

Management of Tuberculosis Training for Health Facility Staff

C. Treat TB Patients

SECOND EDITION



WORLD HEALTH ORGANIZATION
Geneva



TUBERCULOSIS FOUNDATION

**Management of Tuberculosis
Training for Health Facility Staff**



TREAT TB PATIENTS

SECOND EDITION



**World Health Organization
Geneva
2009**



K N C V



TUBERCULOSIS FOUNDATION



WHO Library Cataloguing-in-Publication Data

Management of tuberculosis: training for health facility staff -- 2nd ed.

Contents: Modules: A: Introduction - B: Detect Cases of TB - C: Treat TB Patients - D: Inform Patients about TB - E: Identify and Supervise Community TB Treatment Supporters - F: Manage Drugs and Supplies for TB - G: Ensure Continuation of TB Treatment - H: Monitor TB Case Detection and Treatment - I: TB Infection Control in your Health Facility - J: Field Exercise – Observe TB Management - K: Management of Tuberculosis – Reference Booklet - L: Facilitator Guide - M: Answer Sheets.

1.Tuberculosis, Pulmonary - therapy 2.Health personnel - education 3.Health facilities 4.Teaching materials I.World Health Organization.

ISBN 978 92 4 159873 6

(NLM classification: WF 210)

© World Health Organization 2010

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

WHO/HTM/TB/2009.423c

Treat TB Patients

Contents

	Page
Introduction.....	1
Objectives of this module	2
1. Initiate treatment of a TB patient	3
1.1 Choose the appropriate treatment regimen for the patient	3
1.1.1 Determine the disease site from the results of sputum smear examination and/or a clinician's diagnosis	3
1.1.2 Determine the type of patient by asking whether the patient has previously taken any anti-TB drugs	4
1.1.3 Assess the likelihood that the patient may have MDR-TB	5
1.1.4 Determine the patient's HIV status and ask about any drug therapy	6
1.1.5 Select the correct TB treatment regimen or refer to a clinician for prescription of an anti-TB regimen.....	7
1.2 Help the patient decide where to receive directly-observed treatment	11
1.3 Prepare the patient's <i>TB Treatment Card</i>	12
1.3.1 Record general patient information	14
1.3.2 Record disease site and type of patient	14
1.3.3 Record results of diagnostic sputum examination, the patient's weight, and results of culture and/or chest X-ray (if done)	15
1.3.4 Record who referred the patient for diagnosis or treatment of TB	17
1.3.5 Record information on HIV testing	18
1.3.6 Record TB treatment regimen and dosage for the initial phase	18
1.3.7 Record TB treatment regimen and dosage for the continuation phase.....	26
1.3.8 Record additional information for an HIV-positive TB patient	26
1.3.9 Complete household contacts box	28
1.4 Inform the patient and family about TB and its treatment.....	29
1.5 If needed, identify and prepare a community TB treatment supporter	30
1.6 Obtain or prepare a drug box for the patient.....	30
1.7 Prepare a <i>Tuberculosis Identity Card</i> for the patient	31
2. Give preventive therapy, and immunization if needed, to household contacts of the TB patient.....	32
2.1 Give preventive therapy to household contacts	32

2.2	Give BCG immunization to household contacts, if needed	33
3.	Treat the patient during the entire period of treatment.....	34
3.1	Directly observe treatment and record it on the <i>TB Treatment Card</i>	34
3.1.1	Mark the <i>TB Treatment Card</i> in the initial phase.....	35
3.1.2	Mark the <i>TB Treatment Card</i> in the continuation phase	36
3.2	If the patient has side-effects, give advice or refer	38
3.3	Continue providing information about TB	40
3.4	(If applicable) Monthly, review the community TB treatment supporter's copy of the <i>TB Treatment Card</i> and provide the next month's supply of drugs	41
4.	Monitor progress of treatment	42
4.1	Determine when the patient is due for follow-up sputum examinations	42
4.2	Collect sputum for follow-up examination	43
4.3	If a patient was HIV-negative, recommend HIV testing at the end of the initial phase	43
4.4	If a patient is HIV-positive, update the information on the <i>TB Treatment Card</i> about HIV care.....	43
4.5	Record results of sputum smear microscopy examination	45
4.6	Decide on appropriate action needed.....	46
4.6.1	Assess treatment progress at the end of the initial phase	46
4.6.2	Use sputum examination results at 5 months to assess effectiveness of treatment	47
4.6.3	Record results from sputum culture and DST, if received	47
4.7	Monitoring progress of treatment by follow-up sputum microscopy: summary of schedule.....	48
4.8	Implement treatment decisions	51
4.8.1	When the patient will begin the continuation phase of treatment	51
4.8.2	If and when culture and DST results are received.....	51
4.8.3	If the patient fails treatment.	52
5.	At the end of treatment, record the outcome on the <i>TB Treatment Card</i>	53
	Summary of important points	56

Self-assessment questions	59
Answers to self-assessment questions	65
Exercises	69
Exercise A	71
Exercise B	77
Exercise C	87
Exercise D	93
Exercise E	97

Annexes

A: <i>TB Treatment Card</i>	103
B: <i>Tuberculosis Identity Card</i>	105
C: Recommended treatment regimens	106
Recommended dosages of anti-TB drugs	107
Available presentations of fixed-dose combinations	107
D: Collect sputum for examination	108
E: Periodic follow-up visit to a clinician	109

List of figures

Figure 1: Definitions of type of TB patient	5
Figure 2: Selecting a treatment regimen	8
Figure 3: How to read the drug code for anti-TB treatment regimens	19
Figure 4: Standard number of doses for phases of different duration	20
Figure 5: Recommended TB treatment regimens	21
Figure 6: Anti-TB drug treatment in special situations	25
Figure 7: Give preventive therapy with isoniazid to TB contacts aged less than 5 years	32
Figure 8: How to directly observe anti-TB treatment	34
Figure 9: Marking the <i>TB Treatment Card</i>	36
Figure 10: Side-effects of anti-TB drugs and their management	38
Figure 11: Side-effects in patients on simultaneous anti-TB treatment and ART	39
Figure 12: Schedule for follow-up sputum examinations	49
Figure 13: Actions based on result of follow-up sputum examination	50
Figure 14: Definitions of treatment outcomes	53

Acknowledgements

Management of Tuberculosis: Training for Health Facility Staff, 2nd ed.

This second edition of training modules was prepared by the Stop TB Department of the World Health Organization (Geneva, Switzerland) and Patricia Whitesell Shirey of ACT International (Atlanta, GA, USA). The project was coordinated by Karin Bergstrom. Fabio Luelmo and Malgorzata Grzemska were the main technical advisers. The modules were edited by Karen Ciceri. Natacha Barras provided administrative support and coordinated the layout and printing of the modules.

The following organizations contributed to the development of the modules through the Tuberculosis Control Assistance Program (TB-CAP): the American Thoracic Society (ATS), Management Sciences for Health (MSH), the United States Centers for Disease Control and Prevention (CDC), and the KNCV Tuberculosis Foundation.

The original versions of the training modules (published by the World Health Organization in 2003) were field-tested in Malawi through the support of the National Tuberculosis Control Programme of Malawi.

This updated version was tested through the support of the Division of Tuberculosis Elimination of the United States Centers for Disease Control and Prevention.

The United States Agency for International Development financially supported the development of these training modules through its Grant to the World Health Organization and through the sub-agreement to WHO of the Cooperative Agreement with the KNCV Tuberculosis Foundation for the Tuberculosis Control Assistance Program (TB-CAP).

Treat TB Patients

Introduction

Module B: *Detect Cases of TB* described how to identify TB suspects and determine whether they have TB. This module C describes how to treat TB patients. Treatment for TB 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 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 minimal 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 another TB treatment supporter in the community to watch each patient swallow the drugs. This **directly-observed treatment** (also known as fully supervised 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.

Directly-observed treatment allows the health worker to know immediately if treatment is interrupted and to 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 its treatment.

The effect of 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 regimen or refer to a clinician for prescription of treatment.
- Help the patient decide where to receive directly-observed treatment.
- Prepare the patient's *TB Treatment Card*.

- Inform the patient and family about TB, transmission of the disease, risk factors and treatment.
- Help the patient to choose a community TB treatment supporter (if needed); and prepare the community treatment supporter.
- Obtain or prepare a drug box for the patient.
- Prepare a *Tuberculosis Identity Card* for the patient to keep.
- Give preventive treatment to household contacts of the TB patient as appropriate.

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

Objectives of this module

Participants will learn:

Refer to section:

- | | |
|---|----------|
| • How to choose the appropriate TB treatment regimen or decide to refer the patient to a clinician for prescription of anti-TB treatment | 1.1 |
| • How to help the patient decide where to receive directly-observed treatment | 1.2 |
| • How to prepare a patient's <i>TB Treatment Card</i> , including recording diagnostic results, HIV testing and drug therapy, and the TB treatment regimen and dose | 1.3 |
| • How and when to provide preventive therapy for household contacts of the TB patient | 1.3.9, 2 |
| • How to give directly-observed treatment and record it on the <i>TB Treatment Card</i> | 3.1 |
| • How to recognize side-effects and manage them | 3.2 |
| • How to determine when a patient is due for follow-up sputum examination | 4.1, 4.7 |
| • How to decide, based on sputum smear microscopy, the action needed | 4.6, 4.8 |
| • How to determine treatment outcomes | 5 |

Note: This module outlines some of the steps involved in treating TB patients. More detail is provided in the following modules:

- Providing information about TB to the patient and the family is taught in module D: *Inform Patients about TB*.

- Helping a patient to choose a community TB treatment supporter and preparing the 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 TB treatment regimen for the patient

You may be able to select the TB treatment regimen for the patient or you may need to refer the patient to a clinician for prescription of anti-TB treatment. This decision depends on:

- whether the patient is a new case of TB, or whether the patient was previously treated for TB and, if so, the outcome of the previous course of treatment, and
- the likelihood that the patient may have MDR-TB

Begin by determining the following information that is needed to register a TB patient:

- disease site
- type of patient
- results of sputum smear microscopy examination
- HIV status, and
- if HIV-positive, current HIV care.

Your country has determined a standardized regimen for each of the defined patient groups: new TB cases, previously treated cases, and MDR-TB cases.

1.1.1 Determine the disease site from the results of sputum smear microscopy 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 previously taken any anti-TB drugs

The six possible “types” of TB patients are based on their treatment history, as shown in Figure 1. To determine the type of patient, first 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 TB?**
- **Have you ever taken injections for more than 1 or 2 weeks? Why?**
- **Have you ever taken a medicine that turned your urine orange or red?**

It is critical to determine whether a patient has previously been treated for TB. Previously treated patients may have acquired drug resistance and may therefore need a different treatment regimen than that for new patients. Regimens differ in type and strength of drugs as well as length of treatment. The regimen for new patients may 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 or 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 previously treated patients. The previously treated patient needs a stronger regimen to be cured than a new patient.

If a patient was previously treated for TB, ask about the outcome of that treatment. Ask to see any documentation that the patient may have, such as a *Tuberculosis Identity Card*. Ask:

- **For how many months did you take treatment?**
- **Did you complete the TB treatment or did you stop before completing it?**
 - If the patient stopped, **how long ago did you stop?**
 - If the patient completed treatment, **did the health staff tell you that you were cured?**
- **Did a health worker tell you that your treatment did not work, or that it failed?**

From the patient’s answers determine the **type of TB patient**.

Figure 1: Definitions of type of TB patient

Type of TB patient		Definition
New		A patient who has never had treatment for TB or who has taken anti-TB drugs for less than 1 month
Previously treated	Relapse	A patient previously treated for TB, declared cured or treatment completed, who is diagnosed with bacteriologically positive TB (by sputum smear microscopy or culture)
	Treatment after failure	A patient who is started on a retreatment regimen after having failed previous treatment
	Treatment after default	A patient who returns to treatment, positive bacteriologically, following interruption of treatment for 2 or more consecutive months
	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, such as patients for whom it is not known whether they have been previously treated. Also patients who were previously treated but for whom the outcome of their previous treatment is unknown, and/or patients who have returned to treatment with smear-negative pulmonary TB or bacteriologically-negative extrapulmonary TB.

1.1.3 Assess the likelihood that the patient may have MDR-TB

Previous treatment for TB is a strong determinant of drug resistance. Worldwide, approximately 15% of previously treated patients have resistance to multiple anti-TB drugs (or so-called multidrug-resistant TB [MDR-TB]). MDR-TB is critical to detect because the standard regimens with first-line drugs¹ are much less effective in treating it. If MDR-TB is not detected and not treated correctly with second-line drugs², MDR-TB patients will have poor treatment outcomes and spread MDR-TB in their communities.

WHO recommends that all previously treated TB patients should have specimens obtained for culture and drug susceptibility testing (DST) before or at the start of treatment. However, the laboratory capacity of each country will determine when or if DST results are available for deciding the best regimen for an individual patient. In most cases, a treatment regimen must be selected based on the presumed likelihood of MDR-TB for that patient. When DST results are received (days, weeks, or months later), if they indicate that a change in regimen is needed, the regimen can be modified at that time.³

¹ The first drug normally used to treat a particular condition. The standard regimens for new TB cases and retreatment cases use first-line drugs.

² A therapeutic agent that is not the drug of choice or the first drug normally used to treat a particular condition. Generally, second-line agents are used when standard “first-line” therapy fails. MDR-TB regimens use second-line drugs.

³ In settings where rapid DST is available, results are available within hours or days and should guide the choice of a treatment regimen. In settings where conventional DST provides results in weeks or months, WHO recommends the country’s standard MDR regimen for patient groups with high levels of MDR, and the standard Retreatment regimen with first-line drugs for patient groups with medium or low levels of MDR, until DST results are received. Where there is not yet laboratory capacity to

Many factors influence the level of MDR-TB in previously treated patients, and levels vary widely. Whether the different types of previously treated patients (default, relapse, failure) are presumed to have medium vs high likelihood of MDR-TB is decided by your national programme based on the best available data.

In most settings, a patient who has failed previous treatment has a high likelihood of MDR-TB. Patients who return to treatment after defaulting or because they have relapsed after one course of treatment have a low or medium likelihood of MDR-TB. However, patients who return to treatment after defaulting or because they have relapsed after a second or subsequent course of treatment have a high likelihood of MDR-TB.

Other factors affect the likelihood of MDR-TB. For example, a new case who is a contact of a known case of MDR-TB has a high likelihood of MDR-TB. Another very important factor affecting likelihood is the quality of a patient's previous anti-TB treatment.

To assess the likelihood of MDR-TB, ask the patient:

- **Has anyone in your family ever had TB or MDR-TB (no time limit)?**
- **If yes, what were the results of treatment?**

If the patient was treated for TB previously, ask:

- **By whom were you treated? Was this at a public clinic or by a private provider?**
- **Was your treatment taken regularly or was it "on and off"?**
- **How many drugs did you take?**
- **Where did you get the drugs? Did you have to purchase them?**

Listen to the patient's answers and assess whether any previous treatment was of good quality. If the patient took the drugs irregularly, had to purchase the drugs, took fewer drugs than recommended, received treatment from a private provider who may not have used a standard treatment regimen or used drugs of questionable quality, it is likely that the previous treatment created drug resistance. If you decide that the previous treatment seems to have been of poor quality, consider that the patient has a high likelihood of MDR-TB.

1.1.4 Determine the patient's HIV status and ask about any drug therapy

Ask the TB patient about his or her HIV status.

- **Do you know your HIV status?**
- **Do you have written documentation of the test result?**

HIV status should only be determined based on written documentation. Note that a negative HIV test result may be obsolete. If the TB patient tested HIV-negative more than 3 months ago, recommend another HIV test.

routinely conduct DST for each previously treated patient, it is urgent to strengthen laboratory capacity. As a temporary measure, a country may consider a short term policy to start the MDR regimen for patients in a group shown to have high levels of MDR, without confirmation of isoniazid and rifampicin resistance in the individual.

If the patient is HIV-positive, ask whether the patient is receiving drug therapy.

- **Are you receiving care for HIV?**
- **Are you on ART** (antiretroviral therapy)?
- **Are you taking daily co-trimoxazole** (known as co-trimoxazole preventive therapy or CPT)?

Ask for any written documentation that the patient has about HIV drug therapy, for example on an *HIV Care/ART Care Card*, and/or obtain information from the clinic providing HIV care.

Note that there may be problems in obtaining this information. A patient may not wish to reveal HIV status. An HIV clinic may not provide information because of limitations of confidentiality. The patient may not know the date that CPT or ART was begun. If the HIV care clinic is in a different location, you may not have a method or time available to contact the HIV clinic.

