *Mycobacteria TB*.

9.5.1 Diagnosis

MDR is best diagnosed bacteriologically from cultures of sputum, gastric lavage or other relevant specimens. Any child in contact with an individual with proven MDR-TB should be followed up closely for evidence of progression to TB disease for at least 2 years. No Isoniazid prophylaxis should be given. Any child who is culture negative, or in whom specimens were not obtained, drug resistant TB should be assumed. These children should be referred to specialized MDR-TB treatment centres for management.

9.5.2 Case finding strategies for MDR TB

The division enrolls patients from the high risk groups for drug susceptibility testing. This includes all re-treatment patients (category 2 i.e. failures of Category 1, relapses and return after default), failures of Category 2 and symptomatic close contacts of MDRTB cases.

9.5.3 Classification of MDR TB cases

1. New Category IV patient (primary resistance)
This is a MDRTB patient who has never received anti-tuberculosis treatment or one that has received anti-tuberculosis treatment for less than one month, or one who had DST at the start of a WHO category I regimen and then switched to a Category IV regimen because of evidence of MDRTB.

2. Category IV patients previously treated with first-line drugs (acquired or secondary)
This is a MDRTB patient who has been treated for one month or more with first-line drugs only.

3. Category IV previously treated with second-line drugs
This is a MDRTB patient who has been treated for one month or more with second-line drugs, with or without first-line drugs. They could be:
Return after default – a MDRTB patient who was on second line treatment, who interrupted treatment but has been found and returned to treatment.

4. Transfer in.
This is a MDRTB patients who have been transferred from one district register of drug resistant TB patients to another.

5. Others
These are MDRTB patients who do not fit any of the above definitions.

9.6 Treatment and follow up of drug resistant TB.

The treatment of patients with drug resistant TB is complex and requires trained TB clinicians. Treatment should be offered in settings where infection control measures are in place.

Mono-resistant TB:
When there is resistance to any one single drug, only the offending drug should be substituted; Ethambutol replaces Isoniazid; Fluoroquinolone replaces Rifampicin.

Poly-resistant TB:
When there is resistance to two or more drugs but **excluding** both Rifampicin and Isoniazid, the same principle holds. The two offending drugs should be replaced.

MDR-TB
This is resistance to both Isoniazid and Rifampicin.In Kenya the treatment for MDR-TB is based on a **standard regimen** using the following drugs:

6Cm- Ofx- Pto-Cs-(E/Z)/18 Ofx- Pto-Cs-(E/Z)

- The number shown before each phase stands for the duration of time in months and is the minimum recommended time the phase should last.
- An alternative drug(s) appears as a letter(s) in parentheses.
- The drugs in the higher groups are written first followed in descending order of potency.

9.6.1 Duration of Treatment

The duration of treatment is guided by smear and culture conversion. The minimum recommended duration of treatment is 18 months after culture conversion. The treatment consists of two phases as follows;

Intensive Phase - **6Cm-Pto-Ofx-Cs-(E/Z)**
This lasts for a minimum of 6 months or after sputum conversion and uses the following drugs

a) Inj. Capreomycin [Cm]
b) Tabs Prothionamide [Pto]
c) Tabs Ofloxacin [Ofx]
d) Tabs Cycloserine [Cs]
e) Either Tabs Ethambutol [E] or Tabs Pyrazinamide [Z]

Continuation Phase– 18Pto-Ofx-Cs-(E/Z)

This lasts for 18 months and uses the following drugs
a) Tabs Prothionamide [Pto]
b) Tabs Ofloxacin [Ofx]
c) Tabs Cycloserine [Cs]
d) Either Tabs Ethambutol [E] or Tabs Pyrazinamide [Z]

9.6.2 Extra-pulmonary MDR-TB Treatment

The treatment strategy is the same as in patients with pulmonary MDR-TB.

9.6.3 Treatment delivery and adherence

All centers managing MDRTB should have in place an MDRTB management committee. The role of the committee is to ensure comprehensive MDR-TB patient care. These includes

- Capacity building
- Resource mobilization
- Ensuring that Infection control measures are put in place
- Ensuring necessary logistics and supplies are in place.
- Monitoring and evaluation of MDR-TB services.

9.6.4 Patient care

There is need for strict adherence to DOT and patient support to ensure case holding. As far as possible, all necessary patient and family support should be put in place to increase adherence to treatment. These may include patient support groups, psychological counseling, transportation, subsidy, food baskets etc. All MDRTB patients, their families and communities health education, including stigma reduction

9.6.5 Treatment adherence

Treatment of MDRTB should aim to ensure maximum adherence. To prevent non-adherence and default from treatment the following measures are essential:

- Education of patients
- Assessment for risk factors for non-adherence
- Appropriate treatment delivery settings
- Default prevention and retrieval

9.7 Patient monitoring

9.7.1 Initial evaluation monitoring of treatment

Pre-treatment screening and evaluation is done to ensure a baseline for this treatment and to identify patients who are at risk of increased incidents of side effects

Monitoring & evaluation	**Recommended frequency**
Evaluation by clinician	At baseline, then monthly till conversion then every 2-3 months
Sputum smear and cultures	Baseline, monthly till conversion, then monthly smears and quarterly cultures every 3 months
Weight	At baseline and monthly
DST	Baseline and if treatment failure is suspected
CXR	At base line then 6 monthly
Serum creatinine	At base line then monthly while on injectable drug
Serum potassium	At baseline then monthly while on the injectable agent
TSH	At baseline then 6 monthly if on ethionamide/ protionamide / PAS
	Monitor monthly for hypothyroidism
Liver function tests	At baseline then 1-3 monthly if on pyrizinamide
HIV screening	At baseline and if clinically indicated
Pregnancy test	At baseline for women in child bearing age and repeat if indicated

9.7.2 Sputum conversion while on second line treatment

This refers to two sets of consecutive negative smears and cultures taken 30 days apart. The Intensive phase lasts 6 months or until sputum conversion is achieved.

9.7.3 Management of patients after MDR-TB treatment failure

While treating MDRTB some unfavorable outcomes are anticipated including treatment failures and such patients may have extreme drug resistant TB (XDRTB). When this happens**,** the following steps are recommended:

1. Review the treatment card and assess adherence to determine if the patient is receiving all the right drugs and doses.
2. Review the treatment regimen in relation to medical history to determine if the patient may have been re-infected during the course of treatment.
3. Review all DST reports to determine the adequacy of the regiment and consider an alternative regiment where possible.

9.7.4 Signs indicating treatment failure:

- Persistent cultures and positive smears past 8-10 months of treatment
- Progressive extensive and bilateral lung damage confirmed on X-Ray with no option for surgery.
- Worsening patient's condition usually including weight loss and respiratory insufficiency

9.7.5 Suspending Therapy:

Treatment should be suspended when it is confirmed that all the drugs have been administered and there is no possibility of adding other drugs or carrying out any surgical intervention. At this point, supportive care regimen is considered. The 2 most important considerations to suspend therapy and consider supportive care:

- Patient's quality of life: continued use of the failing regimen can cause additional suffering without any benefits

- Public health concern**:** Continuing with the failing regimen can amplify resistance in the patient's strain and hence subsequent infection to the public.
- This decision to suspend treatment should be made by the MDRTB management team.

Prepare the supportive care plan for the patient after consensus with the patient and the family members. This may include pain relief, management of respiratory insufficiency, nutritional support, and regular medical visits-particularly psychosocial support, home nursing care, prevention and infection control measures as these patients normally remain infectious for long and hence need for infection control measures.

9.8 Treatment outcomes

Cured:

- This is a MDRTB patient who has completed treatment according to the protocol and has at least five consecutive negative cultures from samples collected at least 30 days apart in the final 12 months of treatment, or
- A patient with only one culture positive and no concomitant clinical evidence of deterioration, provided that this positive is followed by a minimum of three consecutive negative cultures taken at least 30 days apart.

Treatment completed:

- This is a MDRTB patient who has completed treatment according to protocol but lacks bacteriological results

Died:

- This is a MDRTB patient who dies from any reason during the course of MDR-TB treatment

Failed:

- This is a MDRTB patient whose two or more of the five cultures recorded in the final 12 months of therapy are positive or
- One of the final three cultures is positive or
- A clinical decision has been made to terminate treatment early because of poor response or adverse events.

9.9 Treatment under special conditions

Drug resistance may coexist with any number of medical problems and thereby present clinical challenges in the management of both diseases. These challenges include increased risk of drug toxicity, alterations in drug metabolism or pharmacokinetics that requires dose adjustment, multiple drug therapies leading to drug-drug interactions etc. These co-morbid conditions often require high level of clinical expertise and therefore early cross referrals with relevant clinicians with this expertise where feasible is highly recommended. Some common clinical conditions that may co-exist with TB include pregnancy, breastfeeding, contraceptives, drug resistant TB in Children, diabetes mellitus, renal insufficiency, liver disorders, seizure disorders, psychiatric disorders, drug and other substance abuse and HIV infection and use of anti-retroviral drugs.

9.10 Side effects and their management

The appearance of adverse events should be recorded and categorized as follows:

- Mild: Awareness of sign or symptom but easily tolerated.
- Moderate: Discomfort sufficient to cause interference with normal activity.
- Severe: Incapacitating or life threatening.

Note: All adverse events irrespective of the severity must be recorded in the patient record card.

Common side effects is shown in the the below

Drug	Daily dose	Side effects	Side effects control test	interaction
Capreomycin (Cm)	15-30mg/Kg	VIII cranial nerve lesion Nephrotoxicity	Vestibular function Audiometry BUN	Neuromuscular blockers
Kanamycin (Km)	15-30mg/Kg	VIII cranial nerve lesion Nephrotoxicity	Vestibular function Audiometry BUN	Neuromuscular blockers
Ethionamide (Eth)	15-30mg/Kg	GIT disturbances Hepatotoxicity	SGOT SGPT	nil
PAS	150mg/Kg	GIT disturbances Hepatotoxicity	SGOT SGPT	Not reported
Cycloserine (Cs)	10-20mg/Kg	Psychosis Seizures Rash	Psychological test	Alcohol
Ofloxacin (Ofx)	800mg daily	Hepatotoxicity		

Management of side effects is crucial in MDR-TB treatment is crucial. The table below gives practical approach to management of side effects *(Refer to MDR treatment guidelines for more details*).

Side effects	Suspected agent	Management
Hepatitis	Z,H,R,Th,Ofx,L,Cx,PAS	Stop therapy Rule out other causes Re-introduce drugs serially while monitoring for liver function, with most likely agent introduce last
Renal failure	S,Km,Am,Cm	Discontinue suspected agent Consider using Cm if an aminoglycoside had been prior parenteral regimen
Athralgia	Z,Ofx.L,Cx	Therapy with NSAIDs Initiate exercise regimen Lower dose of suspected agent, if can be done without compromising regimen Discontinue suspected agent if can be done without compromising regimen
Gastritis(severe form is rarely observed)	PAS, Tha, H, E, Cfz, Z	Give antacids, this should timed so as not to interfere with absorption of anti-TB drugs
Nausea and Vomiting	PAS, Tha, H, E, Cfz, Z	Rehydratrion Anti-emesis Lower doses of suspected agent, if can be done without compromising regimen Discontinue suspected agent if can be done without compromising regimen
Seizures (History of prior convulsion is not CI for therapy)	Cs,H,Ofx,L,Cx	Anti-convulsive therapy(Phenytoin, Vaproic acid), continued until MDR-TB treatment is completed Increase Pyridoxine to 300mg daily Lower doses of suspected agent, if can be done without compromising regimen Discontinue suspected agent if can be done without compromising regimen
Psychosis	Cs,Ofx,L,Cx,H, Tha	Initiate anti-psychotic drugs Hold suspected for short period of time (1-4 wks) while symptoms are brought under control Lower doses of suspected agent, if can be done without compromising regimen Discontinue suspected agent if can be done without compromising regimen
Hearing loss	S,Km,Am,Cm, Clr	Change parenteral to Cm Lower doses of suspected agent, if can be done without compromising regimen Discontinue suspected agent if can be done without compromising regimen
Peripheral neuropathy	Nearly all	Increase Pyridoxine to 300mg daily Change parenteral to Cm Begin exercise regimen focusing on affected region Initiate therapy with tricyclic anti-depressants
Hypothyroidism	PAS,Tha	Initiate thyroxine therapy Substitute the two drugs

CHAPTER 10: PREVENTION OF TB TRANSMISSION AT HEALTH CARE SETTINGS – INFECTION CONTROL

10.1. Infection control strategies

There are three levels of TB infection control: administrative (managerial) control measures, environmental control measures, and personal protective equipment (respiratory protection). Administrative control measures are the most important since environmental control measures and personal protective equipment (respiratory protection) will not work in the absence of solid administrative control measures. Each level operates at a different point in the transmission process:

- Administrative control measures reduce HCW and patient exposure
- Environmental control measures reduce the concentration of infectious droplet nuclei
- Personal protective equipment (respiratory protection) protects HCWs in areas where the concentration of droplet nuclei cannot be adequately reduced by administrative and environmental control measures.

1st Priority	**Administrative Control Measures**
2nd Priority	**Environmental Control Measures**
3rd Priority	**Personal Protective Equipment (Respiratory Protection)**

10.2. Administrative (managerial and policy) control measures

The first and most important level of control is the use of administrative control measures to prevent droplet nuclei from being generated and thus reducing the exposure of HCWs and patients to *M. tuberculosis*. Important administrative control measures include **early diagnosis of potentially infectious TB patients, prompt separation or isolation of infectious TB patients, and the prompt initiation of appropriate anti-tuberculosis treatment.**

Other important administrative control measures include an assessment of the risk of transmission in the facility, the development of a TB Infection Control Plan that details in writing the measures that should be taken in a given facility, and adequate training of HCWs to implement the plan. It is essential that one individual be assigned responsibility and accorded authority to monitor the implementation of the TB Infection Control Plan.

