Management of Tuberculosis
Training for Health Facility Staff

C: Treat TB Patients

WORLD HEALTH ORGANIZATION
Geneva

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Training for Health Facility Staff

C

TREAT TB PATIENTS

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Treat TB Patients

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Treat TB Patients

Introduction

In module B: *Detect Cases of TB*, you learned how to identify TB suspects and determine whether they have TB. This module describes how to treat TB patients. Treatment for tuberculosis consists of two different phases of taking special combinations of drugs. The specific drugs and schedule may vary somewhat, but during the first 2 months, called the **initial phase**, a new case of pulmonary TB takes 3 or 4 drugs, depending on the case classification. During the following 4–6 months, called the **continuation phase**, the patient takes 2 drugs, either daily or intermittently (3 times per week).

If anti-TB drugs are taken incorrectly or irregularly, the patient will not be cured and drug resistance may develop. The disease will be prolonged and will be more difficult to treat in the future. Therefore, it is very important that TB patients take all their medications correctly to be cured with a minimum risk of relapse. If left on their own, at least 30% of patients will not comply with their treatment (that is, take the treatment as directed) during the first 2 months. Predicting who will or will not comply is impossible.

Health workers must take an active role to ensure that every patient takes the recommended drugs, in the right combinations, on the correct schedule, for the appropriate duration. The best way to ensure this is for a health worker or a community TB treatment supporter to watch each patient swallow the drugs. This is called **directly observed treatment** (also known as fully supervised treatment). Directly observed treatment can take place at a hospital, a health centre or health post, the patient's workplace, or at the home of the patient, a health worker, or a community TB treatment supporter.

With directly observed treatment, the health worker knows immediately if treatment is interrupted and can take action, such as tracing the patient and encouraging the patient to resume treatment. In addition to ensuring that the drugs are swallowed, directly observed treatment can build a supportive relationship between the patient and the health worker or community TB treatment supporter. A good relationship enables the patient to discuss any questions or fears about the disease and treatment.

The effect of TB treatment on a patient's pulmonary TB should be monitored by **follow-up sputum examination**. Negative sputum smears at specific times indicate good treatment progress, which encourages the patient and the health worker responsible for supervising the treatment. Sputum examinations are also required to determine whether the TB patient is cured.

Below is a summary list of the procedures to treat TB cases.

Initially:

- Select the patient's treatment category.
- Determine where the patient will receive directly observed treatment.
- Prepare the patient's *TB Treatment Card.*
- Inform the patient and family about TB and its treatment.
- Identify and prepare a community TB treatment supporter (if needed).
- Obtain or prepare a drug box for the patient.

On an ongoing basis:

- Directly observe and record drug treatment over a period of months.
- Monitor whether the patient has side-effects.
- Continue to give the patient information and support for continuing treatment.
- Monitor whether the patient is taking the anti-TB drugs, and resupply the community TB treatment supporter with drugs monthly (if applicable).

At specified intervals:

- When patient is due, collect sputum for follow-up examination.
- Record laboratory results and take action needed.

Objectives of this module

Participants will learn:	**Refer to section:**
• How to choose the appropriate treatment category	1.1
• How to determine where a patient will receive directly observed treatment	1.2
• How to prepare a patient's *TB Treatment Card*, including specifying the treatment regimen and dose	1.3
• How and when to provide preventive therapy for household contacts of the TB patient	2
• How to give directly observed treatment and record it on the *TB Treatment Card*	3.1
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• How to determine when a patient is due for follow-up sputum examination	4.1
• How to decide, based on sputum results, the appropriate action needed	4.4
• How to determine treatment outcome	5

Note: Some steps of these procedures are described in the appropriate place in the sequence of steps for treating TB cases, but more detail is provided in other modules:

- Providing information about TB to the patient and the family is taught in module D: *Inform Patients about TB.*
- Identifying and preparing a community TB treatment supporter is taught in module E: *Identify and Supervise Community TB Treatment Supporters*.
- Preparing a drug box for the patient is taught in module F: *Manage Drugs and Supplies for TB*.
- Dealing with problems, such as when a patient stops coming for treatment, is taught in module G: *Ensure Continuation of TB Treatment*.

If you need to look up an unfamiliar word, refer to the glossary at the end of module A: *Introduction*.

1. Initiate treatment of a TB patient

1.1 Choose the appropriate treatment category for the patient

Consider the disease site, the type of patient, and laboratory results to choose the correct category of treatment (Category I, II, III, or IV). Your country has determined a particular drug regimen for each category of treatment.

1.1.1 Determine the disease site from the results of sputum smear examination and/or a clinician's diagnosis

There are two possible classifications by anatomical site of the disease:

- **Pulmonary –** disease affecting the lung
- **Extrapulmonary** – disease affecting organs other than the lungs, for example lymph nodes, bones and joints, genitourinary tract, meninges, pleura, or intestines.

Sputum smear-positive pulmonary TB is detected when tubercle bacilli are found in sputum examined by microscopy. **Sputum smear-negative** pulmonary TB and extrapulmonary TB are diagnosed by a clinician. The clinician will also specify the particular location of extrapulmonary TB.

A patient in whom both pulmonary and extrapulmonary TB are diagnosed should be classified as having **pulmonary TB**.

1.1.2 Determine the type of patient by asking whether the patient has ever taken any drugs for TB before

Ask whether the patient has ever taken any drugs for treatment of TB. If so, find out for how long and whether the full regimen was completed or when the treatment was stopped. A patient who has never taken anti-TB drugs (or has taken these drugs for less than 1 month) is a "new" case.

The initial interview with the patient must be thorough, to enable you to choose the correct regimen. Take time to talk with the TB patient and listen carefully. Ask several questions to find out about any previous treatment, and explain why this information is important. Otherwise, the patient may omit information about any past treatment, appear to be a new case, and receive an incorrect regimen.

Ask:

- **Have you ever been treated for tuberculosis?**
- **Have you ever taken injections for more than 1 or 2 weeks? Why?**
- **Have you ever taken a medicine that turned your urine orange-red?**

It is critical to determine whether a patient has previously been treated for TB. Previously treated patients may have acquired drug resistance and need a different treatment regimen from new patients. Drug regimens differ in type and strength of drugs and length of

treatment. The treatment regimen for new patients will not work for a previously treated case. Thus, the three questions in bold type (above) should be asked directly of every TB patient.

If a patient has taken injections for more than 1 or 2 weeks, it is likely that the drug was streptomycin. If the patient has taken a medicine that turned the urine orange/red, it is likely to be rifampicin. If you think a patient is hiding past treatment for TB, explain that new patients do not receive better drugs than re-treatment patients. The re-treatment patient needs a stronger regimen than a new patient to be cured.

Determine from the patient's answers the **type of patient**:

Figure 1: Definitions of type of patient

Type of patient	Definition
New	A patient who has never had treatment for TB or who has taken anti-TB drugs for less than 1 month
Relapse	A patient previously treated for TB who has been declared cured or treatment completed, and is diagnosed with bacteriologically positive (smear or culture) TB
Treatment after failure	A patient who is started on a re-treatment regimen after having failed previous treatment
Treatment after default	A patient who returns to treatment, positive bacteriologically, following interruption of treatment for 2 months or more
Transfer in	A patient who has been transferred from another TB register to continue treatment
Other	All cases that do not fit the above definitions. (This group includes **chronic case,** a patient who is sputum-positive at the end of a re-treatment regimen.)

1.1.3 Select the correct treatment category

Consider the disease site, type of patient, and results of sputum smear examination to select the appropriate treatment category (Category I, II, III or IV). Your country has specified a particular drug regimen for each category of treatment.

Treatment regimens for **new cases** (Category I) have an initial phase lasting 2 months and a continuation phase usually lasting 4–6 months. During the initial phase, consisting of 3 or 4 drugs, there is rapid killing of tubercle bacilli. Infectious patients become non-infectious within about 2 weeks. The patient's symptoms improve. Most patients with sputum smear-positive TB become smear-negative within 2 months. In the continuation phase, fewer drugs (2 drugs) are given either daily or intermittently (3 times per week) but for a longer time. The sterilizing effect of the drugs eliminates remaining bacilli and prevents relapse.

Because **previously treated patients** (Category II) are more likely to have bacilli resistant to isoniazid and perhaps other drugs, the re-treatment regimen is longer. During the initial phase of 3 months, the regimen consists of 5 drugs for 2 months, and 4 drugs for the third month. During the continuation phase, it consists of 3 drugs for 5 months.

In patients with sputum smear-negative pulmonary TB or extrapulmonary TB (usually Category III, non-infectious cases), regimens consist of 3 or 4 drugs during the initial phase, and 2 drugs in the continuation phase.

In patients with chronic or multidrug-resistant (MDR) TB (Category IV), specially designed standardized or individualized regimens are suggested.

There are four categories of treatment. The table below shows the appropriate treatment category for each TB case.

Figure 2: Selecting a treatment category

A clinician diagnoses and prescribes treatment for cases in the shaded boxes. A health worker or a clinician can select the treatment category for the other cases (unshaded).

<table>
<tr><th>Disease site</th><th>Sputum smear examination results</th><th colspan="2">Type of patient</th><th>Recommended treatment category</th></tr>
<tr><td rowspan="5">Pulmonary</td><td rowspan="4">Sputum smear-positive [a]</td><td colspan="2">New</td><td>CAT I</td></tr>
<tr><td rowspan="3">Previously treated</td><td>Relapse</td><td>CAT II</td></tr>
<tr><td>Treatment after failure</td><td>CAT II</td></tr>
<tr><td>Treatment after default</td><td>Usually CAT II</td></tr>
<tr><td>Chronic or MDR-TB</td><td>CAT IV</td></tr>
<tr><td>Sputum smear-negative [b]</td><td colspan="2">→</td><td>CAT I or III [c]</td></tr>
<tr><td>Extrapulmonary [b]</td><td colspan="3">→</td><td>CAT I or III [c]</td></tr>
</table>

[a] If only one sputum sample is positive, the patient must be referred to a clinician for diagnosis.

[b] Pulmonary sputum smear-negative cases and extrapulmonary cases may rarely be previously treated (treatment after failure, relapse, treatment after default, chronic). Diagnosis should be based on bacteriological and pathological evidence.

[c] As recommended by WHO, Category III treatment may be the same regimen as for Category I (see Annex B, page 93.) Each country will decide whether Categories I and III are different drug regimens or not. If they are different, the selection of a regimen for a particular patient will depend on the severity of disease.

As a health worker, you can select:

- Category I treatment for a new patient with sputum smear-positive TB[1]
- Category II treatment for a sputum smear-positive patient who was previously treated for TB (relapse or treatment after failure).

However, a clinician must diagnose and prescribe treatment for all other TB suspects or patients. Therefore, you should refer (for diagnosis and/or prescription of treatment category):

- A patient who defaulted (that is, interrupted TB treatment for 2 months or more) and has returned to the health facility requesting treatment. The clinician will consider the medical condition of the patient and other factors such as sputum examination results, type and duration of treatment before interruption, and duration of the interruption.
- A sputum smear-negative suspect who is still sick with respiratory symptoms
- A person suspected of having extrapulmonary TB
- A suspected chronic or multidrug-resistant TB case.

Now do Exercise A – Written Exercise

When you reach this point in the module, turn to Exercise A on page 61 and read the instructions. First the group will do Case 1 together. Then you will do Cases 2–4 by yourself and discuss your answers with a facilitator.

[1] As you learned in module B: *Detect Cases of TB*, a TB suspect can be determined to have sputum smear-positive TB in one of two ways:

- if two (or three) of the sputum specimens examined for diagnosis are positive, or
- if only one specimen is positive and an X-ray shows signs of active tuberculosis. If only one specimen is positive, the health worker refers the patient to a clinician so that the clinician can make a clinical assessment of whether the patient has TB.

1.2 Determine where the patient will receive directly observed treatment

Directly observed treatment is essential during the initial phase of treatment (the first 2–3 months) and may also be needed during the continuation phase.[1] Directly observed treatment ensures that the drugs are taken in the right combinations and on schedule, and that the patient continues treatment until all the doses have been taken.

Many TB patients live or work close to a health facility. For these patients, a health facility worker will directly observe their treatment. The health facility is the recommended place of treatment because of the ease of supervision. However, some patients live far away or do not find it convenient to come to a health facility for treatment. For these patients, a community TB treatment supporter is needed to directly observe treatment at a place and time more convenient for the TB patient.

If the patient is very ill and needs hospital care, or if the patient cannot walk or lives very far away and has no other way to have drug therapy administered, the patient may be hospitalized for TB treatment. Hospitalization should be rare.[2]

To decide where the patient will receive directly observed treatment, discuss with each new patient:

- the specific treatment needed (daily directly observed treatment for 2 or 3 months in the initial phase)
- whether the patient can come to the health facility each day.

Note: If the patient's treatment regimen includes a streptomycin injection, a trained health worker must observe the treatment and give the injections. A trained health worker and the supplies for giving sterile injections are usually available only at a health facility.

- ***If the patient will come to the health facility each day***, a health worker at the health facility will directly observe treatment. This is the preferred option.

- ***If it is not convenient for the patient to come to the health facility each day***, explain to the patient that a community TB treatment supporter, that is, a person from outside the health facility, may provide directly observed treatment. Explain that a community TB treatment supporter may observe treatment in the community or workplace. This treatment supporter will keep the patient's drugs, observe as the patient swallows the treatment each day, and mark the necessary records.

If the patient needs a community TB treatment supporter, discuss possible locations and individuals. How to choose and prepare a suitable community TB treatment supporter is described in step 1.5 below and in more detail in module E: *Identify and Supervise a Community TB Treatment Supporter.*

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[1] WHO recommends that directly observed treatment continue through the continuation phase if the regimen includes rifampicin.

[2] One approach is to hospitalize the TB patient during the initial phase. However, hospitalization impedes the patient's ability to continue work to maintain the family, is more expensive, and is no more effective curing the disease than directly observed outpatient treatment.

1.3 Prepare the patient's *TB Treatment Card*

The *TB Treatment Card* is the record of the patient's diagnosis and TB treatment. (Fold out the *TB Treatment Card* on page 69 now or open to the *TB Treatment Card* in the *Reference Booklet.* Refer to the card as you read this section.)

Whenever a patient is classified as having TB or is transferred in from another health facility, open a *TB Treatment Card*. See the example card below for a patient who recently began treatment.

The *TB Treatment Card* stays at the health facility. It is essential that the card be filled in completely and accurately and then kept up to date throughout treatment. (If the patient will have a community TB treatment supporter, a duplicate copy is made for the supporter to record drugs administered; the original card is kept at the health facility and updated periodically by copying from the treatment supporter's card.)

Front of card

TUBERCULOSIS TREATMENT CARD

Name *Paul Black* District TB No. _____

Complete address *Olive Street 138, Merletown* Health facility *Mercy Hospital*

Sex: M ☑ F ☐ Age *42*

Name and address of community treatment supporter (if applicable) *Lisse Onagu, Olive Street 231, Merletown*

Disease site
Pulmonary ☑ Extrapulmonary ☐ (specify) _____

Type of patient
New ☑ Treatment after failure ☐
Relapse ☐ Treatment after default ☐
Transfer in ☐ Other (specify) ☐ _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☑ 3 times/week ☐

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	CAT II	CAT III	CAT IV
New case ☑ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ☐	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
3			
HR Z E (S)	HR Z E S	HR Z E	

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0	*6/6/01*	++	*1427*	*51*

Tick appropriate box after the drugs have been administered

Drugs given to supporter

MONTH \ DAY	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	Number doses this month	Total number doses given	DATE	DOSES
June								✓	✓	–	✓	✓	✓	✓	✓	–	✓	✓																		
July																																			
August																																			

Please turn over for continuation phase

Back of card

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ☑

Tick category:	**CAT I**	**CAT II**	**CAT III**	**CAT IV**
	New case ☑ (smear-positive, or seriously ill smear-negative or EP)	Re-treatment ❑	New case ❑ (smear-negative or EP)	Chronic or MDR-TB ❑
Indicate number of tablets per dose:	3 (4 months) HR or (6 months) HE	(5 months) HR E	(4 months) HR or (6 months) HE	

MONTH \ DAY	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	Number doses this month	Total number doses given

Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

Name and address of contact person *A.J. Ngigi, 61 High Street, Merletown*

Treatment outcome

Date of decision _____

Cure ❑
Treatment completed ❑
Treatment failure ❑
Died ❑
Default ❑
Transfer out ❑

1.3.1 Record general patient information

Fill in the general patient information at the top of the front of the *TB Treatment Card*, as shown on the previous page. Be sure to write the patient's complete address, one that you could use to visit the patient if necessary.

Write the name of the health facility. If the patient will have a community TB treatment supporter, write the supporter's name and address (see section 1.5 below). If the patient will come to the health facility for directly observed treatment, leave blank the line for community TB treatment supporter.

The District TB Number is assigned when the patient is entered in the District TB Register. As soon as the patient is assigned a District TB Number, the TB District Coordinator or your supervisor should inform you or record it on the *TB Treatment Card*.