However, knowing the TB patient's HIV status is important for decisions about treatment, such as the need for ART and CPT. If a TB patient is on ART, this affects the choice of anti-TB drugs, and may affect the choice of treatment place and supporter. HIV status is also important for counselling and advice on TB and HIV regarding prognosis, side-effects and associated diseases.

1.1.5 Select the correct TB treatment regimen or refer to a clinician for prescription of an anti-TB regimen

There are three standard treatment regimens:

- New patient regimen
- Retreatment regimen
- MDR-TB regimen

When the health worker has detected TB based on positive sputum smear microscopy results (or if a clinician has diagnosed smear-negative pulmonary or extrapulmonary TB), a health worker may select the New patient regimen or Retreatment regimen for the patient and begin that treatment at the health facility. (The exception is when the patient is on ART.) However, a health worker cannot start treatment with the MDR-TB regimen; this requires diagnosis of MDR-TB by a clinician based on DST results or presumed risk of MDR-TB, and supply of a course of treatment with the second-line drugs (which are not stocked at first-level health facilities).



Consider the type of TB patient, the likelihood that the patient may have MDR-TB, HIV status⁴ and current HIV care to select the appropriate treatment regimen or to decide to refer the patient to a clinician. Your country has specified a standard regimen for defined patient groups.

Figure 2 summarizes how a health worker selects a treatment regimen based on the type of patient and history of previous treatment; the selected regimen is the same regardless of whether the disease is pulmonary or extrapulmonary and whether or not the smear or culture results are positive.

⁴ Note: Do not delay TB treatment if there is no HIV test result or while awaiting the result of an HIV test.

The table below indicates the appropriate treatment regimen for different patient groups.

Figure 2: Selecting a treatment regimen

If type of TB patient is: 		Then the likelihood of MDR-TB is: 	And the recommended regimen is:
New		Low ^a	New patient regimen: 2RHZE/4RH^b (Refer if on ART) ^c
Previously treated	Treatment after failure	High	Refer for MDR-TB regimen
	Treatment after default or Relapse after one course of treatment	Medium (or High if previous treatment was poor quality)	Retreatment regimen: 2RHZE/RHZE/5RHE (Refer if on ART; refer if pregnant) (If high, refer for MDR-TB regimen)
	Treatment after default or Relapse after second or subsequent course of treatment	High	Refer for MDR-TB regimen
Transfer in		Continue current treatment regimen	
Other		Estimate using best information available about the outcome of the patient's previous treatment	If low, New patient regimen If medium, Retreatment regimen If high, refer for MDR-TB regimen

^a Exception: if the patient is a contact of a known MDR-TB case, the likelihood of MDR-TB is high.

^b Some countries specify 4RHE in the continuation phase if the patient is HIV-positive or if resistance to isoniazid is high.

^c If the patient is already on ART, refer to a clinician for prescription of an anti-TB treatment regimen; the clinician should consider the possibility of interaction between ART and anti-TB drugs.

The **New patient regimen** (2RHZE/4RH) has an initial phase⁵ lasting 2 months and a continuation phase lasting 4 months. During the initial phase, consisting of 4 drugs, the tubercle bacilli are killed rapidly. 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) for 4 months. The sterilizing effect of the drugs eliminates any remaining bacilli and prevents relapse of the disease.

Because previously treated patients are more likely to have bacilli resistant to isoniazid or perhaps other drugs, the **Retreatment regimen** (2RHZE5/RHZE/5RHE) 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.

A patient with MDR-TB (TB resistant to at least isoniazid and rifampicin) receives a specially designed standardized or individualized **MDR-TB regimen** prescribed by a clinician. Treatment for MDR-TB consists of 18 months to 2 years of daily observed treatment with second-line drugs.

The HIV status of the TB patient does not change the treatment regimen. However, HIV-positive patients who are on ART should not be started on TB treatment at the first-level facility because there are potential problems with simultaneous ART and TB treatment that need to be considered (such as drug interactions and immune reconstitution inflammatory syndrome, or IRIS). A clinician may need to adjust the anti-TB or ART regimens. **Refer the TB patient who is on ART to a clinician for prescription of anti-TB treatment.**

Before selecting the treatment regimen, ask female TB patients whether they are or may be pregnant. Most anti-TB drugs are safe for use in pregnancy with the exception of streptomycin, which is part of the Retreatment regimen. If the woman is or may be pregnant, refer her to a clinician who can prescribe an appropriate anti-TB regimen.

As a health worker, you can select:

- A New patient regimen for a new TB case (unless the patient is already on ART)
- A Retreatment regimen for a previously treated patient who is a relapse, or return after default (unless the patient is on ART or is pregnant).

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

- A TB patient who has failed treatment
- Any TB patient who has a high likelihood of MDR-TB
- A TB patient who is on ART
- A TB patient who is or may be pregnant
- A child with suspected TB (remember that a paediatrician or second-level clinician will diagnose TB in a child and prescribe treatment.)

⁵ The initial phase of an anti-TB regimen is called the intensive phase in some WHO documents. There is no difference in "initial" and "intensive" phase; these modules use the term "initial" phase.



STOP

Now do Exercise A – Written Exercise

When you reach this point in the module, turn to Exercise A on page 71 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.

1.2 Help the patient decide where to receive directly-observed treatment

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.⁶

To assist the patient to decide where he or she will receive directly-observed treatment, discuss with the patient:

- the specific treatment needed (daily directly-observed treatment for 2 or 3 months in the initial phase, followed by directly-observed treatment either daily or 3 times weekly for 4 or 5 months in the continuation phase)
- whether the patient can come to a health facility each day.

Note: If a patient will be on the Retreatment regimen, a trained health worker must observe the treatment and give a daily streptomycin injection for the first 2 months of treatment. 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 a health facility each day***, a health worker at the health facility will directly observe treatment. This is the preferred option.
- ***If the patient could be treated more conveniently at a different facility*** (public or private) closer to the patient's home, refer the patient to that facility (prior to registration as a TB patient at your facility). Complete a *Tuberculosis Treatment Referral/Transfer*⁷ and send the patient to the other facility. Discuss the referral with the patient, describe the location of the facility that is expecting the patient, and stress the need to begin TB treatment without any delay.
- ***If the patient prefers not to come to a health facility each day***, explain to the patient that a community TB treatment supporter, that is, a community member, who volunteers and is trained for the job may provide directly-observed treatment. Explain that a community TB treatment supporter may observe treatment in the home, community or workplace. This treatment supporter will obtain the patient's drugs from the health facility, give the

⁶ One approach is to hospitalize the TB patient during the initial phase. However, hospitalization interferes with the patient's ability to continue work and to maintain the family, is more expensive and is no more effective in curing the disease than directly observed outpatient treatment.

⁷ How to use the *Tuberculosis Treatment Referral/Transfer* form is described in module G: *Ensure Continuation of TB Treatment*.

patient the tablets each day and observe as the patient swallows them, and record intake on the patient's *TB Treatment Card*.

If the patient needs a community TB treatment supporter, discuss possible locations and individuals. How to help the patient choose a suitable community TB treatment supporter and how to prepare the supporter for the job is described in step 1.5 below and in more detail in module E: *Identify and Supervise a Community TB Treatment Supporter*. Bear in mind that there are other types of supporters (for example, for HIV, breastfeeding) that may provide moral support and counselling; these fulfill different functions than a TB treatment supporter who provides directly-observed treatment.

If the patient is currently receiving HIV care, this may affect the selection of a TB treatment supporter. Note, however, that while an individual who is already providing support to the patient related to HIV care may be an acceptable TB treatment supporter as well, the individual will require additional training and supervision to perform the duties of a TB treatment supporter.

1.3 Prepare the patient's *TB Treatment Card*

The *TB Treatment Card* is the record of the patient's diagnosis and TB treatment. (Open the *TB Treatment Card* in Annex A or the *Reference Booklet* and refer to the card as you read this section.)

Whenever a patient is classified as having TB or is a TB patient transferred in from another health facility, open a *TB Treatment Card*. The example card on the next page is for a new 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.)

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 include directions on how to find the house).

Write the name of the health facility. If the patient will have a TB treatment supporter from the community, 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 the line blank.

The District TB Number (upper right corner of *TB Treatment Card*) is assigned by the District TB Coordinator 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. (This is a different person than the treatment supporter.)

If the patient will be hospitalized, fill in the top of the card, prepare a *Tuberculosis Referral/Transfer Form*⁸ 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 Figure 1 (page 5) for definitions of the six types of patients.

Example one:

Most commonly, you will check "Pulmonary" and "New."

Disease site (check one)
☒ Pulmonary ☐ Extrapulmonary, specify _____
Type of patient (check one)
☒ New ☐ Treatment after default
☐ Relapse ☐ Treatment after failure
☐ Transfer in ☐ Other

Example two:

Disease site (check one)
☐ Pulmonary ☒ Extrapulmonary, specify lymph nodes
Type of patient (check one)
☒ New ☐ Treatment after default
☐ Relapse ☐ Treatment after failure
☐ Transfer in ☐ Other

If extrapulmonary, also write the particular site of the disease.

⁸ 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, the patient's weight, and results of culture and/or chest X-ray (if done)

a) Record sputum microscopy results

Find the results of the sputum examination on the bottom part of the *Request for Sputum Examination* form. The laboratory technician records the result of examination of each specimen by ticking under NEG, or if positive, the appropriate positive (grading) column (to categorize the number of acid-fast bacilli present).

Example of laboratory results

REQUEST FOR SPUTUM SMEAR MICROSCOPY EXAMINATION							
<i>The completed form with results should be sent promptly by laboratory back to the referring facility</i>							
Referring facility ¹	Parma Health Centre			Date	8/5/09		
Name of patient	John Chweno			Age	33	Sex: <input checked="" type="checkbox"/> M <input type="checkbox"/> F	
Complete address	4352 Maso Road North Parma 23						
Reason for sputum smear microscopy examination:							
<input checked="" type="checkbox"/> Diagnosis							
OR <input type="checkbox"/> Follow-up Number of month of treatment: _____ District TB Register No. ² _____							
Name and signature of person requesting examination <u>AJ. Bwit</u>							
1. Including public or private health facility/providers 2. Be sure to enter the patient's District TB Register No. for follow-up of patients on TB treatment							
RESULTS (to be completed in the laboratory)							
Laboratory Serial No. <u>630</u>							
Date collected ³	Sputum Specimen	Visual appearance ⁴	RESULTS				
			NEG	(1-9)	(+)	(++)	(+++)
5/5	1	Muco-p			✓		
7/5	2	Muco-p				✓	
	3						
3. To be completed by the person collecting the sputum 4. Blood-stained, muco-purulent, or saliva							
Examined by <u>RJ. Namshaw</u>							
Date <u>9/5/09</u>		Signature <u>RJ. Namshaw</u>					

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 (obtain this date from the bottom of the laboratory form, recorded by the person who examined the sputum), the lab number, and the results. Under “Result,” record one of the following:

- If all results were negative, write NEG, or
- If any result was positive:⁹
 - 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 (adult or child’s) weight. This weight will determine drug dosages and will later be helpful to track the patient’s progress.

Example: Recording microscopy results and weight 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*:

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0	9/5/09	630	++	48

Record the date of the sputum examination.

Record only the highest grading of the positive smears.

b) Record a positive culture result for diagnosis of pulmonary or extrapulmonary TB (when available)

In areas where culture is done only occasionally¹⁰, when a positive culture result for diagnosis of pulmonary or extrapulmonary TB is received, you should record it on the *TB Treatment Card*. Record the date and result on the back of the card in the “Comments” section.

c) Record the date and results of a chest X-ray, if one was done as a part of the diagnostic process

⁹ 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 one or more positive sputum smears or by a clinician. Smear-negative pulmonary TB or extrapulmonary TB was diagnosed by a clinician.

¹⁰ In areas where culture is used routinely, there is a different set of forms that include specific boxes for recording culture results.

If a chest X-ray was done, read the notes from the clinician who read the X-ray to determine the result. Then find the box on the back of the *TB Treatment Card* and record the date and result of the chest X-ray. (This box is intended to record an X-ray done as part of diagnosis or at the beginning of treatment, not an X-ray that might be done later to monitor progress of treatment.)

Example: Recording chest X-ray on TB Treatment Card

Chest X-ray (at start)
Date: 2/5/09
(-) Normal <u>(+) Abnormal</u> ND Not done

The clinician may state clearly that the X-ray was normal or abnormal. However, the report may use different terms that require interpretation. If the notes say that the chest X-ray was clear, or negative (–), meaning that no evidence of TB was seen, circle *Normal* in the box. If the notes mention terms such as pathological, miliary, cavities, infiltrates, compatible with TB, or positive (+), this means that evidence of TB was seen in the X-ray. In this case, circle *Abnormal* in the box and copy any key words from the clinician’s notes.

If there was no X-ray, just circle ND (not done).

1.3.4 Record who referred the patient for diagnosis or treatment of TB

Ask the patient who referred him or her to the health facility, or suggested that he should come to the health facility for diagnosis of illness or for treatment of TB. If the patient himself decided to come, tick the box next to Self-referral. If a family or community member

Referral by: <input type="checkbox"/> Self-referral <input type="checkbox"/> Community member <input type="checkbox"/> Public facility <input checked="" type="checkbox"/> Private facility/provider: <u>Dr Pho, Town Center clinic 33-4354</u> <input type="checkbox"/> Other, specify: _____
--

made the suggestion, tick Community member. If another public facility (such as a smaller clinic, or an HIV clinic) referred the patient, tick Public facility. If a private facility (such as a mission clinic, private hospital) or a private provider referred the patient, tick Private facility/provider. Also record the name, address and/or telephone number of the private provider on the line so that it will be possible to send information about the patient back to

the provider. If another type of institution or provider referred the patient, tick “Other” and record who made the referral.

1.3.5 Record information on HIV testing

If the patient has documentation of an HIV test, or if results are available from an HIV test performed at the same time that sputum samples were collected, record the test date and results. All TB patients whose HIV status is unknown or who were previously HIV-negative should be tested for HIV. If there are results from more than one test, record only the most recent. If the test was not recommended, or if the patient declined the test, the test will be recommended again.

Record the most recent test date and result.

The second line is available in case the patient is tested again during the period of TB treatment.

TB/HIV		
	Date	Result*
HIV test	2/3/09	neg
HIV test		
CPT start		
ART start		

* (Pos) Positive; (Neg) Negative; (I) Discordant/Inconclusive; (ND) Not Done/unknown

1.3.6 Record TB treatment regimen and dosage for the initial phase

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) **Under Initial Phase, tick the appropriate regimen (New or Retreatment).**
(A TB patient who is prescribed the MDR regimen will need a different, specially designed *TB Treatment Card*.)

Example

I. INITIAL PHASE - prescribed regimen and dosages

Regimen: ☒ New ☐ Retreatment

Number of tablets per dose, doses per week, dosage of S:

(RHZE)	S

- b) **Look in your national TB manual for the specific drugs and dosages for the regimen.**

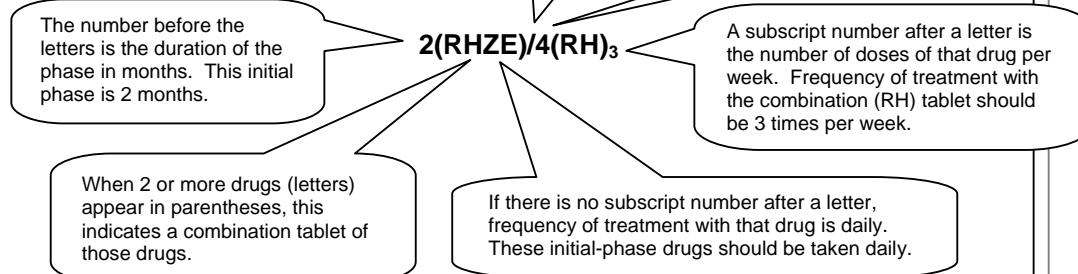
Anti-TB regimens are usually described using a standard code.

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:

rifampicin (R)
isoniazid (H)
pyrazinamide (Z)
ethambutol (E)
streptomycin (S)

Example one: A common regimen is written:



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

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

Example two: **2(RHZE)S/1(RHZE)/5(RH)₃E₃**

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

The continuation phase is 5 months. Drug treatment is with the FDC tablet (RH) given 3 times per week (subscript number ₃ after the letters) and ethambutol (E), also given 3 times per week.¹¹

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).

¹¹ If the FDC (RHE) is supplied, the regimen for the continuation phase is 5(RHE) given daily.

- 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	4 months = 48 doses
3 months = 84 doses	5 months = 60 doses
5 months = 140 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 56 doses for the phase.

Figure 5 shows the recommended regimens for new cases and for retreatment. (The examples in this module use these regimens.) Annex C 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.