Administrative Control measures include:

- prompt identification of infectious TB patients (smear positive) by same day sputum examination
- Initiation of treatment of infectious cases.
- Establishment of an infection control committee
- Appointment of an infection control office
- Formulation of an infection control plan
- Physical separation of patients suspected or known to have TB including those with MDR-TB from other patients especially those patients who are immuno-compromised. (Isolation wards / rooms / one section of the ward)
- Triaging of patients with chronic cough (two or more weeks).

Queues and waiting lines

In many outpatient facilities, hundreds of patients wait to be seen everyday. The waiting areas, hallways and corridors are crowded with patients, their families and HCWs. Persons suspected of having TB should:

1. Be ensured that they will receive the service or services for which they are waiting
2. Be offered a place at the head of the line so that they can be seen promptly and to decrease the potential for transmission of TB to other patients in the waiting areas.

10.3. Environmental control measures

Since the exposure to infectious droplet nuclei usually cannot be eliminated, various environmental control measures can be used in high-risk areas to reduce the concentration of droplet nuclei in the air. Such measures include maximizing natural ventilation and controlling the direction of airflow. Although many environmental control measures require resources that may not be available in many situations (e.g., most district levels health facilities), some (e.g., opening windows to increase natural ventilation and use of fans to control the direction of air flow) can be implemented in resource-limited settings.

Environmental control measures include:

- Natural and or mechanical ventilation
- Use of and high efficiency particulate air filtration.
- Upper room Ultraviolet Germicidal Irradiation (UVGI).

10.4. Personal protective equipment (respiratory protection)

At both the district and referral levels, efforts should be made to limit HCW and patient exposures to infectious TB droplet nuclei through the use of administrative and environmental control measures. In specialized settings in referral hospitals, HCWs may be exposed to infectious droplet nuclei during sputum induction procedures, while providing patient care in TB isolation rooms or in non-well ventilated ambulatory rooms, and while performing autopsies, bronchoscopy or other cough-inducing or aerosol-generating procedures. In addition to administrative and environmental control measure in these circumstances, the recommended control measure is the protection of the HCW from inhaling infectious droplets through the use of respiratory protective devices, which are designed to fit over the mouth and nose and filter out infectious TB particles. Respiratory protective devices for HCWs that are capable of adequately filtering out infectious particles are more expensive than surgical or procedure masks. Nevertheless, their use in high-risk MDR/XDR-TB settings is recommended, particularly in high burden HIV settings where many health care workers may be HIV infected. In addition, **respiratory protection should be used only when all other administrative and/or environmental control measures are fully implemented.**

The development of an infection control plan that specifies the activities to be implemented from the three levels of control measures is a crucial first step towards putting infection control in place at a health facility or congregate setting.

10.5. Isolation of patients with Multidrug-Resistant TB

In general, patients with MDR/XDR-TB require specialized management at a referral center. Because of the prolonged period that such patients are infectious and the consequent increased risk of nosocomial transmission, whenever possible, patients suspected of having MDR/XDR-TB should be placed in a separate area or building in the facility, preferably in well-ventilated individual patient rooms where the possibility of contact with other patients who do not have TB or do not have MDR/XDR-TB is minimal. If this is not feasible and there is a large number of patients suspected of having MDR/XDR-TB, then an MDR/XDR-TB ward or area of a ward should be established. As limitations in diagnostic capacity in many countries inhibit laboratory diagnosis of MDRXDR-TB, countries face challenges to make informed policy and related interventions in the absence of sufficient data. Increasing partnerships between NTPs and international partners (eg Global Fund, PEPFAR) as well as South-South collaborations may be pursued to fill in the critical gaps.

As an example, in all of Africa, there are only 25 reference laboratories with the capacity to grow TB cultures and test for drug resistance. On a positive note, the recent focus on MDR and XDR TB has put a spotlight on the need to strengthen laboratory and infection control and has spurred funding and global effort among international organizations and implementing partners to address the urgent issues.

10.5.1 MDR-TB and HIV

It is of utmost importance to ensure that patients with known or suspected MDR TB and/or XDR TB be identified and that efforts be made to separate them from patients who have HIV infection both in the outpatient and inpatient settings. In the absence of laboratory confirmation, TB patients who have been identified as treatment failures and chronics should be particularly noted

10.5.2 Enforcing isolation policies

Isolation policies should be strictly enforced:

- Except for when infectious TB patients must undergo essential diagnostic procedures outside their rooms, they should not be allowed to leave their rooms or wander the hospital grounds (a designated area outside for suspect or confirmed infectious TB patients can be used for fresh air and exercise)
- a disposable surgical or procedure mask should be placed on infectious and suspect TB patients whenever they leave the isolation areas (i.e., for a medically essential procedure or diagnostic examination).
- if possible, visitation hours should be held in a designated area outdoors

10.6. Special areas and topics: radiology, sputum induction, theatre, autopsy, ICU, HIV

In addition to wards and outpatient clinics, there are a number of settings where risk of TB transmission to HCWs and patients may be increased. In addition, special consideration should be given to reducing nosocomial TB transmission in settings where patients, HCWs, or both, have HIV infection.

10.6.1. Radiology

Radiology departments in referral level facilities often provide services to a variety of patients many of whom may be at particularly high risk of TB disease if they become infected with *M. tuberculosis* (e.g., young children or immuno-compromised patients). Therefore, radiology departments should attempt to:

- schedule inpatient chest radiographs on infectious and suspect TB patients for non-busy times, such as the end of the afternoon
- provide coughing patients with a surgical or procedure mask to wear; alternatively provide tissues or cloth
- provide expedited priority service to potentially infectious TB patients to minimize the length of time spent in the department
- restrict access to the radiology suite during operating hours to patients and essential personnel only (e.g., post signs, enforce the policy).
- use the room with the best ventilation for taking images of potentially infectious TB patients

10.6.2. Sputum induction and cough-inducing procedures

Cough-inducing procedures (e.g., sputum induction or bronchoscopy) should be done only when absolutely necessary on patients who may have TB. Sputum induction should only be done if the patient is unable to produce an adequate specimen without induction. Likewise, bronchoscopy should be used as a last resort after other less risky diagnostic measures have been taken. Bronchoscopy on patients with an established TB diagnosis should be avoided. Administrative control measures in such settings are essential, although strong consideration should be given in such settings to implementing environmental control measures and personal protective equipment (respiratory protection).

10.6.3 Surgical and Autopsy suites

Surgery and autopsy suites are often poorly ventilated and may pose considerable risk of *M. tuberculosis* infection to HCWs if procedures are performed on TB patients. In general, elective surgery on potentially infectious TB patients should be postponed. Efforts should be made to establish adequate environmental control measures to protect both the patient and the HCW. In addition, personal protective equipment (respiratory protection) should be used by all personnel working in the operating room or autopsy suite when procedures are performed on suspected or known TB patients.

10.6.4 Intensive care areas

Intensive care areas also may be high risk areas especially when potentially infectious TB patients are intubated:

- intubation and management of a patient's airway (e.g., suctioning) can create aerosols
- intensive care units are often small and poorly ventilated

To decrease the risk of nosocomial TB transmission:

- avoid intubation on potentially infectious TB patients
- "think TB" in intensive care patients

- improve ventilation in intensive care areas
- use respiratory protection for procedures that are likely to create aerosols in potentially infectious TB patients

10.6.5 Immunosuppression and TB

HCWs as well as patients who are immunosuppressed are at increased risk of:

- reactivation of previous TB infection
- re-infection

Suspect or known infectious TB patients pose a special threat to other immunosuppressed patients and HCWs. Therefore, it is especially important to prevent the exposure of immunocompromised HCWs to patients who are known or suspected of having TB, particularly MDR TB.

Immunocompromised HCWs should be given opportunities to work in areas with a lower risk of exposure to *M. tuberculosis*. In most areas of the world, TB should be strongly considered as part of the differential diagnosis for immunocompromised HCWs with respiratory complaints. Immunocompromised HCWs suspected of having TB should be promptly evaluated, and those diagnosed with TB treated, preferably on an outpatient basis.

CHAPTER 11: MONITORING AND EVALUATION OF TB CONTROL ACTIVITIES

Monitoring is the routine tracking of service and programme performance. It is a continuous process intended to provide information on the extent to which a programme is achieving its intended targets within specified timeframes.
Evaluation is a time specific assessment of results that can be attributed to programme activities. It uses routine monitoring data and, often, indicators that are not collected through routine information systems. A well designed evaluation should allow for the causes of failure to achieve intended results to be identified. This can be achieved by all health workers at all levels utilizing the information collected routinely to improve service delivery with the aim of achieving the set targets.
Tuberculosis case recording and reporting is an important tool for monitoring and evaluating TB control activities at the health facility, region and nationally. The importance of completing correctly the data collection tools at every TB treatment facility cannot be overemphasized.

Every health care provider who treats TB has a professional responsibility to record and report all cases he or she treats.

Accurate keeping of records of all individual patients and maintenance of registers are minimum requirements that need to be met by all health care workers involved with the diagnosis and treatment of tuberculosis patients. It is the responsibility of the facility In-charge (I/C) with training and technical support (supervision) from the DTLC to ensure that recording of details about patients is done properly and correctly. The number and design of cards, forms and registers has been limited and kept as simple as possible to enable the DLTLD to have good patient care and monitoring of performance at all levels.

All patients diagnosed in health care facilities supervised by the DLTLD must be registered at the start of treatment.

Note: TB is a notifiable disease under the Public Health Act Cap 242, and therefore all TB Cases (diagnosed by the public or private sector) must be notified to the MOPHS.

11.1 Registers, cards and forms

The following registers, cards and forms are used for the management of TB at health care facilities supported by the DLTLD:

1. Tuberculosis Patient Management:
- TB Patient Record Card
- TB Patient Appointment Card
- TB Treatment Facility Register
- TB Treatment District Register
- TB Patient Pack Control Card (currently in-printed on the Packs)
- Referral Form to TB clinic
- Referral Form from TB Clinic to other care providers.

2. Laboratory:
- TB Sputum-smear Examination Request Form
- Laboratory Register for Sputum-smear Examination (AFB Register)
- TB Culture and sensitivity Request Form.

3. Drugs and other supplies:
- Daily Activity Drug Register (DADR)
- Facility CDRR (Consumption Drug Report & Request)Form
- District CDRR
- Bin Card
- S11.

4. Others

- TB/leprosy Patient Defaulter Tracing Chart
- TB/leprosy Patient Transfer Form
- Facility Supervision Tool
- Patient Interview Schedule
- Quarterly Case Finding Report Form
- Cohort Report Forms
- Quarterly AFB Report Form

11.2 Instructions for recording

11.2.1 TB appointment card

This card has to be filled by the health worker when the patient is started on treatment. The card remains with the patient during and after the full period of treatment. This will enable the patient to collect drugs and to continue treatment at another TB clinic other than the one he/she is registered when in transit or moving residence. In case of a more or less permanent transfer, a transfer form must be filled and given to the patient.

The appointment card holds the following information:

***District*:** - Write the name of the District

District registration number -This is the number under which the patient is registered in the district register and can only be given by the DTLC when he/she visits the clinic during supervision rounds and fills the district registration number in the treatment unit register. When the patient comes to collect drugs, the number should be written on the card. *It is not necessary that a patient should have a district registration number before treatment can be started*. Take note, that in case a patient has to continue treatment in another unit other than the one where he/she was diagnosed and started on treatment, the registration number should be given at the health unit where the patient will continue treatment.

Name of the facility*:* Write the name of the *facility* where the patient is/will be registered.

Full name of the patient: Write the three names of the patient.

Address: Write the location where patient can be traced (residence or work spot) and note down his/her phone number, or the number of a relative, friend or treatment supporter, if the patient does not have a phone, or any other useful detail.

Age: Write the age (in years) of the patient

Sex: Write the sex of the patient (“M” for Male and “F” for Female)

Pulmonary Tuberculosis: Tick as appropriate in the provided box if Smear Positive, Smear Negative, or Extra-pulmonary

The regimen*:* Tick in the appropriate box the regimen patient is started on.

Date Started Treatment*:* Write the date when treatment started.

Date Cured or TC: Write the date when the patient is declared cured or has completed treatment.

- Note: The latter is important in case the patient gets tuberculosis again after finalizing treatment. For this reason it is also important that the patient keeps the card even after the end of treatment.

Monthly body weight (in kg): Weigh the patient (in Kg) at the start of treatment and every 28 days when the patient comes to collect drugs and write the respective weight in the provided boxes

Intensive phase of treatment*:* Tick the card after observing the patient swallowing the daily dose.

***Note*:** When Rifampicin is among the drugs the patient is taking, it is critical to ensure that a patient support system is available to ensure adherence to treatment. This must include DOT by a treatment supporter. The first day TB drugs are collected; the health care worker will demonstrate how to observe TB patients swallowing their medicines and how to tick the appointment card. The observation by the DOT supporter will be done for the whole duration of treatment in case of the 6-month regimen and during the intensive phase only in case of the 8-month regimen. This means that although the drugs are dispensed for seven days, the very first dose should be taken at the health facility.
The patients should be encouraged to bring back with them to the facility the empty blister packs as evidence of treatment compliance. The empty blister packs should be put back in the patient pack.

The first two months of treatment*:* Write the dosage of the drugs the patient should take during the different phases of treatment expressed in tablets per day.

Continuation Phase New (months 3-8)*:* Write Dates of four-weekly drug collection in the continuation phase.

