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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 sputum microscopy services.

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 *Pneumocystis 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.

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 the 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).

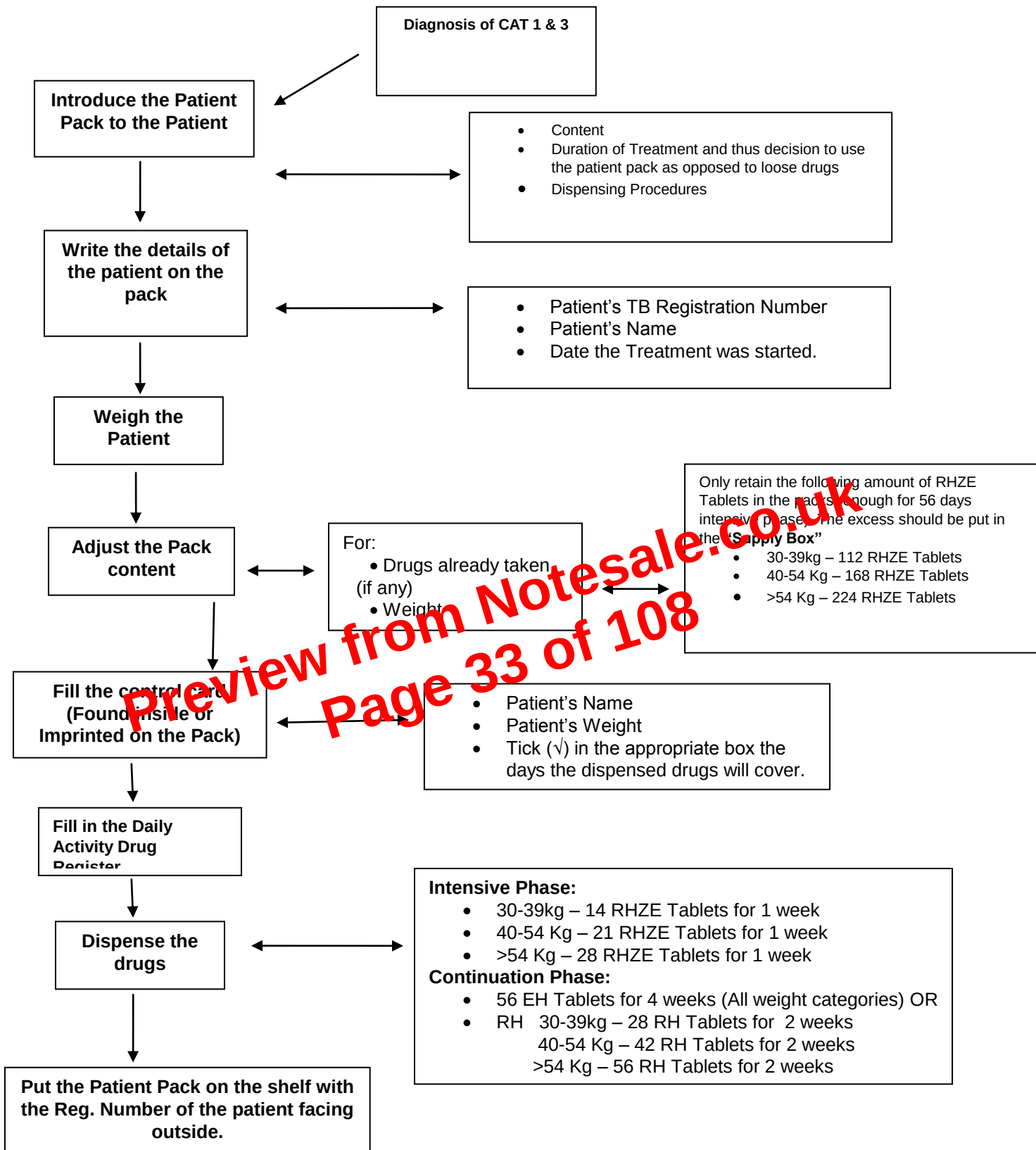
Please note that Miacetazone is no longer used for TB treatment in Kenya. This is because of the high HIV prevalence among TB patients and the attendant high incidence of cutaneous adverse reactions including Steven-Johnson syndrome.

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.

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 ototoxicity.

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 one hand, children more often than adults develop extra-pulmonary TB (EPTB), and severe, disseminated TB (e.g. miliary TB and TB meningitis) is especially common 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	<1 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:

Patient Weight	No of tablets to give	
	Rifampicin 150mg + Isoniazid 75mg + Pyrazinamide 400mg	Rifampicin 150mg + Isoniazid 75mg
<10 kg	1/4	1/4
10 – 14 kg	1/2	1/2
15 – 19 kg	1	1
20 – 24kg	1 1/2	1 1/2
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

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 TB 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.

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.

- **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

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

- **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 drugs 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

X-ray Y/N	Culture Yes/ND/DNR Culture Results R/S				Lab. serial number and result sputum smear examination				HIV Test Pos/Neg/N D/Declined (Date done))	Partner tested for HIV Pos/Neg/ND/Declin ed/No Partner (Date done)	Referred BY: VCT/HCC/STI /HBC/PS/ANC /SR/CI	Referred TO: VCT/HCC/STI/ HBC/PS/ANC	Cotrimoxazol e 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
HIV Comprehensive Care unit = HCC
Home Based Care = HBC
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

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

Culture

Yes

Not Done

DNR=Done No Results

Note: If Culture Results Available indicate the resistance Pattern:
R=Resistant, S= Sensitive

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 start 8-th month