Your national TB programme has determined the particular regimens that are effective and affordable in your country. Refer to your national TB manual for the regimens recommended in your country.

**Figure 5: Recommended TB treatment regimens
(by weight and using fixed-dose combination drugs)**

New patient regimen

Regimen Patient's weight (kg)	Initial phase (2 months)	Continuation phase (4 months)	
	2(RHZE)	4(RH) ₃	4(RH)
	Daily 56 total doses	3 times per week 48 total doses	Daily 112 total doses
	(rifampicin 150 mg + isoniazid 75 mg + pyrazinamide 400 mg + ethambutol 275 mg)	(rifampicin 150 mg + isoniazid 150 mg)	(rifampicin 150 mg + isoniazid 75 mg)
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

Retreatment regimen (for previously treated relapse and default)

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

* 750 mg for patients aged over 60 years

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

Referring to a table of recommended regimens (such as Figure 5 on page 21 or in your national TB manual), determine the drugs and the frequency recommended for the patient.

Under Initial Phase, tick the box for the patient's selected regimen (New or Retreatment). In the box below each drug abbreviation¹², 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 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.

Remember that an FDC is represented by placing the drug abbreviations within parentheses. (RHZE) in the example below shows that the tablet contains 4 drugs (R, H, Z and E). To record the regimen for this combination tablet, write the number of tablets per dose in the box. A patient weighing 40–56 kg needs 3 of these tablets for one dose.

Then record the recommended frequency by writing beside the drug abbreviation a subscript "3" if 3 times per week. No subscript indicates the drug should be taken daily. A subscript "5" or "6" may be written to be clear about the number of days per week that treatment should be taken. "Daily" means in some countries seven days per week, and in other countries five or six consecutive days per week (for instance Monday to Friday or Monday to Saturday) to fit with the opening of health facilities.

Example

I. INITIAL PHASE - prescribed regimen and dosages

Regimen: ☒ New ☐ Retreatment

Number of tablets per dose, doses per week, dosage of S:

(RHZE)	S
3	

Co-trimoxazole

ARV

Referral by:

- ☒ Self-referral
☐ Community member
☐ Public facility
☐ Private facility/provider:

☐ Other, specify:

Other

¹² If the drug available is different than that printed on the card, cross out the printed abbreviation and write the correct one above it.

Example one

23

In example two, the patient is sputum smear-positive TB, relapse). The nurse ticks the box for the Retreatment regimen. 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(RHZE)S/1(RHZE). 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 (RHZE) 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 RHZE). The nurse writes a reminder to discontinue the streptomycin injections after 2 months (56 doses of S).

Example two

Tuberculosis Treatment Card										District TB Register No. _____																											
Name: <u>Mary Abatu</u>										Disease site (check one)																											
Sex: <input type="checkbox"/> M <input checked="" type="checkbox"/> F Date of registration in District TB Register: _____										<input checked="" type="checkbox"/> Pulmonary <input type="checkbox"/> Extrapulmonary, specify _____																											
Age: <u>19</u> Health facility: <u>Patangeta HC</u>										Type of patient (check one)																											
Address: <u>33 Primos Road, Patangeta</u>										<input type="checkbox"/> New <input type="checkbox"/> Treatment after default <input checked="" type="checkbox"/> Relapse <input type="checkbox"/> Treatment after failure <input type="checkbox"/> Transfer in <input type="checkbox"/> Other																											
Name / address of treatment supporter (if applicable) _____																																					
I. INITIAL PHASE - prescribed regimen and dosages Regimen: <input type="checkbox"/> New <input checked="" type="checkbox"/> Retreatment Number of tablets per dose, doses per week, dosage of S: <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 2px;">(RHZE) 3</div> <div style="border: 1px solid black; padding: 2px;">S 0.75g</div> </div>										Referral by: <input type="checkbox"/> Self-referral <input checked="" type="checkbox"/> Community member <input type="checkbox"/> Public facility <input type="checkbox"/> Private facility/provider: <input type="checkbox"/> Other, specify: _____																											
Cotrimoxazole		ARV				Other																															
Note: Stop streptomycin after 2 months (56 doses) Tick appropriate box after the drugs have been administered Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (—●—) through number of days supplied. Ø = drugs not taken																																					
Day Month	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			
Oct																			✓																		

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0	16/10	667-2	+++	50

TB/HIV		
	Date	Result*
HIV test		
HIV test		
CPT start		
ART start		

* (Pos) Positive; (Neg) Negative; (I) Discordant/Inconclusive; (ND) Not Done/unknown

Figure 6: Anti-TB drug treatment in special situations

- **Pregnancy**

Ask female patients whether they are or may be pregnant. Most anti-TB drugs are safe for use in pregnancy with the exception of streptomycin, which is part of the standard Retreatment regimen. **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 regimen must not include streptomycin. Use ethambutol instead of streptomycin. Refer pregnant TB patients who need a Retreatment regimen to a clinician who can prescribe the appropriate 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.

- **HIV patients on ART**

TB patients with HIV infection or HIV/AIDS may experience a temporary worsening of symptoms and signs after beginning TB treatment due to immune reconstitution inflammatory syndrome (IRIS); it usually does not require intervention. 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; this requires adjusting the HIV or TB regimens. In patients with HIV-related TB, the priority is to treat TB. A clinician may choose to defer antiretroviral treatment until TB treatment is completed; defer until completing the initial phase and use HE (isoniazid and ethambutol) in the continuation phase; or use antiretrovirals that are less likely to interact with anti-TB drugs.

If you decide to refer the TB patient to a clinician so that the clinician can prescribe anti-TB treatment (for example, because of suspected MDR-TB, current treatment with ART, or pregnancy), complete the patient's *TB Treatment Card* to the extent possible. After the patient returns, you will write the treatment regimen prescribed by the clinician on the *TB Treatment Card* and begin treatment.

Consult the drug tables for the continuation phase in your national TB manual. On the back of the card under Continuation phase (shown below), write the number of tablets for one dose in the box with the appropriate regimen. If the frequency of treatment is 3 times per week, write a subscript “3” next to the drug, as shown in the example below.

Four tablets of E will be taken 3 times per week

1.3.8 Record additional information for an HIV-positive TB patient

The *TB Treatment Card* has boxes for recording information about drug therapy that may be taken by an HIV-positive patient and also other information about the patient's HIV care. It is helpful to record as much of this information as can be obtained, so that the health workers caring for the patient's TB can be aware of and coordinate with the care that is provided for HIV.

a) Record dosage of co-trimoxazole for prophylaxis

It is recommended that all HIV-positive persons take daily co-trimoxazole to help prevent other infections. This is referred to as co-trimoxazole preventive therapy or CPT.

If an HIV-positive patient is not currently taking daily co-trimoxazole, start giving CPT. The dosage is one double-strength (960mg) or two single-strength (480mg) tablets of co-trimoxazole daily. This may be given at the same time as directly-observed treatment for TB.

Write drug dosage needed in co-trimoxazole box on the front of the *TB Treatment Card*.
Write today's date as start date.

Caution: Before giving co-trimoxazole, ask the patient about previous history of sulpha (sulfa) allergy (to co-trimoxazole/Septim®, Bactrim®, Spetra®, S-P/Fansidar®, etc.). Do not give co-trimoxazole if there may be an allergy.

If the patient is already taking CPT, record the dose and the date that CPT was started.

b) If patient is on ART, record the date that ART started, and names and doses of antiretrovirals (ARVs)

Ask the TB patient if he or she is on antiretroviral therapy (or ART), and if so, the date that ART was started. Also ask for the ART regimen. The patient may have a card with this information, such as an *HIV Care/ART Care Card*, or you may need to obtain this information from the health facility that provides the HIV care.

In the excerpts below, the patient started CPT on 12 March 2009. He takes 2 tablets of co-trimoxazole daily. He is not on ART.

Example: Recording HIV-related information on the front of the TB Treatment Card

TB/HIV		
	Date	Result*
HIV test	2/3/09	pos
HIV test		
CPT start	12/3/09	
ART start		

* (Pos) Positive; (Neg) Negative; (I) Discordant/Inconclusive; (ND) Not Done/unknown

Co-trimoxazole	ARV	Other
2		

c) Record information about the patient's current HIV care

Information to complete the HIV care box shown below (from the back of the *TB Treatment Card*) can be obtained from the patient's records at the facility where he or she is receiving HIV care. If this is a different location than your health facility, the information may be more difficult to obtain. An HIV-positive patient must undergo a process of assessment and preparation in order to begin ART, and this box documents some of that process.

HIV care	
Pre ART Register No.	67
CD4 result	
ART eligibility (Y/N/Unknown)	N
Date eligibility assessed	12/3/09
ART Register No.	

1.3.9 Complete the Household contacts box

How to identify TB suspects among household contacts of TB patients has been described in module B: *Detect Cases of TB*. To summarize:

- Ask the TB patient for the names, ages and relationship of all persons who live in the household and write them in the box on the back of the *TB Treatment Card*.
- Ask the TB patient to bring in for assessment all persons in the household age 5 or older who have a cough, and every child age less than 5 years living in the household.
- Assess each household contact:
 - If a contact age 5 or older has coughed for 2 weeks or more, the person is a TB suspect. Collect three sputum samples for examination. Record the results of sputum microscopy when they are returned.
 - If a child aged less than 5 years has chronic signs or symptoms suggestive of TB--cough or other respiratory symptoms lasting more than 21 days, fever (above 38°C) for more than 2 weeks, loss of weight or failure to gain weight (failure to thrive)--suspect possible TB and refer the child to a second-level facility or paediatrician for diagnosis or exclusion of TB. Close contact with a smear-positive case increases the suspicion of TB in children.
- Record the result of your assessment in the Household contacts box.

Example: Recording assessment of household contacts on the back of the TB Treatment Card

Household contacts

First names and surnames	Age	Relationship to case	Date seen	Result
<i>Osa Abatu</i>	<i>25</i>	<i>husband</i>	<i>25/10</i>	<i>Cough 1 week</i>
<i>Luca Abatu</i>	<i>1</i>	<i>son</i>	<i>20/10</i>	<i>No symptoms</i>
<i>Keema Onyango</i>	<i>40</i>	<i>mother</i>		<i>No cough</i>
<i>Ruth Onyango</i>	<i>17</i>	<i>sister</i>		<i>No cough</i>

Keep 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.



STOP

Now do Exercise B – Written Exercise

When you reach this point in the module, turn to Exercise B on page 77 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
- What are signs and symptoms of TB
- Who else should be examined or tested for TB
- How TB is a problem for people with HIV infection
- The relationship of TB with HIV
- Other risk factors for TB
- Necessity of directly-observed treatment
- Details of treatment regimen
- What to expect; what to do next
- Importance of stopping smoking
- The TB patient's rights and responsibilities.

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 the patient decided not to come to a health facility for treatment, and the patient's treatment will be observed by a community TB treatment supporter, you must help the patient 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. Adjust the number of tablets as needed (add or take out tablets) for a patient who is not in the average weight band.

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.

1.7 Prepare a *Tuberculosis Identity Card* for the patient

If your health facility has *Tuberculosis Identity Cards* available, prepare one for the TB patient. This card differs from the *TB Treatment Card* in that it is for the patient to keep and to show when attending other medical services. It provides information about the patient and the TB treatment regimen. It also reminds the patient of upcoming appointments, such as for assessment by a clinician or for follow-up.

Complete the left side of the *TB Identity Card* by copying the necessary information from the *TB Treatment Card*. Then write in the patient's next appointment and any additional reminders.

Tuberculosis Identity Card																																	
Name <u>Mary Abetu</u>				District TB Register No. _____																													
Address <u>33 Primas Road, Patangeta</u>				Appointment dates: _____																													
Sex: <input type="checkbox"/> M <input checked="" type="checkbox"/> F Age <u>19</u> Date treatment started <u>18/10/09</u>				_____																													
Health facility: <u>Patangeta Health Centre</u>				_____																													
Supporter (name and address) _____				_____																													
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="4" style="text-align: center;">Sputum smear microscopy</th> <th rowspan="2" style="text-align: center;">Weight (kg)</th> </tr> <tr> <th style="text-align: center;">Month</th> <th style="text-align: center;">Date</th> <th style="text-align: center;">Lab No.</th> <th style="text-align: center;">Result</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">0</td> <td style="text-align: center;">16/10/09</td> <td style="text-align: center;">667-2</td> <td style="text-align: center;">+++</td> <td style="text-align: center;">50 kg</td> </tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>				Sputum smear microscopy				Weight (kg)	Month	Date	Lab No.	Result	0	16/10/09	667-2	+++	50 kg																_____
Sputum smear microscopy				Weight (kg)																													
Month	Date	Lab No.	Result																														
0	16/10/09	667-2	+++	50 kg																													
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="padding: 5px;"> Disease site (check one) <input checked="" type="checkbox"/> Pulmonary <input type="checkbox"/> Extrapulmonary, specify _____ </td> </tr> <tr> <td colspan="2" style="padding: 5px;"> Type of patient (check one) <input type="checkbox"/> New <input type="checkbox"/> Treatment after default <input checked="" type="checkbox"/> Relapse <input type="checkbox"/> Treatment after failure <input type="checkbox"/> Transfer in <input type="checkbox"/> Other </td> </tr> </table>					Disease site (check one) <input checked="" type="checkbox"/> Pulmonary <input type="checkbox"/> Extrapulmonary, specify _____		Type of patient (check one) <input type="checkbox"/> New <input type="checkbox"/> Treatment after default <input checked="" type="checkbox"/> Relapse <input type="checkbox"/> Treatment after failure <input type="checkbox"/> Transfer in <input type="checkbox"/> Other																										
Disease site (check one) <input checked="" type="checkbox"/> Pulmonary <input type="checkbox"/> Extrapulmonary, specify _____																																	
Type of patient (check one) <input type="checkbox"/> New <input type="checkbox"/> Treatment after default <input checked="" type="checkbox"/> Relapse <input type="checkbox"/> Treatment after failure <input type="checkbox"/> Transfer in <input type="checkbox"/> Other																																	
I. INITIAL PHASE <input type="checkbox"/> New <input checked="" type="checkbox"/> Retreatment <table border="1" style="display: inline-table; margin-left: 10px;"> <tr><td style="text-align: center;">(RHZE)</td></tr> <tr><td style="text-align: center;">3</td></tr> </table> <table border="1" style="display: inline-table; margin-left: 10px;"> <tr><td style="text-align: center;">S</td></tr> <tr><td style="text-align: center;">0.75g</td></tr> </table> <table border="1" style="display: inline-table; margin-left: 10px;"> <tr><td style="text-align: center;">Other</td></tr> <tr><td> </td></tr> </table>					(RHZE)	3	S	0.75g	Other																								
(RHZE)																																	
3																																	
S																																	
0.75g																																	
Other																																	
II. CONTINUATION PHASE <table border="1" style="display: inline-table; margin-right: 10px;"> <tr><td style="text-align: center;">(RH)₃</td></tr> <tr><td style="text-align: center;">3</td></tr> </table> <table border="1" style="display: inline-table; margin-right: 10px;"> <tr><td style="text-align: center;">(RHE)</td></tr> <tr><td> </td></tr> </table> <table border="1" style="display: inline-table;"> <tr><td style="text-align: center;">E₃ Other</td></tr> <tr><td style="text-align: center;">4</td></tr> </table>					(RH) ₃	3	(RHE)		E ₃ Other	4																							
(RH) ₃																																	
3																																	
(RHE)																																	
E ₃ Other																																	
4																																	
REMEMBER <div style="border: 1px solid black; padding: 10px; margin: 10px auto; width: 80%;"> <p style="font-size: 1.2em;">Come for TB drugs 6 days each week!</p> </div>																																	

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

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 other people in the household who have cough.

If any of these contacts are found to have TB, they should begin treatment for TB. Contacts who do not have TB may be given preventive therapy to reduce the chance of developing TB disease.

2.1 Give preventive therapy to household contacts

Preventive therapy with isoniazid can reduce the risk of TB developing in children and in adults who are infected but who have not yet developed TB disease. Because of the seriousness of TB in small children, most countries recommend isoniazid preventive therapy (IPT) 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 IPT. Follow the guidelines in your national TB manual. A course of isoniazid, usually 10 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: Give preventive therapy with isoniazid to TB contacts aged less than 5 years

- Give isoniazid preventive therapy **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 or fever for 2 weeks or more, or weight loss, refer the child to a clinician for assessment for TB.
 - If the child does not have TB, give isoniazid (H) daily for 6 months to prevent TB.
- **Give 10 mg/kg isoniazid daily for 6 months.**
- See the 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) who are HIV-positive, give it also to these contacts. Give 10 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, if needed

Immunization with BCG can reduce the risk of developing TB by 50–80% if given before infection. After a 6 month course of isoniazid preventive therapy, or IPT, give one dose of BCG vaccine to children aged less than 2 years who do not have symptoms of HIV/AIDS and who have not already had BCG immunization. (If a child had a positive tuberculin skin test, the child is already infected with TB; BCG is not useful.)