Sputum-smear examination*:* Write the result at start of treatment. Thereafter, for new smear-positive PTB patients, enter the follow-up results at 2, 5, 8 months (2, 5 and 6 for Rifampicin throughout regimen). For smear positive re-treatment patients, this will be at 3, 5, 8 (6) months. The last sputum smear examination should be done when the patient comes to collect the last 4-weekly (or 2-weekly for Rifampicin throughout regimen) supply of drugs.

Weekly Drug Collection: Write the dates of the weekly drug collection and the due date for the next collection for the intensive phase.

11.2.2 TB Patient Record Card

Although, seemingly, containing more or less the same information as the Appointment Card, the Patient Record Card is focussed more on the clinical aspects of patient management. It also contains information, which cannot be put on the Appointment Card, and as such cannot be replaced by it. The Patient Record Card is a very valuable source of information for operational/clinical research on TB management. It contains data, which often cannot be found in the TB Registers. The card should be filled as completely as possible, during every visit of the patient by the health worker who manages their treatment. It must be left at the unit where the patient receives treatment.

***Note: The TB Patient Record Card contains medical information, which is strictly confidential, and must be handled accordingly*.**

The Patient Record Card holds the following information:

- ***District registration number***. *(See TB appointment card)*
- ***Name of the clinic*** where the patient is/will be registered.
- ***Name of the district***
- ***Dates when treatment started*** and when the ***patient is declared cured or has completed*** *treatment*. The latter is important in case the patient gets tuberculosis again after finalizing treatment.
- ***Full name*** of the patient
- ***Address*** of the location where patient can be traced (residence or work spot), but also the name of the primary school nearest to the patient's residence.

- ***Name & address of the patient's treatment supporter*** (if applicable) and the relationship of the treatment supporter to the patient. The latter can be a household member/friend, a health care worker (including CHW) or a community volunteer.

- ***Age (in years) and sex*** of the patient

- ***Disease classification****:* Pulmonary or extra-pulmonary TB

Children (<15 years) who are diagnosed as a PTB case, but have no smear result, will be classified as smear negative. A patient older than 15 years, who has been diagnosed as a PTB case based on a chest X-ray or on clinical grounds, but without sputum smear results, must be classified as having PTB but smear not done. This latter way of diagnosing PTB patients should however be limited as much as possible.

If a patient has extra-pulmonary TB (EPTB) the location (or locations) must be ticked on the card.

- ***Patient classification***: Patients are categorized for epidemiological and operational reasons. The following categories are used in the DLTLD. To produce reliable and comparable data, health staff should strictly adhere to the definitions given below:

  New
  This is a tuberculosis patient who has never received anti-tuberculosis treatment before, or has been treated for less than 4 weeks.

  Smear positive relapse
  A smear-positive PTB patient is one who has been treated before and was declared *cured (sputum-smear negative)*, or *treatment was completed (no sputum-smear result done)* after which the patient presents again with active disease.

  Smear negative/extra pulmonary relapse
  A smear-negative PTB or extra-pulmonary TB patient is one who has been treated before and was declared *cured (sputum-smear negative)*, or *treatment was completed (no sputum-smear result done)* after which he/she presents again with active disease.

  Failure
  This is a smear-positive PTB patient who, while on treatment, remained or became smear positive again at 5 months, or later during the course of treatment.

  Return after Default (RAD)
  This is a TB patient who returned to the health service after having interrupted previous treatment for 2 months which they had received for longer than 4 weeks.

  Transfer in
  A patient who has been transferred into a district from another where he/she has been registered for treatment. Preferably the treatment outcomes of such patients should be reported to the district in which they were initially registered.

  Note: If it is already known at the start of treatment that a patient will transfer to another district after a short period of treatment it is not advisable to register them in the district were they were diagnosed and/or started on treatment. It is better to register the patient as a new patient in the district they are transferring to. On the Transfer Form it must be mentioned that they have not been registered in the district they have transferred "from".

  Such a patient should be given one week supply of drugs to take until he reports to the new facility where he/she wishes to continue treatment. It should be ensured that this patient has actually arrived at this facility.

- ***The regimen****: The TB treatment* the patient is started on.

- ***Sputum-smear examination****:* Is done for all PTB suspects (new and re-treatment) and thereafter, for follow-up of PTB+ patients.

- ***Intensive Phase (daily) - 2 months****:* This is the first two months of treatment and number of tablets the patient has to take every day, or the daily dosage of Streptomycin to be injected.

- ***Continuation Phase (daily*) – 4 to 6 months**: This is the number of tablets the patient has to take daily during the continuation phase of treatment.

- ***Monthly body weight (in kg)****:* The patient's body weight must be filled every month when they come to collect drugs. It is an indicator for improvement of the patient's condition. *It should not be used to adjust the dosage of drugs during treatment however.*

- ***Culture and Drug Sensitivity Testing results****:* If a sputum sample (or another clinical sample) was sent for culture and DST (all re-treatment cases), the results must be filled in the relevant chart. An '***S****'* should be filled if the TB bacilli are *sensitive* to the listed drug; an '**R**' should be filled if the TB bacilli are *resistant* to the drug. Also the *date of collection of the sample* from the patient must be filled.

- ***Treatment outcome****:* The eventual outcome of treatment, and the date this occurred, must be recorded in the relevant chart. This information is very important for the health services because it monitors how effective the programme is in curing and controlling TB. This information is used to facilitate planning for programme improvement. The following outcomes of treatment are used (inter)-nationally

  - ***Cured***
  This refers to a TB patient who was initially sputum-smear positive and completed his or her treatment ending with a negative sputum-smear examination result.

  - ***Treatment completed***
  This refers to a TB patient who completed treatment but without a sputum-smear examination at the end of treatment.

  - ***Died***
  This is the results recorded if a tuberculosis patient dies during treatment irrespective of the cause of the death. However, the cause of death should be recorded if known.

  - ***Out of Control***
  This refers to a TB patient who fails to attend three consecutive four-weekly clinics during the continuation phase (Note: A defaulter is a patient who fails to collect drugs at the due date).

  - ***Transferred out***
  This is a patient who changes treatment point from one district to another. The patient will be recorded as "Transferred in (TI)" in the receiving district.

- Patient referred by/Patient referred to:
  a) Patient referred by
  The following units should refer every person who tests positive for HIV or any person with signs/symptoms suggestive of tuberculosis to a TB diagnostic centre for screening and, if indicated, TB treatment, by means of the recently introduced *Referral Form for* ***TB screening and/or treatment***
  - VCT centre
  - HIV (comprehensive) care clinic
  - STI clinic
  - Home based care (programme)
  - Antenatal/PMTCT clinic

- Private sector; private practitioner or private institution referring TB suspects or patients for screening or (further) treatment at the DLTLD clinics.
- Chemists/Pharmacists are encouraged to refer patients coughing longer than 2 weeks when they present themselves to the chemist/pharmacy to procure cough medications or other medicines. Therefore attendants at the chemists/pharmacies should ask all patients who make enquiries about drugs for cough "how long they had have the cough''. And all those who have had a cough for longer than two weeks directed to the nearest TB diagnostic facility for sputum smear microscopy. DTLCs are encouraged to disseminate lists of TB diagnostic facilities to all chemists/pharmacists in their areas.
- It should also be marked in the relevant chart if a TB suspect presented themselves at the TB diagnostic centre by:
  - *Self-referral:* (directly at the TB clinic or through the OPD)
  - *Contact-invitation*: a close contact of a TB patient with signs/symptoms that are suspect for tuberculosis (invited directly by the healthcare worker treating the TB patient or by the TB patient him/herself)

b) Patient referred to

Every TB clinic should refer a diagnosed TB case for HIV testing (if the service is not available at the health unit) or, in case the TB patient tests HIV positive, for additional care including counselling (if not available at the health unit), psycho-social support, ART and/or Cotrimoxazole prophylactic therapy (if not available at the TB clinic or after finalizing TB treatment), STI treatment etc. Any patient who wants to continue treatment under supervision of a private health care provider too should be referred as needed. The patient can be referred using the *Referral Form for TB patients* to other care services to the following units:

- VCT centre
- HIV (comprehensive) care clinic
- STI clinic
- Antenatal/PMTCT clinic
- Private sector
- Home based care programme

- ***HIV status/Regular sexual partner(s) tested for HIV***: HIV infection is the single highest risk factor for a person to develop tuberculosis disease. An estimated 52% of TB cases in Kenya are HIV positive. Death rates amongst HIV infected patients with active TB are high, even when they receive appropriate TB treatment. Because of the increasing availability of ART and Co-trimoxazole prophylactic therapy, survival rates and life expectancy are increasing significantly for these patients. It has been shown that 14% of couples are discordant with regard to HIV. It is therefore of utmost importance that HIV high risk groups, like TB patients/suspects and their partners, are tested for HIV to enable them access additional care and prevent further transmission of HIV to their negative partner(s) or others. The DLTLD's policy, in accordance with the *GoK/MOPHS Policy on HIV testing in clinical settings*, is, that *every TB patient must be counselled and tested for HIV*, as part of the diagnostic routine (DTC), *unless the patient refuses* this (opt-out). HIV testing and counselling should be done as soon as the TB diagnosis is made, preferably at the health unit where the patient is first seen. Postponing testing might give the health worker temporary reprieve of telling the bad or good news to the patient, but it won't benefit the latter.

For more elaborate information on HIV testing and counselling of TB cases and their partner(s) see the relevant chapter in these guidelines or consult the stand alone guidelines on TB/HIV collaborative activities.

An appropriate entry should be made in the relevant chart and space provided for HIV status of patient to indicate if the patient was tested and if so, what the HIV test result was. The date the HIV testing was done should be written in the space provided

.

An appropriate entry should be made in the space provided for HIV status of the sexual partner of the patient to indicate if an HIV test was carried out on the partner too. The date when the sexual partner underwent the HIV test should be written in the space provided. The

test result of the partner should not be entered into the medical file of the patient, but into their own medical file.

- ***Prophylaxis for opportunistic infections***: The treatment provided to a HIV infected TB patient to prevent opportunistic infections (Co-trimoxazole) should be indicated (ticked) in the space provided and the dates when this treatment is initiated or stopped.

- ***CD 4 counts***. Although it is not mandatory for all HIV positive TB patients to have their CD 4+ counts done, the ART programme requires these patients undergo several tests including CD4 counts prior to initiation of ARVs. When the CD4 count of a HIV infected TB patient is known, it should be entered in the space provided. Monitoring the CD4+ count is an important tool for assessing the efficacy of ART.

- ***Anti Retroviral Therapy (ART)****:* Most HIV positive TB patients in Kenya are eligible for ART during their TB treatment and all of them should be referred, as soon as feasible, to a Comprehensive Care Clinic (CCC) for further evaluation and start of ART. The ART regimen used will depend on the phase of TB treatment the patient is in, and especially if the TB patient is taking Rifampicin at the time. The HIV positive TB suspects, who are already on an ART regimen, should be referred from the CCCs for diagnosis and treatment of their TB. This might result in a change of the ART regimen they are on. The details of the ART provided to the patient should be entered in the appropriate space provided (ticked) and the date when this treatment was started or stopped. In case a patient is being shifted to another ART regimen, the new regimen should be indicated (ticked) and the also the date when the new treatment was initiated or stopped.

- ***Initial phase of treatment (8 weeks)***: This table is for ticking and /or writing down the date of daily drug intake during the initial phase of treatment (8 weeks) as observed by a health worker or another treatment supporter.

- ***Continuation phase of treatment (6 x 4 weekly periods)****:* This section of the chart allows the date of the next 4 weekly drug collections during the continuation phase to be written down. In case of a smear-positive PTB case, a reminder for follow-up sputum collection is printed under the 5-th and 8-th 4 weekly periods.

Remarks: The full third page and part of the fourth page of the Patient Record Card is reserved for additional information not covered by the different tables.

11.2.3 Tuberculosis Facility Treatment Register

The TB Treatment Register must be maintained at each health facility where tuberculosis treatment is supported by the DLTLD. It should not be carried by the DTLC or kept in his/ her office. The Tuberculosis Treatment Unit/facility Register is one of the most important monitoring & evaluation tools of the DLTLD. Based on the information in this register all reports on TB/HIV case finding and treatment outcome related data are analysed and translated into activities essential for TB control in the country. Maintenance of this register is the task of the health worker(s) who are responsible for the TB clinic, and because of its contents this register should be handled as any other medical document containing confidential information. It must be kept in a lockable place where unauthorized persons don't have access to it. However, it should be accessible to visiting DLTLD technical staff.

It is the responsibility of the DTLC to train and supervise the health worker(s) involved in the proper keeping of this register.

Every patient receiving tuberculosis treatment at the health facility must be recorded in this register. The register contains most of the information also found in the TB Patient Record Card and therefore should be consistent with the latter. It must be updated immediately after a patient attends the clinic for drug collection or when additional information becomes available like sputum examination results, HIV test results etcetera.

To facilitate filling of proper information in the Register's columns, links guide you to the items as mentioned under the TB Patient Record Card and the legends at the bottom of the pages in the register.

11.2.4 Referral Form to TB clinic

This Patient Referral Form was recently introduced for use by different types of health units or services, and it is intended to facilitate the referral of TB suspects or PLWHAs to a TB clinic for TB screening and subsequent treatment.
The forms are provided in a booklet in duplicate. One copy is filled and goes with the patient to the unit he/she is referred to and the other copy remains in the booklet at the referring unit. Since these forms contain confidential medical information, the booklet must be kept in a secure, lockable place.

Name, age and sex should be filled.

Reason for referral: Tick one or more of the listed reasons for referral. In case "other" is ticked, it should be specified on the line underneath the table.

Name of referring unit should be filled.