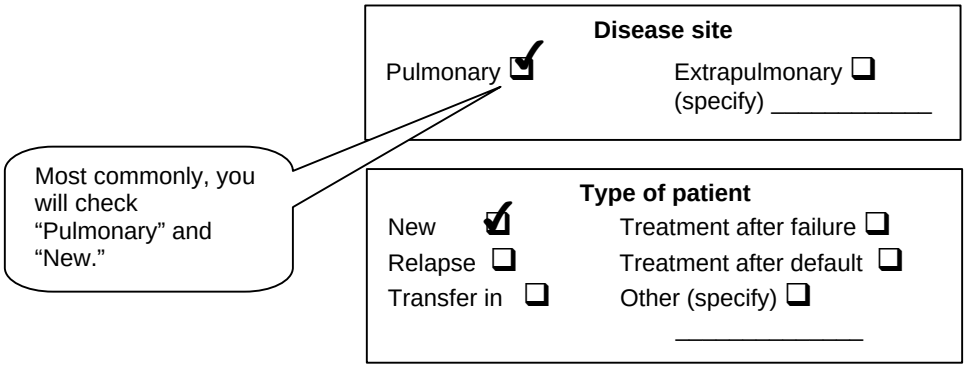
Also record the name and address of a contact person on the back of the card (at the bottom). This should be a person such as a neighbour or friend, who will know how to find the patient if not at home.

If the patient will be hospitalized, fill in the top of the card, prepare *a Tuberculosis Referral/Transfer Form*[1] and refer the patient for hospital care.

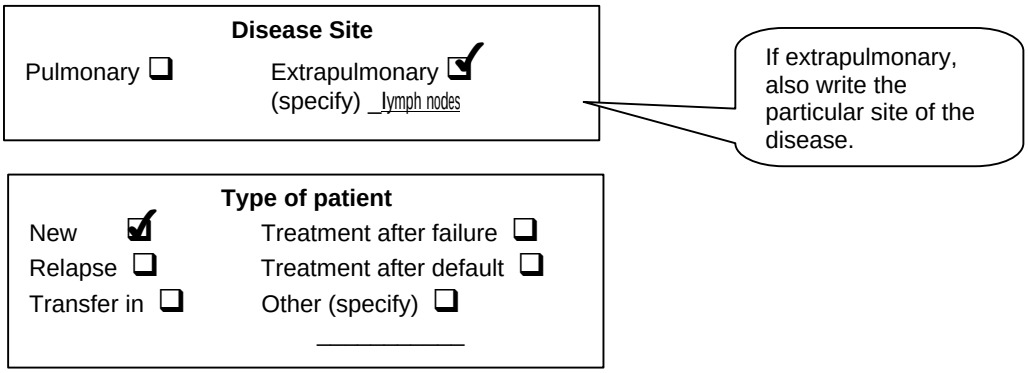
1.3.2 Record disease site and type of patient

Tick the correct site and then tick the box for the type of patient, as shown in these examples for two different patients. Refer to section 1.1.2 (page 4) for definitions of the six types of patients.

Example one:



Example two:



[1] How to complete a *Tuberculosis Referral/Transfer Form* is described in module G: *Ensure Continuation of TB Treatment.*

1.3.3 Record results of diagnostic sputum examination and the patient's weight

Find the results of the sputum examination on the bottom part of the *Request for Sputum Examination* form. The laboratory technician records whether each sputum specimen was positive or negative and, if positive, ticks the appropriate positive (grading) column (to categorize the number of acid-fast bacilli present).

Example of laboratory results

TB LABORATORY FORM
REQUEST FOR SPUTUM EXAMINATION

Name of health facility Porma Date 3/5/ 01

Name of patient John Chweno Age 33 Sex: M ✓ F ☐

Complete address 4352 Maso Road
North Porma 23 Porma District

Reason for examination: ✓ 14
Diagnosis ☐ TB Suspect No. _____
OR Follow-up ☐ Patient's District TB No.* _____

Disease site: Pulmonary ☐ Extrapulmonary ☐ (specify) 3

Number of sputum samples sent with this form 3/5/01 AJ Bwat

Date of collection of first sample _____ Signature of specimen collector _____

* Be sure to enter the patient's District TB No. for follow-up of patients on TB treatment.

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RESULTS (to be completed by Laboratory)

Lab. Serial No. ✓

(a) Visual appearance of sputum:
Mucopurulent ☐ Blood-stained ☐ Saliva ☐

(b) Microscopy: 4/5 Pos ✓

DATE	SPECIMEN	RESULTS	POSITIVE (GRADING)			
			+++	++	+	scanty (1–9)
4/5	1	Pos	☐	✓ ☐	☐	☐
4/5	2	Neg	☐	☐	☐	☐
4/5/2001	3	R. J. Namshaw	☐	☐	☐	☐

Date _____ Examined by (Signature) _____

The completed form (with results) should be sent to the health facility and to the District Tuberculosis Unit.

Record the results of the diagnostic sputum smear examination on the *TB Treatment Card* on the row for "Month 0." Record the date of the sputum examination. If there are two dates, record the earliest. Under "Smear," record the result as one of the following:

- If all results were negative, write NEG, or
- If any result was positive:[1]
  - write the highest grading of any of the positive smears (e.g. record +++, ++, or +), or
  - if the highest result is "Scanty", write the number recorded in that box (1–9).

Also record the patient's weight. This weight will determine drug dosages and will later be helpful to track the patient's progress.

Example: Recording results on TB Treatment Card

See how the health worker recorded the laboratory results (shown on the previous page) in the results table on the *TB Treatment Card*:

Results of sputum examination				Weight
Month	Date	Smear	Lab. No.	**(kg)**
0	4/5/01	+ +	630	48

Record the date of the sputum examination.

Record only the highest grading of the positive smears.

[1] Each patient for whom you are preparing a *TB Treatment Card* has already been diagnosed with TB. Smear-positive pulmonary TB was diagnosed either by two or more positive sputum smears or by one positive smear plus radiographic abnormalities identified by a clinician. Smear-negative or extrapulmonary TB was diagnosed by a clinician.

1.3.4 Record TB treatment regimen and dosage for both phases

There are two sections on the *TB Treatment Card* to write the regimen and dosage of drugs for the patient. The initial phase of treatment is recorded on the front of the card, and the continuation phase of treatment is recorded on the back.

a) On the front, tick the box for the appropriate category of treatment (I, II, III, or IV) (see example on page 16).

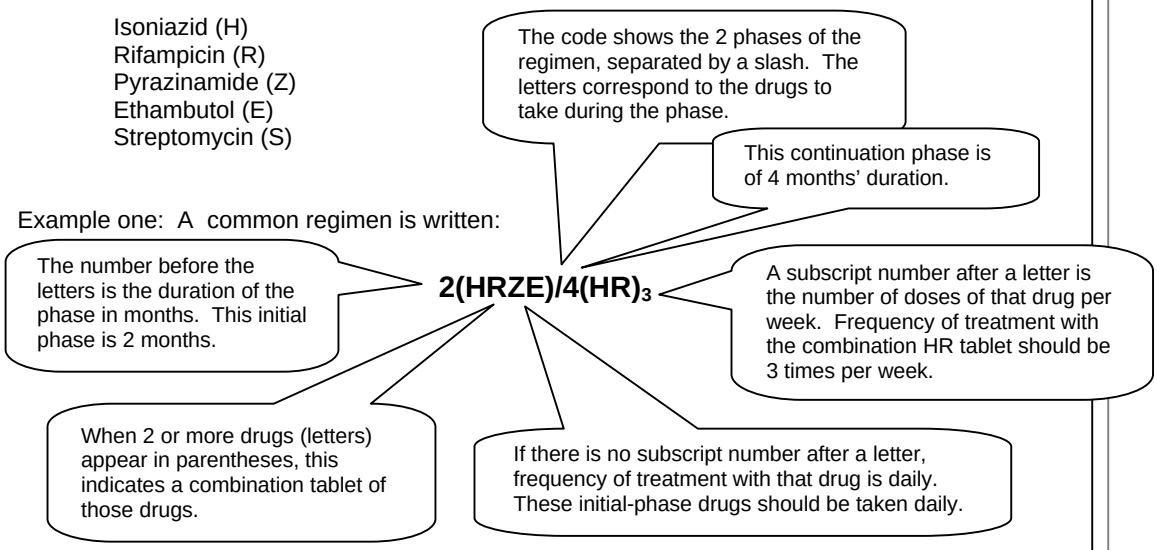
b) Look in your national TB manual for the specific drug regimen and dosages for the category.

Anti-TB drug regimens are usually described using a standard code.

Figure 3: How to read the drug code for TB treatment regimens

TB treatment regimens are described using a standard code where each anti-TB drug has an abbreviation. Those abbreviations are:

Isoniazid (H)
Rifampicin (R)
Pyrazinamide (Z)
Ethambutol (E)
Streptomycin (S)



The above regimen uses 2 fixed-dose combination tablets (also called FDCs). In the initial phase of 2 months, each day the TB patient would take a certain number (depending on the patient's weight) of the combination tablet of isoniazid, rifampicin, pyrazinamide and ethambutol.

In the continuation phase, the TB patient would take a certain number of FDCs of isoniazid and rifampicin (HR) 3 times per week for 4 months.

Example two: **$2(HRZE)S\,/1(HRZE)\,/5(HR)_3E_3$**

The initial phase is 3 months but has two parts. For 2 months, drug treatment includes an FDC with isoniazid, rifampicin, pyrazinamide and ethambutol (HRZE) administered daily and also a daily injection of streptomycin (S). In the third month, drug treatment is with the combination tablet (HRZE); the streptomycin is not given.

The continuation phase is 5 months. Drug treatment is with the FDC tablet (HR) given 3 times per week (subscript number $_3$ after the letters) and ethambutol (E), also given 3 times per week.

In the standard code for TB treatment regimens, the duration of each phase is stated in months. How many doses is that? The number of doses is standardized as follows:

- One month is considered to be 4 weeks.
- For a daily regimen, a patient needs 28 doses per month (4 weeks x 7 days).
- For a 3 times per week regimen, a patient needs 12 doses per month (4 weeks x 3 doses per week).
- Multiply either 28 or 12 by the number of months in the phase to determine the total doses required.

Figure 4: Standard number of doses for phases of different duration

For a daily regimen (1 month = 28 doses):	For a 3 times per week regimen (1 month = 12 doses):
2 months = 56 doses	
3 months = 84 doses	4 months = 48 doses
5 months = 140 doses	5 months = 60 doses
6 months = 168 doses	

Actually, a patient may require more than the stated number of months to take all the doses, as will happen, for example, when a patient on a daily regimen skips Sundays. For example, taking all 56 doses of a 2-month initial phase of treatment may require 9–10 weeks, and this is acceptable. The phase is completed when the patient has taken all the doses for the phase.

Figure 5 shows the recommended regimens for 3 categories of treatment. (The examples in this module use these regimens.) Annex B provides additional information on recommended dosages of anti-TB drugs and possible presentations.

FDCs (fixed-dose combinations) are tablets that contain 2, 3 or 4 different anti-TB drugs in the appropriate strengths. Countries are urged to use FDCs in their regimens as soon as they can be made available. FDCs have the advantage of being easier for health workers and patients to use. Fewer tablets are required and fewer errors occur in counting and dosage.

For each category of treatment, your national TB programme has determined a particular drug regimen that is effective and affordable in your country. Refer to your national TB manual for the drug regimens recommended in your country.

Figure 5: Examples of recommended treatment regimens

(by weight and using fixed-dose combination drugs)

Category I regimen

Regimen / Patient's weight	**Initial phase** (2 months)	**Continuation phase** (4 or 6 months)	
	2(HRZE)	$4(HR)_3$	6(HE)
	Daily 56 total doses	3 times per week 48 total doses	Daily 168 total doses
	(Isoniazid 75 mg + rifampicin 150 mg + pyrazinamide 400 mg + ethambutol 275 mg)	(Isoniazid 150 mg + rifampicin 150 mg) for 4 months	(Isoniazid 150 mg + ethambutol 400 mg) for 6 months
30–39 kg	2	2	1.5
40–54 kg	3	3	2
55–70 kg	4	4	3
Over 70 kg	5	5	3

Category II regimen

Regimen / Patient's weight	**Initial phase (3 months)**		**Continuation phase (5 months)**	
	2(HRZE)S / 1(HRZE)		$5(HR)_3E_3$	5(HR)E
	Daily 84 total doses of HRZE plus 56 doses of S		3 times per week 60 total doses	Daily 140 total doses
	(Isoniazid 75 mg + rifampicin 150 mg + pyrazinamide 400 mg + ethambutol 275 mg)	Streptomycin (vials, IM) 2 months	(Isoniazid 150 mg + rifampicin 150 mg) + ethambutol 400 mg	(Isoniazid 75 mg + rifampicin 150 mg) + ethambutol 400 mg
30–39 kg	2	0.500	2 + 2	2 + 1.5
40–54 kg	3	0.750	3 + 4	3 + 2
55–70 kg	4	1 g*	4 + 6	4 + 3
Over 70 kg	5	1 g*	5 + 6	5 + 3

** 750 mg for patients aged over 60 years*

Category III regimen

May be same as Category I (see above) or as below (without ethambutol in initial phase)

Regimen / Patient's weight	**Initial phase (2 months)**	**Continuation phase (4 or 6 months)**	
	2(HRZ)	$4(HR)_3$	6(HE)
	Daily 56 total doses	3 times per week 48 total doses	Daily 168 total doses
	(Isoniazid 75 mg + rifampicin 150 mg + pyrazinamide 400 mg)	(Isoniazid 150 mg + rifampicin 150 mg) for 4 months	(Isoniazid 150 mg + ethambutol 400 mg) for 6 months
30–39 kg	2	2	1.5
40–54 kg	3	3	2
55–70 kg	4	4	3
Over 70 kg	5	5	3

c) Record the drug regimen for the initial phase on the *TB Treatment Card*

Referring to a table of recommended drug regimens (such as Figure 5 on page 15 or in your national TB manual), determine the frequency of the drug regimen recommended for the patient, that is, daily or 3 times per week. Under Initial Phase on the front of the *TB Treatment Card*, tick the recommended frequency.

Under the patient's selected (ticked) category (I, II, III or IV) on the card, in the boxes above each drug abbreviation, write a digit to indicate the number of tablets of that drug in a dose. One dose is all the drugs, in the correct amounts, that the patient should take at a time. Use the patient's weight and refer to the recommended drug regimens to determine the tablets needed for one dose. For streptomycin (S), which is given by injection, write the number of grams in one dose.

To record the drug regimen when FDCs are used, circle (or put between parentheses) the abbreviations of the drugs in the combination tablet and write the number of tablets per dose in one of the boxes. For example, the circle below shows that the tablet contains 4 drugs, H, R, Z, and E. The patient needs 3 of these tablets for one dose.

Example

I. INITIAL PHASE — Prescribed regimen and dosages

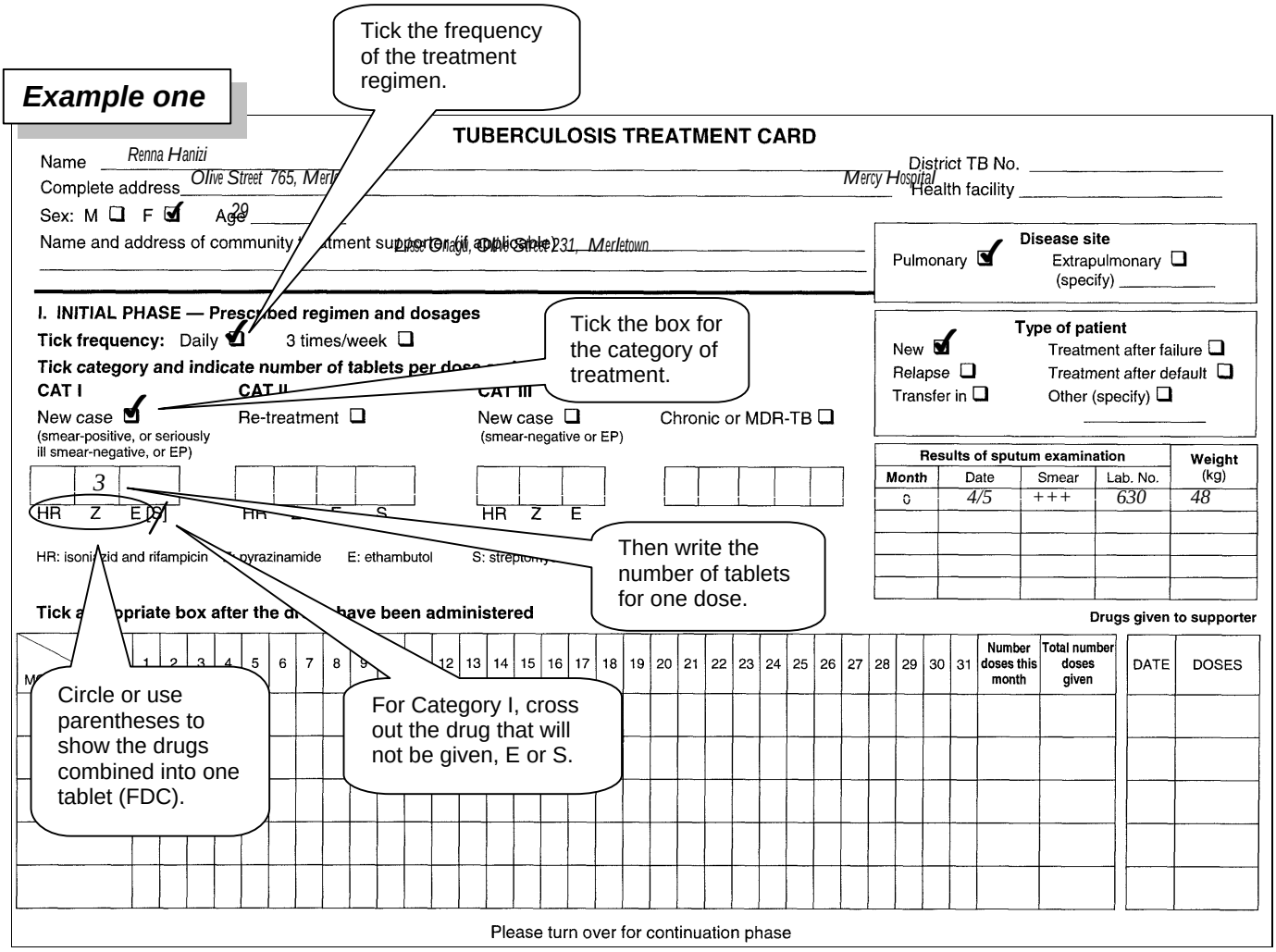
Tick frequency: Daily ☑ 3 times/week ☐

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	**CAT II**	**CAT III**	**CAT IV**
New case ☑ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ☐	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
3 (HR Z E [S])	HR Z E S	HR Z E	

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

In Example one below, the patient is Category I (new sputum smear-positive pulmonary TB). The nurse ticks the box for Category I and looks at the table in the national TB manual to determine the regimen for the initial phase, 2(HRZE), and the dose of the tablets. According to the national TB manual, the frequency is daily, and the dose for a 48-kg person is 3 of the combination tablet (HRZE). The patient should take a total of 56 doses (28 doses per month for 2 months) to complete the initial phase of treatment.