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 IPT should first complete the course of isoniazid and then receive BCG immunization.

Give one dose of BCG vaccine to a child aged less than 2 years who

- is a household contact of a TB case
- has completed a 6-month course of IPT
- has not had BCG immunization previously, and
- is healthy and thriving.

Do not give a BCG vaccine to a child who had a positive tuberculin skin test.

3. Treat the patient during the entire period of treatment

3.1 Directly observe treatment and record it on the *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 should watch the patient (adult or child) swallowing each dose: you must see the patient swallow the drugs. When health workers give drugs to patients but do not watch them swallow each dose, patients may not take the drugs, take some but not all of the drugs, sell some of the drugs, or save the drugs for later.

The main way to prevent transmission of TB to health workers and others at the health facility is for TB patients to take their drugs regularly. This will make them non-infectious in a week or two. Proper ventilation of the health facility is also important.

Make directly-observed treatment quick and easy for TB patients. Avoid their waiting in a queue at the health facility. Rather, arrange for them to see the appropriate health worker immediately, perhaps by coming to a side door or back entrance where they can take the day's dose of anti-TB drugs quickly and be on their way. Unnecessary delays are discouraging and unacceptable.

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, yoghurt or gruel.)
3. Open the patient's box of drugs and take out today's doses.
4. Put the tablets into the patient's hand and watch the patient swallow each dose. If the patient finds the drugs difficult to swallow at one time, suggest a brief pause. 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 treatment administered daily, it is customary not to give drugs on one or two days each week, such as during the weekend. Skipping one or two days 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 Mark the *TB Treatment Card* in the initial phase

Begin marking the intake observed on the *TB Treatment Card* from the first day that directly-observed treatment is given. On the front of the card on 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 misses an appointment, put a “Ø” under that date to indicate that a dose was missed. Make a dash (–) for Sunday (or a customary day off).

Sometimes a patient will not be able to come for treatment for a day or more because of a planned absence such as for 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.

In some areas, the patient has directly-observed treatment for 5 or 6 days per week plus a self-administered dose on the weekend (marked with a line).

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 3 days and would return on 20 September. After the health worker watched her swallow the day’s dose, he also gave her three doses to take with her. The health worker drew a line through 3 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	✓	✓	✓	–	✓	✓	✓	Ø	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	26	30
Sept	–	✓	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	–	–	–	✓	✓	–	✓	✓	✓	✓	✓	✓	–	✓	X	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 dose to take in front of you. Do not give a double dose. Since the patient has a certain number of doses to take during 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 a total of 56 doses during the initial phase of treatment, so it is easy to see that one more dose is needed to complete this 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* in the Comments section. See module G: *Ensure Continuation of TB Treatment* for guidance on action to take.

Figure 9: Marking the *TB Treatment Card*

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

3.1.2 Mark the *TB Treatment Card* in the continuation phase

The next page shows how the back of a *TB Treatment Card* would be marked during the continuation phase.

This patient has **directly-observed treatment** 3 times weekly (on Mondays, Wednesdays and Fridays). He skipped his appointment on 21 October but returned the next day for the missed dose. He also missed two doses on 18 and 20 November. The missed doses will extend the end of this phase of treatment: he has taken 26 doses but must continue treatment for several more weeks to complete all 48 doses required during the continuation phase.

Example

II. CONTINUATION PHASE

Number of tablets per dose, doses per week

(RH) ₃	(RHE)	Other
3		

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (———●) through number of days supplied. Ø = drugs not taken

[illegible]

Chest X-ray (at start)
Date:
(-) Normal (+) Abnormal <u>ND Not done</u>

HIV care	
Pre ART Register No.	
CD4 result	
ART eligibility (Y/N/Unknown)	
Date eligibility assessed	
ART Register No.	

Comments: 18-20 Nov - out of town for funeral

Treatment outcome

Date of decision _____

☐ Cure

☐ Treatment completed

☐ Died

☐ Treatment failure

☐ Default

☐ Transfer out

Household contacts				
First names and surnames	Age	Relationship to case	Date seen	Result
Sinda Modi	33	wife		
Vin Modi	11	son		

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

In the “total” columns on the right, the health worker records the doses directly observed during the month.



Now do Exercise C – Written Exercise and Discussion

When you reach this point, you are ready to do Exercise C. Turn to page 87 and follow the instructions. Do the exercise by yourself and then discuss your answers with a facilitator.

3.2 If the 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 may develop adverse reactions to the anti-TB drugs. Monitor side-effects by:

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

When a TB patient comes for directly-observed treatment, 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 (see Figure 10 below) or of simultaneous anti-TB treatment and antiretroviral therapy [ART] (see Figure 11 overleaf). Side-effects may be minor or major. A patient who has major side-effects should stop treatment immediately and be referred to a clinician or second-level facility. A patient with minor side-effects may continue to receive anti-TB drugs. Reassure the patient and give advice on how to relieve symptoms. Bear in mind that side-effects are more common in HIV-infected people.

A patient who continues to be concerned about a minor side-effect even after following advice should be referred 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 of anti-TB drugs and their management

Minor side-effects	Management
• Anorexia, nausea, abdominal pain	Take drugs with food, yogurt or gruel.
• Joint pains	Give acetylsalicylic acid (aspirin) or paracetamol.
• Burning sensation in feet	Give pyridoxine (100 mg daily).
• Orange or red urine	Reassure patient that this is expected (with rifampicin).

Major side-effects	Management
► Itching of skin, skin rash ^a	Stop anti-TB drugs and refer the patient urgently to a clinician.
► Deafness (<i>confirm that this is not due to ear wax</i>)	
► 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 (a drug 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. Urgently refer a vomiting patient to a clinician.

Figure 11: Side-effects in patients on simultaneous anti-TB treatment⁺ and ART⁺⁺

Minor side-effects	Management
• Diarrhoea	Rehydrate. Reassure patient that if due to ART, diarrhoea will improve in a few weeks.
• Headache	Give paracetamol or aspirin. If on AZT or EFV ⁺⁺ , reassure that headache is usually limited.
• Anorexia, nausea, abdominal pain	Take drugs with food (except for DDI or IDV ⁺⁺). If on AZT ⁺⁺ , reassure that this is usually limited. Treat symptomatically.
• Orange or red urine	Reassure patient that this is expected (with rifampicin).
• Burning sensation in feet	Toxicity of H ⁺ , DDI or d4T ⁺⁺ . Give pyridoxine (100 mg daily).
• Cough or difficult breathing	May be immune reconstitution inflammatory syndrome (IRIS) or an opportunistic infection. Call for advice or refer.
• Blue or black nails	Reassure that this is normal with AZT ⁺⁺ .
• Fever	Check for common causes of fever. May be a side-effect, an opportunistic infection or IRIS. Call for advice or refer.
• Pallor, anaemia (severe pallor or very low haemoglobin, that is <8 g/dL; or <7 g/dL in pregnant women)	Refer or consult (and stop AZT; substitute d4T ⁺⁺).
• Joint pains	Give aspirin or paracetamol.

Major side-effects	Management <i>Stop drugs and refer urgently to a clinician</i>
► Itching of skin, skin rash	If on co-trimoxazole, suspend drug (may be allergy to sulpha). If generalized itching, rash, or peeling, stop TB and ART drugs and refer for advice.
► Deafness (<i>not due to ear wax</i>); dizziness, lack of balance	If on S, Km, Am or Cm ⁺ , suspend drug. Call for advice or refer.
► Jaundice (yellow skin or eyes), abdominal or flank pain	Stop TB and ART drugs. May be hepatitis due to H, Z, or R ⁺ . Abdominal pain may be pancreatitis from DDI or d4T ⁺⁺ . Call for advice or refer.
► Vomiting repeatedly	Check for common causes of vomiting (see <i>IMAI Acute Care</i>). Stop TB and ART drugs and call for advice or refer.
► Difficulty with vision	If on E ⁺ , suspend drug. Refer for advice.
► Psychosis, depression	If on Cs ⁺ , suspend drug. Call for advice or refer if severely depressed, suicidal or psychotic.

⁺ Anti-TB drugs:

- First-line: E (ethambutol), H (isoniazid), R (rifampicin), S (streptomycin)
- Second-line: Am (amikacin), Cm (capreomycin), Km (kanamycin), Cs (cycloserine), Z (pyrazinamide)

⁺⁺ Antiretroviral drugs: AZT (zidovudine), DDI (didanosine), d4T (stavudine), EFV (efavirenz), IDV (idinavir)

When a TB patient begins ART, there may be a worsening of TB signs and symptoms caused by IRIS (this may also be called a paradoxical reaction). Common signs include high fever, lymphadenopathy, worsening of X-ray findings and herpes zoster. IRIS is not life-threatening but is a sign that the immune system is working again. If you suspect that a patient has IRIS, continue both anti-TB treatment and ART and refer the patient to a clinician for assessment.

Record your observations of any TB patient's side-effects or worsening condition on the back of the *TB Treatment Card* in the Comments section. If you refer a patient to a clinician or second-level facility, 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 patients daily (or 3 times per week) to directly observe their treatment, continue also to reinforce messages about TB and its treatment. Give support to encourage them to continue taking the drugs on schedule and to complete all the required doses. Inform patients about the dangers of irregular or incomplete treatment. (See module D: *Inform Patients about TB*.)

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

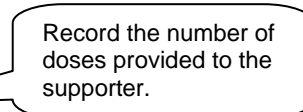
- Side-effects of drugs (if reported or observed)
- Type, colour, number of tablets and frequency of doses
- Importance of continuing treatment
- Consequences of taking only some of the drugs or of stopping or interrupting treatment
- What to do if the patient is planning an absence
- Frequency and importance of required sputum examinations, meaning of results.

Getting out the day's drugs, watching the patient swallow each dose and marking the *TB Treatment Card* can be done quickly! Ask the patient questions about side-effects and planning for an absence, etc. as needed (not every day). If directly-observed treatment takes more than just a few minutes each day, it will interfere with the patient's life and may discourage adherence.

3.4 (If applicable) Monthly, review the 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* (kept at the health facility) the dates when the patient received treatment. Then record (on the front of the *TB Treatment Card*) the number of doses given to the TB treatment supporter for the next month.

Drugs given to supporter	
Date	Doses
5 Apr	26
7 May	28



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

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

4. Monitor progress of treatment

Monitor patients with smear-positive pulmonary TB by periodic follow-up sputum smear microscopy examinations. These examinations are important in assessing progress and making decisions about care. The sputum of smear-positive patients will convert to smear-negative when the anti-TB drugs are taken regularly for the required time period. Sputum conversion from positive to negative is the best indicator that the drugs were regularly taken during the initial phase of treatment and the treatment was effective.

Periodic visits to a clinician are also recommended. A clinician can evaluate clinical improvement, answer questions about TB and its treatment, and provide support for continuing treatment. Annex E provides 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 and all children with TB a clinician should monitor the progress of treatment by assessing clinical status. Increases in a patient's weight indicates treatment progress; increases in weight and height are particularly important in children. Pulmonary TB patients who are smear-negative at the start of treatment should also have smear microscopy at the end of the initial phase.

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

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

- For a patient on the New patient regimen, do follow-up sputum examinations at the end of 2 months, 5 months, and 6 months of treatment.
- For a patient on the Retreatment regimen, do follow-up sputum examinations at the end of 3 months, 5 months, and 8 months of treatment.

This schedule applies to both smear-positive and smear-negative cases. **“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, collect sputum in the last week of the second month of treatment. Collect sputum several days before you need the results of the examination and early enough for the results of the examination to be available to you at the end of the specified month.

If a patient has smear-positive results at the end of 3, 5 or 6 months of treatment, you will collect sputum to send for culture and DST. This is explained in section 4.6.

(A patient on treatment for MDR-TB will have a special schedule for follow-up sputum microscopy and cultures, which is not described in this module.)

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 sample 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 D of this module for instructions on sputum collection; module B: *Detect Cases of TB* contains additional guidance.)

Complete a *Request for Sputum Smear Microscopy 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 that the reason for examination is “Follow-up.” Also write the patient’s District TB Register number. See the *Request for Sputum Smear Microscopy 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.

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.

4.3 If a TB patient was HIV-negative, recommend HIV testing at the end of the initial phase of treatment

In areas of high HIV prevalence, TB patients should be retested for HIV at the end of the initial phase of treatment in case an HIV test at the beginning of treatment did not accurately reflect a patient’s HIV status (window period) or they became infected with HIV after starting anti-TB treatment. The HIV status of a TB patient is important for making decisions about treatment, such as the need for ART and CPT. It is also important for counselling and advice on TB and HIV regarding prognosis, side-effects and associated diseases.

4.4 If a TB patient is HIV-positive, update the information on the *TB Treatment Card* about HIV care

At each visit for follow-up, ask the HIV-positive TB patient about the care that he or she is receiving for HIV and update the *TB Treatment Card* accordingly. For example, update the card when the patient becomes eligible for ART, starts ART or changes antiretroviral drugs.

Example**REQUEST FOR SPUTUM SMEAR MICROSCOPY EXAMINATION**

The completed form with results should be sent promptly by laboratory back to the referring facility

Referring facility¹ Patangeta Hospital Outpatient Date 7 Aug 2009

Name of patient Christina Koffi Age 57 Sex: ☐ M ☒ F

Complete address 45 Long Street
Patangeta

Reason for sputum smear microscopy examination:

☐ Diagnosis

The reason for this sputum examination is Follow-up.

OR ☒ Follow-up Number of month of treatment: 2 District TB Register No.² 417

Name and signature of person requesting examination 

1. Including public or private health facility/providers

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

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

For follow-up, two samples are needed

RESULTS (to be completed in the laboratory)

Laboratory Serial No. 1630

Date collected ³	Sputum Specimen	Visual appearance ⁴	RESULTS				
			NEG	(1-9)	(+)	(++)	(+++)
6/8/09	1	Muco-purulent	✓				
7/8/09	2	ditto	✓				
	3						

3. To be completed by the person collecting the sputum

4. Blood-stained, muco-purulent, or saliva

Examined by Rajiv Ferrar

Date 10/8/09 Signature 

4.5 Record results of sputum smear microscopy examination

A laboratory technician records the results of sputum smear examination on the bottom half of the *Request for Sputum Smear Microscopy Examination* form and returns it to the health facility, as shown on the previous page. One or more positive sputum smears means 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. Also record the results on the patient's *TB Identity Card*, if used.

Example: Look back at the *Request for Sputum Smear Microscopy 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															District TB Register No. <u>417</u>																				
Name: <u>Christina Koffi</u>															Disease site (check one)																				
Sex: <input type="checkbox"/> M <input checked="" type="checkbox"/> F Date of registration in District TB Register: <u>25/6/09</u>															<input checked="" type="checkbox"/> Pulmonary <input type="checkbox"/> Extrapulmonary, specify																				
Age: <u>49</u> Health facility: <u>Patangeta Health Centre</u>															Type of patient (check one)																				
Address: <u>45 Long Street, Patangeta</u>															<input checked="" type="checkbox"/> New <input type="checkbox"/> Relapse <input type="checkbox"/> Transfer in <input type="checkbox"/> Treatment after default <input type="checkbox"/> Treatment after failure <input type="checkbox"/> Other																				
Name / address of treatment supporter (if applicable) <u>Salima Arata, Centre Street #3, Patangeta</u>															Weight (kg) <table border="1"> <tr> <th>Month</th> <th>Date</th> <th>Lab No.</th> <th>Result</th> <th>Weight (kg)</th> </tr> <tr> <td>0</td> <td>3/6/09</td> <td>175</td> <td>++</td> <td>42</td> </tr> <tr> <td>2</td> <td>10/8/09</td> <td>1630</td> <td>neg</td> <td>43</td> </tr> </table>		Month	Date	Lab No.	Result	Weight (kg)	0	3/6/09	175	++	42	2	10/8/09	1630	neg	43				
Month	Date	Lab No.	Result	Weight (kg)																															
0	3/6/09	175	++	42																															
2	10/8/09	1630	neg	43																															
I. INITIAL PHASE - prescribed regimen and dosages															Referral by:																				
Regimen: <input checked="" type="checkbox"/> New <input type="checkbox"/> Retreatment															<input type="checkbox"/> Self-referral <input checked="" type="checkbox"/> Community member <input type="checkbox"/> Public facility <input type="checkbox"/> Private facility/provider																				
Number of tablets per dose, doses per week, dosage of S:															<input type="checkbox"/> Other, specify:																				
(RHZE)					S																														
3																																			
Cotrimoxazole					ARV					Other																									
Tick appropriate box after the drugs have been administered Daily intake observed: enter ✓; Periodic supply: enter X on day when drugs are collected and draw a horizontal line (—) through number of days supplied. Ø = drugs not taken																																			
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	
Month																																		Date	Doses
June					✓	✓	—	✓	✓	✓	✓	✓	✓	—	✓	✓	Ø	✓	✓	✓	—	✓	✓	✓	Ø	Ø	✓	—	✓	✓	✓	19	19	5/6	28
July	✓	✓	✓	✓	—	✓	✓	✓	✓	✓	✓	✓	✓	—	✓	✓	Ø	✓	✓	✓	—	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	26	45	8/7	28
Aug	✓	—	✓	✓	✓	✓	Ø	✓	—	✓	✓	✓	✓	✓	—																	11	56		

Health worker wrote new result here

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

4.6 Decide on appropriate action needed

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

4.6.1 Assess treatment progress at the end of the initial phase

Use the results of the first follow-up examination to determine treatment progress. At the end of the second month of treatment for a case on the New patient regimen (or the third month for a case on the Retreatment regimen), most patients will have a negative sputum smear microscopy examination (two samples negative). These patients have had sputum conversion, which indicates good treatment progress. However, 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 the 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 is not responding to first-line treatment.