Type of referring unit*:* Tick one of the listed types. In case of "others", specify the type on the line underneath the table.

Name of TB diagnostic facility the client/patient is referred to should be filled.

Date of referral must be filled.

The Referral Form *must be signed.*

11.2.5 Referral form from TB clinic to other care providers

This recently introduced form is used by the TB clinics to refer TB patients to other care providers for additional or continuing care.
The forms are provided in a booklet in duplicate. One copy is filled and goes with the patient to the unit he/she is referred to and the other copy remains in the booklet at the referring unit. Since these forms contain confidential medical information, the booklet must be kept in a secure, lockable place.

Name, age and sex should be filled

Type of tuberculosis: Tick one of the given options

Treatment regimen used*:* Tick the regimen the patient is on.

TB drugs used at present*:* Tick the anti -TB drugs the patient is taking at the time of referral.

Patient referred to*:* Tick one of the options given. In case of "other", specify.

Reason for referral: Tick one of the options on the list. In case of "other", specify.

Name of the facility the patient is referred *to* and the name of the referring facility should be filled.

Name/ signature of person referring and ***date of referral*** must be present on the form.

11.3 Laboratory forms and registers

11.3.1 Laboratory request form for sputum examination{PRIVATE }

This form should be used by health care workers who are examining patients at the outpatient departments, chest clinics, and wards of health facilities. The following must be filled:

***Name**:* All three names of the patient must appear in the Request Form.

***Age**:* The actual age of the patients must be written (not adult or child), estimate age when not known.

***Address**:* Care should be taken that the address is properly filled so that the patient can be traced in case if necessary.

***Reason**:* The reason for the request must be clearly written irrespective if it is a new or follow-up patient. For follow-up patients, indicate the month i.e. 2, 5, 8 (8) months

Name requesting: Health workers making the request and their signature should also be written too.

11.3.2 AFB Laboratory Register

This register is kept and maintained by the laboratory staff. The following entries must be done:

Serial number: The laboratory serial number should start at 1 with the first patient examined in the year and end with the serial number of the last patient examined at the end of the year.

The date stands for the 1st date of registration of the request.
The column for ***Registration number*** is for follow-up patients who already have their DLTLD TB district registration numbers

***Name**:* All three names of the patient should be entered in this column.

***OPD/WD/clinic**:* It is important to fill column to facilitate the delivery of lab report to the right place in a timely manner.

***Age**:* The actual age should be entered in this column.

Sex: The correct sex (M/F) should be entered into this column.

Results column: The results for the same patient should be indicated in the same row. Positive results should be quantified and written with a red pen, Negative results should be indicated with a '**0**' sign.

Examined by - This column should have the ***name***, not the signature of the laboratory technician who examined the smear. Absence of the lab tech's name makes the entry into the register incomplete.

11.3.3 Culture Request Form

Culture and sensitivity examination must be done for every pulmonary tuberculosis re-treatment case. The Culture Request Form must be filled by the Clinician handling the patient.
In the first paragraph the following information should be clearly written:

- ***Name*** (all three names)
- ***District registration number***
- ***OP/IP number***
- ***Address***
- **A*ctual age of patient***
- ***Sex of patient***
- ***Referring clinic*** *or* ***ward****,*

- ***Facility name***
- ***Type of specimen***
- ***Date of collection,***
- ***Clinician's name*** *and* ***signature*****.**
- ***Examination required***: Specify whether for smear, culture or sensitivity
- ***Type of patient****:* Tick the correct type of patient.
- ***Previous treatment***: Indicate the duration of treatment and drugs used.

On the opposite side of the same form there is room for the laboratory report for direct smear, culture report, and sensitivity testing. The report should also have the *name, signature and designation* of the laboratory officer and the *date* the report was finalized.

CHAPTER 12: LABORATORY SUPPORT IN TB/HIV CONTROL

TB control is based on sputum smear microscopy for suspected adult pulmonary tuberculosis. There is an ever-expanding network of laboratories performing sputum smear microscopy in Kenya. The division has introduced fluorescent microscopy in high volume facilities to enhance sputum turn-around time.

In 2008, 980 facilities were performing smear microscopy.

While TB culture is the gold standard for TB diagnosis, its turn-around time is long, expensive and requires a lot of expertise. In order to shorten turn-around time, liquid culture media have been introduced [MGIT 960]. Currently culture services are being used for MDR-TB surveillance.
The Central Reference Laboratory is able to carry out *Mycobacterium tuberculosis* cultures and drug susceptibility testing to first line anti-TB drugs (SRHE). The laboratory is linked to the Queensland Supranational Mycobacterium Reference Laboratory, Prince Charles Hospital, Brisbane, Australia. The CTRL currently uses both Lowenstein Jensen and the MGIT960 system for culture and drug susceptibility testing.

12.1 Correct collection and transportation of sputum specimen.

This is important ensuring that the result is accurate and reliable.

12.1.1 Sputum Containers
- Only appropriate containers provided by the DLTLD should be used.
- Never re-use Containers.
- Label Containers; *on the pot* (not on the lid), with the name of the patient as soon as it's issued on arrival at the lab. The AFB-Lab Register Number *must* be added**.**

12.1.2 Collection Procedures
Sputum collection is a high-risk procedure, and therefore should be collected in an open space, as far away as possible from other people.

Three (now two specimens: one spot and one early morning) specimens should be collected for diagnosis as follows:
- One spot specimen when the patient first attends the health facility.
- One early morning specimen (preferably the next day)
- One spot specimen when the early morning is submitted to lab.

Instructions to the patient should include:
- Make it clear that what is required is sputum; from deep in the chest, not saliva or nasal secretions.
- Several deep inspirations with forced expiration will help in producing sputum.
- Morning specimen is the first sputum coughed up after rising from bed.

Follow-up during treatment is required at 2, 5 and 8 (6) months. At each occasion one morning-sputum will be requested (handing the container to the patient at the visit preceding the time of collection).

12.1.3 Reception of Specimens
The quality of the specimen must always be checked and the patient encouraged providing a better specimen in case this appears to be saliva or mostly blood. However, if after proper instructions, to the patient cannot provide a better specimen; a less satisfactory one should be examined. Never reject a specimen!
- Record on the form: Date of reception and appearance

Copy essential information to the sputum lab register; name, age, clinic/ward/OPD, sex, new or follow-up patient and Identification Number. If possible two people, to avoid clerical errors, should do this.
Note the sputum lab register number on the container and form.

12.1.4 Specimen storage and transport

If needed, sputum containers holding specimens should be transported in special boxes of metal or wood. Check that each container is well closed and properly labelled. Request forms should be attached at the outside of the box.

For AFB smears the temperature and time in transit are not critical, examination must be performed even for delayed specimens. Nevertheless, in the interest of rapid diagnosis and treatment all efforts must be done to assure fast transport.

At arrival, the box should be opened and carefully inspected for signs of leakage. In such a case, cracked or broken containers must be discarded and the box with its contents disinfected. Check that specimens have been adequately labelled and record all necessary details in the sputum lab register as soon as possible (before processing of specimens). The result of sputum smear should be sent back to the clinician as fast as possible.

12.2 AFB smear laboratory safety

TB transmission is through aerosol droplet which is generated by

- Patient coughing
- Manipulation of liquids containing high numbers of TB bacilli

Exposure to these TB bacilli can be reduced by:

- Collecting sputum outdoors - Never collect sputum indoors!
- Good ventilation of the laboratory (in absence of open windows this may require an exhaust fan)
- Handling specimen containers with care
- Manipulating sputum gently during smearing.
- Appropriate use of disinfectants (discard jar).
- Universal precautions for infection prevention
- Functioning safety hoods (facility handling more than 10 smears per day). If hoods are not available, good natural ventilation (open windows) should be ensured and is sufficient to limit exposure to bacili.

12.3 Quality Assurance

This is a system for continuously improving the reliability, efficiency, and use of services. A quality assurance system has been rolled out to all provinces and districts. Individual diagnostic centers undertake internal Quality control (IQC) using known positive and negative slides. High volume facilities may undertake IQC daily, while once weekly may be adequate for low volume facilities.

External quality assurance (EQA) is undertaken through blinded slide rechecking. This means that the controllers do not know the original result of the microscopy. Sputum smear slides for rechecking are collected using lot quality assurance sampling (LQAS) method as recommended by the WHO/IUATLD and CDC guidelines. The PMLTs and DMLTs are responsible for EQA at district level facilities and while the CRL is responsible for provincial and referral hospitals' laboratories.
Sampling of slides for peripheral laboratories is carried out by DTLCs. This is done by PMLTs and CRL for provincial and referral hospitals respectively, using acceptable means for ensuring blinded re-cheking.

*Note: **All** examined slides (positive and negative) should be kept in slide boxes in a dark and dry place, ordered according to their laboratory numbers and discarded only after EQA sampling.*

Sampled slides are examined by the first controller and results recorded. Discordant slides are passed on to the second controller for re-checking. A report on errors and other smear characteristics is thereafter prepared by DMLT (or PMLT, CRL) for feed-back to respective laboratories.
DMLTs, PMLTs and CRL are responsible for providing quarterly feed-back on EQA and supportive supervision (using a standard checklist) for the laboratories.
PMLTs compile quarterly AFB workload and EQA reports and submits to DLTLD

CHAPTER 13: ADVOCACY COMMUNICATION AND SOCIAL MOBILISATION (ACSM)

13.1 Advocacy

Advocacy for TB is to be understood as a broad set of coordinated interventions, designed to place TB high on the political and development agenda, foster political will and increase and sustain financial and other resources.

Target areas of advocacy activities

Activity area	Desired position	Activities
Legislation	Increased awareness and utilization of existing laws and regulations Policy guidelines in place to support legislation (TB infection and drug control)	Updating of public health officers/DMOPHS Sensitization of community, health care workers formulation of policy guidelines, sensitization guidelines
TB and HIV collaboration	Stigma reduction Increased participation of persons affected, infected by TB/HIV. Strengthened collaboration/linkages between TB and HIV programs.	Harmonization of the guidelines and strategic plans of TB and HIV programs. Strengthening National, Provincial and District levels to implement and monitor mechanism for enforcing standards and by-laws regarding diagnosis and treatment. Inclusion of TB groups in priority planning processes for TB and HIV
Partner involvement	Partner base expanded and partner activities harmonized.	Identification of potential partners. Advocacy/mobilization of the potential partners to take greater role in TB/HIV control. Inventory of Partner activities Coordination and harmonization of partner activities
Financial management	Funds management and financial reporting streamlined, and decentralized.	Advocacy meeting with JICC Joint discussions with DLTLD, MOPHS/MPHS and MOF to identify current issues in affecting MOPHS and Stop TB targets that are related to funding. Development of action steps to address identified issues.
Human resource management for TB/HIV control	Health facilities adequately staffed with skilled and motivated personnel	Rationalization of staffing based on human resource performance standards and quantification tools Advocacy meetings with HR in MOPHS, Department of Personnel Management (DPM), MOF and other partners Recruitment of staff Training of health providers
HIV care for TB?HIV co-infected patients	ARV/counseling/OI management decentralized to Health Centre/dispensary levels.	Joint forum for HIV and TB programs at all levels. Establishments of linkages for TB/HIV services. Implementation of decentralization plans at all levels.
Involvement of patients and communities in TB/HIV control	TB and TB/HIV patients and their communities play an active role in the planning and implementation of TB control services.	Identify and strengthen the groups of affected persons. Annual forum for TB and TB/HIV support groups sharing experiences.

Activity area	Desired position	Activities
Involvement of CSO/NGOs in TB/HIV control.	CSOs/NGOs play key roles in representing and furthering issues of community and stakeholders at national levels. TB groups empowered to respond to emerging issues of people affected by TB.	Identify and strengthen potential NGOs/CSOs for TB and TB/HIV services. Consultative meetings between relevant stakeholders including DLTLD, CSOs/NGO and selected TB groups. Undertake inventory and strengthen capacity of CSOs/NGOs and TB groups in TB/HIV control.
MDR/XDR-TB preparedness	Health workers are informed how MDR and XDR can be prevented through good DOTS. MDR/XDR preparedness and response plan on all levels. Health workers prepared to manage MDR/XDR-TB. Communities well sensitized on their role in MDR/XDR-TB prevention and management. Media persons sensitized on packaging MDR/XDR-TB messages. Resources available to cope with MDR/XDR-TB.	Inform health workers and patients on how to prevent MDR/XDR. Dissemination and implementation of guidelines for MDR and XDR-TB management. Capacity building for health workers to manage MDR/XDR-TB. Resource mobilization for MDR/XDR-TB. Consultative forum for community leaders, media persons, TB groups, and CSOs/NGOs/CBO on MDR/ XDR-TB.
Promotion of public-private partnership in TB/HIV control	Private sector fully participates in TB/HIV control at all levels Policy guidelines on public-private partnerships developed.	Sensitize and strengthening private sector involvement in TB/HIV control. Expand cooperation with non-public providers.
Rationale use of TB/HIV/STI drugs	Irrational use of TB/HIV/STI drugs minimized	Join forum on rationale use of TB/HIV/STI drugs Enforcement of control use of TB/HIV/STI drugs at all levels
Information, Education & Communication of TB, TB/HIV issues to the public	Improved health-seeking behavior Improved (early) case detection Knowledge about TB and TB/HIV in the community (see 12.3)	Sensitization of the communities by DHMTs, DTLCs, PHOs etc. Mass media messages on TB and TB/HIV DLTCs to join DHMT advocacy efforts to inform about TB and TB/HIV

13.2 Communication

Within countries, and in the context of TB control, communication primarily seeks to create and improve knowledge among the general public about TB (e.g. its symptoms and curability), TB control services (e.g. diagnosis and treatment) and improve interpersonal communication between patients and service providers contributing to behavioral change or to meet a particular behavioral goal.

