

Management of Tuberculosis Training for Health Facility Staff

K. Management of Tuberculosis Reference Booklet

SECOND EDITION



WORLD HEALTH ORGANIZATION
Geneva



TUBERCULOSIS FOUNDATION

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



**MANAGEMENT OF TUBERCULOSIS
REFERENCE BOOKLET**

*Job-aids, worksheets and forms
for use by health facility staff*

SECOND EDITION



**World Health Organization
Geneva
2009**



K N C V



TUBERCULOSIS FOUNDATION



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Reference Booklet

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I. SPUTUM COLLECTION AND DIAGNOSIS

Identify TB Suspects

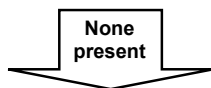
- **Identify TB suspects among people coming to your health facility for a current illness**

1. Assess for emergency signs

- Respiratory rate >30 breaths per minute?
- Fever >38 °C?
- Pulse > 120 beats per minute? or
- Unable to walk unaided?



If any emergency sign is present, refer patient to a clinician for assessment and care without delay.



Then determine:

2. Did the patient come because of cough?

3. Does the patient have signs or symptoms compatible with TB without cough?

- bloody sputum?
- night sweats?
- fever? or
- weight loss?

4. Is the patient at high risk of TB?

- HIV-positive?
- household contact of a person with infectious TB? or
- immunocompromised?



If yes to any of these, the patient is a TB suspect and should have a sputum examination.

- **Screen all adults entering the facility for TB suspects**

Ask every adult (aged 15 years or older) who comes to the health facility:

- Do you have a cough?
- How long have you been coughing for?

Any adult who has coughed for 2 weeks or more is a “TB suspect” for pulmonary tuberculosis and should have a sputum examination.

Collect sputum samples for examination

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

- ▶ **Explain** that the TB suspect needs a sputum examination to determine whether there are TB bacilli in the lungs.
- ▶ **List** the TB suspect's name and address in the *Register of TB Suspects*.
- ▶ **Label** 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 Smear Microscopy 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.)

SPUTUM COLLECTION AND DIAGNOSIS

Instructions and example: Use one row for every TB suspect. Assign a number to each TB suspect; enter the name, age and address; and collect sputum. Enter the date sputum samples are sent to the laboratory. Complete the rest of the form as shown in the example below.