In Example two, the patient is Category II (sputum smear-positive TB, treatment after failure). The nurse ticks the box for Category II (Re-treatment). The nurse then looks at the table in the national TB manual and finds that the regimen for the initial phase is daily and has two parts: 2(HRZE)S/1(HRZE). This is a 3-month initial phase. For the first 2 months, the dose for a 50-kg patient is 3 of the combination tablets (HRZE) and an injection of 0.750 grams of streptomycin daily. In the third month, the patient should take just the 3 combination tablets daily (total 84 doses of HRZE). The nurse writes a reminder to discontinue the streptomycin injections after 2 months (56 doses of S).

Example two

TUBERCULOSIS TREATMENT CARD

Name Mary Abatu — District TB No. _____

Complete address 33 Primos Road, Patangeta — Patangeta HC — Health facility _____

Sex: M ☐ F ☑ Age 19

Name and address of community treatment supporter (if applicable) _____

Disease site
Pulmonary ☑ ☐ Extrapulmonary ☐ (specify) _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☑ ☐ 3 times/week ☐

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	CAT II	CAT III	CAT IV
New case ☐ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ☑ ☐	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
	3 0.75g		
HR Z E [S]	(HR Z E) S	HR Z E	

Note: Stop streptomycin after 2 months (56 doses)

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Type of patient
New ☐ Treatment after failure ☑ ☐
Relapse ☐ Treatment after default ☐
Transfer in ☐ Other (specify) ☐ _____

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0	16/10/02	+ + +	667-2 50	

Tick appropriate box after the drugs have been administered

Drugs given to supporter

October MONTH / DAY	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	Number doses this month	Total number doses given	DATE	DOSES
														✓																					

Please turn over for continuation phase

Figure 6: Anti-TB drug treatment in special situations

- ***Pregnancy***

  Ask women patients whether they are or may be pregnant. Most anti-TB drugs are safe for use in pregnancy with the exception of streptomycin. **Do not give streptomycin to a pregnant woman** as it can cause permanent deafness in the baby. Pregnant women who have TB must be treated, but their drug regimen must not include streptomycin. Use ethambutol instead of streptomycin. Refer pregnant TB patients to a clinician who can prescribe an anti-TB drug regimen.

- ***Oral contraception***

  Rifampicin interacts with oral contraceptive medications with a risk of decreased protection against pregnancy. A woman who takes the oral contraceptive pill may choose between the following two options while receiving treatment with rifampicin: following consultation with a clinician, she could take an oral contraceptive pill containing a higher dose of estrogen (50 μg). Alternatively, she could use another form of contraception.

- ***Breastfeeding***

  A breastfeeding woman who has TB can be treated with the regimen appropriate for her disease classification and previous treatment. The mother and baby should stay together and the baby should continue to breastfeed in the normal way. Give the infant a course of preventive therapy (isoniazid). When preventive therapy is completed, give the infant BCG if not yet immunized. (See section 2, page 23.)

- ***HIV patients on antiretrovirals***

  TB patients with HIV infection or HIV/AIDS may experience a temporary worsening of symptoms and signs after beginning TB treatment. In TB patients infected with HIV, treatment with antiretrovirals may interact with treatment of TB, reducing the efficacy of antiretrovirals and of anti-TB drugs and increasing the risk of drug toxicity. In patients with HIV-related TB, the priority is to treat TB. Options are to defer antiretroviral treatment until TB treatment is completed; defer until completing the initial phase and use HE in the continuation phase; or use antiretrovirals that are less likely to interact with anti-TB drugs.

d) Record the drug regimen for the continuation phase on the back of the *TB Treatment Card*

On the back of the card under Continuation phase (shown below), tick the appropriate treatment category. Consult the drug tables for the continuation phase in your national TB manual. Tick the frequency and, in the appropriate box under the selected category, write the number of tablets for one dose.

Example

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☐ 3 times/week ☑

Tick category:	**CAT I**	**CAT II**	**CAT III**	**CAT IV**
	New case ☐ (smear-positive, or seriously ill smear-negative or EP)	Re-treatment ☑	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
Indicate number of tablets per dose:	HR ☐ (4 months) or HE ☐ (6 months)	HR 3 E 4 (5 months)	HR ☐ (4 months) or HE ☐ (6 months)	☐☐☐☐

MONTH \ DAY	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	Number doses this month	Total number doses given

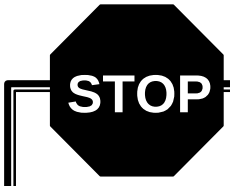
Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

Name and address of contact person Luisa Hanizi, 551 Olive Street, Patangeta

Treatment outcome
Date of decision _____
Cure ☐
Treatment completed ☐
Treatment failure ☐
Died ☐
Default ☐
Transfer out ☐

Put the *TB Treatment Card* in a box with the cards of all TB patients currently receiving treatment at your health facility. You will make the cards available when the District TB Coordinator visits to update the District TB Register and monitor your health facility's work in TB control.



Now do Exercise B – Written Exercise

When you reach this point in the module, turn to Exercise B on page 67 and read the instructions. First the group will do Case 1 together. Then you will do Cases 2–4 by yourself and discuss your answers with a facilitator.

1.4 Inform the patient and family about TB and its treatment

The success of directly observed treatment requires the patient's cooperation and motivation. Health workers should therefore always be polite and considerate when interacting with patients, counselling them so that they understand the disease and the need to adhere to the treatment regimen. If good rapport develops between the patient and health worker or community TB treatment supporter, the patient will be more likely to come to take the anti-TB drugs according to the agreed schedule.

Essential information about TB to discuss with the patient during the first contact includes:

- What is tuberculosis (TB)?
- TB can be cured
- How TB spreads
- How to prevent TB from spreading
- Who else should be examined or tested for TB?
- Necessity of directly observed treatment
- Details of treatment regimen
- What to expect; what to do next.

> See module D: *Inform Patients about TB* for guidance on providing initial and continuing information to the patient and the family.

1.5 If needed, identify and prepare a community TB treatment supporter

If you determined that the patient will <u>not</u> come to the health facility for treatment, and the patient's treatment will be observed by a community TB treatment supporter, you must identify a specific person to serve in this role.

Discuss possible treatment supporters in the community who would be convenient and acceptable to the patient. Discuss only persons who can be supervised by the health facility, preferably a health facility worker living in the same village as the patient, or a trained community health worker, or a community volunteer. (If the patient's treatment regimen will include streptomycin, the treatment supporter must be someone trained to give sterile injections.) Discuss where and when the patient could meet regularly with the community TB treatment supporter, such as in the workplace or the treatment supporter's home, and times that would be most convenient for the patient to come for treatment. Help the patient to find a suitable community TB treatment supporter.

When a possible community TB treatment supporter has been identified, you will need to meet with this person to confirm that he or she is willing to do the job. If so, you will provide the supporter with a duplicate copy of the patient's *TB Treatment Card* and the first month's supply of drugs. If the supporter has done this job before, the need for training may be

minimal. However, if this is the first time that the individual will be a TB treatment supporter, training will take more time and must be done carefully.

> See module E: *Identify and Supervise Community TB Treatment Supporters* for more information on how to select, prepare and supervise a community TB treatment supporter.

1.6 Obtain or prepare a drug box for the patient

Obtain from the supply of anti-TB drugs in your health facility a drug box that contains the correct total number of doses for the patient's treatment regimen (both phases). Be sure that you have obtained the correct regimen, with the required drugs and total number of doses specified on the drug dosage chart.

> ***Reminder: Standard number of doses for a phase***
>
> ***Daily regimen**: 28 doses per month x number of months in phase*
>
> ***Three times per week regimen**: 12 doses per month x number of months in phase*

Check the expiry date of the drugs and do not use the box if any of the drugs are close to expiry. Label the box with the patient's name (and District TB number, when available).

> See module F: *Manage Drugs and Supplies for TB* for more information about the importance of setting aside all the drugs for the patient's entire treatment regimen and how to prepare the necessary drugs.

2. Give preventive therapy, and immunization if needed, to household contacts of the TB patient

A **household contact** is a person who lives (that is, sleeps and eats at least one meal per day) in the home of a TB patient and who is therefore at greater risk of becoming infected. As described in module B: *Detect Cases of TB*, health workers ask TB patients to bring to the health facility the following household contacts to be checked for TB:

- any children aged less than 5 years in the household
- any others in the household who have cough.

If any of these contacts are found to have TB, they should begin treatment for TB.

2.1 Give preventive therapy to household contacts

Preventive therapy with isoniazid can reduce the chance of TB developing in children and in adults who are infected but have not yet developed TB disease. Because of the seriousness of TB in small children, most countries recommend preventive therapy for any child aged less than 5 years who has contact with a sputum smear-positive patient and does not have TB disease.

For household contacts aged less than 5 years who do not have TB, give a course of isoniazid as preventive therapy. Follow the guidelines in your national TB manual. A course of isoniazid, usually 5 mg/kg given daily for 6 months, can greatly reduce the chance of TB developing in a child already infected with tubercle bacilli. Instruct the mother of the child about the reason for taking isoniazid, the dose and schedule. Dispense 1 month's supply initially and ask the mother to bring the child back monthly.

Figure 7: Preventive therapy with isoniazid for TB contacts aged less than 5 years

- Give preventive therapy with isoniazid ONLY to children who do not have TB or possible TB.
- Children aged less than 5 years are at special risk.
  - If a child aged less than 5 years has cough, fever or weight loss, refer to clinician for assessment of TB.
  - If child does not have TB, give isoniazid (H) daily for 6 months to prevent TB.
- **Give 5 mg/kg isoniazid daily for 6 months**.
- See child monthly. Give 1 month's supply at each visit.

Note: If your country also recommends preventive therapy with isoniazid for older household contacts (school-age children and/or adults), give it to these contacts also. Give 5 mg/kg isoniazid daily for 6 months, up to a maximum dose of 300 mg daily. This preventive therapy must not be given to any child or adult who has TB or possible TB.

2.2 Give BCG immunization to household contacts aged less than 2 years, if needed

Immunization with BCG can reduce the chance of developing TB by 50–80% if given before infection. After a course of preventive therapy, give one dose of BCG vaccine to children aged less than 2 years who have not already had BCG immunization. Determine whether a child has already had BCG by checking the child's immunization card or checking for a scar on the upper left arm. Follow the recommendations of your country's immunization programme and use sterile procedures to administer any vaccine. A child who is receiving preventive therapy with isoniazid should first complete the course of isoniazid and then receive BCG immunization.

3. Treat the patient during the entire period of treatment

3.1 Directly observe each treatment and record on *TB Treatment Card*

Directly observe the patient's intake of anti-TB drugs, either daily or 3 times per week, according to the recommended schedule. This means that at every appointment you must watch the patient actually swallow the dose. You must see the patient swallow the drugs. When health workers hand the drugs to patients but do not watch patients swallow them, patients may take some but not all of the drugs, sell some of the drugs, save them for later, etc.

> *The primary way **to prevent transmission of TB to health workers** and others at the health facility is for TB patients to take their drugs regularly. They will then become non-infectious in a week or two. Good ventilation of the place where treatment is provided is also important.*

When giving directly observed treatment, make it quick and easy for the TB patient. Do not make TB patients wait in a queue at the health facility. Arrange for TB patients to see the appropriate health worker without waiting, perhaps by coming to a side or back entrance. There they can take the day's dose of anti-TB drugs quickly and be on their way. Any delays discourage TB patients and are not acceptable.

Figure 8: How to directly observe TB treatment

1. Take out the patient's *TB Treatment Card*.
2. Pour a glass of water for the patient. (If the patient gets nausea, suggest taking the drugs with food or gruel.)
3. Open the patient's box of drugs. Take out all the drugs that the patient should take today.
4. Put the tablets into the patient's hand and then watch the patient swallow the tablets one at a time. If it is difficult to swallow them one after the other, the patient may pause briefly. The drugs must be taken together to make sure that they work together.
5. If the patient's regimen includes streptomycin, give the injection after the patient has swallowed all the tablets. Use a sterile needle and syringe. Check the *TB Treatment Card* for the correct dose of streptomycin.
6. Record the treatment on the *TB Treatment Card*.

When a drug schedule calls for directly observed daily administration, it is customary to skip giving drugs for one day on the weekend. Skipping one day per week is allowed and will not affect the effectiveness of the regimen. Be sure that the patient knows on which days to come for treatment.

3.1.1 How to mark the *TB Treatment Card* in the initial phase

On the first day that you give directly observed treatment, begin marking treatment administered on the front of the *TB Treatment Card.* In the table at the bottom, write the month and then tick under the day of the month. For example, if the first day of treatment is 27 July, write July in the month column and tick under 27.

Each day that you observe the patient swallowing the drugs, tick the date. If the patient does not come for an appointment, put a "0" under that date to indicate that a dose was missed. Make a dash (–) for Sunday (or the customary day off).

Sometimes a patient will not be able to come for directly observed treatment for a day or more because of a conflict such as travel or a funeral. In this situation, you may give the patient the tablets to take home for self-administered treatment on those few days. Mark this on the card by drawing a line through the days for which you provided doses.

Example

This patient began treatment on 27 July. She takes treatment daily except for Sundays. She missed her appointment on 8 August. On 16 September, the patient told the health worker that she was going away for 2 days and would return on Thursday. After the health worker watched her swallow the day's dose, he also gave her two doses to take with her. The health worker drew a line through 2 days to show that he had provided doses for self-administration on those days.

Tick appropriate box after the drugs have been administered

MONTH \ DAY	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	Number doses this month	Total number doses given
July																								✓	–	✓	✓	✓	4		4		
Aug	✓	✓	✓	-	✓	✓	✓	0	✓	✓	–	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	26	30	
Sept	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	———	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓		25	55	
Oct																																	

Please turn over for continuation phase

If a patient who takes drugs daily misses a scheduled day but comes the next day, give the patient only one day's drugs to take in front of you. Do not give a double dose. Since the patient has a certain number of doses to take for the phase of treatment, each missed dose will delay or extend the completion of the phase by a day.

At the end of the month, count the ticks and write the number in the "Number doses this month" column. Also write the sum of all doses given so far under "Total number doses given." In the example above, the patient needs 56 total doses for the initial phase of treatment. It is easy to see that the patient now needs one more dose to complete the initial phase.

If a patient is more than 24 hours late for an appointment, take action quickly, for example by tracing the patient and encouraging the patient to resume treatment. Make a note of your actions and findings on the back of the *TB Treatment Card* under Observations. See module G: *Ensure Continuation of TB Treatment* for guidance on action to take.

Figure 9: Marking the *TB Treatment Card*

✓	=	directly observed treatment given
– (a dash)	=	Sunday (or regular day off)
0	=	missed appointment
No mark (blank day)	=	non-scheduled day in 3 times per week regimen
¾ ¾ ¾ ¾ ¾ ¾ (Line drawn through some days)	=	days for which drugs were supplied for self-administered treatment

3.1.2 How to mark the *TB Treatment Card* in the continuation phase

When the patient begins the continuation phase of treatment, there are two possible ways for the patient to receive the drugs. Some regimens for the continuation phase must be directly observed, and some may be self-administered. For a self-administered regimen, the health worker gives the patient a 2–4 weeks' supply of drugs to take at home.[1] The patient self-administers the drugs daily and returns to the health worker when the supply of drugs is finished (or almost finished).

It is recommended that directly observed treatment continue through the continuation phase <u>if the regimen includes rifampicin</u>.[2] Other continuation phase regimens may be self-administered; self-administered regimens should be daily since patients on self-administered treatment are better able to adhere to a daily regimen than to an intermittent regimen. Your national TB programme has determined whether each regimen is directly observed or self-administered. Follow the recommendations of your national TB programme.

On the next two pages are the *TB Treatment Cards* for two different patients, to show how the back of the cards would be marked during the continuation phase.