The objectives of communication in TB/HIV control include the following

1. To create a clear understanding in the general population that TB is curable, regardless of HIV status.

2. To build the capacity of frontline health workers and other caregivers to thoroughly understand the clinical manifestations of TB, HIV, and AIDS and to deliver care and treatment with a positive attitude, hope, and compassion.

3. To create understanding of the warning symptoms of TB and the consequences of delay in seeking diagnosis at a recommended health facility.

4. To create confidence that public health facilities can diagnose, treat, and cure TB and that TB drugs are available at no fee to the patient.

13.3 Social Mobilization

In the national and sub-national contexts, social mobilization is a process of generating public will by actively securing broad consensus and social commitment within civil society to fight stigma and eliminate TB as a public health threat. That is, social mobilization seeks to convert knowledge into demonstrable action.

CHAPTER 14: LEPROSY DISEASE

14.1 Introduction

Kenya is in the post elimination phase of leprosy (1: in 10,000 pop). However, there is need to ensure intensive case detection to mop up all the leprosy cases, especially the infectious type (multi-bacillary Leprosy). It is now recommended that the contacts of all new leprosy cases be screened too. Leprosy advocacy activities should be intensified in communities where leprosy cases are detected.
Because of the low numbers of cases detected, the skills and knowledge of health workers to diagnose and manage leprosy have gradually declined. There is therefore there need for training of health care workers in the diagnosis, treatment and referral of leprosy patients. There is also need to produce IEC materials for distribution in the affected districts. Mechanisms are being put in place to ensure prevention of disability in new leprosy cases and provision of care to former patients disabled by the disease.

14.2 Definition:

Leprosy is an infectious disease with a slow onset and a chronic course if not treated properly at an early stage. It is caused by a bacillus, *Mycobacterium Leprae.*
The bacillus multiplies very slowly (every 14 – 30 days), which explains why the incubation period is so long - on average 5 to 8 years. The bacillus causes inflammatory reactions damaging the skin and peripheral nerves, which constitute some of the coolest places in the body. The nerve damage affects the 3 modalities of the nerve function i.e. sensory, motor and autonomic functions. The resulting symptomatology is represented by loss of sensation, weakness and/or paralysis in innervated muscles and skin dryness due to lack of sweating and hypo-pigmentation of the innervated skin.

Classification of Leprosy:

According to WHO classification, there are two major forms of leprosy:

1. Pauci-bacillary (PB) or tuberculoid type of leprosy. The bacilli are few, and difficult to observe in a skin smear or a skin biopsy. They are concentrated in the superficial skin layers and in peripheral nerves.

2. Multi-bacillary (MB) or lepromatous type of leprosy. The bacilli are numerous and can spread to almost all parts of the body except the brain and spinal cord. All other organs may be affected by the leprosy bacilli and may be damaged in the long run if the disease is not treated early.

14.3 Body Immunity

Leprosy is an infectious disease. However, most people have sufficient body defence (immunity) to prevent them getting the disease. Only a minority of infected people will actually develop the full blown disease.

The disease has different manifestations depending on the level of immunity (resistance). Patients with a high degree of immunity will develop pauci-bacillary leprosy, and those with low immunity will develop multi-bacillary leprosy. These two spectrums of the disease have varying modes of presentation and require different approaches in management.
At the moment, leprosy diagnosis depends on presentation and skill of health care providers. Therefore the skills and knowledge of the health workers are important in identifying suspects and diagnosing cases of leprosy among the patients who visit the health units.
Leprosy case finding has over the years relied on *passive case finding*; with general health staff identifying suspected leprosy cases among the patients who visit the health units for any service. It is now recommended that the contacts of all new leprosy cases be screened too.

When is leprosy suspected?
A patient should be suspected of having leprosy if one or more of the following signs or symptoms are present:

- Complaints of burning sensations in the skin
- Pale (hypo-pigmented) patches on the skin with loss of sensation
- Numbness and tingling sensation in the feet and/or hands
- Weakness of eyelids, hands or feet
- Enlarged and tender peripheral nerves
- Painless swellings or lumps, especially on the face and ear lobes
- Painless wounds or unnoticed burns on the hands or feet.

The health worker should try to rule of leprosy in such patients and/ or if in doubt refer them to the DTLC or a dermatologist at the earliest possible time.

14.4 Diagnosis of Leprosy: "the three cardinal signs"

A diagnosis of leprosy is made if **one** of the following signs is present:

- *Skin patch with loss of sensation*
- *One or more enlarged peripheral nerves*
- *The presence of leprosy bacilli on the slit skin smear*

14.5 Classification: type of leprosy

14.5.1 Pauci-bacillary leprosy

Skin*:* 1 to 5 skin patches

Skin smear*:* usually Negative

Reaction*:* Type I reaction is very common (See Leprosy Complication below)

Nerves*:* Early damage to one or more peripheral nerves

Disabilities and deformities*:* Both are common as a result of irreversible nerve damage. The deformities in particular create the common and feared image of leprosy disease.

14.5.2 Multi-bacillary leprosy

Skin*:* 6 or more patches, infiltration and nodules

Skin smear*:* usually positive, Bacilli present

Reaction*:* Type I and II reactions may occur

Nerves*:* Late damage to peripheral nerves

Disabilities and deformities*:* Mainly develop at a late stage of the disease process (See chapter 14 leprosy complication)

14.5.3 Nerve Involvement

Nerves affected by leprosy are usually swollen and often tender on palpation. Nerves should, therefore, be examined in every patient suspected of having leprosy.

14.5.4 Grading of leprosy patients

All leprosy patients should be assessed for the degree of disability and the grading recorded. The criteria given in the table below should be used:

Table 14.1 Disability Grading of leprosy

Any of the two features or both		***Grade***
Eyes	***Limbs***	
No visual impairment	No abnormality detected	0
Eye complication but can see	Anaesthesia, weakness or dryness	1
Impaired visual acuity	Obvious permanent deformity	2

To ensure people seek early treatment and leprosy related disabilities are prevented, the following strategies can be used:

1. Health Education to patients on leprosy reactions and how to care for theirs eyes and feet.

2. Early detection and treatment of reactions. This will involve quarterly Voluntary Muscle Testing (VMT) – Sensory Testing (ST) to detect and prevent any damage

3. Provision of protective foot-ware to leprosy patient with loss of sensation in their feet (Disability Grade one) and provision of reconstructive surgery. DLTLD coordinates this with AMREF.

4. Socio-economic rehabilitation to former leprosy patients.

CHAPTER 15: TREATMENT OF LEPROSY

15.1 Classification of patients

Leprosy patients are classified into the following groups and reported in the Leprosy Register for epidemiological and treatment reasons:

- **New (N)**: This is a patient who has never been treated before.
- **Relapse (R)**: This is a patient who has received treatment and was declared cured but now has leprosy again.
- **Transferred in (TI)**: This is a patient who was registered in another district and has now reported to another district for continuation of treatment.
- **Treatment resumed (TR)**: This is a patient who interrupted his treatment, and was declared "out of control", but is now resuming treatment.
- **OOC** –this is a patient who has missed his leprosy drugs for 12 months and was declared out of control.

15.2 Multiple drug therapy (MDT)

The regimen that is being used by the DLTLD to treat leprosy is multiple drug therapy (MDT), as advocated by the WHO. Multiple drug therapy was introduced in 1984 and replaced Dapsone monotherapy. During the introduction of MDT, many patients who were still on mono-therapy were assessed and released from treatment. Some of these patients however, may present with signs and symptoms suggestive of relapse of leprosy and may require further assessment and possible treatment with MDT.

MDT differs from mono-therapy in being a combination of several powerful anti-leprosy drugs. This combination prevents the development of drug resistant bacilli, and has shortened the duration of treatment to six months in pauci-bacillary leprosy and to one year in multi-bacillary leprosy (Tables 11 and 12).

Table 15.1 MDT for pauci-bacillary leprosy (PB) patients (duration six months)

	0-5 years	6-14 years	>14 years
Dapsone daily	25 mg	50 mg	100 mg
Rifampicin four-weekly supervised	150 mg	300 mg	600 mg

Table 15.2 MDT for multi-bacillary leprosy (MB) patients (duration one year)

	0-5 years	6-14 years	>14 years
Dapsone daily	25 mg	50 mg	100 mg
Clofazimine (Lamprene) four-weekly supervised	100 mg	200 mg	300 mg
Clofazimine (Lamprene) unsupervised	50 mg alt. days	50 mg daily	50 mg daily
Rifampicin four-weekly supervised	150 mg	300 mg	600 mg

15.3 Outcome of Treatment

At the end of treatment Leprosy patients can be classified as:

- **Released from treatment (RFT):** This is a leprosy patient who has completed his/her treatment as required.

- **Out of Control (OOC):** This is a leprosy patient who has not attended twelve (12) consecutive clinics and all efforts to motivate him/her to attend the clinic have failed.

- **Transferred out (TO):** A patient who is transferred to continue treatment in another region.

- **Died (D):** A patient who died during treatment irrespective of cause of death.

Note: Many leprosy patients may have been declared cured (released from treatment, (RFT) but may still suffer from the sequelae (reactions) of the disease e.g. ulcers, paralysis in hands, feet or eyes. These should be managed separately.

CHAPTER 16: COMMONLY ENCOUNTERED SIDE EFFECTS OF ANTI-LEPROSY DRUGS

The anti-leprosy drugs related side effects are classified as minor and major as highlighted below:

16.1 Minor Side Effects

In the event of minor side effects, inform the DTLC or dermatologist on your next visit to the clinic. Continue MDT.

Slight itching
This is often caused by Dapsone and should be treated symptomatically with antihistamines.

Gastro-intestinal disturbances
These are mostly caused by Clofazimine and include nausea, vomiting, and abdominal pains. To reduce these, give the drug after a meal.

Red urine
This is caused by Rifampicin and is harmless. No significant action needs to be taken but there is need to reassure the patient.

Red skin, eyes
This is caused by Clofazimine and is harmless. No action is needed. The patient has no complaints at all apart from the cosmetic effect.

Symptoms similar to severe flu
This is caused by Rifampicin. Treat symptomatically and reduce the dosage to half until the symptoms have disappeared.

16.2 Major Side Effects

Refer the patient to the medical officer or DTLC as soon as possible and stop all MDT drugs, if major side effects present.

Jaundice
This is caused by Rifampicin. Stop all drugs immediately and refer patient to DTLC.

Anaemia
This is caused by Rifampicin and Dapsone. Rule out other causes of anaemia (parasites, malaria etc). Refer the patient to the medical officer or the DTLC.

Exfoliate dermatitis
This is caused by Dapsone. The skin is itchy, and later peels off. The patient is very ill. Stop drugs immediately and refer the patient to the medical officer or DTLC or to the nearest hospital.

Fixed drug eruption
This is caused by Dapsone. Stop Dapsone immediately. The eruption will slowly clear after stopping.

CHAPTER 17: LEPROSY COMPLICATIONS

It is very important that all health staff, dealing with leprosy patients, are aware of the complications that can occur in these patients during or after chemotherapy because they can lead to serious deformity and disability. Health staff should be able to determine which complications can be managed at their level and which need urgent referral to the DTLC or a dermatologist.

> ***Treat or refer complications of leprosy disease in accordance with the set guidelines***

17.1 Reactions

Most deformities and disabilities in leprosy are as a result of reactions. The early diagnosis and adequate treatment of reactions is therefore extremely important in the prevention of disabilities.

In the case of a leprosy reaction, the body's immune system suddenly reacts to the leprosy bacilli in the body (dead or alive) causing an acute inflammation at the affected sites with swelling, pain, redness, warmth, and loss of function. In severe cases, the patient may be in great pain because of the swelling of nerves, and be very ill with a high fever. A reaction may occur ***before, during*** **and** ***after*** chemotherapy. It can also be provoked by a disturbance of the body's defence system, especially by inter-current disease or during and after pregnancy.

There are two types of reactions:
- Reversal (or Type I reaction)
- Erythema nodosum leprosum (or Type II reaction).

17.1.1 Reversal reaction (RR), Type I Reaction

This type of reaction occurs both in PB and MB leprosy patients and the patient must be referred immediately.

> ***Patients with reversible reactions must be referred immediately!***

Suspect Reversal Reaction when you observe the following:
- Acute or sub-acute redness and swelling of one or more skin patches
- Oedema of hands, feet or face
- Acute or sub-acute pain, swelling and tenderness of peripheral nerves; combined with acute or slowly developing loss of sensation and weakness in the area innervated by the affected peripheral nerve.

17.1.2 Silent neuritis

This is a type of reversal reaction which is asymptomatic. Nerve function deteriorates slowly and goes unnoticed by the patient. It can only be detected by doing regular - at least quarterly - assessments of sensation and muscle function (VMT/ST). It is the responsibility of the DTLC to do this.

17.1.3 Treatment of reversal reaction

All patients with reversal reaction must be examined by a DTLC and referred immediately. Any delay may increase loss of nerve function. The patient should be treated with anti-inflammatory drugs - aspirin or indomethacin in mild cases, or high doses of prednisolone in severe cases.

Depending on the patient's condition and his accessibility to a health unit, the patient is admitted for treatment or will be treated ambulatory from a health centre or dispensary. In cases of ambulatory treatment, the DTLC should refer the patient back to the health unit with a detailed treatment schedule. The total duration of treatment may be six months.

17.1.4 Erythema Nodosum Leprosum (ENL), Type II Reaction

This reaction occurs only in multi-bacillary patients. The severe form may be life threatening.