Year 2009

REGISTER OF TB SUSPECTS

Facility: Patangeta Health Centre

Date (dd/mm)	TB Suspect Number	Name of TB Suspect	Age		Complete Address	Result of HIV test *	Date first sputum collected	Date sputum sent to laboratory	Date results received	Results of Sputum Examinations			TB Treatment Card opened? (record date)	Observations/ Clinician's diagnosis
			M	F						1	2	3		
8/10	332	Evaristo Sarda	48		Rambar Village, Bardu	neg	8/10	10/10	15/10	Neg	Neg			
	333	Jai Shrestha	24		980 Center Street, Patangeta	ND	8/10	10/10	15/10	Neg	Neg			Dr. Pho, Town Ctr. 333-4354
9/10	334	Ahmed Masud	44		House 4/1E, Street 12,	Record "Neg" if negative or, if positive, record the grade.	9/10	10/10	15/10	Neg	+		17/10	Ahmed Masud has smear-positive TB. So do Sheena Arday, Mary Abatu, and Kamran Nyathi. A treatment card was opened for each of them.
	335	Sheena Arday		34	1A Hope Road, Patangeta		9/10	12/10	18/10	++	+++		19/10	
	336	Phyllis Kotei		40	71 Long Street, Patangeta	ND	9/10	10/10	15/10	Neg	Neg			
10/10	337	Emil Avornyo	38		Bulo House, Market St, Patangeta	neg	10/10	12/10	18/10	Neg	Neg			
	338	Mary Abatu		19	33 Primos Road, Patangeta	ND	10/10	12/10	18/10	++	+++		20/10	A treatment card was opened for each of them.
12/10	339	Grace Msiska		27	Parmu Village	ND	12/10	17/10	19/10	Neg	Neg			
15/10	340	Mary Musowe		22	34 Airport Rd, Patangeta	ND	15/10	17/10	19/10	Neg	Neg			
	341	Josiah Kasere	24		Isoli Village	neg	15/10			Neg	Neg			
16/10	342	Kamran Nyathi	49		Half Tree Rd, Isoli Village	ND	16/10			+	3		27/10	
	343	Sarah Nyathi		39	Half Tree Rd, Isoli Village	neg	16/10	19/10	22/10	Neg	Neg			Ref'd - fever, cough
	344	Mohammed Fazal	41		312 Dubar St, Patangeta	pos	17/10	19/10	22/10	Neg	Neg			HIV clinic ref'd
17/10	345	Mansour Osman	54		10A Market Rd., Patangeta	ND	17/10	19/10	22/10	Neg	Neg			
18/10	346	Nesa Farah		36	Parmu Village	pos	18/10	19/10	24/10	Neg	Neg		30/10	Extrapul TB
	347	Bhagban Dutta	61		114D Airport Rd, Patangeta	neg	29/10	2/11	4/11	Neg	Neg			
19/10	348	A.K. Prakash	55		Middle Street, # 22, Raman	ND	19/10	24/10	31/10	Neg	Neg			
22/10	349	K. Misra		31	Street 9, Bel Village	ND	22/10	24/10						A clinician diagnosed extrapulmonary TB, and a treatment card was opened.
	350	Ram Singh	22		Bulrat Street, # 4, Patangeta	This suspect's results were not received. Ask the laboratory about them.				Neg	Neg			
	351	Reeza Himonga		25	Rickshaw Rd, K House, Patangeta	ND		24/10	31/10	Neg	Neg			

* (Pos) Positive; (Neg) Negative; (I) Discordant/Inconclusive; (ND) Not Done/unknown. Documented evidence of HIV test performed during or before TB treatment is reported here.

Instructions and example: *Request for Sputum Examination*

Fill out the *Request for Sputum Examination* as shown below in an example for a new TB suspect. Write the patient's complete name and address. Send this form with the patient's sputum samples to the microscopy laboratory. After the sputum examination, the laboratory will complete the results section and then return the form to the health facility. (Note that this same form is used when requesting sputum smear examination for diagnosis and also when sending sputum for follow-up of treatment.)

REQUEST FOR SPUTUM SMEAR MICROSCOPY EXAMINATION

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

Referring facility¹ Patangeta Health Centre Date 10/10/09

Name of patient Mary Abatu Age 19 Sex: ☐ M ☒ F

Complete address 33 Primos Road, Patangeta

Reason for sputum smear microscopy examination:

☒ Diagnosis

When this form is used for a follow-up of treatment, the "Reason for Examination" is "Follow-up."

When the examination is for follow-up of treatment, record the District TB Number (assigned by the district after diagnosis).

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

Name and signature of person requesting examination Sister E Callner 

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. _____

Date collected ³	Sputum Specimen	Visual appearance ⁴	RESULTS				
			NEG	(1-9)	(+)	(++)	(+++)
9/10/09	1						
10/10/09	2						
	3						

Write the date that each sputum sample was collected. For diagnosis of a TB suspect, two samples should be included. (Two samples are required for follow-up examination also.)