Whatever the reason, if a patient has a positive sputum smear at the end of the initial phase, review the quality of the patient's support and supervision and promptly intervene if necessary. If a New patient is smear-positive at 2 months, repeat the sputum examination in one more month. If a patient¹⁴ is still smear-positive at 3 months (on New or Retreatment regimen), collect sputum and send it for culture and DST, if available; DST can determine whether the patient has MDR-TB.¹⁵

In any case, begin the continuation phase of treatment when all the drugs for the initial phase have been taken, and continue with it until the treatment is completed, or treatment failure or MDR-TB is detected.

Even if the patient was smear-negative at the start of treatment, it is important to check a sputum smear at the end of the initial phase of treatment, in case the patient has become smear-positive. This would indicate that the TB has worsened as a result of non-adherence to treatment or drug resistance, or because there was an error at the time of initial diagnosis.

¹⁴ A child who is still sputum smear-positive at the end of 3 months of treatment should be referred to a paediatrician or second-level clinician for assessment. The child may have MDR-TB.

¹⁵ Where there is not yet laboratory capacity to routinely conduct DST for TB patients who remain smear-positive, it is urgent to strengthen laboratory capacity.

If the results of sputum testing of a smear-negative TB patient after the initial phase of the New or Retreatment regimen are:

- **smear-positive:** assess the patient. Then
 - *if there is clinical deterioration*, refer to a clinician.
 - *if clinically the same*, review the quality of the patient's support and supervision and promptly intervene as needed. Then, proceed as with a smear-positive patient, that is, start the continuation phase of treatment, repeat the smear at 3 months and do additional follow-up sputum examinations according to the schedule for smear-positive patients.
- **smear-negative:** no further sputum examination is needed.

4.6.2 Use sputum examination results at 5 months to assess effectiveness of treatment

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

If the sputum of a patient on the New patient or Retreatment regimen is still smear-positive at the end of the fifth month of treatment or later, this constitutes **treatment failure**. Treatment failure is rare with directly-observed treatment, usually occurring in less than 1–2% of cases in countries with low levels of drug resistance. In countries with a high prevalence of MDR-TB, failures may be higher, perhaps 3–5%.

- 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." Staple the old card to the new card.
- Suspect MDR-TB, collect sputum and send the samples for culture and DST if possible, and refer the patient to a clinician for assessment.

If the sputum is smear-negative after 5 months of treatment, the treatment is working. 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 "a patient whose sputum smear or culture was positive at the beginning of treatment, but who was smear or culture 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." Section 5 of this module describes how to determine and record treatment outcomes.

4.6.3 Record results of sputum culture and DST, if received

If a clinician requested that culture and DST be done on the sputum collected for diagnosis, or if sputum was sent for culture and DST after 3 or 5 months of treatment, the results will be received some months later, during the continuation phase. Whenever culture or DST results are received, record the results on the back of the patient's *TB Treatment Card* in "Comments."

If DST shows resistance to R and H, the patient has MDR-TB and is classified as a treatment failure. Refer the patient to a clinician to decide on any changes in TB treatment according to national guidelines. For example, if DST reveals MDR-TB, the clinician will switch to an MDR-TB regimen. Follow instructions from the clinician on any changes in treatment. If the patient will begin a different treatment regimen, record the patient's treatment outcome as treatment failure, and open a new card for the regimen.

Note: In countries or districts where culture is done routinely, *TB Treatment Card, Form III*, which provides boxes for recording culture and DST results, will be used. However, if culture is used only occasionally, write on the patient's *TB Treatment Card* in "Comments," the date of collection of the sample and the results of culture and/or DST.

4.7 Monitoring progress of treatment by follow-up sputum microscopy: summary of schedule and action to take

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 its outcome.

New patient: Do follow-up sputum microscopy examinations **at the end of 2 months, 5 months and 6 months (the last month of treatment)**. However, if the examination at the end of 2 months is positive, do follow-up sputum examinations at the end of 3 months, 5 months and 6 months. If results are positive at 3 months, 5 months or 6 months, collect sputum and send it to the appropriate laboratory for culture and DST.

Retreatment patient: Do follow-up sputum examinations **at the end of 3 months, 5 months and 8 months**. If any of these examination results are positive, collect sputum and send it for culture and DST.

Any patient who is smear or culture positive after 5 months of treatment or later is defined as a treatment failure and requires re-registration and change of treatment. Refer the patient to a clinician for assessment; he or she may need an MDR-TB treatment regimen.

Whenever DST results are received, if DST shows that the patient has MDR-TB, refer the patient to a clinician for an MDR-TB regimen.

Figures 12 and 13 show the schedules for follow-up sputum smear microscopy examinations (indicated by ●) and list actions to take based on the result.

Figure 12: Schedule for follow-up sputum examinations

Treatment regimen	Months of treatment							
	1	2	3	4	5	6	7	8
New patient <i>2RHZE/4RH</i> (smear-positive at start of treatment)	[=====]	=====] ● If result is positive, repeat smear exam at month 3. If result is negative, repeat smear exam at 5 months	[-----] (●) (Do only if smear was positive at month 2) If result is positive at month 3, send sputum for culture and DST*	-----]	-----] ● If smear-positive, is Treatment failure** Send sputum for culture and DST*	-----] ● If smear-positive, is Treatment failure** Send sputum for culture and DST*		
New patient <i>2RHZE/4RH</i> (smear-negative at start of treatment)	[=====]	=====] ● If result is positive, repeat smear exam at month 3. If result is negative, no more sputum exams needed	[-----] (●) (Do only if smear was positive at month 2) If result is positive at month 3, send sputum for culture and DST*	-----]	-----] ● If smear-positive, is Treatment failure** Send sputum for culture and DST*	-----] ● If smear-positive, is Treatment failure** Send sputum for culture and DST*		
Retreatment (patients returning after default or relapse) <i>2RHZES/1RHZE/5RHE</i> (smear-positive at start of treatment)	[=====]	=====] ● If result is positive at month 3, send sputum for culture and DST*	[-----]	-----] ● If smear-positive, is Treatment failure** Send sputum for culture and DST*	-----]	-----]	-----]	-----] ● If smear-positive, is Treatment failure** Send sputum for culture and DST*

Key:

[=====] Intensive phase

[-----] Continuation phase

● Do sputum examination during the last week of the month of treatment.

* Whenever DST results are received, if DST shows patient has MDR-TB, begin or refer for MDR-TB regimen.

** Smear or culture positive at month 5 or later is defined as treatment failure, and necessitates re-registration and change of treatment. Refer the patient to a clinician for assessment; he or she may need an MDR-TB regimen.

Figure 13: Actions based on result of follow-up sputum examination

→ If sputum examination result is negative:

- Begin or complete continuation phase of treatment.
- Do subsequent follow-up sputum examinations according to schedule (Figure 12).
- Exception: If patient who is smear-negative at start of treatment is smear-negative at end of the initial phase, no additional sputum examinations are needed.

→ If the sputum examination result is positive:

At end of initial phase of treatment (New patient regimen):

- Review whether treatment has been irregular. If so, discuss with patient the importance of regular treatment. Continue the treatment regimen.
- If an initially smear-negative patient is smear-positive, assess patient. If patient is clinically much worse, refer to clinician.
- Do follow-up sputum examination after one more month.
- If sputum smear is positive at 3 months, collect sputum and send for culture and DST.

At end of initial phase of treatment (Retreatment regimen):

- Review whether treatment has been irregular. If so, discuss with the patient the importance of regular treatment. Continue the treatment regimen.
- Collect sputum and send for culture and DST.

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).
- Collect sputum and send for culture and DST.
- Suspect MDR-TB and refer patient to a clinician (The clinician may prescribe an MDR-TB regimen based on high MDR-TB risk or on DST results when they are available).

STOP

Now do Exercise D – Written Exercise

After you have studied Figures 12 and 13 above, turn to page 93 and follow the instructions for Exercise D. Do the exercise by yourself. When you have finished, discuss your answers with a facilitator.

4.8 Implement treatment decisions

Meet with the patient to explain the results of the follow-up sputum examination and the next step of treatment. If the patient has a community TB treatment supporter, meet also with the treatment supporter.

4.8.1 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 explain that it is time to begin the continuation phase of treatment.
- Look at the back of the patient's *TB Treatment Card* for the needed drugs and be sure that the patient's drug box contains the correct number of doses.
- If the patient had a negative sputum result, explain that the initial phase of treatment has worked well. The patient is no longer infectious.
- If a patient on the New patient regimen had a positive sputum result, explain that there are still tubercle bacilli in the sputum. There will be another sputum examination in one month to check again.
- Describe 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).
- Begin giving the patient the continuation-phase drugs, marking the *TB Treatment Card* each time that you administer the drugs.

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 should happen in the continuation phase.

4.8.2 If and when culture and DST results are received

Use the results of culture and DST to decide whether a change of regimen is needed.

- Record the results on the back of the patient's *TB Treatment Card* in the "Comments" section.
- If DST results show that the patient is resistant to at least isoniazid (H) and rifampicin (R):
 - Refer the patient to a clinician for prescription of an MDR-TB regimen. (If referral is not possible, consult the District TB Coordinator who should tell you what to do.)
 - ***If the clinician recommends a change in regimen***, close the patient's *TB Treatment Card* (Outcome = Treatment failure) and open a new card (Type of patient = Treatment after failure).
 - Follow instructions from the clinician (or the District TB Coordinator) to provide the treatment.
- If the patient's DST results show susceptibility to isoniazid and rifampicin, continue the 6-month New patient regimen.
- Also record the results of culture and DST and any changes in treatment on the patient's *TB Identity Card* (if used).

4.8.3 If the patient is a treatment failure

If the patient is smear-positive at 5 months of treatment or later:

- Close the *TB Treatment Card* and record the outcome as “Treatment failure.”
- 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 and are probably resistant to the most commonly used drugs.
- Collect sputum and send it for culture and DST.
- Suspect MDR-TB and refer the patient to a clinician for assessment.
- Explain to the patient that there may be one last treatment regimen, much longer, and that expert medical knowledge is required to decide the regimen. This is why you are referring the patient to the next level of care.

5. At the end of treatment, record the outcome on the *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 have been taken, which will be some days or weeks longer.

Inform the patient that there is a possibility of relapse of TB, particularly in HIV-infected persons. Tell the patient to return to the health facility for assessment without delay if the signs and symptoms of TB develop again.

Some patients do not complete treatment because they die or stop coming for treatment and cannot be located. When a patient does not complete treatment, return all drugs remaining in the patient's drug box to the drug supply room.

When each patient completes treatment or stops coming for treatment, record that patient's outcome on the *TB Treatment Card*. Figure 14 gives definitions of the six possible treatment outcomes.

Figure 14: Definitions of treatment outcomes

Treatment outcome	Definition
Cure	A patient whose sputum smear or culture was positive in the beginning of the treatment, but who was smear or culture negative in the last month of treatment and on at least one previous occasion
Treatment completed	A patient who completed treatment but who does not have a negative sputum smear or culture result in the last month of treatment ¹⁶
Treatment failure	A patient whose sputum smear or culture is positive at 5 months or later during treatment. Also included are patients found to harbour a multidrug resistant (MDR) strain at any point in time during the treatment.
Died	A patient who dies for any reason during the course of treatment
Default	A patient whose treatment was interrupted for 2 consecutive months or more
Transfer out	A patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is not known

¹⁶ The sputum examination may not have been done, or the results may not be available. This definition applies to pulmonary smear-positive and smear-negative patients, and to patients with extrapulmonary disease.

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 <u>12 Aug 2009</u>
<input checked="" type="checkbox"/> Cure
<input type="checkbox"/> Treatment completed
<input type="checkbox"/> Died
<input type="checkbox"/> Treatment failure
<input type="checkbox"/> Default
<input type="checkbox"/> 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.¹⁷ 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 who cannot be located or 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 enquire 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” are not possible outcomes because these outcomes are based on whether a patient has sputum conversion (positive to negative) in follow-up sputum smear examinations. However,

¹⁷ If a clinician requested an end-of-treatment culture and the results are positive, ask the patient to return for re-evaluation. Inform the District TB Coordinator about the results; he or she will decide about the final treatment outcome.

the other outcomes are possible: “Treatment completed,” “Died,” “Default,” and “Transfer out.”

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 its TB cases.



STOP

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 97 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. For new patients, the initial phase is 2 months and the continuation phase is 4 months. **If anti-TB drugs are taken incorrectly or irregularly, the patient will not be cured.** The disease will be prolonged and become 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, by watching the TB patient swallow each dose of drugs as 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 regimen is selected on the basis of the type of patient and previous treatment, the likelihood of MDR-TB, HIV status and current HIV care.
- Health workers can choose:
 - New patient regimen for a new case (unless the patient is a contact of a known MDR-TB case or is already on ART)
 - Retreatment regimen for a previously treated TB patient who is a relapse or treatment after default (unless the patient has a high likelihood of MDR-TB, is on ART or is pregnant).

Health workers should follow a clinician's instructions for treatment of other cases (such as a patient who has a high likelihood of MDR-TB, a treatment after failure, a patient on ART, a patient who is or may be pregnant, and a child with TB).

- 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.** On the back of the card, 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 control programme for the patient. Record on the *TB Treatment Card* the drugs for both phases of treatment as well as the number of tablets for each dose.
- Discuss where the patient would like to receive directly-observed treatment. If it is convenient for the 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. Discuss with the patient possible members of the community who could provide directly-observed treatment under supervision by the health facility, and places that the patient can conveniently come for treatment. Help the patient choose a suitable treatment supporter. Record the name and address of the treatment supporter on the *TB Treatment Card*.
- The *TB Treatment Card* has space to record the date and results of HIV testing. For HIV-positive TB patients, record whether the patient takes CPT or ART, and other information about current HIV care.

- Obtain or prepare a drug box for the patient containing 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 "Ø" for a missed dose.)
- Record the result of your assessment of the patient's household contacts on the back of the *TB Treatment Card*. Any contact who is a TB suspect should have a sputum smear examination.
- To prevent TB in household contacts of TB patients:
 - Give a 6-month course of isoniazid preventive therapy (IPT) to any child aged less than 5 years in the household who does not have TB or possible TB.
 - (According to national policy) give a course of IPT to household contacts (all ages) who are HIV-positive.
 - After the course of IPT is finished, give BCG immunization to children aged less than 2 years who have not already been immunized, who are healthy and thriving, and who have not had a positive tuberculin skin test.
- A patient may develop side-effects of the anti-TB drugs (see Figure 10), or of simultaneous anti-TB treatment and ART (see Figure 11). **If a patient has major side-effects, stop giving the anti-TB drugs and refer the patient immediately to a clinician or hospital.** If the patient has minor side-effects, reassure the patient and give advice on how to relieve the symptoms. Side-effects are more common in HIV-infected people.
- 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 there has been sputum conversion. If a patient on the New patient regimen has positive sputum results, repeat the sputum examination in one month. If a patient on the New patient regimen or Retreatment regimen has positive results at 3 months, collect sputum and send it for culture and DST.

- If a patient’s sputum is still positive at 5 months or later, the patient is a treatment failure. Collect and send sputum for culture and DST and refer the patient to a clinician for assessment; he or she may need an MDR-TB regimen.
- 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 patient who was initially sputum smear or culture positive, but who is smear or culture 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 learnt. Then compare your answers to those on pages 65–68.