Suspect ENL reaction with:

- A history of sudden onset
- The appearance of red, tender nodules in the skin. They remain for about three days, disappear and crop up again in other places
- Mild to high fever
- A painful red eye with loss of vision
- Painful swollen testicles
- Tender nerves
- Other organs: swollen tender lymph nodes and joints, swollen liver/spleen.

When to suspect the severe form of ENL:

- Temperature higher than 38.5 ^{o}C
- Red painful eye
- Painful swollen testicles
- Ulcerating skin nodules
- Severe arthritis, lymphadenitis
- Severe nerve pains.

17.1.5 Management of ENL reaction

Mild ENL: paracetamol, indomethacin or other anti inflammatory drug. These forms may be treated with paracetamol or indomethacin for a period of one week by the general health staff. If no improvement has occurred by then, the patient should be referred to the DTLC.

Severe ENL: refer as an emergency. These forms should be referred immediately to the DTLC. The patient should be treated with prednisolone and/or clofazimine for 4 - 6 weeks, on average. This reaction may recur repeatedly. As in reversal reactions, patients may be treated in hospital, or on an ambulatory basis.

17.2 Eye complications

Eye problems are most commonly caused by leprosy reactions and subsequent nerve damage. They are mentioned separately because of their serious consequences to patients and their specific management. Every health worker working with leprosy patients should be on the lookout for each of the following conditions in a leprosy patient.

17.2.1 Lagophthalmus

The patient is unable to close the eyelids, due to weakness of the muscles that close the eyelids. The patient does not blink properly and the cornea is usually insensitive. If these muscles are very weak, the eye may water continuously. The cornea is at risk of drying out and is exposed to foreign bodies, which may adhere to it without the patient noticing them.
This is quite a common condition in leprosy patients. The patient is at risk of becoming blind in the affected eye. However, this can be prevented with proper treatment and simple preventive measures.

17.2.2 Red eye

This is a very serious sign in a leprosy patient, especially if it is combined with lagophthalmos. It needs careful examination and often quick referral.

Check for the following in the eyes and manage appropriately:

- ***Foreign body****:* a hair, an insect, a piece of grit, etc. that may be causing irritation and redness.
- ***Management:*** Inspect and remove the foreign body, apply anti-biotic eye ointment and an eye bandage for two days.

- ***Keratitis****:* This is an inflammation of the cornea as a result of an infection by bacteria or a virus, often enhanced by drying out (particularly in patients with lagophthalmos). The cornea is not clear, and the eye is red and painful. Sometimes you can see an ulcer in the cornea.
- ***Management:*** Apply antibiotic eye ointment and an eye pad. Refer the patient immediately to an eye doctor, the DTLC or the nearest hospital.

- ***Acute iridocyclitis****:* In a MB leprosy patient this is a form of Type II reaction. It is characterised by:
  - Acute red eye
  - Loss of vision
  - Pin-point pupils, not reacting to light
  - Intolerance to light.
- **Management:** Start the patient on Atropine eye ointment t.d.s. and apply an eye pad. The patient should then be referred immediately to an eye doctor, DTLC or PTLC. The patient will then be treated with locally applied Corticosteroids and Atropine under close supervision.

17.3 Wounds

- Determine which factors have contributed to causing the wound
- Assist the patient to prevent recurrence of the wound

Wounds are common in leprosy patients and are very often recurrent, because the patients are not able to adopt behaviour that will prevent recurrence. Sometimes patients maintain the wound to generate income.

Usually, wounds are the result of overuse of a hand or limb. People with healthy nerves feel pain when their eyes, hands and feet are injured, and will do something about it. First of all, they will unconsciously adopt pain-evading behaviour, which will rest the injured limb or eye - they have protective sensation. Leprosy patients do not have this protective sensation and can continue to walk on blisters or on an infected foot. Frequently, they report for medical assistance when the wound has become severely infected.

It is important for general health staff to take a good history including details of the patient's living conditions, in order to give appropriate advice on how to prevent the recurrence of wounds and how to stop this seemingly inevitable process of increasing deformity and disability.

- ***Wound management***

Apply the following principles in wound management:

- Engage in a dialogue with the patient, do not give a sermon
- Promote a self-help attitude
- Use appropriate available materials (e.g. clean cloth as a bandage).

Patient co-operation is essential for successful treatment of wounds. A good relationship, and an understanding of the patient's living conditions, will create the basis for the mutual co-operation that can lead to successful treatment and prevention of recurrent wounds. The general health worker should promote a self-help attitude in the patient. The patient will only be motivated to take care of himself if

he/she understands the reasons for the occurrence and recurrence of wounds, accepts responsibility for changing his/her own behaviour, and is in a position to do so.

- ***Superficial ulcers***
  The patient at home can treat these, especially after proper practical instructions have been given and are understood.

- ***Basic treatment***
  - Soak the wound in soapy or salty water for a minimum of 20 minutes
  - Trim the wound edges by rubbing with a stone (or by the nurse with a scalpel)
  - Bandage the wound with a clean cloth that can be made from old clothes
  - Rest the affected limb - carry the arm in a sling, or walk as little as possible and with a stick or crutch.

- ***Deep wounds/ pus-discharging wounds/ infection***
  These wounds should be referred to a hospital or the DTLC/PTLC for possibly X-ray and surgical treatment.

17.4 Rehabilitation

Patients with deformities and/or disabilities often lead a miserable life on the edge of human existence, frequently as the result of stigmatisation and abandonment by their relatives. The country has a responsibility to assist in the rehabilitation of such patients within the context of community-based rehabilitation. This is not a prime responsibility of the Ministry of Public Health and Sanitation.

17.5 Health Education of leprosy patients

- Is a dialogue, not a lecture
- Is essential to attain a high cure rate
- Is essential to prevent defaulting

It is the task of health staff to educate leprosy patients about their disease. Education is essential for obtaining the patient's co-operation over the required treatment. An understanding, sympathetic and concerned attitude on the part of the health staff is essential for getting the message across.

Like in tuberculosis treatment, leprosy patients have to take drugs on a strict and regular basis in order to obtain a high cure rate. They need much support from medical staff and their families throughout their treatment period in order to maintain good compliance.

17.6 Factors that complicate leprosy management

- People with the disease are still stigmatised.
- The patches in pauci-bacillary patients only disappear several years after MDT has been stopped and the patient is told that he/she is cured.
- Leprosy reactions with complications such as paresis, paralysis or blindness can occur months or years after a patient is declared cured.
- Leprosy disabilities are often irreversible if patients report very late. They may have expected their disabilities to be "cured"; therefore this leads to disappointment and may influence their compliance with treatment.
- Even with MDT the treatment period is still quite long (6 months to 1 year) and this causes problems with the regular intake of drugs.

In these circumstances, it is clear that education of leprosy patients must be a painstaking task, which requires patience and understanding of the patient's way of thinking and his/her individual circumstances.

CHAPTER 18: WHAT EVERY LEPROSY PATIENT SHOULD KNOW

18.1 At diagnosis

- Leprosy is an infectious disease caused by bacteria not by a curse, witchcraft, or anything else.
- The patient may have infected several other people who may also develop leprosy. They should therefore encourage those people to get checked for leprosy when they develop patches.
- Leprosy bacilli are killed by MDT if the drugs are taken regularly for the recommended period.
- Much of the damage that had been done to nerves and tissues before the patient was started on MDT cannot be reversed.
- During (and after) MDT, patients are no longer infectious and therefore pose no danger at all to other family members or the community.
- In PB patients, patches will still be present when the MDT course is already finished. The patches will disappear slowly over a period of 1 - 3 years.
- Tablets need to be taken daily, as prescribed, and preferably at the same time each day.
- Drugs have to be collected from the clinic every four weeks. On the clinic day the patient takes Rifampicin and Clofazimine under supervision, and collects Dapsone and Clofazimine to be self-administered at home.
- Keep the drugs out of reach of children.

18.2 During MDT

A patient on MDT should report immediately to the clinic if one of the following happens:

- If patches start becoming red and swollen again
- If he/she notices sudden weakness of muscles
- If he/she notices that one or both of his/her eyes are red and painful
- If he/she notices pain in one of his/her limbs
- If he/she notices the appearance of red, swollen, tender nodules in the skin

Additionally the patient should be advised about the following:

- To take the drugs after a meal or in the evening just before going to bed if he/she feels any nausea after ingesting them.
- To inform the staff at the clinic when they intend to travel. An adequate supply of drugs can then be given to cater for the period they are away.
- To inform the staff at the clinic when they intend to move to another area. The clinic staff will then write a transfer letter and give advice on where they should continue treatment.

18.3 After MDT

- Leprosy reactions can still develop after MDT. These reactions must not be treated with a new course of MDT but can be effectively treated with other drugs. Early reporting is absolutely necessary to prevent irreversible damage.
- Patients should report as soon as they notice new patches or if old patches become thick and red. This may indicate that the disease has started again, or that a reaction is taking place.
- Patients should report as soon as they notice/ feel pain in their hands and feet.

18.4 Wound Prevention

The patient education should be individualized, case by case, and may be advised as follows:

Care for insensitive feet

- Wear protective footwear throughout the day to avoid injury.
- Avoid too much walking because this is the most common cause of a sole wound in an insensitive foot. So, take a ride on a bicycle when you can; send others in your place; if you must go, stop often, rest your feet and watch where you step.
- Learn from any earlier wounds to your feet so that you do not make similar mistakes again.

- Avoid heat. Sit with your feet protected, when you sit close to a fire.
- Avoid sitting on your lower legs when you sit on the ground because this may cause pressure ulcers.

Daily foot inspection

- Inspect insensitive parts of your feet and legs and also to look for signs of injury, dryness, cracks, and swellings. A small mirror is useful for inspecting the sole of your feet.
- Feel for warm spots: this may warn of injury, and to press for tenderness caused by infection in the deeper layers of the sole of the foot.

Care of dry feet

- Soak for 20 minutes twice daily in salty water, then to rub oil into the skin. This helps to keep the skin of your feet moist and prevents cracks.
- Trim and rub off any callus.

Care of wounds at home

- Remove the cause, e.g. a nail or small stone in a shoe.
- Soak the wound in soapy or salty water for 20 minutes, at least once a day, or more frequently when the wound is discharging. Remove dirt gently.
- Cover the wound with a bandage. This can be made of old clean cloth.
- Rest the foot.

Care for insensitive hands

Generally apply the same kind of care as for the feet. Hands are most frequently damaged during cooking (burns) and manual labour as a result of too much friction.

Care for eyes with lagophthalmos

Patients with lagophthalmos (inability to close the eye) need special attention. Patients should be advised to:

- Wear sunglasses
- Check their eyes daily in the mirror for redness and foreign bodies
- Bind a pad of clean cloth over the eyes at night
- Avoid rubbing the insensitive eye.

CHAPTER 19: RECORDING AND REPORTING OF LEPROSY CASES

The health staff in charge of the tuberculosis or leprosy clinic is responsible for filling in and maintaining the following records and registers used for case reporting, analysis of treatment and defaulter tracing:

- Leprosy Patient Treatment File
- Leprosy Appointment Card
- Leprosy Treatment Register
- Defaulter Action Card

Defaulter tracing

Defaulter tracing is the responsibility of all health staff. During the full course of leprosy treatment and the continuation phase of tuberculosis treatment, patients attend clinics at four-weekly intervals. Failure to attend this clinic may lead to interruption of treatment and treatment failure. Therefore, any leprosy patient who has missed one clinic should be traced as soon as possible to establish why he/she has defaulted and to persuade him/her to attend again.

CHAPTER 20: COMMODITY MANAGEMENT

This section provides standardised operating procedures (SOPs) and guidelines for the logistics management of Tuberculosis/Leprosy drugs and related commodities. The manual will guide the healthcare workers as they perform some or all of the following activities:

- Determine supply needs.
- Order, receive, and store supplies properly.
- Distribute and maintain adequate supplies.
- Record and report accurate information about supplies and their use.
- Monitor logistics activities and supervise the staff that carries them out.

By using these procedures to manage supplies, health staff can ensure adequate supplies of quality products for their clients throughout the country.