3. To be completed by the person collecting the sputum

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

Examined by _____

Date _____ Signature _____

Send sputum samples to laboratory

- ▶ Keep the samples in a refrigerator or in as cool a place as possible until transport.
- ▶ When you have two samples from a patient, pack the sputum containers in a transport box. Enclose the *Request for Sputum Smear Microscopy Examination*. If there are samples for more than one patient, enclose a *Request for Sputum Smear Microscopy Examination* for each patient's samples.
- ▶ If a patient does not return to the health facility within 3 days with the second sample, send the first sample to the laboratory anyway.
- ▶ Send the samples to the laboratory as soon as possible. Do not hold samples for microscopy for longer than 3–4 days. Samples for microscopy do not require warming or cooling during shipping, except in very hot climates where they should be kept cool. Samples should reach the laboratory within 5 days of collection.
- ▶ If samples will be sent for culture, they should be kept refrigerated, properly packed to avoid leakage and shipped promptly. Transportation must be arranged so that the samples are kept in cold conditions (refrigerated, not frozen) and reach the laboratory within 1–2 days of collection.¹
- ▶ Prepare a dispatch list to accompany each transport box. (See example below.) The dispatch list should identify the sputum samples contained in the box. Before sending the box to the laboratory:
 - Check that all containers are closed and wiped clean.
 - Check that the dispatch list states:
 - the correct total number of sputum containers in the box,
 - the identification numbers on the containers,
 - the name of each patient.
 - Check that a *Request for Sputum Smear Microscopy Examination* is enclosed for each patient.
 - Close the box carefully.
 - Write the date on the dispatch list.
 - Put the dispatch list in an envelope and attach envelope to the outside of the transport box.

Example

TB sputum samples dispatch list

Health facility: Patangeta Health Centre

Contents: Total number of sputum containers: 6

TB suspect name	Specimen ID numbers
Sheena Arday	335-1, 335-2
Emil Avornyo	337-1, 337-2
Mary Abatu	338-1, 338-2

Packed by (signature): Nurse Bob

Date: 12/10/09

In this example, the specimen ID number is the TB suspect number followed by -1 or -2.

¹ A national reference laboratory should provide instructions for health facilities on how to best collect, pack and send specimens for culture and DST. As these tests become available, the District TB Coordinator should disseminate this information to health facilities.

In HIV-prevalent settings, recommend HIV testing to TB suspects during the diagnostic procedure

Recommend HIV testing to all patients (adults and children) who come to the facility **with cough or other symptoms compatible with TB** and to all patients **diagnosed with TB**. HIV testing should be recommended to these patients at the same time (on the same day) that the initial sputum sample is collected for sputum smear microscopy examination.

As a part of the diagnostic procedure, **ask all patients who have cough or other signs or symptoms compatible with TB whether they know their HIV status.**

- | | | |
|---|---|---|
| <p>If a patient knows his or her HIV status:</p> <ul style="list-style-type: none"> • ask to see written documentation of the test result • record the test result and date in the <i>Register of TB Suspects</i>. | } | <p>recommend that the patient be tested (or re-tested) for HIV today.</p> |
|---|---|---|

Depending on the capabilities at your health facility, the patient may be tested and receive the result on the same day or at the same time that the sputum microscopy results become available.¹

A clinician, nurse, ART aid or other counsellor, or another health worker who has been trained for this task, can provide the pre-test information, obtain informed consent and do the HIV test on-site in the clinic. This is more efficient and more likely to be successful than referring patients elsewhere for HIV testing and counselling. Group education sessions can also be used to provide the pre-test information and counselling in many settings.

Advising a TB suspect or a TB patient to have an HIV test includes several important components, often referred to as the 3 C's: counselling, confidentiality and consent. Pre-test information given by the health worker includes three main steps:

1. Providing key information on HIV/AIDS and its interaction with TB.
2. Sharing key information about HIV testing: clinical and preventive benefits of knowing HIV status, confidentiality, and available services and costs.
3. Confirming the willingness of the patient to proceed with the HIV test and seeking informed consent. Provide additional information as necessary and refer the patient for additional counselling, as needed.

When the results of the HIV test become available, inform and counsel the patient accordingly. All patients must be counselled when the test results are given, regardless of the test result. Also record the HIV test result on the *Register of TB Suspects* as either:

- (Pos) positive
- (Neg) negative
- (I) discordant or inconclusive (when two tests are done and one is positive and the other is negative)
- (ND) not done.

If HIV testing is not done on the same day that sputum samples are collected for microscopy, the test will be recommended again to all patients who are diagnosed with TB.