[1] Giving a 2-week supply facilitates improved supervision and reduces interruption of treatment. However, a longer supply may be more convenient for the patient.

[2] If doses of rifampicin are skipped, the patient is likely to develop resistance to an otherwise very effective drug. Skipping doses of rifampicin must be prevented.

Example one

This patient comes 3 times weekly (Monday, Wednesday, and Friday) for **directly observed treatment**. You can see that he missed his appointment on 11 October, but came in for the missed dose on 12 October. He missed two doses on 18 and 20 November. The missed doses will extend the end of the phase. Since 26 doses have been taken so far, he must continue treatment for several more weeks to complete all 48 doses in the continuation phase.

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☐ 3 times/week ☑

Tick category:	**CAT I**	**CAT II**	**CAT III**	**CAT IV**
	New case ☑ (smear-positive, or seriously ill smear-negative or EP)	Re-treatment ☐	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
Indicate number of tablets per dose:	3 (4 months) HR (circled) or ☐ (6 months) HE	☐☐ (5 months) HR E	☐ (4 months) HR or ☐ (6 months) HE	☐☐☐☐

MONTH \ DAY	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	Number doses this month	Total number doses given
Sept																											✓	–	✓	/	*2*	*2*
Oct		✓		✓		–	✓		✓		*0*	✓	–	✓		✓		✓		–	✓		✓		✓		–	✓		✓		*13*	*15*
Nov	✓		–	✓		✓		✓		–	✓		✓		✓		–	*0*		*0*		✓		–	✓		✓		✓		/	*11*	*26*

Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations: *18-20 Nov = went out of town for funeral*

Name and address of contact person *JD Bundri, Grocery, Rim Road, Aruna*

Treatment outcome

Date of decision _____

Cure ☐
Treatment completed ☐
Treatment failure ☐
Died ☐
Default ☐
Transfer out ☐

Example two

Below is the *TB Treatment Card* of a patient on daily **self-administered treatment**. She comes once a month (approximately every 4 weeks[1]) to get her drugs (28 doses). The health worker marks with an "X" the day when he sees the patient and gives her the drugs. He draws a line to show the number of days for which drugs were given.

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☐ 3 times/week ☑

Tick category:

	CAT I	CAT II	CAT III	CAT IV
	New case ☑ (smear-positive, or seriously ill smear-negative or EP)	Re-treatment ☐	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
Indicate number of tablets per dose:	☐ (4 months) HR or 2 (6 months) HE	☐☐ (5 months) HR E	☐ (4 months) HR or ☐ (6 months) HE	☐☐☐☐

MONTH \ DAY	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	Number doses this month	Total number doses given
September																											X	¾	¾	¾	/	28	28
October	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾						X	¾	28	56
November	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	X	¾	¾	¾	/	28	84
December	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾					X	¾	¾	28	112
January	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾	¾								

Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

Name and address of contact person *Sultana Koffi, 223 Market Street, Patangeta*

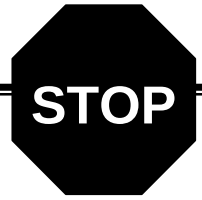
Treatment outcome

Date of decision _____

Cure ☐
Treatment completed ☐
Treatment failure ☐
Died ☐
Default ☐
Transfer out ☐

In the "total" columns on the right, the health worker records the doses supplied to the patient during the month. With a self-administered regimen, these totals indicate the doses provided to the patient to take at home, instead of the doses swallowed.

[1] A patient on self-administered daily treatment may take the anti-TB drugs 7 days per week or 6 days per week. Depending on this and whether any additional days are missed, a range of 28 to 35 days is normal for the patient to take 28 doses. A 6-month continuation phase (168 doses) could be completed in 5.5 months or may require slightly more than 6 months. A duration within this range is acceptable; the important thing is to complete all the required doses.



Now do Exercise C – Written Exercise and Discussion

When you reach this point, you are ready to do Exercise C. Turn to page 75 and follow the instructions. Do the exercise by yourself and then discuss your answers with a facilitator.

3.2 If patient has side-effects, give advice or refer

Most TB patients complete their treatment without any significant **side-effects**. However, watching all TB patients for side-effects is important during treatment because some patients do develop them. Monitor side-effects by:

- asking patients to report problems if they develop
- periodically questioning patients to determine whether they have developed any side-effects.

When you see a TB patient to give treatment, you will ask how the patient is feeling. Listen to the reply carefully to identify any complaints that may indicate side-effects of the anti-TB drugs. Side-effects may be minor or may be major. If the patient has major side-effects, stop giving the anti-TB drugs and refer the patient to a clinician or hospital. If the patient has minor side-effects, continue giving anti-TB drugs. Also reassure the patient and give advice on how to relieve the symptoms. Bear in mind that side-effects are more common in HIV-infected people.

If the patient continues to be concerned about a minor side-effect even after following the advice, refer the patient to a clinician.

Reminder: If at any time you observe that a patient's condition has significantly worsened, refer the patient to a clinician or hospital for further assessment and treatment.

Figure 10: Side-effects and their management

Minor side-effects	**Management**
Anorexia, nausea, abdominal pain	Take drugs with food or gruel
Joint pains	Aspirin
Burning sensation in feet	Pyridoxine 100 mg daily
Orange/red urine	Reassure patient that this is expected (with rifampicin)

Major side-effects	**Management**
Itching of skin, skin rash [a]	Stop anti-TB drugs. Refer the patient urgently to a clinician.
Deafness *(confirm that this is not due to ear wax)*	
Dizziness, lack of balance	
Jaundice (yellow skin or eyes)	
Vomiting repeatedly [b]	
Difficulty with vision	

[a] Itching of skin is extremely serious if the patient is taking thioacetazone (not recommended by WHO).

[b] Vomiting repeatedly is a problem because the drugs are not being absorbed. Vomiting with confusion is very serious because it is a sign of liver failure. Refer a vomiting patient to a clinician.

Record your observations of a patient's side-effects or worsening condition on the back of the *TB Treatment Card*, under Observations. If you refer a patient to hospital or a clinician, use a *TB Referral/Transfer Form* (see module G: *Ensure Continuation of TB Treatment* for instructions on using this form). Also record the details of the referral on the back of the *TB Treatment Card*. Ask the patient to return to the health facility to continue TB treatment after being discharged by the clinician or hospital.

3.3 Continue providing information about TB

As you continue to see a patient daily (or 3 times per week) to directly observe treatment, continue to reinforce messages about TB treatment. Give support for the patient to continue taking the drugs on schedule and to complete all the required doses. The patient should be informed about the dangers of irregular or incomplete treatment. (See module D: *Inform Patients about TB.*)

Review the following information with the patient periodically during the initial phase and once a month during the continuation phase:

- Side-effects of drugs (if reported/observed)
- Type, colour, amount, and frequency of drugs
- Importance of continuing treatment
- What happens if the patient takes only some of the drugs or stops treatment
- Frequency and importance of required sputum examinations, meaning of results.

3.4 (If applicable) Monthly, review community TB treatment supporter's copy of the *TB Treatment Card* and provide the next month's supply of drugs

For patients who receive directly observed treatment from a community TB treatment supporter (instead of coming to the health facility each day), each month you will need to check the *TB Treatment Card* that is kept by the treatment supporter. When the community TB treatment supporter visits the health facility to collect the next month's supply of drugs, review the supporter's copy of the *TB Treatment Card* and discuss any problems. Copy onto the original *TB Treatment Card* (which is kept at the health facility) the days that the patient took the treatment. Then record on the front of the *TB Treatment Card* the drugs that you provide to the supporter for the next month.

Drugs given to supporter

DATE	DOSES
5 April	*I – 28*
7 May	*I – 28*

Record the category of treatment (I, II or III) and the number of doses provided to the supporter.

Module E: *Identify and Supervise Community TB Treatment Supporters* describes how to do these steps.

If possible, also interview the patient periodically to assess the community TB treatment supporter's work. Ask questions about the drugs the patient is receiving and the relationship with the community treatment supporter. Assess whether treatment is correct and the relationship with the community TB treatment supporter is positive and supportive.

4. Monitor progress of treatment by follow-up sputum examinations

Monitor patients with smear-positive pulmonary TB by periodic follow-up sputum examinations. These sputum examinations are important to determine the patient's progress and to make decisions about care. Sputum of smear-positive patients will convert to smear-negative when the anti-TB drugs are taken on a regular basis for the required time period. Sputum conversion from positive to negative is the best indicator that the initial phase of treatment was taken regularly and was effective.

Periodic visits to a clinician are also recommended. A clinician can evaluate clinical improvement, answer any questions the patient may have about the disease or treatment, and provide support for continuing the treatment. See Annex D for a brief description of steps that a clinician should perform at a follow-up visit.

For patients with smear-negative pulmonary TB or extrapulmonary TB, the progress of treatment is monitored by a clinician who assesses clinical status. Increase in the patient's weight is also a useful indicator.

4.1 Determine when the patient is due for follow-up sputum examinations

In general, you will collect sputum for follow-up examination at the end of the initial phase, at 5 months, and in the last week of treatment.

- For a **Category I** patient, do follow-up sputum examinations at the end of 2 months, 5 months, and 6 months of treatment.
- For a **Category II** patient, do follow-up sputum examinations at the end of 3 months, 5 months and 8 months.
- For a **Category III** (smear-negative pulmonary TB) patient, do a follow-up sputum examination at the end of 2 months.

"**At the end of**" means that you should collect sputum in the last week of that month of treatment. When a patient is due for follow-up sputum examination at the end of 2 months of treatment, you will collect sputum in the last week of the second month of treatment. Sputum must be collected several days before you need the results of the examination. Collect sputum early enough for the results of the examination to be available to you at the end of the specified month.

The schedule for later sputum examinations can vary somewhat from the above. Sometimes the initial phase of treatment must be extended by 1 month; this is recommended when the first follow-up sputum examination is still positive. (Extending the initial phase is explained in section 4.4.) Then the total duration of treatment is 1 month longer and the subsequent sputum examinations are pushed 1 month later.

4.2 Collect sputum for follow-up examination

Two sputum specimens are required for a follow-up sputum examination. **During the last week of the initial phase of treatment**, give the patient a labelled sputum container to take home. Instruct the patient to collect an early morning sputum and to bring it to you when returning for the next dose. Review how to collect the sputum. When the patient brings this sputum sample, collect a second sample on the spot at the health facility. Also weigh the patient and record the weight on the *TB Treatment Card*. (See Annex C of this module for guidelines for sputum collection. There is additional guidance in module B: *Detect Cases of TB*.)

Complete a *Request for Sputum Examination* form to send with the sputum samples. Complete the form much as you would for a diagnostic examination. However, tick the box to indicate the reason for examination is "Follow-up." Also write in the patient's disease site and District TB number. See the *Request for Sputum Examination* form on the next page. The health worker completed the top half to submit sputum samples for follow-up examination in the last week of the second month of treatment.

Send the sputum for examination. The laboratory results must be available to you when the patient comes for the last dose of the initial phase. At this time, you will decide whether the patient is ready to begin the continuation phase or not.

> *Reminder: Sputum should be collected several days before you need the results of the sputum examination. Collect sputum in the last week of the specified month of treatment so that the results of the examination will be available to you at the end of the month.*

Example

The reason for this sputum examination is Follow-up.

TB LABORATORY FORM
REQUEST FOR SPUTUM EXAMINATION

Name of health facility _Patangeta Hospital Outpatient__ Date _1 Aug, 2001__

Name of patient _____Christina Koffi_____ Age __ Sex: M ❒ F ❒ ✓

Complete address ____45 Long Street_____

_____Patangeta_____ District __Patangeta____

Reason for examination:

Diagnosis ❒ TB Suspect No. _____

OR Follow-up ☒ Patient's District TB No.* __417_____

Every TB patient should have a District TB Number by this point in treatment.

Disease site: Pulmonary ☒ Extrapulmonary ❒ (specify)_____

Number of sputum samples sent with this form __2___

Date of collection of first sample 1 Aug___ Signature of specimen collector _____

* Be sure to enter the patient's District TB No. for follow-up of patients on TB treatment.

For follow-up, two samples are needed. For diagnosis, three samples are needed.

RESULTS (to be completed by Laboratory)

Lab. Serial No. _____1630_____

(a) Visual appearance of sputum:

Mucopurulent ☒ Blood-stained ☐ Saliva ☐

(b) Microscopy:

DATE	SPECIMEN	RESULTS	POSITIVE (GRADING)			
			+++	++	+	scanty (1–9)
4/8/01	1	NEG	☐	☐	☐	☐
4/8/01	2	NEG	☐	☐	☐	☐
	3		☐	☐	☐	☐

Date _4/8/01__ Examined by (Signature) _____

The completed form (with results) should be sent to the health facility and to the District Tuberculosis Unit.

4.3 Record results of sputum examination

The laboratory technician will record the examination results on the bottom half of the *Request for Sputum Examination* form and return it to the health facility. One or two positive sputum smears mean that the patient is still sputum smear-positive. If both smear specimens are negative, the patient is sputum smear-negative.

Record the results of the follow-up examination on the patient's *TB Treatment Card*. Write in the month of treatment, and the result. Record the result as "neg" or if positive, record the highest grading.

Example: Look back at the *Request for Sputum Examination* form on the previous page to see the results recorded by the laboratory technician. Then see how the health worker added those results to the patient's *TB Treatment Card* below.

When a patient who was sputum smear-positive changes to sputum smear-negative, there has been "sputum conversion."

Example

TUBERCULOSIS TREATMENT CARD

Name *Christina Koffi* — District TB No. *417*

Complete address *45 Long Street, Patangeta* — Health facility *Patangeta Health Centre*

Sex: M ☐ F ☑ Age *49*

Name and address of community treatment supporter (if applicable) *Salima Arata, Centre Street #3, Patangeta*

Disease site: Pulmonary ☑ Extrapulmonary ☐ (specify) _____

Type of patient: New ☑ Relapse ☐ Transfer in ☐ Treatment after failure ☐ Treatment after default ☐ Other (specify) ☐ _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☑ 3 times/week ☐

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	CAT II	CAT III	CAT IV
New case ☑ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ☐	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
3 3 2 (HR) Z E [S]	HR Z E S	HR Z E	

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Health worker wrote new result here

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0	*3/6*	*++*	*175*	*42*
2	*10/8*	*neg*	*1630*	*43*

Tick appropriate box after the drugs have been administered

Drugs given to supporter

MONTH \ DAY	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	Number doses this month	Total number doses given	DATE	DOSES
June		–			✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	✓	0	✓	✓	✓	–	✓	✓	✓	0	0	✓	–	/	*19*	*19*	*5/6*	*I – 28*
July	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	✓	0	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	*26*	*45*	*8/7*	*I – 28*
August	✓	✓	✓	–	✓	✓	✓	0	✓	✓	–	✓	✓	✓																		*11*	*56*		

Please turn over for continuation phase

This patient completed all 56 doses of the initial-phase drugs.

4.4 Decide on appropriate action needed

The appropriate action for the patient will depend on the category of treatment, when the sputum examination is done (that is, in what month of treatment), and whether the result is negative or positive.

4.4.1 Decide whether to begin the continuation phase

Category I and II: Use the results of the follow-up examination to determine whether the patient is ready for the continuation phase. At the end of the second month of treatment for a new sputum smear-positive case (or the third month for a re-treatment case), most patients will have a negative sputum smear examination (two sputum samples negative). These patients should then begin and complete the continuation phase of treatment.[1]

If a patient still has a positive sputum smear at the end of the initial phase, this may indicate one of the following:

- Most frequently: The initial phase of treatment was poorly supervised and drugs were not taken correctly or on schedule.
- Sometimes: There is a slow rate of progress with sputum smear conversion, for example, if a patient had widespread destruction of lung tissue and an initial heavy bacillary load, or if there is a problem with drug absorption.
- Rarely: The patient may have drug-resistant TB that does not respond to first-line treatment.

Whatever the reason, if a patient on Category I or II treatment has a positive sputum smear at the end of the initial phase, the patient should be given one additional month of the initial phase of treatment.[2] Obtain an additional month of initial-phase drugs (28 doses for a daily regimen). Continue giving directly observed treatment with initial-phase drugs, recording the treatment on the front of the *TB Treatment Card*.

When the patient has almost completed the extra 28 doses of the initial phase of treatment, collect sputum for another follow-up sputum examination. When the patient has finished all doses of the initial-phase drugs, start the patient on the continuation phase of treatment, regardless of the laboratory result. (One month is the maximum extension of the initial phase.)

Category III (smear-negative pulmonary TB)[3]: If the results after 2 months of treatment are negative, begin the continuation phase. If the results are positive (that is, a smear-negative pulmonary case became smear-positive), there are three possibilities: the results

---

[1] If the results of the follow-up sputum smear examination are not available when the patient has finished all of the initial-phase drugs, the health worker may assume that the results will be sputum smear-negative as this is the most frequent occurrence, and start the patient on the continuation-phase drugs. If the results then arrive within a reasonable time, such as within 2 weeks, and are sputum smear-positive, the patient must be contacted to add an extra month of the initial-phase drugs.

[2] A Category II patient should continue with the 4 drugs taken in the third month, not the 5 drugs taken in the initial month.

[3] Extrapulmonary TB patients cannot be monitored by sputum smear examinations.

of the diagnostic examination were wrong; the results of the follow-up examination are wrong; or the patient has indeed become sputum smear-positive. In any case, the drugs are not working.