1. a) If 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 treatment regimen is needed?
 - d) A patient who previously received “on and off,” poor-quality treatment for TB has a high likelihood of MDR-TB. Why?
2. A health worker at a first-level facility can select the TB treatment regimen and begin TB treatment for some TB cases. However, some TB patients should be referred to a clinician for prescription of an anti-TB regimen. Which of the cases below should be referred? (tick all that should be referred)
 - ☐ a) pregnant woman with new smear-positive TB
 - ☐ b) new patient with extrapulmonary TB; no family members have had TB
 - ☐ c) man with new smear-positive TB who is on ART
 - ☐ d) man with new smear-positive TB who is HIV-positive (not on ART)
 - ☐ e) 4-year-old girl with smear-positive TB
 - ☐ f) woman who previously completed treatment for TB (good quality); now sputum smear-positive
 - ☐ g) woman with new smear-positive TB whose husband is on treatment for MDR-TB
 - ☐ h) man with new smear-positive TB who refuses an HIV test
 - ☐ i) man who was a treatment failure after 5 months on the New patient regimen.
3. 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 alone 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. He decided to come to the health centre because of his cough. His contact person is Mr Jamil, the shopkeeper who lives across Castle Road.

His laboratory results dated 10 March are shown below.

Laboratory Serial No. 685

Date collected	Sputum specimen	Visual appearance	RESULTS				
			NEG	(1-9)	(+)	(++)	(+++)
5 March	1	Muco-pur			✓		
7 March	2						✓
	3						

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 box indicating the treatment regimen and record the drug regimen he should take. Also enter the 3 times per week 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 21.)

Tuberculosis Treatment Card															District TB Register No. _____																																																																																																																																																																																																																																	
Name: _____															Disease site (check one)																																																																																																																																																																																																																																	
Sex: <input type="checkbox"/> M <input type="checkbox"/> F Date of registration in District TB Register: _____															<input type="checkbox"/> Pulmonary <input type="checkbox"/> Extrapulmonary, specify _____																																																																																																																																																																																																																																	
Age: _____ Health facility: _____															Type of patient (check one)																																																																																																																																																																																																																																	
Address: _____															<input type="checkbox"/> New <input type="checkbox"/> Treatment after default <input type="checkbox"/> Relapse <input type="checkbox"/> Treatment after failure <input type="checkbox"/> Transfer in <input type="checkbox"/> Other																																																																																																																																																																																																																																	
Name / address of treatment supporter (if applicable) _____																																																																																																																																																																																																																																																
I. INITIAL PHASE - prescribed regimen and dosages Regimen: <input type="checkbox"/> New <input type="checkbox"/> Retreatment Number of tablets per dose, doses per week, dosage of S: <div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; padding: 2px;">(RHZE)</div> <div style="border: 1px solid black; padding: 2px;">S</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div style="border: 1px solid black; padding: 2px;">Cotrimoxazole</div> <div style="border: 1px solid black; padding: 2px;">ARV</div> <div style="border: 1px solid black; padding: 2px;">Other</div> </div>															Referral by: <input type="checkbox"/> Self-referral <input type="checkbox"/> Community member <input type="checkbox"/> Public facility <input type="checkbox"/> Private facility/provider: <input type="checkbox"/> Other, specify: _____																																																																																																																																																																																																																																	
															Sputum smear microscopy <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Month</th> <th>Date</th> <th>Lab No.</th> <th>Result</th> <th>Weight (kg)</th> </tr> </thead> <tbody> <tr><td>0</td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table>										Month	Date	Lab No.	Result	Weight (kg)	0																																																																																																																																																																																																																		
Month	Date	Lab No.	Result	Weight (kg)																																																																																																																																																																																																																																												
0																																																																																																																																																																																																																																																
															TB/HIV <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Date</th> <th>Result*</th> </tr> </thead> <tbody> <tr><td>HIV test</td><td></td><td></td></tr> <tr><td>HIV test</td><td></td><td></td></tr> <tr><td>CPT start</td><td></td><td></td></tr> <tr><td>ART start</td><td></td><td></td></tr> </tbody> </table>											Date	Result*	HIV test			HIV test			CPT start			ART start																																																																																																																																																																																																											
	Date	Result*																																																																																																																																																																																																																																														
HIV test																																																																																																																																																																																																																																																
HIV test																																																																																																																																																																																																																																																
CPT start																																																																																																																																																																																																																																																
ART start																																																																																																																																																																																																																																																
Tick appropriate box after the drugs have been administered Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (—) through number of days supplied. Ø = drugs not taken																																																																																																																																																																																																																																																
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Day</th> <th>1</th><th>2</th><th>3</th><th>4</th><th>5</th><th>6</th><th>7</th><th>8</th><th>9</th><th>10</th><th>11</th><th>12</th><th>13</th><th>14</th><th>15</th><th>16</th><th>17</th><th>18</th><th>19</th><th>20</th><th>21</th><th>22</th><th>23</th><th>24</th><th>25</th><th>26</th><th>27</th><th>28</th><th>29</th><th>30</th><th>31</th> <th>Number doses this month</th> <th>Total number doses given</th> </tr> </thead> <tbody> <tr><td>Month</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table>															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	Month																																																																																																																																																																										<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Drugs given to supporter</th> </tr> <tr> <th>Date</th> <th>Doses</th> </tr> </thead> <tbody> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </tbody> </table>										Drugs given to supporter		Date	Doses								
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																																																																																																																																																																																																															
Month																																																																																																																																																																																																																																																
Drugs given to supporter																																																																																																																																																																																																																																																
Date	Doses																																																																																																																																																																																																																																															

II. CONTINUATION PHASE

Number of tablets per dose, doses per week

(RH)

(RHE)

Other

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (———●) through number of days supplied. Ø = drugs not taken

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	
Month																																		

Chest X-ray (at start)

Date: _____

(-) Normal
(+) Abnormal
ND Not done

HIV care

Pre ART Register No. _____

CD4 result _____

ART eligibility (Y/N/Unknown) _____

Date eligibility assessed _____

ART Register No. _____

Comments: _____

Treatment outcome

Date of decision _____

☐ Cure

☐ Treatment completed

☐ Died

☐ Treatment failure

☐ Default

☐ Transfer out

Household contacts

First names and surnames	Age	Relationship to case	Date seen	Result

Name and address of contact person: _____

4. 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?
5. a) Who should receive isoniazid to prevent TB?
- b) Which household contacts should receive a BCG immunization against TB?
6. 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) A patient who takes treatment daily missed the appointment yesterday. What should be given for treatment today?
7. A TB patient complains of headache in the evenings after work and has orange urine. What should you do?
8. a) When should a patient on the New patient regimen have a first follow-up sputum examination?
- b) When should a patient on the Retreatment regimen have a first follow-up sputum examination?
- c) On how many occasions should most patients have follow-up sputum examinations?
- d) If a patient on the Retreatment regimen has a positive sputum smear examination after 3 months of treatment, when should the next sputum be collected and why?
9. Below are the laboratory results for Mr Zide's follow-up sputum examination after 5 months of treatment. His weight is 47 kg today.

Laboratory Serial No. 1119

Date collected	Sputum specimen	Visual appearance	RESULTS				
			NEG	(1-9)	(+)	(++)	(+++)
10 Oct	1	Muco-pur			✓		
10 Oct	2	"			✓		
	3						

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

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0	4/5	630	+++	48
2	12/7	801	++	48
3	13/8	898	+	47

10. What action is now needed for Mr Zide (the patient described in question 9)?

11. State the treatment outcome for the following cases:

- a) A new 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 patient completed all of the 6 months of the New patient regimen. The sputum examination results were as follows:

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0	4/5	630	+++	48
2	6/7	919	Neg	49
5	8/10	1120	Neg	

What was the treatment outcome?

- c) This patient has completed 5 months of the New patient regimen. The sputum examination results are as follows:

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
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 patient completed 8 months of the Retreatment regimen. The sputum examination results are as follows:

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0	22 Oct	116	++	27
3	26 Jan	399	Neg	28
5	29 Mar	767	Neg	
8	2 July	1087	Neg	

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 the New patient regimen. (See 1.1.2, 1.1.5)
 - d) Patients who received poor-quality treatment are likely to have bacilli that are resistant to some or all of the drugs taken previously. DST will determine whether the TB bacilli are resistant to rifampicin (R) and isoniazid (H). (See 1.1.3, 1.1.5)
2. The TB cases that are ticked should be referred to a clinician for prescription of an anti-TB regimen.

- ☒ a) pregnant woman with new smear-positive TB
- ☐ b) new patient with extrapulmonary TB; no family members have had TB (*This patient can start the New patient regimen.*)
- ☒ c) man with new smear-positive TB who is on ART
- ☐ d) man with new smear-positive TB who is HIV-positive (not on ART) (*This patient can start the New patient regimen.*)
- ☒ e) 4-year-old girl with smear-positive TB
- ☐ f) woman who previously completed treatment for TB (good quality); now sputum smear-positive (*This patient is a relapse and can start the Retreatment regimen.*)
- ☒ g) woman with new smear-positive TB whose husband is on treatment for MDR-TB (See 1.1.2)
- ☐ h) man with new smear-positive TB who refuses an HIV test (*This patient can start the New patient regimen.*)
- ☒ i) man who was a treatment failure after 5 months on the New patient regimen.

(See 1.1.5)

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

The Retreatment regimen used below is 2(RHZE)/S/1(RHZE)/5(RH)₃E₃. The doses were determined from Figure 5 on page 21. You may have used the Retreatment regimen recommended in your country instead.

Tuberculosis Treatment Card					District TB Register No. _____																																																																																																																																																																																																																						
Name: <u>Jon Narayam</u>					Disease site (check one)																																																																																																																																																																																																																						
Sex: <input checked="" type="checkbox"/> M <input type="checkbox"/> F Date of registration in District TB Register: _____					<input checked="" type="checkbox"/> Pulmonary <input type="checkbox"/> Extrapulmonary, specify _____																																																																																																																																																																																																																						
Age: <u>35</u> Health facility: <u>Ghandi Health Facility</u>					Type of patient (check one)																																																																																																																																																																																																																						
Address: <u>222 Castle Rd, North Akton, Kelbe</u>					<input type="checkbox"/> New <input type="checkbox"/> Treatment after default <input checked="" type="checkbox"/> Relapse <input type="checkbox"/> Treatment after failure <input type="checkbox"/> Transfer in <input type="checkbox"/> Other																																																																																																																																																																																																																						
Name / address of treatment supporter (if applicable) _____																																																																																																																																																																																																																											
I. INITIAL PHASE - prescribed regimen and dosages Regimen: <input type="checkbox"/> New <input checked="" type="checkbox"/> Retreatment Number of tablets per dose, doses per week, dosage of S: (RHZE) <u>4</u> S <u>1.0g</u> Cotrimoxazole _____ ARV _____ Other _____					Sputum smear microscopy <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Month</th> <th>Date</th> <th>Lab No.</th> <th>Result</th> <th>Weight (kg)</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>10/3/09</td> <td>685</td> <td>+++</td> <td>56</td> </tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>		Month	Date	Lab No.	Result	Weight (kg)	0	10/3/09	685	+++	56																																																																																																																																																																																																											
Month	Date	Lab No.	Result	Weight (kg)																																																																																																																																																																																																																							
0	10/3/09	685	+++	56																																																																																																																																																																																																																							
Referral by: <input checked="" type="checkbox"/> Self-referral <input type="checkbox"/> Community member <input type="checkbox"/> Public facility <input type="checkbox"/> Private facility/provider <input type="checkbox"/> Other, specify: _____					TB/HIV <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Date</th> <th>Result*</th> </tr> </thead> <tbody> <tr><td>HIV test</td><td> </td><td> </td></tr> <tr><td>HIV test</td><td> </td><td> </td></tr> <tr><td>CPT start</td><td> </td><td> </td></tr> <tr><td>ART start</td><td> </td><td> </td></tr> </tbody> </table>			Date	Result*	HIV test			HIV test			CPT start			ART start																																																																																																																																																																																																								
	Date	Result*																																																																																																																																																																																																																									
HIV test																																																																																																																																																																																																																											
HIV test																																																																																																																																																																																																																											
CPT start																																																																																																																																																																																																																											
ART start																																																																																																																																																																																																																											
Tick appropriate box after the drugs have been administered Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (—●—) through number of days supplied. Ø = drugs not taken																																																																																																																																																																																																																											
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Day Month</th> <th colspan="31">Days</th> <th rowspan="2">Number doses this month</th> <th rowspan="2">Total number doses given</th> <th colspan="2">Drugs given to supporter</th> </tr> <tr> <th>1</th><th>2</th><th>3</th><th>4</th><th>5</th><th>6</th><th>7</th><th>8</th><th>9</th><th>10</th><th>11</th><th>12</th><th>13</th><th>14</th><th>15</th><th>16</th><th>17</th><th>18</th><th>19</th><th>20</th><th>21</th><th>22</th><th>23</th><th>24</th><th>25</th><th>26</th><th>27</th><th>28</th><th>29</th><th>30</th><th>31</th> <th>Date</th><th>Doses</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>							Day Month	Days																															Number doses this month	Total number doses given	Drugs given to supporter		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Date	Doses																																																																																																																																																
Day Month	Days																															Number doses this month	Total number doses given	Drugs given to supporter																																																																																																																																																																																									
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31			Date	Doses																																																																																																																																																																																								

II. CONTINUATION PHASE		(RH)	(RHE)	E ₃ Other																																																																				
Number of tablets per dose, doses per week		<u>4</u>		<u>6</u>																																																																				
Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (—●—) through number of days supplied. Ø = drugs not taken																																																																								
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Day Month</th> <th>1</th><th>2</th><th>3</th><th>4</th><th>5</th><th>6</th><th>7</th><th>8</th><th>9</th><th>10</th><th>11</th><th>12</th><th>13</th><th>14</th><th>15</th><th>16</th><th>17</th><th>18</th><th>19</th><th>20</th><th>21</th><th>22</th><th>23</th><th>24</th><th>25</th><th>26</th><th>27</th><th>28</th><th>29</th><th>30</th><th>31</th> <th>Number doses this month</th> <th>Total number doses given</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>					Day Month	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																																		
Day Month	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																																							

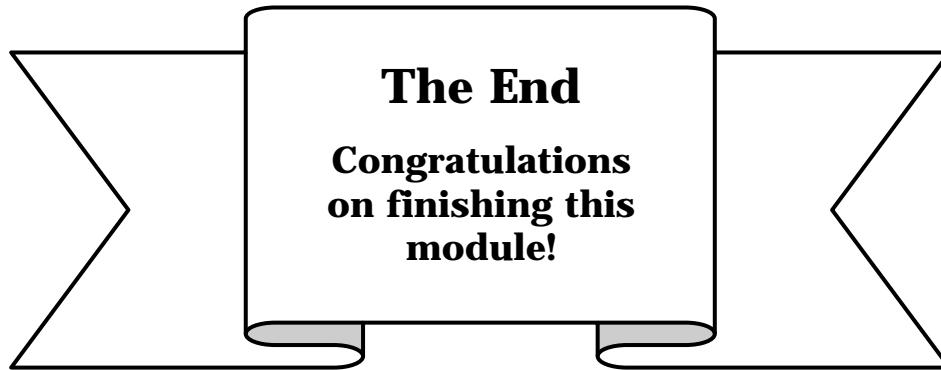
4. a) A community TB treatment supporter is a community member who administers and directly observes a patient's treatment, at a time and location in the community convenient for the patient. (See 1.2 and 1.5)
- b) Any patient who will not go to a health facility for treatment needs a community TB treatment supporter. (See 1.2)
- c) The patient's workplace, the treatment supporter's home, the patient's home. (See 1.5)
5. a) Any child aged less than 5 years who lives in the household of a TB patient and who does not have TB or possible TB, should receive isoniazid as preventive therapy. (See 2.1) Also, any person in the household who is HIV-positive should receive IPT (if national policy recommends this.)
- 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, has not had a positive tuberculin test and does not have symptoms of HIV/AIDS should have a BCG immunization (after completing IPT). (See 2.2)

6. a) *The correct answer is: iii. Watching the patient swallow the drugs. (See 3.1)*
- b) *Give the patient one dose. Do not give a double dose. (See 3.1.1)*
7. *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)*
8. a) *During the last week of the second month of treatment (end of the initial phase of the New patient regimen).*
- b) *During the last week of the third month of treatment (end of the initial phase of the Retreatment regimen).*
- 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.*
- d) *Collect sputum right away to send for culture and DST. (See 4.1, 4.7 and page 49.)*
9. *Below is the portion of Mr Zide's TB Treatment Card with the results for the follow-up sputum examination at 5 months. (See 4.6– 4.8)*

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0	4/5	630	+++	48
2	12/7	801	++	48
3	13/8	898	+	47
5	10/10	1119	+	47

10. *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). Request culture and DST if possible, and refer the patient to a clinician for assessment for MDR-TB. (See 4.6–4.8)*
11. 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 referred for assessment for MDR-TB.)*

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)



Exercises for Module C:
Treat TB Patients



Exercise A

Written Exercise — Selecting a treatment regimen

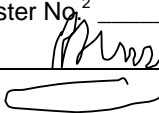
In this exercise, you will select the correct treatment regimen for four patients. Refer to the *Reference Booklet* to familiarize yourself with its contents and become comfortable using it.