Logistics management includes a number of activities that support the six rights i.e. having the right goods, in the right quantities and the right condition which are delivered to the right place, at the right time for the right cost. Over the years, logisticians have developed a systematic approach to describing the activities of a logistics system. They call it the *logistics cycle.*

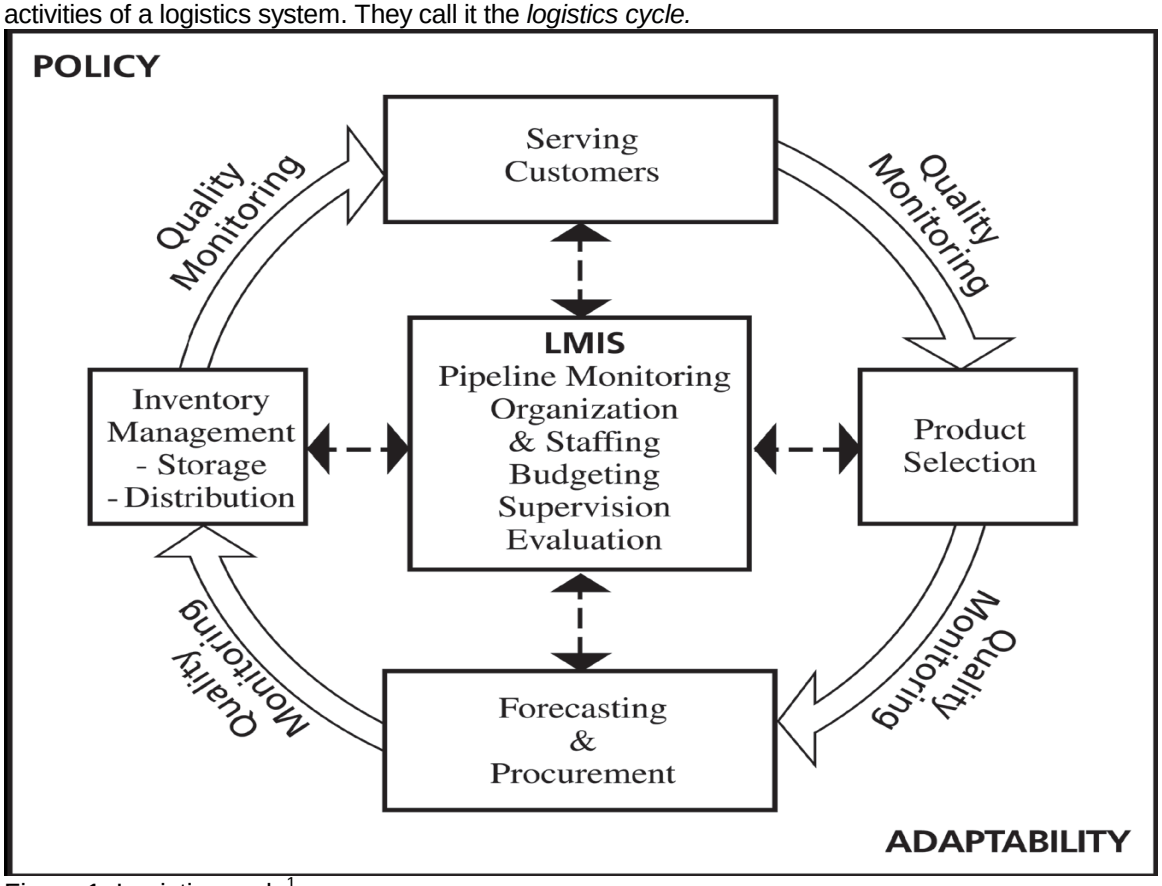


Figure 1: Logistics cycle[1]

The elements in the cycle are:

- Serving Customers

Each person who works in logistics must remember that he or she selects, procures, stores, or distributes products to meet customer needs. The logistics system ensures customer service by fulfilling

the six rights. Each activity in the logistics cycle, therefore, contributes to providing excellent customer service.

Product Selection

This is the responsibility of the national formulary and therapeutics committee, pharmaceutical board, board of physicians or other government appointed group.

- Forecasting and Procurement

Estimation of the quantities of the various commodities that will be needed for a specified time period. The procurement process is lengthy process and involves procurement agencies (government and/or private) and the recipient programs

- Inventory Management: Storage and Distribution

The commodities when procured should be stored until the customer needs are determined. Determination on of the stock required is an important step in the logistics cycle.

20.1 Tuberculosis and leprosy commodity logistics system.

To ensure the availability of drugs for the specified duration of TB treatment and promote DOTS expansion up to and beyond the dispensary level, TB Patient packs were introduced in 2005. Currently we have TB Patient packs for Categories 1 and 3. Each Patient pack contains drugs for both Intensive and Continuation phases of treatment. The country is using the six-month treatment regimen with RH in the continuation phase.

The dose for Rifampicin is weight related. The current patient kit is standardized for patients of 40-54Kg. This therefore requires the adjustment of tablets (by removal) for patients below 40 kg and addition for patients above 54kgs. The extra tablets are put into or dispensed from the **Supply Box**. Remaining drugs in the respective patient packs for patients who have died, are 'transferred out' or 'out of control' are also put into the Supply Box. The contents of the Supply Box should be repacked into patient packs or used for the addition for those above 54Kgs. Patients who are not registered in a given facility e.g. patients on transit to their final destination treatment facility can be supplied with drugs from the Supply Box.

This Logistics system requires that a TB patient Pack is entered in the inventory as one complete pack the day it is opened. It is then assumed to be consumed. If for reasons one is not completed, the remaining amount is put into the "Supply Box" section of the inventory.

20.2 Other Supplies

- ***Laboratory Supplies***

Currently, the laboratory supplies for the sputum examination of TB are supplied by the Ministry of Public Health and Sanitation through DLTLD. Logistics data will therefore be collected through this system. Once the commodities are supplied to the Laboratory from the store, the system will assume they have been consumed. The actual consumption will be validated during monitoring and supervision.

- ***Stationary***

The required stationary for the effective and efficient management of the TB and Leprosy patients will be supplied through this system. Service providers and the DTLCs will be required to request for the necessary stationary and account for them in the monthly and quarterly logistics reports respectively.

- **Leprosy Drugs:**

Drugs for multi-bacillary (MB) and pauci-bacillary (PB) leprosy treatment in adults and children are supplied through this system. The three mainstay drugs are Rifampicin, Dapsone and Clofazimine, and are packed in monthly doses per blister pack. A blister pack received or dispensed will be recorded as such.

- **Cotrimoxazole Tablets:**

It is now a Ministry of Public Health and Sanitation policy that all TB patients who are also HIV infected should be put on Co-trimoxazole prophylaxis. The tablets are supplied by DLTLD and through the essential drugs programme. Logistics data will be collected through both systems.

NB: TB/Leprosy Drugs and related medical supplies are first moved from KEMSA to the regional and then district stores, from where districts / facilities are required to order. Deliveries to districts / health facilities are by PTLCs and DTLCs or other region- / district-specific means. In some instances, health facilities may also individually collect their orders from the regional / district stores.

20.3 Commodity information flow

Provincial and District Tuberculosis & Leprosy Coordinators work with the District and health facility staff to coordinate the management and distribution of TB/Leprosy drugs and related supplies. As products move through the Medical Supply System, information moves up the logistics management information system (LMIS) from health centres to districts, regional levels and on to DLTLD Central Unit. Staffs use this information to make supply decisions to order and issue TB/Leprosy drugs and related supplies at the appropriate time and in adequate quantities.

20.4 Storing Tuberculosis/leprosy drugs and related supplies

Appropriate storage protects and maintains the quality of Tuberculosis/Leprosy drugs and related supplies. It also preserves the integrity of the packaging while, at the same time, makes them available for use. If a product is not stored correctly, the shelf life (i.e. the length of time a product may be stored under ideal conditions without affecting its usability, safety, purity, or potency) may be shortened. Always check for the expiry dates before dispensing, and do not dispense products that have expired. Table 2 below shows the normal shelf lives of Anti-TB's in Government healthcare settings:

Table 20.1

Brand Name	**Shelf Life**	**Storage Conditions**
Isoniazid 100mg	4yrs	Below 25 Degrees
Ethambutol/Isoniazid (EH) 400/100mg	3yrs	Dry place Below 25Degrees
Rifampicin/Isoniazid (RH) 150/75mg	3yrs	Below 25 Degrees
Rifampicin/Isoniazid/Pyrazinamide (RHZ) 150/75/400mg	2yrs	Dry place below 25 degrees
Rifampicin/Isoniazid/Pyrazinamide/Ethambutol (RHZE) 150/75/400/275mg	3yrs	Below 25 Degrees
Co-trimoxazole – 480mg	5yrs	Cool Dry place
Streptomycin 1gr	3yrs	Not exceeding 25 Degrees

20.5 Reviewing Stock Status

This covers procedures that are used to determine how much of each product is needed in relation to the rate at which these commodities are used at the service delivery points.

Months of stock is the number of months TB/Leprosy commodities will last based on the present consumption rate. When reviewing stock status, you need to determine how many months of stock you have in your facility. Three months of stock means that your stock will last three months, as long as consumption remains at the current rate.

To help you maintain adequate stocks, a *maximum months' of stock, minimum months' of stock,* and an *emergency order point* have been established. The maximum months of stock is the largest amount of each TB/Leprosy commodity a facility should hold at any one time. If a facility has more than the maximum, it is overstocked and risks having stocks expire before they are used. The minimum months of stock is the least amount of each TB/Leprosy commodity a facility should hold at any one time. If a facility has less than the minimum, it is under stocked and risks having to place an emergency order or run out. The emergency order point is the level where the risk of stock - out is likely, and an emergency order should be placed immediately.

The maximum months of stock, minimum months of stock, and emergency order points for the different levels of the logistics management system are shown in the following table 3:

Table 10.2

Level	Maximum Months of Stock	Minimum Months of Stock	Emergency Order Point
KEMSA Central Warehouse	12 months	9 months	5 months
Regional Stores	6 months	3 months	1 month
District Stores	6 months	3 months	1 month
Service Delivery Points	3 months	2 months	1 month

20.6 Ordering and Issuing in the Logistics System

In the TB/Leprosy commodities logistics system, TB/Leprosy related commodities move down the system from the KEMSA central warehouse to the regional and then to the district stores. The regional and district stores service orders of drugs and related supplies from the district and service delivery points (including the National Teaching & Referral Hospitals, Provincial General Hospitals (PGH) and District hospitals). Determining how much of each product to order and issue is a critical element in the effective management of these supplies.

In this system:

- By the fifth of each month, the service delivery point submits a Facility Tuberculosis & Leprosy Commodities Consumption Data Report & Request Form (CDRR) to the District Tuberculosis & Leprosy Coordinator. Every three months, the Provincial and District Tuberculosis & Leprosy Coordinator reviews the District and Facility Tuberculosis & Leprosy Commodities Consumption Data Report & Request Form for each district and service delivery point, and prepares a Regional and District Tuberculosis & Leprosy Commodities Consumption Data Report & Request Form for the region and district. S/he then forwards the original copy of the Regional and District Tuberculosis & Leprosy Commodities Consumption Data Report & Request Form to the PTLC

and the DLTLD Central Unit by the tenth and twentieth of the first month of the quarter respectively.

- The PTLC and DLTLD Central Unit determines how much of each commodity to issue to each region and district store. The commodities are then distributed by KEMSA to the respective regions and districts as applicable.

- The ordering and issuing of products in the logistics system is directly linked to the reporting system. If the Provincial and District Tuberculosis & Leprosy Coordinators do not receive a Region or Facility Tuberculosis & Leprosy Commodities Consumption Data Report & Request Form from the district and service delivery points, they cannot determine how much of each product any of the districts or facilities need.

20.7 Logistics Management Information System

The purpose of a Logistics Management Information System is to collect, organize, and report information to all in the health system in order to make decisions regarding the procurement, quantities, receipt, warehousing and timely distribution of Tuberculosis/Leprosy drugs and related supplies to the service points.

Three items that any LMIS needs to capture are:

Stock on Hand: quantities of usable stock at any level of the system (or facility) at a particular point in time.

Consumption Data: the quantity of commodities dispensed or used during a particular period of time.

Data on Losses and Adjustments:
The quantity of commodities no longer available for use, which have not been dispensed/used (e.g. damaged, expired or stolen commodities), and transfers to or from other facilities.

This data is captured in three data collection records namely:

- Stock Keeping Record e.g. Bin cards.
- Transaction Records e.g. S11 and S12.
- Consumption Records e.g. Daily Activity Drug Register (DADR) and Consumption Data Report & Request Forms (CDRR).

The data maintained in these records is summarised periodically and shared upstream for planning and relevant action. For the TB/Leprosy logistics system, Facility and Regional/District Consumption Report & Request forms (CDRR) are used.

20.8 Monitoring and Supervision

It is safe to say that most logistics activities can be monitored by reviewing records and reports, and especially this can be done frequently from the office. For example, by checking reports one can determine if a health facility is maintaining adequate stock balances or if there are unusual quantities of commodities expiring or being lost.

Effective supervision involves planning to spend time supervising and providing on-the-job training when one visits personnel they supervise, whether they are in the same office, at a district laboratory store, or at a service delivery point etc.

20.9. Logistics system management responsibilities

Many health staff play a role in the operation of the Tuberculosis & Leprosy commodities logistic system at different levels of the system. Their logistics responsibilities are ordering and receiving, storage, issuing of the commodities, conducting physical inventory, quality assurance and disposal of unusable products, recording and reporting, and monitoring and evaluation.

The table below describes the personnel who manage the TB & Leprosy Commodities logistics system, its activities, and when the activities should take place at each level of the logistics system.

Responsibilities

Who	Actions	When
Facility In-Charge	• Receives and stores TB & Leprosy Drugs. Ensures that service providers record usage in the Daily Activity Drug Register for TB & Leprosy Drugs, and information about transactions on the stock card.	During the month
	• Completes the DLTLD Facility Consumption Data Report and Request and the Counter Requisition & Issue Voucher (Form S11), and submits them to the District Tuberculosis & Leprosy Coordinator.	Monthly
	• Receives and stores Laboratory supplies used for the laboratory diagnosis of Tuberculosis and Leprosy.	During the month
District Tuberculosis & Leprosy Coordinator	•Reviews and compiles information on drug and laboratory supplies quantities required for service delivery points (SDP) in the district, using stock on hand and consumption data from each SDP	Monthly
	• With the District Store In-Charge, the DTLC completes the DLTLD District Consumption Data Report and Request Form for the district and submits it to the KEMSA/DLTLD Logistic Management Unit (LMU) (where applicable) with a copy to PTLC.	Quarterly
District Store In-Charge	•Receives from KEMSA / regional stores and issues Tuberculosis & Leprosy commodities to service delivery points in the district. Records district store transaction information on the inventory control card.	
	• With the District Tuberculosis & Leprosy Coordinator, completes the DLTLD District Consumption Data Report and Request Form for the district and submits to the KEMSA/LMU/CENTRAL UNIT.	Quarterly
Provincial Tuberculosis & Leprosy Coordinator	•Reviews quantities required for the districts using stock on hand and consumption data from each district	Monthly
	• With the Regional KEMSA In-charge, completes the DLTLD Provincial Consumption Data Report and Request Form for the regional and submits to DLTLD Central Unit where the Pharmaceutical Unit handles the re-supply orders according to need.	Quarterly
Regional KEMSA	•Receives from KEMSA, Nairobi, stores and issues Tuberculosis & Leprosy commodities to the districts. Records district store transaction information on the inventory control card.	
	• With the Provincial Tuberculosis & Leprosy Coordinator, completes the DLTLD Provincial Consumption Data Report and Request Form for the region and submits to DLTLD Central Unit.	Quarterly
KEMSA Central Warehouse Manager	•Manages warehousing of Tuberculosis & Leprosy commodities and records information about transactions	Quarterly
	• Coordinates health commodity needs with the regional KEMSA and ensure the uninterrupted availability of Tuberculosis & Leprosy commodities	

20.10 Miscellaneous

Anti-TB drugs and other commodities arriving at National KEMSA in Nairobi should undergo baseline analysis i.e. few batch samples are taken for routine analysis at the National Quality Control Laboratory (NQCL) in Nairobi. All drugs arriving at KEMSA should be fully registered with the Pharmacy and Poisons Board (PPB), which as part of its process, subjects them to analysis.