The appropriate action in this situation is to repeat the sputum smear examination to exclude laboratory error. If the results are still positive:

- Close the *TB Treatment Card* and record the outcome as "Treatment failure."
- Open a new *TB Treatment Card* for the patient and mark the "Type of patient" as "Other," and
- Begin Category II treatment.

4.4.2 Use sputum examination results for decisions during the continuation phase

Use the results of a follow-up examination at 5 months to determine whether the treatment is effective or the patient is a treatment failure.

If the sputum is still positive at the end of the fifth month or later, this constitutes **treatment failure**. (Treatment failure is rare with directly observed treatment, usually occurring in less than 1–3% of cases in countries with low levels of drug resistance.)

- Close the patient's *TB Treatment Card* and record the outcome as "Treatment failure."
- Open a new *TB Treatment Card* for the patient and mark the "Type of patient" on the new card as "Treatment after failure."
- Start the patient on a full course of the re-treatment regimen (Category II).

If the sputum is negative after 5 months of treatment, complete treatment with the remaining doses of the continuation phase drugs.

Collect sputum again just before the end of treatment for proof that the patient is cured. The definition of a cure is a "sputum smear-positive patient who is smear-negative in the last month of treatment and on at least one previous occasion." Thus it is important for the health facility to have sputum examination at all the recommended times so that patients can have an outcome of "cured," rather than just "treatment completed." How to determine and record outcome is described in section 5 of this module.

4.5 Monitoring progress of treatment by follow-up sputum examinations: summary of schedule

Remember to collect the two sputum samples for follow-up sputum examination ***in the last week of the month of treatment*** indicated below, so that the results will be available at the end of the month to make decisions about treatment or outcome.

Category I patient: Do follow-up sputum examinations **at the end of 2 months, 5 months, and the last month of treatment**. However, if the examination at the end of 2 months is positive, extend the initial phase of treatment by 1 extra month (28 daily doses). Then do follow-up sputum examinations at the end of 3 months, 5 months and the last month.

Category II patient: Do follow-up sputum examinations **at the end of 3 months, 5 months, and 8 months**. However, if the examination at the end of 3 months is positive, extend the initial phase of treatment by 1 month (28 daily doses). Then do follow-up sputum examinations at the end of 4 months, 6 months, and 9 months.

Category III patient (smear-negative pulmonary): Do a follow-up sputum examination **at the end of 2 months**.

Carefully read the table on the next page. It shows the schedule for sputum examinations (indicated by ●) and lists actions to take as a result. A copy of this table is provided in the *Reference Booklet,* which you may consult whenever you need to.

Now do Exercise D – Written Exercise

After you have studied the table on the next page, turn to 81 and follow the instructions for Exercise D. Do the exercise by yourself. When you have finished, discuss your answers with a facilitator.

Figure 11: Schedule for follow-up sputum examinations

(for pulmonary TB cases only)

Treatment category	Months of treatment								
	1	2	3	4	5	6	7	8	9
Category I *new smear-positive pulmonary*	[===== [===== [————	● =====]	[--------- [————	---------- ————	● ---------- ✪ ————	● ---------] ————	————	✪ ————	
Category II *previously treated smear-positive pulmonary*	[===== [————	====== ————	● =====] ————	[--------- ————	● ---------- ————	---------- ————	---------- ————	● ---------] ————	
Category III *smear-negative pulmonary*	[===== [————	● =====]	[--------- ————	---------- ————	---------- ————	---------] ————	————	————	

[========] Initial phase of treatment

[----------] Continuation phase of treatment (directly observed)

[————] Alternative continuation phase of treatment (HE self-administered)

● Follow-up sputum examination due during the last week of the month of treatment

✪ Follow-up sputum examination for regimens with 6 months' HE self-administered in the continuation phase

® **<u>If sputum examination result is negative</u>: Begin or complete continuation phase of treatment.**

® **<u>If the sputum examination result is positive</u>:**

At end of initial phase of treatment (Category I or II):

- Extend the initial phase of treatment by 1 extra month.
- Review whether treatment has been irregular. If so, discuss with patient the importance of regular treatment.
- Adjust the schedule for follow-up sputum examination as shown in Figure 12 below.

At 5 months or later*:*

- Consider the case a treatment failure.
- Close the *TB Treatment Card* (Outcome = Treatment failure) and open a new *TB Treatment Card* (Type of patient = Treatment after failure).
- Begin Category II treatment (or Category IV if proven multidrug-resistant).

At end of initial phase of treatment for a smear-negative pulmonary case (Category III)*:*

- Open a new *TB Treatment Card* (Type of patient = Other) and begin Category II treatment.

Figure 12: Adjusted schedule for subsequent follow-up sputum examinations

(after extra month of initial-phase drugs given)

Treatment category	Months of treatment								
	1	2	3	4	5	6	7	8	9
Category I *with extra month of initial-phase drugs*	[===== [————	● ====== ————	● =====] ————	[--------- [————	● ---------- ✪ ————	---------- ————	● ---------] ————	————	✪ ————
Category II *with extra month of initial-phase drugs*	[===== [————	====== ————	● ===== ————	● =====] ————	[--------- ————	● ---------- ————	---------- ————	---------- ————	● --------] ————

4.6 Implement treatment decisions

Meet with the patient to explain the results of the follow-up sputum examination and the next step of treatment. In addition, if the patient has a community TB treatment supporter, meet with the treatment supporter as well.

4.6.1 When the patient will begin the continuation phase of treatment

- Be sure that the patient finishes all doses of the initial-phase drugs, and then start the patient on continuation-phase drugs.
- Look at the back of the patient's *TB Treatment Card* for the needed drugs and be sure that the correct number of doses are in the patient's drug box.
- Explain to the patient who had a negative sputum result that the initial phase of treatment has worked well. The patient is no longer infectious and is ready to begin the next phase of treatment.
- Explain to the patient about the continuation phase of treatment, including what to do differently from the initial phase, the drugs to take and the schedule, and how long this treatment phase will last (how many doses to take). If the patient will begin self-administered treatment, explain how this will work.
- Begin giving the patient the continuation phase of treatment, marking the *TB Treatment Card* each time that you administer the drugs (or each time that you give the patient another month's supply of drugs for self-administration).

Note: If the patient had a community TB treatment supporter for the initial phase, talk with both the patient and the treatment supporter about what will happen in the continuation phase. If the patient will self-administer the drugs, tell the treatment supporter that the job is finished and thank the treatment supporter.

4.6.2 If the patient should continue the initial phase of treatment for an additional month

- Obtain one additional month's supply of drugs for the initial phase. Put them into the patient's drug box at the health facility or give them to the patient's community TB treatment supporter.
- Explain to the patient that the sputum examination showed that there are still tubercle bacilli in the sputum. This means that the patient needs one more month (28 more doses) of the initial-phase drugs.
- Continue giving directly observed treatment with initial-phase drugs, and record this on the front of the patient's *TB Treatment Card* each day.
- Collect sputum for examination at the end of the additional month.
- When the patient finishes all doses of the initial phase, begin the continuation phase of treatment.

4.6.3 If the patient is a treatment failure

- Close the *TB Treatment Card* and record the outcome as "Treatment failure." Prepare a new *TB Treatment Card*. Under Type of patient, tick "Treatment after failure." Select Category II treatment. Staple the new card to the old card.
- Collect new drugs for Category II treatment and put them into the patient's treatment box. Return any unused Category I drugs from the patient's treatment box to the supply room.
- Explain to the patient that the laboratory result means that the drugs have not worked as hoped. Tubercle bacilli are still present in the sputum. The patient is still infectious and needs a different drug regimen.
- Explain to the patient about the new drug regimen, including what to do differently, the drugs to take and the schedule, and how long this treatment phase will last (how many doses to take).
- If the patient has a community TB treatment supporter, explain the above to the treatment supporter as well.
- Begin giving directly observed initial-phase Category II treatment (or give the drugs to the treatment supporter). The *TB Treatment Card* should be marked each time that you or the treatment supporter gives directly observed treatment.

4.6.4 If a smear-negative pulmonary patient has become sputum smear-positive

- Close the *TB Treatment Card* and record the outcome as "Treatment failure." Prepare a new *TB Treatment Card*. Under Type of patient, tick "Other." Select Category II treatment. Attach the new card to the old card.
- Collect new drugs for Category II and put them into the patient's treatment box. Return any unused Category I drugs from the patient's treatment box to the supply room.
- Explain to the patient that the laboratory result means that tubercle bacilli are present in the sputum. The patient is infectious and needs a new, stronger drug regimen.
- Explain to the patient about the new drug regimen, including what to do differently, the drugs to take and the schedule, and how long this new treatment regimen will last (how many doses to take).
- If the patient has a community TB treatment supporter, explain the above to the treatment supporter as well.
- Begin giving directly observed initial-phase Category II treatment (or give the drugs to the treatment supporter). The *TB Treatment Card* should be marked each time that you or the treatment supporter gives directly observed treatment.

5. At end of treatment, record outcome on *TB Treatment Card*

When treatment is completed, discharge the patient. The treatment regimen is completed when the patient has taken the correct number of doses of the continuation-phase drugs. If the patient has missed some doses along the way, the duration of the treatment extends until all the doses in the patient's drug box are taken, which will be some days or weeks longer.

Some patients do not complete treatment because they die or stop coming for treatment and cannot be located.

When each patient completes treatment or stops coming for treatment, record that patient's outcome on the *TB Treatment Card*. Figure 13 gives definitions of the six possible treatment outcomes.

Figure 13: Definitions of treatment outcomes

Treatment outcome	Definition
Cure	Sputum smear-positive patient who is sputum smear-negative in the last month of treatment and on at least one previous occasion
Treatment completed	Patient who has completed treatment but who does not meet the criteria to be classified as a cure or a failure
Treatment failure	Patient who is sputum smear-positive at 5 months or later during treatment [a]
Died	Patient who dies for any reason during the course of treatment
Default	Patient whose treatment was interrupted for 2 consecutive months or more
Transfer out	Patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is not known

[a] Also sputum smear-negative patients who become sputum smear-positive at 2 months.

On the back of the *TB Treatment Card* is a box to record the outcome. Note down the date that you are recording the outcome. For most patients, the date will be the last day of treatment. Tick the outcome that describes the patient.

Treatment outcome

Date of decision: *12 Aug 2001*

Cure ✓❒

Treatment completed ❒

Died ❒

Treatment failure ❒

Default ❒

Transfer out ❒

Note that a patient cannot be classified as a "Cure" unless the patient was initially sputum smear-positive and then had a negative sputum examination during the last month of

treatment and at least once previously. A patient with sputum smear-positive pulmonary TB who completed treatment but did not have the necessary number of negative sputum examinations can be classified only as "Treatment completed."

A patient who has stopped coming for treatment and cannot be located or cannot be convinced to resume treatment is classified as a "Default" after 2 months of missed treatment. Therefore, do not mark this treatment outcome on a patient's card until a patient has missed treatment for 2 months.

When you transfer a patient to another facility to continue treatment, record the date and mark the outcome "Transfer out" on the back of the *TB Treatment Card*. If the transfer is confirmed, you will inquire later about the treatment outcome. When you learn the patient's outcome from the other health facility, record the final treatment outcome and the date of that outcome on the card. Only if you cannot determine another outcome, leave the outcome "Transfer out" with the date of the transfer.

Try to find out what has happened to any patient who stops coming for treatment and try to convince the patient to resume treatment. Also, prevent loss of contact with patients by reminding them to inform you if they are going to move away, so that you can coordinate their transfer to another health facility for TB treatment. See module G: *Ensure Continuation of TB Treatment* for suggestions on how to better maintain contact with patients and minimize defaults.

If a patient was a transfer from another health facility (type of patient was "Transfer in"), remember to report the patient's treatment outcome to the originating health facility.

In smear-negative pulmonary and extrapulmonary TB patients, "Cure" and "Treatment failure"[1] are not possible outcomes because these outcomes are based on whether or not a patient has sputum conversion (positive to negative) in follow-up sputum smear examinations. However, the other outcomes are possible: "Treatment completed," "Died," "Default," and "Transfer out."

When a patient does not complete treatment, return all drugs remaining in the patient's drug box to the drug supply room.

The treatment outcome of every TB patient is important information for monitoring your health facility's success. In addition, your District TB Coordinator will visit your facility to review *TB Treatment Cards* and record each patient's outcome in the District TB Register. Later, the district will analyse information on patient outcomes from all health facilities as a measure of how well the district is managing TB cases.

[1] An exception is a smear-negative pulmonary TB patient who becomes sputum smear-positive at 2 months. Record the outcome for this patient as "Treatment failure." Reregister the patient as "Other" and start Category II treatment.

Now do Exercise E – Written Exercise

When you have reached this point, you are ready to do the last exercise in this module. Turn to page 85 and follow the instructions. Do Exercise E by yourself. When you have finished the exercise, discuss your answers with a facilitator.

Summary of important points

- Treatment for TB consists of two different phases of taking special combinations of drugs. Generally, the initial phase is 2 months, and the continuation phase is 4–6 months. **If anti-TB drugs are taken incorrectly or irregularly, the patient will not be cured.** The disease will be prolonged and more difficult to treat in the future.

- Health workers must take an active role in ensuring that every TB patient takes the recommended drugs, in the right combinations, on the correct schedule, for the appropriate duration. **A health worker does this by giving directly observed treatment, that is, watching each patient swallow the tablets every day scheduled.** The health worker can immediately detect any interruption in treatment and take action, such as tracing the patient and encouraging the patient to resume treatment. Directly observed treatment can also build a supportive relationship that improves adherence to the treatment regimen.

- The correct treatment category (I, II, III, or IV) is selected on the basis of the disease site, type of patient, and results of sputum smear examination.
  - Determine the disease site (pulmonary or extrapulmonary) from the results of sputum smear examination and/or a clinician's diagnosis.
  - Determine the type of patient by asking whether the patient has ever taken any drugs for TB before. A patient who has never taken anti-TB drugs (or has taken them for less than 1 month) is a "new" case. Previously treated patients may have acquired drug resistance and need a different treatment regimen.

- Health workers can choose:
  - Category I treatment for a new patient with sputum smear-positive pulmonary TB.
  - Category II treatment for a sputum smear-positive patient who was previously treated for TB (relapse or treatment after failure).

  Health workers should follow a clinician's instructions for treatment of other cases (such as sputum smear-negative cases or patients who return after default).

- The *TB Treatment Card* is the record of the patient's TB diagnosis and treatment. Fill it out completely. **Be sure to record a complete address, one that you could use to locate a patient who stops coming for treatment**. Also record the name and address of a contact person who will know how to locate the patient if needed.

- Look up the drug regimen recommended by your national TB programme for the patient's category of treatment. Record on the *TB Treatment Card* the drugs for both phases of treatment. Record the frequency and number of tablets for each dose. Note the total number of doses required to complete each phase.

- If it is convenient for a patient to come to the health facility each day, a health facility worker will directly observe treatment. If it is not convenient, the patient will need a community TB treatment supporter. In this situation, discuss with the patient possible persons in the community who could provide directly observed treatment and who can be supervised by the health facility. Discuss possible places, such as the workplace or the treatment supporter's home, that would be convenient for the patient to come for treatment. Agree how the patient will receive directly observed treatment.

- Obtain or prepare a drug box for the patient that contains all the drugs that will be needed for that patient's entire treatment regimen (total doses needed for both phases). Use that drug box for the patient, and only that patient, until all the drugs are taken.

- Inform the patient and the family about TB so that they understand the disease and the need to complete the treatment regimen correctly. As you continue to see the patient, reinforce messages about TB treatment and give support for continuing to take the drugs. Ask the patient to inform you of any plans to move or go away for a few days, so that you can arrange uninterrupted treatment.

- To directly observe TB treatment, remember:
  - **Do not make TB patients coming for directly observed treatment wait in a queue at the health facility.**
  - Watch the patient swallow the tablets.
  - Record the treatment on the *TB Treatment Card* by ticking (✓) the date. (Record "0" for a missed dose.)

- To prevent TB in household contacts of TB patients:
  - Give a course of isoniazid as preventive therapy to any child aged less than 5 years who does not have TB and who lives in the household of a TB patient.
  - After the course of preventive therapy is finished, give BCG immunization to children aged less than 2 years who have not already been immunized.

- **If a patient has major side-effects**, **stop giving the anti-TB drugs and refer the patient to a clinician or hospital**. If the patient has minor side-effects, reassure the patient and give advice on how to relieve the symptoms. (See Figure 10, page 31.) Side-effects are more common in people infected with HIV.

- If the patient has a community TB treatment supporter, review and copy the *TB Treatment Card* that is kept by the treatment supporter each month and discuss any problems. Provide drugs for the next month.

- Monitor a patient's progress by follow-up sputum examination. Sputum conversion from positive to negative is the best indicator that the initial phase of treatment was taken regularly and was effective. **Collect sputum for follow-up examination at the end of the initial phase, at 5 months, and at the end of treatment.** Two sputum samples are required for each follow-up examination.
  - Use the results of the first follow-up examination to determine whether the patient is ready for the continuation phase. If the sputum results are positive, extend the initial phase of treatment for one extra month. If negative, begin the continuation phase.
  - If the sputum is still positive at 5 months or later, the patient is a treatment failure. Open a new *TB Treatment Card* and begin Category II treatment.