The next pages contain information about cases 1–4. 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 out that she has never been treated for TB before. No one in her family has ever had TB. She has written confirmation of a negative HIV test done on 6/6/08.

REQUEST FOR SPUTUM SMEAR MICROSCOPY EXAMINATION							
The completed form with results should be sent promptly by laboratory back to referring facility							
Referring facility ¹ <u>Cochar Health Centre</u>			Date <u>26/08/09</u>				
Name of patient <u>Adesa Abkar</u>			Age <u>22</u>		Sex: <input type="checkbox"/> M <input checked="" type="checkbox"/> F		
Complete address <u>27 Market Street, Aruna</u>							
Reason for sputum smear microscopy examination:							
<input checked="" type="checkbox"/> Diagnosis							
OR <input type="checkbox"/> Follow-up Number of month of treatment: _____ District TB Register No. ² _____							
Name and signature of person requesting examination <u>M Maturughy</u> 							
1. Including public or private health facility/providers							
2. Be sure to enter the patient's District TB Register No. for follow-up of patients on TB treatment							
RESULTS (to be completed in the laboratory)							
Laboratory Serial No. <u>497</u>							
Date collected ³	Sputum Specimen	Visual appearance ⁴	RESULTS				
			NEG	(1-9)	(+)	(++)	(+++)
25-8-09	1	M-p				✓	
26-8-09	2	BS					✓
	3						
3. To be completed by the person collecting the sputum							
4. Blood-stained, muco-purulent, or saliva							
Examined by <u>Romi Ferrah</u>							
Date <u>29-8-09</u>		Signature <u>R Ferrah</u>					

- 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 is her likelihood of MDR-TB? ☐ High ☐ Medium ☐ Low
- d) What treatment regimen would you select, or would you refer the patient to a clinician for prescription of treatment?

Case 2: Marcus Marin

Marcus said that he was treated for TB at the Aruna City Clinic and completed treatment last year. He took the treatment every day and then 3 times per week. You know this clinic and believe the quality of treatment was good. He had an HIV test, which he said was negative, but has no documentation of it. He declined an HIV test today (25/8/09).

REQUEST FOR SPUTUM SMEAR MICROSCOPY EXAMINATION

The completed form with results should be sent promptly by laboratory back to referring facility

Referring facility¹ Cochar Health Centre Date 28/08/09


Name of patient Marcus Marin Age 33 Sex: ☒ M ☐ F

Complete address 131 Longstreet, Aruna

Reason for sputum smear microscopy examination:

☒ Diagnosis

OR ☐ Follow-up Number of month of treatment: _____ District TB Register No.² _____

Name and signature of person requesting examination M Maturughy 

1. Including public or private health facility/providers

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

RESULTS (to be completed in the laboratory)

Laboratory Serial No. 489

Date collected ³	Sputum Specimen	Visual appearance ⁴	RESULTS				
			NEG	(1-9)	(+)	(++)	(+++)
25-8-09	1	M-p			✓		
27-8-09	2	M-p				✓	
	3						

3. To be completed by the person collecting the sputum

4. Blood-stained, muco-purulent, or saliva

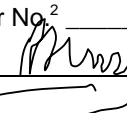
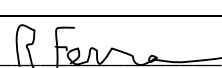
Examined by Romi Ferrah

Date 30-8-09 Signature R Ferrah

- 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 is his likelihood of MDR-TB? ☐ High ☐ Medium ☐ Low
- d) What treatment regimen would you select, or would you refer the patient to a clinician for prescription of treatment?

Case 3: Raj Makena

When you interview Raj, you discover that he is HIV-positive (documentation dated 19 September 2007) and he takes co-trimoxazole and ART. He said that the government clinic where he receives ART asked him to go to this health centre for sputum examination. He has never been treated for TB before, nor has anyone in his family.

REQUEST FOR SPUTUM SMEAR MICROSCOPY EXAMINATION							
<i>The completed form with results should be sent promptly by laboratory back to referring facility</i>							
Referring facility ¹ <u>Cochar Health Centre</u>				Date <u>28/08/09</u>			
Name of patient <u>Raj Makena</u>				Age <u>28</u>		Sex: <input checked="" type="checkbox"/> M <input type="checkbox"/> F	
Complete address <u>11 Market Place, Aruna</u>							
Reason for sputum smear microscopy examination:							
<input checked="" type="checkbox"/> Diagnosis							
OR <input type="checkbox"/> Follow-up Number of month of treatment: _____ District TB Register No. ² _____							
Name and signature of person requesting examination <u>M Maturughy</u> 							
<small>1. Including public or private health facility/providers</small> <small>2. Be sure to enter the patient's District TB Register No. for follow-up of patients on TB treatment</small>							
RESULTS (to be completed in the laboratory)							
Laboratory Serial No. <u>560</u>							
Date collected ³	Sputum Specimen	Visual appearance ⁴	RESULTS				
			NEG	(1-9)	(+)	(++)	(+++)
25-8-09	1	BS			✓		
27-8-09	2	BS			✓		
	3						
<small>3. To be completed by the person collecting the sputum</small> <small>4. Blood-stained, muco-purulent, or saliva</small>							
Examined by <u>Romi Ferrah</u>							
Date <u>30-8-09</u>			Signature <u>R Ferrah</u> 				

- 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 is his likelihood of MDR-TB? ☐ High ☐ Medium ☐ Low
- d) What treatment regimen would you select, or would you refer the patient to a clinician for prescription of treatment?

Case 4: Janu Nair

Janu said that he took anti-TB drugs for a few months early in the year and then stopped. He explained that he had to purchase the drugs and so he stopped buying them when he started feeling better. He had a rapid HIV test at your health centre on 11/10/09 and it was negative.

REQUEST FOR SPUTUM SMEAR MICROSCOPY EXAMINATION

The completed form with results should be sent promptly by laboratory back to referring facility

Referring facility¹ Cochar Health Centre Date 10/12/09


Name of patient Janu Nair Age 56 Sex: ☒ M ☐ F

Complete address 45 College Street, Aruna

Reason for sputum smear microscopy examination:

☒ Diagnosis

OR ☐ Follow-up Number of month of treatment: _____ District TB Register No.² _____

Name and signature of person requesting examination M Maturughy 

1. Including public or private health facility/providers

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

RESULTS (to be completed in the laboratory)

Laboratory Serial No. 697

Date collected ³	Sputum Specimen	Visual appearance ⁴	RESULTS				
			NEG	(1-9)	(+)	(++)	(+++)
11-10-09	1	M-p	✓				
12-10-09	2	M-p			✓		
	3						

3. To be completed by the person collecting the sputum

4. Blood-stained, muco-purulent, or saliva

Examined by Romi Ferrah

Date 13-10-09 Signature R Ferrah

- 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 is his likelihood of MDR-TB? ☐ High ☐ Medium ☐ Low
- d) What treatment regimen would you select, or would you refer the patient to a clinician for prescription of treatment?

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



Then **GO BACK** to page 11. Read to the next stop sign (page 29).



Exercise B

Written Exercise — Preparing a *TB Treatment Card*

In this exercise, you will prepare *TB Treatment Cards* for the four cases described in Exercise A. Use the information provided about each patient (including the TB laboratory forms) in Exercise A (pages 72–75) and the 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.
- Tick a box to indicate who referred the patient for diagnosis or care. If a private facility or provider, record the name and address or telephone number, so that the referring person can be contacted.
- Record the results of the diagnostic sputum smear examination, any chest X-ray results and any clinician's diagnosis.
- Record HIV status and any information about HIV care.
- Record the TB treatment regimen needed.
- Then look up the drug regimen and the dose for the patient's weight. Record the correct frequency (subscript 3 by the drug; or no subscript, if daily). Fill in the number of tablets (or grams of streptomycin) for each dose for the initial and continuation phases. Use the recommended treatment regimens given on page 21, or in the *Reference Booklet*, or use one provided by your facilitator.
- List the patient's household contacts.
- 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 patient's *TB Treatment Card* together.

Case 1: Adesa Abkar

Today, 2 September 2009, Adesa returned to the health centre for the sputum examination results. She explains that she decided to come to the facility last week because she had been coughing persistently for several weeks and was feeling very poorly. Her weight is 48 kg.

After discussion, she says that she will come to the health centre for directly-observed treatment for TB. Her contact person is Mara Abkar (mother), 102 Market Street, Aruna.

Adesa lives with her new husband, Sowroy Peeyush, who is 25 years old. They have no children, and no one else lives with them.

This health centre uses a 3 times per week regimen in the continuation phase.

You observe as Adesa swallows her first tablets today.

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

On 4 September 2009, Marcus returned to the health centre. You explain to him that the TB in his lungs has returned, and register him for TB treatment. Marcus said that he came to the facility several days ago because his wife was tired of hearing him cough and told him to go. His weight is 56 kg.

After discussion, Marcus said that he would like to receive directly-observed treatment from the pharmacist at Shop Care Rx, at 95 Market Road. His friend is being treated for TB by that man and he is a good man. You agree and ask him to bring the pharmacist with him to the health centre tomorrow. Marcus says that his wife, Anna (same address), will be his contact person.

He declined an HIV test last week. You again recommend that he be tested, because it could make a difference in his response to TB treatment. He agrees to a rapid HIV test today. It is negative.

Living in the household are his wife (28 years old), his three sons – Solomon (5 years old) and twins Mustaq and Tahneed (aged 2 years) – and his mother, Sanjida Marin (aged 50).

This health centre uses a 3 times per week regimen in the continuation phase.

You give Marcus the first dose today and observe his intake.

Case 3: Raj Makena

On 1 September 2009, because Raj Makena is on ART, you referred him to the clinician at the Maduk District Hospital to prescribe his TB treatment. He has returned to your health centre today (3 September 2009) and he gives you a referral note from the clinician, Dr Thun. Dr Thun prescribed the New patient regimen to begin immediately. Raj weighs 53 kg.

Raj has agreed to return daily to this health centre for directly-observed treatment. His contact person is Sajiv Gondar, Circle Road (behind Government House), Aruna.

Raj shows you his *HIV Care Card*. His ART Register number is 322. He began taking both co-trimoxazole (two 480 mg tablets daily) and ART on 28 March 2008. His ART is d4T-3TC in the morning and d4T-3TC and EFV in the evening.

He lives with his wife, Salma (aged 29), his brother, Maliq (aged 31), and his brother's son, Qader (aged 9).

You observe as Raj swallows his first tablets today (3 September) and record the intake.

This health centre uses a 3 times per week regimen in the continuation phase.

Case 4: Janu Nair

Janu Nair was initially referred to the health centre by a private physician, Dr Zia Houk (telephone 355-3147), who suspected that he may have TB again. You collected sputa and sent them to the laboratory. You saw Mr Nair again on 14 October 2009 and registered him for TB treatment. His weight was 42 kg. Because he was “Treatment after default” and had poor-quality treatment previously, he is at high risk for MDR-TB. You referred him to the clinician at the Maduk District Hospital for prescription of TB treatment.

On 16 October 2009, Mr Nair returns with a prescription for the Retreatment regimen. The clinician also took a chest X-ray and noted that it was positive, with cavities (report dated 15 October). He sent sputum for culture and DST, but does not expect to receive the results for several months.

Mr Nair agrees to come to the health centre for directly-observed treatment. His contact person is Bair Prabakar, who manages the grocery at 39 College Street, Aruna.

Mr Nair lives with his son, Prabu, and his daughter-in-law, Kineesha (both aged 35). They have a daughter, Cali (aged 7) and a son, Prabu (aged 10).

This health centre uses a 3 times per week regimen in the continuation phase.

You observe as Mr Nair swallows his first tablets today (16 October) and then give him the streptomycin injection.

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 29. Read to the next stop sign (page 37).

Tuberculosis Treatment Card

District TB Register No. _____

Name: _____

Sex: ☐ M ☐ F Date of registration in District TB Register: _____

Age: _____ Health facility: _____

Address: _____

Name / address of treatment supporter (if applicable) _____

I. INITIAL PHASE - prescribed regimen and dosages

Regimen: ☐ New ☐ Retreatment

Number of tablets per dose, doses per week, dosage of S:

(RHZE)	S

Cotrimoxazole	ARV	Other

Referral by:

- ☐ Self-referral
☐ Community member
☐ Public facility
☐ Private facility/provider: _____

☐ Other, specify: _____

Disease site (check one)

☐ Pulmonary ☐ Extrapulmonary, specify _____

Type of patient (check one)

- ☐ New ☐ Treatment after default
☐ Relapse ☐ Treatment after failure
☐ Transfer in ☐ Other

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0				

TB/HIV		
	Date	Result*
HIV test		
HIV test		
CPT start		
ART start		

* (Pos) Positive; (Neg) Negative; (I) Discordant/Inconclusive; (ND) Not Done/unknown

Tick appropriate box after the drugs have been administered

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (—●—) through number of days supplied. Ø = drugs not taken

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	
Month																																		Date	Doses

II. CONTINUATION PHASE

Number of tablets per dose, doses per week

(RH)	(RHE)	Other

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (———●) through number of days supplied. Ø = drugs not taken

Day Month	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
																								</									

Chest X-ray (at start)

Date:

(-) Normal
(+) Abnormal
ND Not done

HIV care

Pre ART Register No.

CD4 result

ART eligibility (Y/N/Unknown)

Date eligibility assessed

ART Register No.

Comments: _____

Household contacts

First names and surnames	Age	Relationship to case	Date seen	Result

Treatment outcome

Date of decision _____

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

Name and address of contact person: _____

II. CONTINUATION PHASE

Number of tablets per dose, doses per week

(RH)	(RHE)	Other

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (———●) through number of days supplied. Ø = drugs not taken

Day Month	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

Chest X-ray (at start)

Date:

(-) Normal
(+) Abnormal
ND Not done

HIV care

Pre ART Register No.	
CD4 result	
ART eligibility (Y/N/Unknown)	
Date eligibility assessed	
ART Register No.	

Comments: _____

Treatment outcome

Date of decision _____

☐ Cure

☐ Treatment completed

☐ Died

☐ Treatment failure

☐ Default

☐ Transfer out

Household contacts

First names and surnames	Age	Relationship to case	Date seen	Result

Name and address of contact person: _____

Tuberculosis Treatment Card																									District TB Register No. _____												
Name: _____																																					
Sex: <input type="checkbox"/> M <input type="checkbox"/> F Date of registration in District TB Register: _____																																					
Age: _____ Health facility: _____																																					
Address: _____																																					
Name / address of treatment supporter (if applicable) _____																																					
I. INITIAL PHASE - prescribed regimen and dosages Regimen: <input type="checkbox"/> New <input type="checkbox"/> Retreatment Number of tablets per dose, doses per week, dosage of S: <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 2px;">(RHZE)</div> <div style="border: 1px solid black; padding: 2px;">S</div> </div>															Referral by: <input type="checkbox"/> Self-referral <input type="checkbox"/> Community member <input type="checkbox"/> Public facility <input type="checkbox"/> Private facility/provider: _____ <input type="checkbox"/> Other, specify: _____																						
<div style="border: 1px solid black; padding: 2px;">Cotrimoxazole</div>										<div style="border: 1px solid black; padding: 2px;">ARV</div>										<div style="border: 1px solid black; padding: 2px;">Other</div>																	
Tick appropriate box after the drugs have been administered Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (—●—) through number of days supplied. Ø = drugs not taken																																					
Day Month	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	

Disease site (check one)

☐ Pulmonary ☐ Extrapulmonary, specify _____

Type of patient (check one)

☐ New ☐ Treatment after default
☐ Relapse ☐ Treatment after failure
☐ Transfer in ☐ Other

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0				

TB/HIV		
	Date	Result*
HIV test		
HIV test		
CPT start		
ART start		

* (Pos) Positive; (Neg) Negative; (I) Discordant/Inconclusive; (ND) Not Done/unknown

II. CONTINUATION PHASE

Number of tablets per dose, doses per week

(RH)	(RHE)	Other

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (———●) through number of days supplied. Ø = drugs not taken

Day Month	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

Chest X-ray (at start)

Date:

(-) Normal
(+) Abnormal
ND Not done

HIV care

Pre ART Register No.