Annex 1: Unit Serial No._____

Ministry of Public Health and Sanitation
Division of Leprosy, Tuberculosis and Lung Disease
TUBERCULOSIS APPOINTMENT CARD

Province	District
Reg. No.	Clinic

Name		
Address	Age	
Mobile Tel:	Sex	

Pulmonary tuberculosis	Smear +ve		Extra-pulmonary	
	Smear -ve			

Regimen	
2RHZE/6EH	
2RHZE/4RH	
2RHZ/4RH (<15yrs)	
2SRHZE/1RHZE/5RHE	
Other	

Date start treatment	
Date Cured or TC	

Height in metres								
Month	1	2	3	4	5	6	7	8
Weight (Kg)								

EDITION 2009

Intensive phase (56 x daily dose RHZE/RHZ/S)

Write date

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31	32	33	34	35
36	37	38	39	40	41	42
43	44	45	46	47	48	49
50	51	52	53	54	55	56
57	58	59	60	61	62	63
64	65	66	67	68	69	70
71	72	73	74	75	76	77
78	79	80	81	82	83	84

First two months of treatment

RHZE (150/75/400/275 mg)…… ..tabs/day
RHZ (150/75/400 mg) ……tabs/day
Streptomycin ……gram/day

For Children

RHZ (60/30/150 mg)…… ..tabs/day
RH (60/30 mg) ……tabs/day

Continuation Phase

New (month 3-8)

EH (400/150 mg) ……..tabs/day
RH (150/75 mg) ……...tabs/day

Retreatment (month 3)

RHZE (150/75/400/275 mg) ……tabs/day

Retreatment (month 4 – 8)

RH (150/75 mg) ……tabs/day
E (400 mg) ……..tabs/day
RHE (150/75/275mg)……tabs/day

Retreatment Manyatta (month 3-6)

RHZE (150/75/400/275 mg) ……tabs/day

Two-weekly drug collections

Date of collection	Date due		Date of collection	Date due

Sputum smear examinations at month:

	0	2	3	5	6	8
Result						
Serial No.						

Annex 2: District Tuberculosis Register

{PRIVATE **}**

Date of Registr.	District Reg. Nr.	Name (Write 3 names please)	Sex M/F	Age in Yrs	Weigh t (Kgs)	Height (Mtrs)	Physical address(Neighbour Primary School) Cell Phone	Facility	Date start Rx / Regimen	DOT by	Type of TB P/EP	Type of patient	CD4 count (if done) date & result: First two months	CD4 count (if done) date & result: Last two months

N = New (Never been treated before) **R-** = Smear negative relapse **TI** = Transferred in **F**= failure **DOT by**: **HCW** = Healthcare worker **H** = Household member

R+ = Smear positive relapse **REP** = Extra pulmonary relapse **RAD** = Retreatment after defaulting **CV** = Community volunteer **ND** = Not done

X-ray Y/N	**Culture** Yes/ND/DNR **Culture Results** *R/S*	Lab. serial number and result sputum smear examination				HIV Test Pos/Neg/ND/Declined (Date done))	Partner tested for HIV Pos/Neg/ND/Declined/No Partner (Date done)	Referred BY: VCT/HCC/STI /HBC/PS/ANC /SR/CI	Referred TO: VCT/HCC/STI/ HBC/PS/ANC	Cotrimoxazole preventive therapy Y/N (Date)	ART Y/N (DATE)	Nutrition Support (Yes/No)	Date & outcome of treatment C/TC/F/D/OOC/TO	Remarks
		0	2/3	5	6/8									
	S R E H													

Referred by:

VCT center	= VCT	Self referral	= SR
HIV Comprehensive Care unit	= HCC	Contact invitation	= CI
Home Based Care	= HBC	Chemist/Pharmacy	= CP
STI clinic	= STI		
Private Sector	= PS		
Antenatal clinic	= ANC		

Referred to:

Nutrition Support	=NS
VCT center	= VCT
HIV Comprehensive Care unit	= HCC
Home Based Care	= HBC
STI clinic	= STI
Private Sector	= PS
Antenatal clinic	= ANC

Outcome of treatment:

Cured (smear negative)	= C
Treatment Completed (no smear)	= TC
Failure (smear pos. at 5/8 months)	= F
Dead	= D
Out of Control (Defaulted)	= OOC
Transferred Out	= TO

NB. Partners tested for HIV (Y/N) = regular sexual partners of an HIV positive TB case

Drugs:
S = Streptomycin
R = Rifampicin
E = Ethambutol
H = Isoniazid

Culture
Yes
Not Done
DNR=Done No Results
Note: If Culture Results Available indicate the resistance Pattern:
R=Resistant, S= Sensitive

DOT during intensive phase by:

Health Care Worker	= HCW
Household member, friend, relative	= H
Community Volunteer	= CV
Not done	= ND

Type of patient:

New	= N
Smear pos. relapse	= R+
Smear neg. relapse	= R-
Extra Pulmonary relapse	= REP
Failure	= F

CD 4 count (if done):
Write down the date and result of CD 4 count
CD4/I = during first 2 months of treatment
CD4/II = during last 2 months of treatment

Culture
Yes
Not Done
DNR=Done No Results
Note: If Culture Results Available indicate the resistance Pattern:
R=Resistant, S= Sensitive

Serial number	District Registration nr.	Name (Write 3 names please)	Sex M/F	Age in years	Weight (Kgs)	Height (Mtrs)	Physical address (Neighbor/ Primary School) Cell phone No:	DOT by	Type TB P/EP	Type of patient	CD 4 count (if done)		**Culture** Yes/ND/DNR **Culture Results** *R/S*	X-ray Y/N	Lab. Serial number, date and result sputum smear examination				
											CD4/I	CD4/II			0	2/3	5	6	At beginning month 8
													S R E H						

DOT during intensive phase by:

Health Care Worker	= HCW
Household member, friend, relative	= H
Community Volunteer	= CV
Not done	= ND

Type of patient:

New	= N
Smear pos. relapse	= R+
Smear neg. relapse	= R-
Extra Pulmonary relapse	= REP
Failure	= F

CD 4 count (if done):

Write down the date and result of CD 4 count
CD4/I = during first 2 months of treatment
CD4/II = during last 2 months of treatment

Culture

Yes
Not Done
DNR=Done No Results
Note: If Culture Results Available indicate the resistance Pattern: R=Resistant, S= Sensitive

Drugs:

S = Streptomycin
R = Rifampicin
E = Ethambutol
H = Isoniazid

Date treatment started	Initial phase 8 x weekly drug collection (write date)								Continuation phase Year: Indicate date when patient has attended clinic Year:																										HIV Test P+/N-/ND/Declined (Date done)	Partner tested for HIV P+/N-/ND/Declined/No Partner (Date done)	Referred BY	Referred TO	Cotrimo-xazole Preventive Therapy Y/N (Date Started)	ART Y/N (Date Started)	Nutrition Support (Yes/No)	Date and outcome of treatment
Regimen																																										

Referred by:

VCT center	= VCT	Self referral	= SR
HIV Comprehensive Care unit	= HCC	Contact invitation	= CI
Home Based Care	= HBC	Chemist/Pharmacy	= CP
STI clinic	= STI		
Private Sector	= PS		
Antenatal clinic	= ANC		

Referred to:

Nutrition Support	=NS
VCT center	= VCT
HIV Comprehensive Care unit	= HCC
Home Based Care	= HBC
STI clinic	= STI
Private Sector	= PS
Antenatal clinic	= ANC

Outcome of treatment:

Cured (smear negative)	= C
Treatment Completed (no smear)	= TC
Failure (smear pos. at 5/8 months)	= F
Dead	= D
Out of Control (Defaulted)	= OOC
Transferred Out	= TO

NB. Partners tested for HIV (Y/N) = regu
positive TB case

Annex 3 Ministry of Public Health and Sanitation
Division of Leprosy, Tuberculosis and Lung Disease
TB5-Tuberculosis Patient Record Card – Strictly Confidential

Clinic	
Date start of treatment	

District	
Date Cured or TC	

District registration nr.

Patients name							
Age		**Sex**		**Body weight (Kg.)**		**Height (Meters)**	
Patients address							
School/Employers address							
Cell phone no.							

Treatment supporters name		**Relation to patient**	
Treatment supporters address			

Disease classification (Tick)					
Pulmonary TB		**Extra – Pulmonary TB**			
Smear pos.		Pleural effusion		Milliary	
Smear neg.		Lymph nodes		Meningitis	
Smear not done (>15 years)		Skeletal		Abdominal	
		Other (specify)			
Smear not done (<15 years)		Skeletal		Abdominal	
		Other (specify)			

Patient classification	**Tick**
New	
Smear pos. Relapse	
Smear neg. Relapse	
Failure	
Treatment resumed after defaulting	
Transfer in	

SCC regimens	**Tick**
2RHZE/6EH	
2RHZ/6EH	
2SRHZE/1RHZE/5RHE	
2RHZ/4RH (children)	

Result sputum – smear examination at month:								
		2	3	4	5	6	7	8
Date								
Serial No								
Result (Quantify)								

Intensive Phase (daily) – 2 months	**Tabs./gr.**
RHZE (150/75/400/275 mg, tabs) - [4FDC]	
RHZ (150/75/400 mg, tabs) - [3FDC]	
S (1 gm, vial)	
Paeds: RHZ (60/30/150mg) - [3FDC]	

Continuation Phase (daily) – 4 to 6 months	**Tabs.**
RHZE (150/75/400/275 mg, tabs) - [4FDC]	
RHZ (150/75/400 mg, tabs) - [3FDC]	
RHE (150/75/275 mg, tabs)-[3FDC]	
RH (150/75 mg, tabs) - [2FDC]	
EH (400/150 mg, tabs) - [2FDC]	
Paeds RH(60/30mg) - [2FDC]	

Re-treatment (daily) – month 3	Tabs.
RHZE (150/75/400/275 mg, tabs) - [4FDC]	

Monthly body weight (Kg)								
Month	1	2	3	4	5	6	7	8
Date								
Weigh t								
Height								

Culture/Sensitivity results*	
Date:	
Streptomycin (S)	
Rifampicin (R)	
Isoniazid (H)	
Ethambutol (E)	

Treatment outcome	Date
Cured (sm. negative)	
Treatment completed (no smear result)	
Failure (Sm. Positive)	
Dead	
Defaulted	
Transferred out	

**Fill: S = Sensitive or R = Resistant*

Patient referred by		
Unit	Tick	Date
VCT centre		
HIV care clinic		
STI clinic		
Home Based Care		
Antenatal/PMTCT clinic		
Private sector		
Chemist/pharmacist		
Self referral		
Contact invitation		
Community Health worker (CHW)		
Name unit		

Patient referred to		
Unit	Tick	Date
VCT centre		
HIV care clinic		
STI clinic		
Home Based Care		
Antenatal/PMTCT clinic		
Private sector		
Not Referred		
Name unit		

HIV status	
Test result	Tick
Negative	
Positive	
Declined	
Not done	
No Partner	
Date test:	

(If HIV +)

Partner HIV Status	
HIV+	
HIV-	
Declined	
Not Done	
Date test:	

Prophylaxis Opportunistic Infections			
	Tick	Date start preventive therapy	Date stopping preventive therapy
Cotrimoxazole			
Other (……)			

CD 4 count (if done)	
Date	*Result*

Anti Retroviral Therapy			
ART Regimen	Tick	Date start ART	Date stop ART
Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP)			
Stavudine (d4T) + Lamivudine (3TC) + Efavirenz (EFV)			
Zidovudine (ZDV) + Didanosine (ddI) + Lop/r			
Zidovudine (ZDV) + Didanosine (ddI) + Nelfinavir (NFV)			

Nutrition	
Patient on Nutritional Support	

Yes

No

Remarks:

-

-

Initial phase of treatment (8 weeks) – Tick and/or write date of daily drug intake as observed by health worker or treatment supporter																										
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56
57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	79	80	81	82	83	84	

Continuation phase of treatment (6 x 4 weekly periods)						
Month of treatment	3	4	5	6	7	8
Date drug collection						
If smear pos. case:			Sputum examination at **end** 5-th month			Sputum examination at **star**t 8-th month

_____
_____
_____
_____
_____
_____
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References

1. *The Logistics Handbook: A Practical Guide for Supply Chain Managers in Family Planning and Health Programs.* Arlington, Va.: John Snow Inc./DELIVER, for the U.S. Agency for International Development (USAID).

2. Guidance for national tuberculosis programmes on the management of tuberculosis in children. WHO/HTM/TB/2006.371. WHO/FCH/CAH/2006.7