- When the patient completes treatment or stops coming for treatment, record the treatment outcome on the *TB Treatment Card*. The possible outcomes are: Cure, Treatment completed, Treatment failure, Died, Default, Transfer out. "Cure" is a sputum smear-positive patient who is smear-negative in the last month of treatment and on at least one previous occasion.

Self-assessment questions

Answer the self-assessment questions below to check what you have learned. Then compare your answers to those pages 54–56.

1. a) When a patient has a positive sputum smear result, is the disease site pulmonary or extrapulmonary?

   b) How do you determine the type of patient (that is, new, relapse, treatment after failure, etc.)?

   c) If a sputum smear-positive patient has not taken anti-TB drugs before, what is the type of patient? What category of treatment is needed?

   d) Why is a longer, stronger treatment regimen needed for previously treated patients?

2. Fill in the *TB Treatment Card* on the next page for this patient, seen at the Ghandi Health Facility, using the information below:

   Jon Narayam, aged 35, male, lives at 222 Castle Road, North Akton, Kelbe District. He will go to the Ghandi Health Centre for TB treatment. He does not yet have a District TB number. His contact person is Mr Jamil, the shopkeeper who lives across Castle Road. His laboratory results are shown below:

Lab. Serial No. ___685_____
Microscopy:

DATE	SPECIMEN	RESULTS	POSITIVE (GRADING)			
			+++	++	+	scanty (1–9)
5 March	1	POS	☐	☐	☑	☐
5 March	2	POS	☑	☐	☐	☐
5 March	3	POS	☐	☑	☐	☐

   Jon weighs 56 kg. He was treated for TB about 2 years ago. He completed the treatment and the health worker told him that he was cured.

   Tick the category of treatment and write the drug regimen he should take. Also enter the drug regimen for the continuation phase on the back of the card. (To look up the drug regimen, refer to your country's drug recommendations or Figure 5 on page 15.)

TUBERCULOSIS TREATMENT CARD

Name _____ District TB No. _____

Complete address _____ Health facility _____

Sex: M ❑ F ❑ Age _____

Name and address of community treatment supporter (if applicable) _____

Disease site

Pulmonary ❑ Extrapulmonary ❑ (specify) _____

Type of patient

New ❑ Treatment after failure ❑

Relapse ❑ Treatment after default ❑

Transfer in ❑ Other (specify) ❑ _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ❑

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	CAT II	CAT III	CAT IV
New case ❑ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ❑	New case ❑ (smear-negative or EP)	Chronic or MDR-TB ❑
☐☐☐ HR Z E [S]	☐☐☐☐ HR Z E S	☐☐☐ HR Z E	☐☐☐☐☐

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0				

Tick appropriate box after the drugs have been administered

Drugs given to supporter

MONTH \ DAY	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	Number doses this month	Total number doses given	DATE	DOSES

Please turn over for continuation phase

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ❑

Tick category:	CAT I	CAT II	CAT III	CAT IV
	New case ❑ (smear-positive, or seriously ill smear-negative or EP)	Re-treatment ❑	New case ❑ (smear-negative or EP)	Chronic or MDR-TB ❑
Indicate number of tablets per dose:	☐ (4 months) HR or ☐ (6 months) HE	☐☐ (5 months) HR E	☐ (4 months) HR or ☐ (6 months) HE	☐☐☐☐

MONTH \ DAY	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	Number doses this month	Total number doses given

Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

_____

_____

_____

_____

Name and address of contact person _____

Treatment outcome

Date of decision _____

Cure ❑

Treatment completed ❑

Treatment failure ❑

Died ❑

Default ❑

Transfer out ❑

3. a) What is a community TB treatment supporter?

b) Which patients need a community TB treatment supporter?

c) What are some of the places where a community TB treatment supporter could directly observe treatment?

4. a) Who should receive isoniazid to prevent TB?

b) Which household contacts should receive immunization against TB?

5. a) What is the most critical aspect of directly observed treatment? (select one answer)

i. talking to the patient and giving support
ii. providing the drugs to the patient
iii. watching the patient swallow the drugs
iv. recording the treatment on the treatment card

b) If a patient who takes treatment daily missed an appointment yesterday, what should be given for treatment today?

6. A TB patient complains of headache in the evenings after work and orange urine. What should you do?

7. a) When should a new smear-positive pulmonary patient (Category I) have a first follow-up sputum examination?

b) When should a relapse patient (smear-positive pulmonary TB) (Category II) have a first follow-up sputum examination?

c) On how many occasions should most patients have follow-up sputum examinations?

8. Below are the laboratory results for Mr Zide's follow-up sputum examination after 5 months of treatment (Category I). His weight is 47 kg today.

Lab. Serial No. ___1119_____
Microscopy:

DATE	SPECIMEN	RESULTS	POSITIVE (GRADING)			
			+++	++	+	scanty (1–9)
10 Oct	1	POS	☐	☐	☑	☐
10 Oct	2	POS	☐	☐	☑	☐
	3		☐	☐	☐	☐

Record the results on the portion of his *TB Treatment Card* provided below:

Results of sputum examination				**Weight**
Month	Date	Smear	Lab. No.	**(kg)**
0	*4/5*	*+++*	*630*	*48*
2	*12/ 7*	*++*	*801*	*48*
3	*13/8*	*+*	*898*	*47*

9. What action is now needed for Mr Zide in question 8?

10. State the treatment outcome for the following cases.

a) A Category I patient took treatment for 3 months but then stopped coming for treatment. When a health worker visited the house, the neighbours said that the family had moved. Two months have gone by and the patient still has not been seen. What is the treatment outcome?

b) This Category I patient completed all of the 6 months of treatment. The sputum examination results were as follows:

Results of sputum examination				Weight
Month	Date	Smear	Lab. No.	**(kg)**
0	*4/5*	+++	*630*	*48*
2	*6/7*	*Neg*	*919*	*49*
5	*8/10*	*Neg*	*1120*	

What was the treatment outcome?

c) This Category I patient has completed 5 months of treatment. The sputum examination results are as follows:

Results of sputum examination				Weight
Month	Date	Smear	Lab. No.	**(kg)**
0	*10 Feb*	++	*306*	*35*
2	*15 April*	+++	*422*	*35*
3	*14 May*	+	*498*	*34*
5	*15 July*	+	*603*	*35*

What was the treatment outcome?

d) This Category II patient completed 8 months of treatment. The sputum examination results are as follows:

Results of sputum examination				Weight
Month	Date	Smear	Lab. No.	**(kg)**
0	*22 Oct*	++	*116*	*27*
3	*26 Jan*	*Neg*	*399*	*28*
5	*29 Mar*	*Neg*	*767*	
8	*2 July*	*Neg*	*1087*	

What was the treatment outcome?

Now compare your answers with those on the next pages.

Answers to self-assessment questions

If you had difficulty answering any question, turn back and study the section indicated. If you do not understand something, discuss it with a facilitator.

1. a) A patient with a positive sputum smear result is classified as pulmonary TB. The bacilli have been seen in the sputum. (See 1.1.1)

b) Ask the patient about any previous treatment for TB. (See 1.1.2)

c) The patient is New and needs Category I treatment. (See 1.1.2, 1.1.3)

d) Previously treated patients are likely to have resistant bacilli. (See 1.1.3)

2. Compare your entries with those on the TB Treatment Card below and on the next page. (See 1.3)

The drug regimen for Category II used below is $2(HRZE)S/1(HRZE)/5(HR)_3E_3$. Because the initial phase is 3 months, but streptomycin is used for only 2 months (56 doses), it is helpful to write a reminder on the card about when to stop streptomycin. The doses were determined from Figure 5 on page 15. You may have used the Category II drug regimen recommended in your country instead.

TUBERCULOSIS TREATMENT CARD

Name *Jon Narayam* District TB No. _____

Complete address *222 Castle Road, North Akton* Health facility *Ghandi Health Centre*

Sex: M ☑ F ☐ Age *35*

Name and address of community treatment supporter (if applicable) _____

Disease site: Pulmonary ☑ Extrapulmonary ☐ (specify) _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☑ 3 times/week ☐

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	CAT II	CAT III	CAT IV
New case ☐ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ☑	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
HR Z E [S]	4 1g (HR Z E) S	HR Z E	

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Note: Stop streptomycin after 56 doses

Type of patient: New ☐ Treatment after failure ☐ Relapse ☑ Treatment after default ☐ Transfer in ☐ Other (specify) ☐ _____

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0	*5 Mar*	*+++*	*685*	*56 kg*

Tick appropriate box after the drugs have been administered

Drugs given to supporter

MONTH \ DAY	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	Number doses this month	Total number doses given	DATE	DOSES
March																																			
April																																			
May																																			
June																																			

Please turn over for continuation phase

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ☑

Tick category:	**CAT I**	**CAT II**	**CAT III**	**CAT IV**
	New case ❑ (smear-positive, or seriously ill smear-negative or EP)	Re-treatment ☑	New case ❑ (smear-negative or EP)	Chronic or MDR-TB ❑
Indicate number of tablets per dose:	☐ (4 months) HR or ☐ (6 months) HE	4 6 (5 months) (HR) E	☐ (4 months) HR or ☐ (6 months) HE	☐☐☐☐

MONTH \ DAY	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	Number doses this month	Total number doses given

Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

Name and address of contact person *Mr Jamil, shopkeeper across street (Castle Road)*

Treatment outcome

Date of decision _____

Cure ❑
Treatment completed ❑
Treatment failure ❑
Died ❑
Default ❑
Transfer out ❑

3. a) A community TB treatment supporter is a community member who administers and directly observes a patient's treatment, at a time and location in the community convenient for the patient. (See 1.2 and 1.5)

b) Any patient who will not go to a health facility for treatment needs a community TB treatment supporter. (See 1.2)

c) The patient's workplace, the treatment supporter's home, the patient's home. (See 1.5)

4. a) Any child aged less than 5 years who lives in the household of a TB patient and who does not have TB should receive isoniazid as preventive therapy. (See 2.1)

b) Any child aged less than 2 years who lives in a household with a TB patient, and who has not already had a BCG immunization, should have one (after completing preventive therapy with isoniazid). (See 2.2)

5. a) The correct answer is: iii. Watching the patient swallow the drugs. (See 3.1)

b) Give the patient today's dose. Do not give a double dose. (See 3.1)

6. *Explain to the TB patient that the orange urine is a normal side-effect of one of the anti-TB drugs and there is no cause for alarm. You do not know what is causing the headache, but it is probably not a side-effect of the anti-TB drugs. (See 3.2)*

7. a) *During the last week of the second month of treatment (end of the initial phase of Category I treatment).*

   b) *During the last week of the third month of treatment (end of the initial phase of Category II treatment).*

   c) *Most cases should have three follow-up sputum examinations: at the end of (that is, in the last week of) the initial phase, at 5 months, and at the end of treatment. (See 4.1, 4.5 and page 40.)*

8. *Below is the portion of Mr Zide's TB Treatment Card with the results for the follow-up sputum examination at 5 months. (See 4.3)*

Results of sputum examination				**Weight**
Month	Date	Smear	Lab. No.	**(kg)**
0	*4/5*	*+++*	*630*	*48*
2	*12/ 7*	*++*	*801*	*48*
3	*13/8*	*+*	*898*	*47*
5	***10/10***	***+***	***1119***	***47***

9. *Because the follow-up sputum examination after 5 months of treatment is still positive, Mr Zide is considered a treatment failure. The appropriate action is to close the TB Treatment Card (Outcome = Treatment failure). Then open a new TB Treatment Card (Type of patient = Treatment after failure) and begin Category II treatment. (See 4.4)*

10. a) *Default*

    b) *Treatment completed. This case cannot be classified as a Cure because there was no sputum examination at the end of treatment.*

    c) *Treatment failure, because the patient is sputum smear-positive after 5 months of treatment. This patient will be reregistered as a Treatment after failure and started on Category II treatment.*

    d) *Cure. The patient was initially sputum smear-positive, completed all the treatment, and was sputum smear-negative at the completion of treatment and on at least one previous occasion. (See section 5)*


The End
Congratulations on finishing this module!

Exercises for Module C:

Treat TB Patients

Exercise A

Written Exercise — Selecting a treatment category

In this exercise, you will select the correct treatment category for four different patients. Refer to the *Reference Booklet* while you are doing the exercises in this module so that you will learn what is in the *Reference Booklet* and become comfortable using it.

On the next pages you will find information about four TB patients. Your group will discuss the first case together. Then you will do cases 2–4 by yourself.

Read the information given and review the results on the patient's *Request for Sputum Examination* form. Then answer the questions at the bottom of the page.

Case 1: Adesa Abkar

When you interview Adesa, you find that she has never been treated for TB before.

TB LABORATORY FORM
REQUEST FOR SPUTUM EXAMINATION

Name of health facility __Cochan Health Centre_____ Date __26-8- 01____
Name of patient __Adesa Abkar_____ Age __22____ Sex: M ❒ F ❒ √
Complete address ___27 Market Road_____
___Aruna_____ District ___Marduk_____
Reason for examination:
Diagnosis √ ❒ TB Suspect No. ____105_____
OR Follow-up ❒ Patient's District TB No.* _____
Disease site: Pulmonary ❒ Extrapulmonary ❒ (specify)_____
Number of sputum samples sent with this form __3___
Date of collection of first sample _26 – 8 - 01_ Signature of specimen collector _____
* Be sure to enter the patient's District TB No. for follow-up of patients on TB treatment.

RESULTS (to be completed by Laboratory)

Lab. Serial No. ___497_____
(a) Visual appearance of sputum:
Mucopurulent [√] Blood-stained [ ] Saliva [ ]
(b) Microscopy:

DATE	SPECIMEN	RESULTS	POSITIVE (GRADING)			
			+++	++	+	scanty (1–9)
28–8-01	1	POS	[ ]	[√]	[ ]	[ ]
28– 8-01	2	POS	[√]	[ ]	[ ]	[ ]
28 – 8-01	3	POS	[ ]	[ ]	[√]	[ ]

Date _28-8-01_____ Examined by (Signature) _____

The completed form (with results) should be sent to the health facility and to the District Tuberculosis Unit.

a) What is her disease site? Pulmonary ❑ Extrapulmonary ❑

b) What type of patient is she? New ❑ Transfer in ❑ Treatment after default ❑ Relapse ❑ Treatment after failure ❑ Other ❑

c) What category of treatment is needed?

Case 2: Marcus Marin

Marcus said that he was treated for TB and completed treatment last year.

TB LABORATORY FORM
REQUEST FOR SPUTUM EXAMINATION

Name of health facility __Cochan Health Centre___ Date ___21 Aug 2001_____

Name of patient ___Marcus Marin_____ Age __33__ Sex: M ❒ F ❒ √

Complete address ___131 Longstreet_____

___Aruna_____ District ____Marduk____

Reason for examination:

Diagnosis ❒ TB Suspect No. ___78_____

OR Follow-up ❒ Patient's District TB No.* _____

Disease site: Pulmonary ❒ Extrapulmonary ❒ (specify)_____

Number of sputum samples sent with this form __3___

Date of collection of first sample 21 Aug 2001__ Signature of specimen collector _____

* Be sure to enter the patient's District TB No. for follow-up of patients on TB treatment.

RESULTS (to be completed by Laboratory)

Lab. Serial No. _____489_____

(a) Visual appearance of sputum:

Mucopurulent ☑ Blood-stained ☐ Saliva ☐

(b) Microscopy:

DATE	SPECIMEN	RESULTS	POSITIVE (GRADING)			
			+++	++	+	scanty (1–9)
23 Aug	1	POS	☐	☐	☑	☐
23 Aug	2	POS	☐	☑	☐	☐
23 Aug	3	POS	☐	☐	☑	☐

Date _23/8/01 Examined by (Signature) _____

The completed form (with results) should be sent to the health facility and to the District Tuberculosis Unit.

a) What is his disease site? Pulmonary ❑ Extrapulmonary ❑

b) What type of patient is he? New ❑ Transfer in ❑ Treatment after default ❑ Relapse ❑ Treatment after failure ❑ Other ❑

c) What category of treatment is needed?

Case 3: Raj Makena

When you interview Raj, you find that he has never been treated for TB before.

TB LABORATORY FORM
REQUEST FOR SPUTUM EXAMINATION

Name of health facility __Cochan Health Centre_____ Date __28/8/01_____

Name of patient _____Raj Makena_____ Age __28__ Sex: M ☑ F ☐

Complete address ____11 Market Place_____

_____Aruna_____ District __Marduk_____

Reason for examination:

Diagnosis ☑ TB Suspect No. ___136_____

OR Follow-up ☐ Patient's District TB No.* _____

Disease site: Pulmonary ☐ Extrapulmonary ☐ (specify)_____

Number of sputum samples sent with this form __3___

Date of collection of first sample 28/8/01___ Signature of specimen collector _____

* Be sure to enter the patient's District TB No. for follow-up of patients on TB treatment.

RESULTS (to be completed by Laboratory)

Lab. Serial No. _____560_____

(a) Visual appearance of sputum:

Mucopurulent ☐ Blood-stained ☒ Saliva ☐

(b) Microscopy:

DATE	SPECIMEN	RESULTS	POSITIVE (GRADING)			
			+++	++	+	scanty (1–9)
30 - 8	1	POS	☐	☐	☑	☐
30 - 8	2	POS	☐	☐	☑	☐
30 – 8	3	NEG	☐	☐	☐	☐

Date _30 - 8- 01__ Examined by (Signature) _____

The completed form (with results) should be sent to the health facility and to the District Tuberculosis Unit.

a) What is his disease site? Pulmonary ❑ Extrapulmonary ❑

b) What type of patient is he? New ❑ Transfer in ❑ Treatment after default ❑ Relapse ❑ Treatment after failure ❑ Other ❑

c) What category of treatment is needed?