CD4 result

ART eligibility (Y/N/Unknown)

Date eligibility assessed

ART Register No.

Comments: _____

Household contacts

First names and surnames	Age	Relationship to case	Date seen	Result

Treatment outcome

Date of decision _____

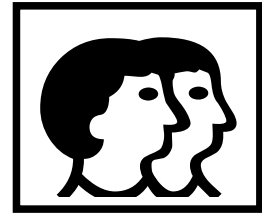
- ☐ Cure
☐ Treatment completed
☐ Died
☐ Treatment failure
☐ Default
☐ Transfer out

Name and address of contact person: _____



Exercise C

Written Exercise and Discussion – Giving directly-observed treatment



In this exercise, you will practise recording treatment on a *TB Treatment Card*. **Find the *TB Treatment Card* for Raj Makena on page 90.** Below is a list of the days that the patient received treatment, or missed a scheduled treatment, or the Cochar 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 at the health centre on Monday, 3 September 2009. He received directly-observed treatment on the following days:

- 4, 5, 6, 7 and 8 September.
- 9 September (Sunday), the health centre was closed.
- 10, 11, 12, 13, 14 and 15 September.
- 16 September was a Sunday.
- He did not come on 17, 18 or 19 September.
- On 20 September, the health worker visited Raj's home, found out that he had been sick and gave him directly-observed treatment in his home.
- 21 and 22 September.
- 23 September was a Sunday.
- 24, 25, 26, 27, 28 and 29 September.
- 30 September was a Sunday.
- 1, 2, 3, 4, 5 and 6 October.
- 7 October was a 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*.
- 8, 9, 10, 11 and 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 and 20 October.
- 21 October was a Sunday.
- 22, 23, 24, 25, 26 and 27 October.
- 28 October was a Sunday.

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

- Received directly-observed treatment on 29, 30 and 31 October.
- Received directly-observed treatment on 1, 2 and 3 November.
- 4 November was a Sunday.
- Received directly-observed treatment on 5, 6, 7, 8 and 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 5/11/09. 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 a Sunday.
- He 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 a Sunday.
- He received directly-observed treatment on 19, 21 and 23 November.
- 25 November was a Sunday.
- He received directly-observed treatment on 26, 28 and 30 November.
- 2 December was a Sunday.
- The next day, he received directly-observed treatment.
- He did not come for treatment on 5 or 7 December.
- 9 December was a Sunday.
- He received directly-observed treatment on 10, 12 and 14 December.
- 16 December was a Sunday.
- He 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 and 30 December were Sundays.
- On 31 December, he received directly-observed treatment.
- He received directly-observed treatment on 2 and 4 January 2010.

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 your answers to the questions below. When the group is ready, there will be a 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 was waiting. The health worker recognized a TB patient, Mary Abatu, and did not want to keep her waiting. He signalled to Mary to come ahead of the queue and handed her the day's tablets. He said to take the tablets with her and swallow them when she found something to drink.

What could happen to those tablets? (List five 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 38.
Read to the next stop sign (page 50).**

Exercise C

Tuberculosis Treatment Card

District TB Register No. 1261

Name: Raj Makena

Sex: ☒ M ☐ F Date of registration in District TB Register: 8 Oct 2009

Age: 28 Health facility: Cochar Health Centre

Address: 11 Market Place, Aruna

Name / address of treatment supporter (if applicable)

I. INITIAL PHASE - prescribed regimen and dosages

Regimen: ☒ New ☐ Retreatment

Number of tablets per dose, doses per week, dosage of S:

(RHZE)	S
3	

Cotrimoxazole	Morning	ARV	Evening	Other
2	d4T-3TC	d4T-3TC, EFV		

Referral by:

- ☐ Self-referral
☐ Community member
☒ Public facility
☐ Private facility/provider:

☐ Other, specify:

Disease site (check one)

☒ Pulmonary ☐ Extrapulmonary, specify _____

Type of patient (check one)

- ☒ New ☐ Treatment after default
☐ Relapse ☐ Treatment after failure
☐ Transfer in ☐ Other

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0	30-8-09	560	+	53

TB/HIV		
	Date	Result*
HIV test	19/9/07	pos
HIV test		
CPT start	28/3/08	
ART start	28/3/08	

* (Pos) Positive; (Neg) Negative; (I) Discordant/Inconclusive; (ND) Not Done/unknown

Tick appropriate box after the drugs have been administered

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (—●—) through number of days supplied. Ø = drugs not taken

Daily intake observed: enter ✓ if intake supply; enter X on day which drugs are collected and draw a horizontal line through number of days supplies																																	Average no. of days supply		
Day Month	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	Dose		
Sept		—	✓	✓	✓	✓	✓	✓	—	✓	✓	✓	✓	✓	✓	—	✓	∅	∅	∅	✓	✓	—	✓	✓	✓	✓	✓	✓	—	31	21			
Oct	✓	✓	✓	✓	✓	✓	—	✓	✓	✓	✓	✓	✓	—	—————					✓	✓	—	✓	✓	✓	✓	✓								

II. CONTINUATION PHASE

Number of tablets per dose, doses per week

Other

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (——●) through number of days supplied. Ø = drugs not taken

[illegible]

Chest X-ray (at start)
Date: _____

(-) Normal
(+) Abnormal
ND Not done

HIV care	
Pre ART Register No.	
CD4 result	
ART eligibility (<i>Y/N/Unknown</i>)	
Date eligibility assessed	
ART Register No.	322

Comments: 1/9/09 - Referred to Maduk District Hospital
For TB treatment plan. 3/9 - Dr Thun prescribes
New patient regimen. 21 Sept - Home visit, has been
sick.

Treatment outcome

Date of decision _____

☐ Cure

☐ Treatment completed

☐ Died

☐ Treatment failure

☐ Default

☐ Transfer out

Household contacts				
First names and surnames	Age	Relationship to case	Date seen	Result
Salma Makena	29	wife		
Malig Makena	31	brother		
Qader Makena	9	nephew		

Name and address of contact person: Sajiv Gondar, Circle Rd behind Government House, Aruna



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 the results of sputum smear microscopy. You may refer to the schedule for follow-up sputum smear examinations in the module on page 49, or in the *Reference Booklet*.

PART I

Case 1: Adesa Abkar

Adesa Abkar is on the New patient regimen. Her sputum smear examination after 2 months was still positive. 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 the Retreatment regimen. 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 the next sputum smear examination?

Case 3: Raj Makena

Raj is on the New patient regimen. His sputum smear examination at 2 months was negative. When is his next sputum smear examination due?

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)?

PART II

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

Case 1: Adesa Abkar (New)

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

Month	Results of sputum examination			Weight (kg)
	Date	Lab. No.	Result	
0	28/8/09	497	+++	48
2	25/10/09	581	+	49
3	24/11/09	687	neg	49
5	28/1/10	67	+	49

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

Case 2: Marcus Marin (Retreatment)

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

Case 3: Raj Makena (New)

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

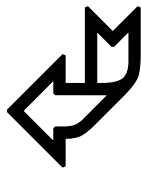
When should he get another sputum smear examination?

Case 4: Janu Nair (Retreatment)

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 51. Read to the next stop sign (page 55).



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 (New)

In the previous exercise, you found out that Adesa Abkar had a positive sputum smear examination after 5 months of treatment (date of sputum examination 28/1/10) 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 _____	
<input type="checkbox"/>	Cure
<input type="checkbox"/>	Treatment completed
<input type="checkbox"/>	Died
<input type="checkbox"/>	Treatment failure
<input type="checkbox"/>	Default
<input type="checkbox"/>	Transfer out

Case 2: Marcus Marin (Retreatment)

Marcus Marin completed 8 months of the Retreatment regimen on 9 May 2009. Below are his sputum smear examination results.

Sputum smear microscopy				Weight (kg)
Month	Date	Lab. No.	Result	
0	23/8/09	489	++	56
3	29/11/09	699	neg	58
5	30/1/10	77	neg	58
8	7/5/10	401	neg	59

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

Treatment outcome	
Date of decision _____	
<input type="checkbox"/>	Cure
<input type="checkbox"/>	Treatment completed
<input type="checkbox"/>	Died
<input type="checkbox"/>	Treatment failure
<input type="checkbox"/>	Default
<input type="checkbox"/>	Transfer out

Case 3: Raj Makena (New)

Raj completed 6 months of treatment on 5 March 2009. Below are his sputum smear examination results.

Month	Results of sputum examination			Weight (kg)
	Date	Lab. No.	Result	
0	30-8-09	506	+	53
2	1-11-09	622	neg	51
5	1-2-10	111	neg	52

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

Treatment outcome Date of decision ____ <input type="checkbox"/> Cure <input type="checkbox"/> Treatment completed <input type="checkbox"/> Died <input type="checkbox"/> Treatment failure <input type="checkbox"/> Default <input type="checkbox"/> Transfer out
--

Case 4: Janu Nair (Retreatment)

Below are the results of Janu's sputum smear examinations. He last came for treatment on 25 April 2010. 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.

Month	Results of sputum examination			Weight (kg)
	Date	Lab. No.	Result	
0	13-10-09	697	+	42
3	28-1-10	119	neg	42
5	18-3-10	252	neg	43

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 56. Read and
work to the end of the module (page 68).

Annexes

A. <i>TB Treatment Card</i>	103
B. <i>Tuberculosis Identity Card</i>	105
C. Recommended TB treatment regimens	106
Recommended dosages of anti-TB drugs	107
Available presentations of fixed-dose combinations	107
D. Collect sputum for examination.....	108
E. Periodic follow-up visit to clinician	109

Tuberculosis Treatment Card

District TB Register No. _____

Name: _____

Sex: ☐ M ☐ F Date of registration in District TB Register: _____

Age: _____ Health facility: _____

Address: _____

Name / address of treatment supporter (if applicable) _____

I. INITIAL PHASE - prescribed regimen and dosagesRegimen: ☐ New ☐ Retreatment

Number of tablets per dose, doses per week, dosage of S:

(RHZE)

S

Co-trimoxazole

ARV

Other

Referral by:

- ☐ Self-referral
☐ Community member
☐ Public facility
☐ Private facility/provider: _____

☐ Other, specify: _____**Disease site** (check one)☐ Pulmonary ☐ Extrapulmonary, specify _____**Type of patient** (check one)

- ☐ New ☐ Treatment after default
☐ Relapse ☐ Treatment after failure
☐ Transfer in ☐ Other

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0				

TB/HIV		
	Date	Result*
HIV test		
HIV test		
CPT start		
ART start		

* (Pos) Positive; (Neg) Negative; (I) Discordant/Inconclusive; (ND) Not Done/unknown

Tick appropriate box after the drugs have been administered

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (———●) through number of days supplied. Ø = drugs not taken

Daily intake observed: enter '+' if chronic supply; enter 'X' on day when drugs are collected and draw a horizontal line () through number of days supplied; 0 = drugs not taken																																	
Day Month	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

II. CONTINUATION PHASE

Number of tablets per dose, doses per week

(RH)	(RHE)	Other

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line (———●) through number of days supplied. Ø = drugs not taken

Daily intake observed: enter 1 if child's supply; enter X on day when drugs are collected and draw a horizontal line () through; number of days supplied; 0 = drugs not taken																																	
Day Month	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

Chest X-ray (at start)
Date:
(-) Normal (+) Abnormal ND Not done

HIV care	
Pre ART Register No.	
CD4 result	
ART eligibility (Y/N/Unknown)	
Date eligibility assessed	
ART Register No.	

Comments: _____

Treatment outcome
Date of decision _____
<input type="checkbox"/> Cure
<input type="checkbox"/> Treatment completed
<input type="checkbox"/> Died
<input type="checkbox"/> Treatment failure
<input type="checkbox"/> Default
<input type="checkbox"/> Transfer out

Household contacts

First names and surnames	Age	Relationship to case	Date seen	Result

Name and address of contact person: _____

Tuberculosis Identity Card

Name _____

District TB Register No. _____

Address _____

Appointment dates: _____

Sex: ☐ M ☐ F Age _____ Date treatment started _____

Health facility: _____

Supporter (name and address) _____

Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0				

Disease site (check one)	
<input type="checkbox"/> Pulmonary	<input type="checkbox"/> Extrapulmonary, specify _____
Type of patient (check one)	
<input type="checkbox"/> New	<input type="checkbox"/> Treatment after default
<input type="checkbox"/> Relapse	<input type="checkbox"/> Treatment after failure
<input type="checkbox"/> Transfer in	<input type="checkbox"/> Other

I. INITIAL PHASE☐ New ☐ Retreatment

Drugs and dosage:

(RHZE)

S

Other

II. CONTINUATION PHASE

Drugs and dosage:

(RH)

(RHE)

Other

REMEMBER

Recommended TB treatment regimens

TB treatment regimen	TB patients	TB treatment regimens		
		Initial phase ^a	Continuation phase ^a	
		Daily (28 doses per month)	Daily (28 doses per month)	3 times per week (12 doses per month)
New	<ul style="list-style-type: none"> New smear-positive or smear-negative pulmonary TB New extrapulmonary TB 	2 (RHZE) = 56 doses of RHZE	4 (RH) = 112 doses of RH	4 (RH)₃ = 48 doses of RH
Retreatment	<ul style="list-style-type: none"> Previously treated sputum smear-positive or smear-negative pulmonary TB: <ul style="list-style-type: none"> - relapse - treatment after default Previously treated extrapulmonary TB 	2 (RHZE)S/ 1 (RHZE) = 84 doses of RHZE plus 56 doses of S	5 (RHE) = 140 doses of RHE	5 (RH)₃E₃ = 60 doses of RHE
MDR	<ul style="list-style-type: none"> Treatment after failure MDR-TB cases 	Specially designed standardized MDR regimen or individualized MDR regimens are suggested for these patients		

^a Direct observation of drug intake is always required during treatment including rifampicin.

Recommended dosages of anti-TB drugs

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

* for children

Available presentations of fixed-dose combinations

Fixed-dose combinations		Presentations (combination tablets)	
		For daily administration	For administration 3 times per week
2-FDC	rifampicin + isoniazid (RH)	(R 150 mg + H 75 mg), or (R 60 mg + H 30 mg)*	(R 150 mg + H 150 mg), or (R 60 mg + H 60 mg)*
2-FDC	isoniazid + ethambutol (HE)	(H 150 mg + E 400 mg)	NA
3-FDC	rifampicin + isoniazid + ethambutol (RHE)	(R 150 mg + H 75 mg + E 275 mg)	NA
3-FDC	rifampicin + isoniazid + pyrazinamide (RHZ)	(R 60 mg + H 30 mg + Z 150 mg)*	NA
4-FDC	rifampicin + isoniazid + pyrazinamide + ethambutol (RHZE)	(R 150 mg + H 75 mg + Z 400 mg + E 275 mg)	NA

* for children

¹ Patients aged over 60 years may not be able to tolerate more than 500–750 mg streptomycin daily.

In many health facilities, the specimen number is the TB suspect number or the patient's District TB number, followed by -1 or -2.

Collect sputum for examination

- ▶ **Explain** that the TB suspect needs a sputum examination to determine whether they have TB bacilli in the lungs.
- ▶ **List** the TB suspect's name and address in the *Register of TB Suspects*.
- ▶ **Label** the sides of the sputum containers (not the lids). Two samples are needed for diagnosis of TB or for follow-up examination.
- ▶ **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, away from other people and 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.

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

Schedule for collecting two 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**).

- ▶ **When you collect the second sample, tell the TB suspect when to return for the results.**
- ▶ **Store**
 - Check that the lid is tight. Wipe off the outside of the container, if needed.
 - Isolate each sputum container in its own plastic bag, if possible, or wrap in newspaper.
 - Store in a cool place. (If samples will be sent for culture, keep refrigerated.)
 - Wash your hands.
- ▶ **Send**
 - Send the samples from health facility to the laboratory.
 - Total time from collection until reaching laboratory should be no more than 5 days. (Samples sent for culture should be sent promptly and reach the laboratory in 1–2 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 periodically evaluate TB patients to monitor their clinical progress. This visit of the TB patient to the clinician should be made when the results of a recent follow-up sputum examination are available, so that they can be discussed with the patient.

This visit should include the steps below.

- Assess the patient's general clinical 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 its treatment and discuss any fears or concerns.
- Review the result of any recent sputum examination (sputum smear and/or culture). 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 MDR-TB or HIV). If in doubt, consult the National TB Control Programme manager or the designated MDR-TB coordinator.²
- Be familiar with the most frequently 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 ensure the patient is receiving HIV care and to identify and treat opportunistic infections. The possible impact of HIV on TB treatment includes 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.

² *Management of drug-resistant tuberculosis: training for health facility staff*. Geneva, World Health Organization, 2009 (WHO/HTM/TB/2009.417A–J).