Case 4: Janu Nair

Based on his laboratory results, Janu was referred to the physician for assessment. The medical diagnosis was positive for pulmonary TB. Janu said that he took anti-TB drugs for a couple of months early in the year and then stopped.

TB LABORATORY FORM
REQUEST FOR SPUTUM EXAMINATION

Name of health facility ___Cochan Health Centre___ Date __10-10-01____

Name of patient __Janu Nair_____ Age __56__ Sex: M ❒ F ❒ √

Complete address ____45 College Street _____

_____Aruna_____ District __Marduk_____

Reason for examination:

Diagnosis √ ❒ TB Suspect No. ___173_____

OR Follow-up ❒ Patient's District TB No.* _____

Disease site: Pulmonary ❒ Extrapulmonary ❒ (specify)_____

Number of sputum samples sent with this form __3___

Date of collection of first sample _10-10-01__ Signature of specimen collector

* Be sure to enter the patient's District TB No. for follow-up of patients on TB treatment.

RESULTS (to be completed by Laboratory)

Lab .Serial No. _____653_____

(a) Visual appearance of sputum:

Mucopurulent [√] Blood-stained [ ] Saliva [ ]

(b) Microscopy:

DATE	SPECIMEN	RESULTS	POSITIVE (GRADING)			
			+++	++	+	scanty (1–9)
12-10-01	1	NEG	[ ]	[ ]	[ ]	[ ]
12-10	2	POS	[ ]	[ ]	[√]	[ ]
12-10	3	NEG	[ ]	[ ]	[ ]	[ ]

Date _13-10-01__ Examined by (Signature) _____

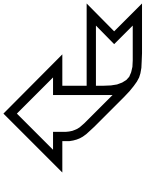
The completed form (with results) should be sent to the health facility and to the District Tuberculosis Unit.

a) What is his disease site? Pulmonary ❑ Extrapulmonary ❑

b) What type of patient is he? New ❑ Transfer in ❑ Treatment after default ❑ Relapse ❑ Treatment after failure ❑ Other ❑

c) What category of treatment is needed?

When you have finished answering the questions about the four cases, review your answers with a facilitator.



Then GO BACK to page 7. Read to the next stop sign (page 20).

Exercise B

Written Exercise -- Preparing a *TB Treatment Card*

In this exercise, you will prepare *TB Treatment Cards* for the patients in Exercise A. Use the information provided on the TB laboratory forms in Exercise A (pages 62–65) and additional information below to prepare a *TB Treatment Card* for each patient. To prepare each card, carry out the following steps:

- Record all the general patient information on the top section of the card. (The District TB Number is not yet assigned to these patients.)
- Mark the disease site and type of patient.
- Record the results of the diagnostic sputum smear examination.
- Tick the correct category of treatment (on the front and back of the card).
- Then look up the drug regimen for the category and the doses for the patient's weight. Tick the correct frequency. Fill in the number of tablets (or grams of streptomycin) for each dose for the initial and continuation phases. Use the recommended treatment regimens on page 15, or in the *Reference Booklet*, or use one provided by your facilitator.
- Record the name and address of the contact person on the back of the card.

Your group will discuss Case 1 and fill out the *TB Treatment Card* together (on an overhead).

Case 1: Adesa Abkar

She will come to the health centre for directly observed treatment. Her contact person is Mara Abkar (mother), 102 Market Road, Aruna. Her weight is 48 kg. This health centre uses a 3 times per week regimen in the continuation phase.

Now prepare TB Treatment Cards for cases 2–4 by yourself:

Write on the three blank *TB Treatment Cards* on the following pages (or *TB Treatment Cards* that your facilitator gives you).

Case 2: Marcus Marin

He will come to the health centre for directly observed treatment. His contact person is Anna Marin (wife), 131 Longstreet, Aruna. His weight is 56 kg. This health centre uses a 3 times per week regimen in the continuation phase.

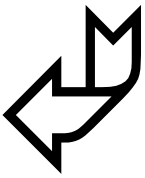
Case 3: Raj Makena

He will come to the health centre for directly observed treatment. His contact person is Sajiv Gondar, Circle Road behind Government House, Aruna. His weight is 53 kg. This health centre uses a 3 times per week regimen in the continuation phase.

Case 4: Janu Nair

He will come to the health centre for directly observed treatment. His contact person is Jair Prabakar (grocery), 39 College Street, Aruna. His weight is 42 kg. This health centre uses a 3 times per week regimen in the continuation phase.

When you have finished preparing *TB Treatment Cards* for Cases 2, 3, and 4, review your work with a facilitator.



Then GO BACK to page 21. Read to the next stop sign (page 30).

TUBERCULOSIS TREATMENT CARD

Name _____ District TB No. _____

Complete address _____ Health facility _____

Sex: M ❑ F ❑ Age _____

Name and address of community treatment supporter (if applicable) _____

_____

Disease site

Pulmonary ❑ Extrapulmonary ❑ (specify) _____

Type of patient

New ❑ Treatment after failure ❑

Relapse ❑ Treatment after default ❑

Transfer in ❑ Other (specify) ❑ _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ❑

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I

New case ❑
(smear-positive, or seriously ill smear-negative, or EP)

HR	Z	E [S]

CAT II

Re-treatment ❑

HR	Z	E	S

CAT III

New case ❑
(smear-negative or EP)

HR	Z	E

CAT IV

Chronic or MDR-TB ❑

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0				

Tick appropriate box after the drugs have been administered

MONTH \ DAY	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	Number doses this month	Total number doses given

Drugs given to supporter

DATE	DOSES

Please turn over for continuation phase

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ❑

Tick category:	**CAT I**	**CAT II**	**CAT III**	**CAT IV**
	New case ❑ (smear-positive, or seriously ill smear-negative or EP)	Re-treatment ❑	New case ❑ (smear-negative or EP)	Chronic or MDR-TB ❑
Indicate number of tablets per dose:	☐ (4 months) HR or ☐ (6 months) HE	☐☐ (5 months) HR E	☐ (4 months) HR or ☐ (6 months) HE	☐☐☐☐

MONTH \ DAY	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	Number doses this month	Total number doses given

Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

_____

_____

_____

_____

Name and address of contact person _____

Treatment outcome

Date of decision _____

Cure ❑

Treatment completed ❑

Treatment failure ❑

Died ❑

Default ❑

Transfer out ❑

TUBERCULOSIS TREATMENT CARD

Name _____ District TB No. _____

Complete address _____ Health facility _____

Sex: M ❑ F ❑ Age _____

Name and address of community treatment supporter (if applicable) _____

_____

Disease site

Pulmonary ❑ Extrapulmonary ❑ (specify) _____

Type of patient

New ❑ Treatment after failure ❑

Relapse ❑ Treatment after default ❑

Transfer in ❑ Other (specify) ❑ _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ❑

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	CAT II	CAT III	CAT IV
New case ❑ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ❑	New case ❑ (smear-negative or EP)	Chronic or MDR-TB ❑
HR Z E [S]	HR Z E S	HR Z E	

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0				

Tick appropriate box after the drugs have been administered

Drugs given to supporter

MONTH \ DAY	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	Number doses this month	Total number doses given

DATE	DOSES

Please turn over for continuation phase

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ❑

Tick category:

CAT I
New case ❑
(smear-positive, or seriously ill smear-negative or EP)

Indicate number of tablets per dose:

☐ (4 months)
HR
or
☐ (6 months)
HE

CAT II
Re-treatment ❑

☐☐ (5 months)
HR E

CAT III
New case ❑
(smear-negative or EP)

☐ (4 months)
HR
or
☐ (6 months)
HE

CAT IV
Chronic or MDR-TB ❑

☐☐☐☐

MONTH \ DAY	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	Number doses this month	Total number doses given

Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

_____

_____

_____

_____

Name and address of contact person _____

Treatment outcome

Date of decision _____

Cure ❑
Treatment completed ❑
Treatment failure ❑
Died ❑
Default ❑
Transfer out ❑

TUBERCULOSIS TREATMENT CARD

Name _____ District TB No. _____

Complete address _____ Health facility _____

Sex: M ❑ F ❑ Age _____

Name and address of community treatment supporter (if applicable) _____

_____

Disease site

Pulmonary ❑ Extrapulmonary ❑ (specify) _____

Type of patient

New ❑ Treatment after failure ❑

Relapse ❑ Treatment after default ❑

Transfer in ❑ Other (specify) ❑ _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ❑

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	CAT II	CAT III	CAT IV
New case ❑ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ❑	New case ❑ (smear-negative or EP)	Chronic or MDR-TB ❑
HR Z E [S]	HR Z E S	HR Z E	

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0				

Tick appropriate box after the drugs have been administered

Drugs given to supporter

MONTH \ DAY	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	Number doses this month	Total number doses given	DATE	DOSES

Please turn over for continuation phase

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ❑

Tick category:

CAT I
New case ❑
(smear-positive, or seriously ill smear-negative or EP)

CAT II
Re-treatment ❑

CAT III
New case ❑
(smear-negative or EP)

CAT IV
Chronic or MDR-TB ❑

Indicate number of tablets per dose:

CAT I: ☐ (4 months) HR
or
☐ (6 months) HE

CAT II: ☐☐ (5 months) HR E

CAT III: ☐ (4 months) HR
or
☐ (6 months) HE

CAT IV: ☐☐☐☐

MONTH \ DAY	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	Number doses this month	Total number doses given

Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

_____

_____

_____

_____

Name and address of contact person _____

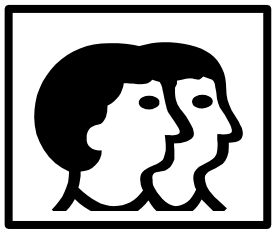
Treatment outcome

Date of decision _____

Cure ❑
Treatment completed ❑
Treatment failure ❑
Died ❑
Default ❑
Transfer out ❑

Exercise C

Written Exercise and Discussion – Giving directly observed treatment



In this exercise you will practise recording treatment on a *TB Treatment Card*. **Fold out the *TB Treatment Card* for Raj Makena on page 79.** Below is a list of the days that the patient received treatment, or missed a scheduled treatment, or the Cochan Health Centre was closed (Sundays).

1. The first several weeks of treatment have already been recorded on the card. Look at the marks on the card to see how the health worker recorded the following:

Raj began his treatment on Monday, 3 September 2001. He came and received directly observed treatment on the following days:

Received directly observed treatment on 4, 5, 6, 7, 8 September.
9 September was Sunday and the health centre was closed.
Received directly observed treatment on 10, 11, 12, 13, 14, 15 September.
16 September was Sunday.
Received directly observed treatment on 17 September.
He did not come on 18, 19, or 20 September.
On 21 September the health worker visited the patient's home and found that Raj had been sick. He gave directly observed treatment at his home.
Received directly observed treatment on 22 September.
23 September was Sunday.
Received directly observed treatment on 24, 25, 26, 27, 28, 29 September.
30 September was Sunday.

Received directly observed treatment on 1, 2, 3, 4, 5, 6 October.
7 October was Sunday.
On 8 October the District TB Coordinator visited the health centre. She registered the patients who had been detected since her last visit. She assigned to Raj Makena the District TB Number 1261. The health worker wrote this number on Raj's *TB Treatment Card*.
Received directly observed treatment on 8, 9, 10, 11, 12 October.
On 13 October he received directly observed treatment. He told the health worker that he was going on a trip to visit his brother for a few days, so the health worker gave him anti-TB drugs to self-administer for 4 days.
He returned to the health centre and received directly observed treatment on 19, 20 October.
21 October was Sunday.
Received directly observed treatment on 22, 23, 24, 25, 26, 27 October.
28 October was Sunday.

2. Read the list below, and mark the card to show each time that the patient received treatment, or missed a scheduled treatment, or the health centre was closed (Sundays).

Received directly observed treatment on 29, 30, 31 October.

Received directly observed treatment on 1, 2, 3 November.
4 November was Sunday.
Received directly observed treatment on 5, 6, 7, 8, 9 November. This completed the initial phase of treatment (2 months x 28 doses per month = 56 doses).
The health centre received sputum examination results for the follow-up sputum samples sent. The results were dated 5-11-01. Both samples were negative. The Laboratory number was 622. On 9 November Raj weighed 51 kg. Record this information on the front of his card.

On 10 November, Raj began the continuation phase of treatment. The drug regimen is 3 times weekly. He agreed with the health worker that he would come to the health centre on Monday, Wednesday and Friday each week for directly observed treatment.
11 November was Sunday.
Received directly observed treatment on 12 November.
He did not come on Wednesday 14 November, but came on 15 and 16 November.
18 November was Sunday.
Received directly observed treatment on 19, 21, 23 November.
25 November was Sunday.
Received directly observed treatment on 26, 28, 30 November.

2 December was Sunday.
Received directly observed treatment on 3 December.
Did not come for treatment on 5 or 7 December.
9 December was Sunday.
Received directly observed treatment on 10, 12, 14 December.
16 December was Sunday.
Received directly observed treatment on 17, 19 and 21 December.
On 21 December, he told the health worker that he would be going to visit his brother for the holidays next week, so the health worker gave him 3 doses to take next week.
23 December was Sunday.
30 December was Sunday.
Received directly observed treatment on 31 December.

Received directly observed treatment on 2 and 4 January 2002.

When you have finished marking the *TB Treatment Card*, review your work with a facilitator. Also write answers to the questions on the next page in preparation for a group discussion.

Discussion

Write answers to the questions below. When everyone is ready, there will be a group discussion of these questions.

a) How many more doses does Raj Makena need to take to complete the continuation phase of treatment? (Hint: Subtract the number of doses that Raj Makena has already taken from the total doses needed in the continuation phase.)

b) A health worker was very busy and a queue of people were waiting. The health worker recognized a TB patient, Mary Abatu, and did not want to keep her waiting long. He signalled to Mary to come ahead of the queue and handed her the day's tablets. He said to take the tablets home and swallow them when she found something to drink.

What could happen to those tablets? (List 5 different possibilities.)

*

*

*

*

*

c) What should the health worker have done when handing the tablets to Mary?

d) If a TB patient does not take the anti-TB drugs correctly or on schedule over a period of time, what might be the consequences?

After the discussion, GO BACK to page 31.
Read to the next stop sign (page 40).

TUBERCULOSIS TREATMENT CARD

Name Raj Makena — District TB No. 1261

Complete address 11 Market Place, Aruna — Health facility Cochan Health Centre

Sex: M ☑ F ☐ Age 28

Name and address of community treatment supporter (if applicable) _____

Disease site
Pulmonary ☑ Extrapulmonary ☐ (specify) _____

Type of patient
New ☑ Treatment after failure ☐
Relapse ☐ Treatment after default ☐
Transfer in ☐ Other (specify) ☐ _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☑ 3 times/week ☐

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	CAT II	CAT III	CAT IV
New case ☑ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ☐	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
3			
HR Z E[S]	HR Z E S	HR Z E	

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0	30/8	+	560	53

Tick appropriate box after the drugs have been administered

Drugs given to supporter

MONTH \ DAY	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	Number doses this month	Total number doses given
Sept			✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	0	0	0	✓	✓	–	✓	✓	✓	✓	✓	✓	–	/	21	21
Oct	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	—	—	—	—	✓	✓	–	✓	✓	✓	✓	✓	✓	–					

DATE	DOSES

Please turn over for continuation phase

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☐ 3 times/week ☑

Tick category:

CAT I
New case ☑
(smear-positive, or seriously ill smear-negative or EP)

Indicate number of tablets per dose:

[3] (4 months)
HR
or
[ ] (6 months)
HE

CAT II
Re-treatment ☐

[ ][ ] (5 months)
HR E

CAT III
New case ☐
(smear-negative or EP)

[ ] (4 months)
HR
or
[ ] (6 months)
HE

CAT IV
Chronic or MDR-TB ☐

[ ][ ][ ][ ]

MONTH \ DAY	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	Number doses this month	Total number doses given

Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

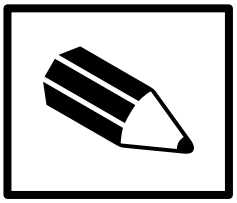
21 Sept - visited Raj at home - has been sick. Gave treatment.
13 Oct - going to brother's - gave Raj 4 doses for 15-18 Oct.

Name and address of contact person Sajir Gondar, Circle Road behind Government House, Aruna

Treatment outcome

Date of decision _____

Cure ☐
Treatment completed ☐
Treatment failure ☐
Died ☐
Default ☐
Transfer out ☐



Exercise D

Written Exercise – Follow-up sputum smear examinations

This exercise has two parts. In Part I, you will decide when each TB patient is due for the next follow-up sputum smear examination. In Part II, you will decide on the action to take for each patient based on sputum smear examination results. You may refer to the schedule for follow-up sputum smear examinations in the module on page 41, or in the *Reference Booklet*.

PART I

Case 1: Adesa Abkar

Adesa Abkar is on Category I treatment. Because her sputum smear examination after 2 months was still positive, the health worker gave her one more month of the initial phase of treatment (Category I). Now she is in the third month of treatment. When should she have the next sputum smear examination?

Case 2: Marcus Marin

This patient is on Category II treatment. He completed 3 months of the initial phase of treatment and the sputum smear examination was negative. He had another examination at 5 months which was also negative. When is he due for a next sputum smear examination?

Case 3: Raj Makena

Raj is on Category I treatment. His sputum smear examination at 2 months was negative. When is he due for the next sputum smear examination?

Case 4: Janu Nair

Review this patient's *TB Treatment Card* on the next page. When is he due for the next sputum smear examination? (give an approximate date)

TUBERCULOSIS TREATMENT CARD

Name Janu Nair — District TB No. 1386

Complete address 45 College Street, Aruna — Health facility Cochan Health Centre

Sex: M ☑ F ☐ Age 56

Name and address of community treatment supporter (if applicable) _____

Disease site
Pulmonary ☑ Extrapulmonary ☐ (specify) _____

Type of patient
New ☐ Treatment after failure ☐
Relapse ☐ Treatment after default ☑
Transfer in ☐ Other (specify) ☐ _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☑ 3 times/week ☐

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	CAT II	CAT III	CAT IV
New case ☐ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ☑	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
HR Z E [S]	3 (HR Z E) 0.75g S	HR Z E	

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Stop S after 56 doses

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0	12.10.01	+	653	42
3	28.1.02	neg	819	42

Tick appropriate box after the drugs have been administered

Drugs given to supporter

MONTH \ DAY	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	Number doses this month	Total number doses given	DATE	DOSES
October																✓	✓	✓	✓	✓	–	✓	✓	✓	0	✓	✓	–	✓	✓	✓	13	13		
November	✓	✓	0	–	✓	✓	✓	0	✓	0	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	23	36		
December	0	–	✓	✓	✓	✓	✓	0	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	0	0	✓	✓	✓	✓	–	✓	22	58		
January	0	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	0	✓	–	✓	✓	✓	✓	25	83		
February	✓																															1	84		

Please turn over for continuation phase

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ☐ 3 times/week ☑

Tick category:	CAT I	CAT II	CAT III	CAT IV
	New case ☐ (smear-positive, or seriously ill smear-negative or EP)	Re-treatment ☑	New case ☐ (smear-negative or EP)	Chronic or MDR-TB ☐
Indicate number of tablets per dose:	☐ (4 months) HR or ☐ (6 months) HE	3 3 (5 months) (HR) E	☐ (4 months) HR or ☐ (6 months) HE	☐☐☐☐

MONTH \ DAY	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	Number doses this month	Total number doses given
February			–	✓		✓		✓		–	✓		0		✓		–	✓		✓		0		–	✓		✓		/	/	/	9	9
March	✓		–	✓		✓		✓		–	0		✓		✓		–	0		✓		✓		–	✓		✓		✓		–	11	20
April																																	
May																																	
June																																	

Enter ✓ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

Gave last dose of streptomycin on 28 Dec

Name and address of contact person Jair Prabakar (grocery), 39 College St, Aruna

Treatment outcome
Date of decision _____
Cure ☐
Treatment completed ☐
Treatment failure ☐
Died ☐
Default ☐
Transfer out ☐

PART II

Decide on the action to take for each patient based on sputum smear examination results.

Case 1: Adesa Abkar (Category I)

Below are the sputum smear examination results from this patient's *TB Treatment Card*.

Results of sputum examination				Weight
Month	Date	Smear	Lab. No.	**(kg)**
0	*28/8/01*	*+++*	*497*	*48*
2	*25/10/01*	*+*	*581*	*49*
3	*24/11/01*	*neg*	*687*	*49*
5	*28/1/02*	*+*	*67*	*49*

What is the appropriate action for this patient now? Explain what the health worker should do and why.

Case 2: Marcus Marin (Category II)

The results of Marcus Marin's sputum smear examinations at 5 months and in the eighth month were negative. What is the appropriate action for this patient now? Explain what the health worker should do now.

Case 3: Raj Makena (Category I)

The results of Raj's sputum smear examination at 5 months were negative. What is the appropriate action for this patient now?

When should he get another sputum smear examination?

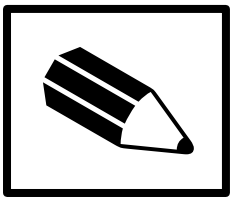
Case 4: Janu Nair (Category II)

The results of Janu's sputum smear examination at 5 months were negative. What is the appropriate action for this patient now?

When should he get another sputum smear examination?

When you have finished this exercise, review your answers with a facilitator.

Then GO BACK to page 42. Read to the next stop sign (page 46).



Exercise E

Written Exercise – Decide treatment outcome

In this exercise you will decide and record the treatment outcomes of the same patients.

Case 1: Adesa Abkar (Category I)

In the previous exercise, you found that Adesa Abkar had a positive sputum smear examination after 5 months of treatment (date of sputum examination 28/1/02), and was therefore a treatment failure.

Record the date and treatment outcome on the excerpt of her *TB Treatment Card* below:

Treatment outcome

Date of decision: _____

Cure ❒
Treatment completed ❒
Died ❒
Treatment failure ❒
Default ❒
Transfer out ❒

Case 2: Marcus Marin (Category II)

Marcus Marin completed 8 months of Category II treatment on 9 May. Below are his sputum smear examination results.

Results of sputum examination				**Weight**
Month	Date	Smear	Lab. No.	**(kg)**
0	*23/8/01*	*++*	*489*	*56*
3	*29/11/01*	*neg*	*699*	*58*
5	*30/1/02*	*neg*	*77*	*58*
8	*7/5/02*	*neg*	*401*	*59*

Record the date and treatment outcome on the excerpt of his *TB Treatment Card* below:

Treatment outcome

Date of decision: _____

Cure ❒
Treatment completed ❒
Died ❒
Treatment failure ❒
Default ❒
Transfer out ❒

Case 3: Raj Makena (Category I)

Raj completed 6 months of Category I treatment on 5 March 2002. Below are his sputum smear examination results.

Results of sputum examination				Weight
Month	Date	Smear	Lab. No.	**(kg)**
0	*30-8-01*	*+*	*506*	*53*
2	*1-11-01*	*neg*	*622*	*51*
5	*1-2-02*	*neg*	*111*	*52*

Record the date and treatment outcome on the excerpt of his *TB Treatment Card* below:

Treatment outcome

Date of decision: _____

Cure ❒
Treatment completed ❒
Died ❒
Treatment failure ❒
Default ❒
Transfer out ❒

Case 4: Janu Nair (Category II)

Below are Jaun's sputum smear examination results. The last date that he came for treatment was 25 April 2002. When the health worker went to his home a couple of weeks later, the apartment was vacant. The contact person, the grocer, told the health worker that the family had moved away. The grocer reported that Janu said that he had finished the TB treatment. The grocer does not know where they moved.

Results of sputum examination				Weight
Month	Date	Smear	Lab. No.	**(kg)**
0	*12-10-01*	*+*	*653*	*52*
3	*16-1-02*	*neg*	*39*	*52*
5	*18-3-02*	*neg*	*252*	*53*

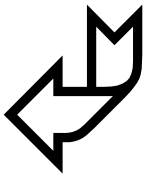
Record the date and treatment outcome on the excerpt of Janu's *TB Treatment Card* below:

Treatment outcome

Date of decision: _____

Cure ❒
Treatment completed ❒
Died ❒
Treatment failure ❒
Default ❒
Transfer out ❒

When you have completed this exercise, review your answers with a facilitator.



Then GO BACK to page 47. Read and work to the end of the module (page 57).

Annexes

TUBERCULOSIS TREATMENT CARD

Name _____ District TB No. _____

Complete address _____ Health facility _____

Sex: M ❑ F ❑ Age _____

Name and address of community treatment supporter (if applicable) _____

_____

Disease site

Pulmonary ❑ Extrapulmonary ❑ (specify) _____

Type of patient

New ❑ Treatment after failure ❑

Relapse ❑ Treatment after default ❑

Transfer in ❑ Other (specify) ❑ _____

I. INITIAL PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ❑

Tick category and indicate number of tablets per dose and dosage of S (grams):

CAT I	CAT II	CAT III	CAT IV
New case ❑ (smear-positive, or seriously ill smear-negative, or EP)	Re-treatment ❑	New case ❑ (smear-negative or EP)	Chronic or MDR-TB ❑
HR Z E [S]	HR Z E S	HR Z E	

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

Results of sputum examination				Weight (kg)
Month	Date	Smear	Lab. No.	
0				

Tick appropriate box after the drugs have been administered

Drugs given to supporter

MONTH \ DAY	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	Number doses this month	Total number doses given	DATE	DOSES

Please turn over for continuation phase

II. CONTINUATION PHASE — Prescribed regimen and dosages

Tick frequency: Daily ❑ 3 times/week ❑

Tick category:

CAT I
New case ❑
(smear-positive, or seriously ill smear-negative or EP)

CAT II
Re-treatment ❑

CAT III
New case ❑
(smear-negative or EP)

CAT IV
Chronic or MDR-TB ❑

Indicate number of tablets per dose:

CAT I: ☐ (4 months) HR
or
☐ (6 months) HE

CAT II: ☐☐ (5 months) HR E

CAT III: ☐ (4 months) HR
or
☐ (6 months) HE

CAT IV: ☐☐☐☐

MONTH \ DAY	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	Number doses this month	Total number doses given

Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line (———) through the number of days' supply given.

Observations:

_____

_____

_____

_____

Name and address of contact person _____

Treatment outcome

Date of decision _____

Cure ❑
Treatment completed ❑
Treatment failure ❑
Died ❑
Default ❑
Transfer out ❑

Recommended regimens for each treatment category

TB treatment category	TB patients	TB treatment regimens			
		Initial phase [a]		Continuation phase [a]	
		Daily (28 doses per month)	3 times per week (12 doses per month)	Daily (28 doses per month)	3 times per week (12 doses per month)
I	New smear-positive patients; New smear-negative PTB with extensive parenchymal involvement; Severe concomitant HIV disease or severe forms of extrapulmonary TB	**2 (HRZE)** [b] = 56 doses of HRZE	**2 $(HR)_3Z_3E_3$** = 24 doses of HRZE	**4 (HR)** = 112 doses of HR **or** **6 (HE)**[c] = 168 doses of HE	**4 $(HR)_3$** = 48 doses of HR
II	Previously treated sputum smear-positive PTB: - relapse; - treatment after default; - treatment after failure.	**2 (HRZE)S/ 1 (HRZE)** = 84 doses of HRZE plus 56 doses of S		**5 (HR)E** = 140 doses of HRE	**5 $(HR)_3E_3$** = 60 doses of HRE
III	New smear-negative PTB (other than in Category I) and less severe forms of extrapulmonary TB.	**2 HRZE** [d] = 56 doses of HRZE	**2 $(HR)_3Z_3E_3$** = 24 doses of HRZE	**4 (HR)** = 112 doses of HR **or** **6 (HE)**[c] = 168 doses of HE	**4 $(HR)_3$** = 48 doses of HR
IV	Chronic and MDR-TB cases (still sputum smear-positive after supervised re-treatment)	Specially designed standardized or individualized regimens are suggested for this treatment category			

[a] Direct observation of drug intake is required during the initial phase of treatment in smear-positive cases, and always in treatment including rifampicin.

[b] Streptomycin may be used instead of ethambutol. In TB meningitis, ethambutol should be replaced by streptomycin.

[c] This regimen may be associated with a higher rate of treatment failure and relapse compared with the 6-month regimen with rifampicin in the continuation phase.

[d] Ethambutol may be omitted in the initial phase of treatment for patients with non-cavitary, smear-negative pulmonary TB who are known to be HIV-negative; patients who are known to be infected with fully drug-susceptible bacilli; and young children with primary TB.

Annex B

Recommended dosages of anti-TB drugs

Drug (with abbreviation)	**Recommended dosage**		**Presentations**
	Daily	3 times per week	
isoniazid (H)	4 – 6 mg/kg	8 – 12 mg/kg	100 mg or 300 mg tablets
rifampicin (R)	8 – 12 mg/kg	8 – 12 mg/kg	150 mg or 300 mg tablets
pyrazinamide (Z)	20 – 30 mg/kg	30 – 40 mg/kg	400 mg tablets
ethambutol (E)	15 – 20 mg/kg	25 – 35 mg/kg	100 mg or 400 mg tablets
streptomycin (S)	12 – 18 mg/kg	12 – 18 mg/kg	Vial 1g (IM)

Available presentations of fixed-dose combinations

Fixed-dose combinations	**Presentations (combination tablets)**	
	For daily administration	For administration 3 times per week
isoniazid + rifampicin (HR)	(H 150 mg + R 300 mg), or (H 75 mg + R 150 mg), or (H 30 mg + R 60 mg)*	(H 150 mg + R 150 mg), or (H 60 mg + R 60 mg)*
isoniazid + ethambutol (HE)	(H 150 mg + E 400 mg)	NA
isoniazid + thioacetazone (HT)	(H 300 mg + T 150 mg), or (H 100 mg + T 50 mg)*	NA
isoniazid + rifampicin + pyrazinamide (HRZ)	(H 75 mg + R 150 mg + Z 400 mg), or (H 30 mg + R 60 mg + Z 150 mg)*	(H 150 mg + R 150 mg + Z 500 mg)
isoniazid + rifampicin + pyrazinamide + ethambutol (HRZE)	(H 75 mg + R 150 mg + Z 400 mg + E 275 mg)	NA

* *for children*

Collect sputum for examination

- **Explain** that the TB suspect needs a sputum examination to determine whether there are TB bacilli in the lungs.

- **List** the TB suspect's name and address in the *Register of TB Suspects.*

- **Label** sputum containers (not the lids).
  - — 3 samples are needed for diagnosis of TB.
  - — 2 samples are needed for follow-up examination.

TB SPECIMEN
Name: _____
Health facility: _____
Date: _____
Specimen no. _____

- **Fill out *Request for Sputum Examination* form.**

- **Explain and demonstrate, fully and slowly, the steps to collect sputum.**
  - Show the TB suspect how to open and close the container.
  - Breathe deeply and demonstrate a deep cough.
  - The TB suspect must produce sputum, not only saliva.
  - Explain that the TB suspect should cough deeply to produce sputum and spit it carefully into the container.

- **Collect**
  - Give the TB suspect the container and lid.
  - Send the TB suspect outside to collect the sample in the open air if possible, or to a well-ventilated place, with sufficient privacy.
  - When the TB suspect returns with the sputum sample, look at it. Is there a sufficient quantity of sputum (not just saliva)? If not, ask the TB suspect to add some more.
  - Explain when the TB suspect should collect the next sample, if needed. (See schedule below.)

Schedule for collecting three sputum samples

Day 1:
- Collect "on-the-spot" sample as instructed above (**Sample 1)**.
- Instruct the TB suspect how to collect an early morning sample tomorrow (first sputum after waking). Give the TB suspect a labelled container to take home. Ask the TB suspect to bring the sample to the health facility tomorrow.

Day 2:
- Receive early morning sample from the TB suspect (**Sample 2**).
- Collect another "on-the-spot" sample (**Sample 3**).

- **When you collect the third sample, tell the TB suspect when to return for the results.**

- **Store**
  - Check that the lid is tight.
  - Isolate each sputum container in its own plastic bag, if possible, or wrap in newspaper.
  - Store in a cool place.
  - Wash your hands.

- **Send**
  - Send the samples from health facility to laboratory.
  - Total time from collection until reaching laboratory should be no more than 5 days.

Periodic follow-up visit to clinician

(Summary for clinicians)

A clinician or other trained higher level worker in a health facility or hospital should conduct a periodic clinical evaluation of TB patients to monitor progress. This visit of the TB patient to the clinician should be made when results are available from a recent follow-up sputum examination, so that the results can be discussed with the patient.

This visit should include the steps below.

- Assess the patient's general condition. If the patient has difficulty breathing or is acutely ill, first assess and classify the illness. Refer if necessary for serious conditions. Treat the acute illness, if mild.

- Weigh the patient.

- Review the drugs that the patient is taking. Examine the patient's *TB Treatment Card* and ask the patient about the drugs actually taken. Ask about symptoms and side-effects. If the patient is experiencing side-effects, manage them appropriately. This may include reassuring a patient who has minor side-effects.

- Reinforce important information on TB and its treatment. Encourage the patient to ask questions. Answer any questions the patient may have about the disease or treatment and discuss any fears or concerns.

- Review the result of any recent sputum examination. Explain it to the patient in simple terms. If any change in treatment is needed, prescribe it according to usual procedures (so that the health facility staff will know what to do.) Explain the change to the patient.

- Assess whether the patient is improving. If the patient has weight loss, other signs of disease, or poor clinical progress, consider other causes (such as HIV) and give appropriate treatment or refer if needed.

  Be familiar with the most frequent associated diseases and other problems of patients with TB in the area and how to manage them. In an area of high HIV prevalence, the initial medical history should obtain information to assess HIV risk factors. If a patient is known to be HIV-positive, give additional support and follow-up to identify and treat opportunistic infections. The possible impact of HIV on TB treatment includes delayed sputum smear conversion, increased mortality, and drug side-effects.

- Motivate the patient to take the treatment regularly. Praise the patient for successfully taking the treatment so far, and give the patient support for continuing the treatment. Do not blame the patient when there are problems with compliance. This can discourage patients and cause default. One of the biggest problems in TB control is the negative attitude of health workers toward patients. If there are any problems with continuing the treatment, work with the patient to overcome the problems. Changing the treatment supporter is sometimes a solution.