¹ Offer HIV testing **only if** the facility is capable of providing the appropriate testing and counselling. Staff at the facility must receive training and supervision to enable them to:

- give individuals sufficient information to make an informed and voluntary decision to be tested for HIV
- maintain patient confidentiality
- perform post-test counselling
- make referrals to appropriate services.

Note that separate clinical evaluations for TB and HIV will mean more patient visits.

Diagnosis based on sputum smear microscopy (two sputum samples)

If: Then:	
One or more samples are positive	Patient is sputum smear-positive (has infectious pulmonary TB)
All samples are negative	<p>Patient is sputum smear-negative for infectious pulmonary TB.</p> <ul style="list-style-type: none"> If no longer coughing and has no symptoms consistent with TB, inform the suspect that the sputum examination found no pulmonary TB and that no treatment is needed. If still coughing or has other symptoms consistent with TB, refer to a clinician for clinical assessment.¹ Note the referral in the <i>Register of TB Suspects</i>.

Diagnosis by clinician

Clinicians may diagnose a patient by sputum smear microscopy (as above) or by using X-rays, clinical assessment and complimentary tests (e.g. culture, other methods). The left column below shows possible case classifications. The far right column shows the definition of each.

Case classification	Diagnosed by	Definition used for diagnosis
Pulmonary TB, sputum smear-positive (PTB+)	Health worker	One or more initial sputum smear examinations positive for acid-fast bacilli (AFB)
Pulmonary TB, sputum smear-negative (PTB-)	Clinician	<p>Sputum smear examination is negative for AFB (all samples) and</p> <p>A. Culture is positive for <i>Mycobacterium tuberculosis</i></p> <p>or</p> <p>B. Decision is made by a clinician to treat with a full course of anti-TB therapy</p> <p>and</p> <p>Radiographic abnormalities consistent with active pulmonary TB and either</p> <ul style="list-style-type: none"> laboratory or strong clinical evidence of HIV infection <p>or</p> <ul style="list-style-type: none"> if HIV negative (or unknown HIV status living in an area of low HIV prevalence), no response to a course of broad-spectrum antibiotics (excluding anti-TB drugs and fluoroquinolones).
Extrapulmonary TB	Clinician	A patient with TB of organs other than the lungs.

¹ If a smear-negative patient is seriously ill and there is strong suspicion of TB, but there will be delay in consulting by a clinician and/or receiving the results of culture and X-ray, TB treatment should be initiated.

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

II. SELECTING DRUG TREATMENT

Select a TB treatment regimen

1. Determine 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 previous treatment is unknown, and/or patients who have returned to treatment with smear-negative pulmonary TB or bacteriologically-negative extrapulmonary TB.

2. Is the patient a suspect for MDR-TB?

In areas with high prevalence of MDR-TB and where health facilities have the capability of treating MDR-TB patients using second-line drugs free of charge, assess whether each TB patient is a suspect for MDR-TB.

Ask the TB patient the questions shown below. Previous TB treatment (outcome and quality) and contact with a known case of MDR-TB are strong determinants of MDR-TB. If you suspect MDR-TB, this will affect the selection of the TB treatment regimen.

Ask:

- **Has anyone in your family ever had TB or MDR-TB (no time limit)?**
 - **If yes, what were the results of treatment?**
- If a family member
- failed previous TB treatment, or
 - was treated with second-line drugs, or
 - had known MDR-TB,
- **this patient has a high likelihood of MDR-TB.**

If the patient has been treated for TB previously, ask:

- **By whom were you treated? Was this a public clinic or 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?**
- If the patient
- admits irregular treatment, or
 - had to purchase the drugs, or
 - may have taken fewer drugs than recommended, or
 - received treatment from a private provider who may not have used a standard treatment regimen, or
 - used drugs of questionable quality,
- **suspect the possibility of poor treatment quality and development of drug resistance. This patient has a high likelihood of MDR-TB.**

When you suspect MDR-TB, refer the patient to a clinician.

Depending on national guidelines, the clinician will decide on a treatment regimen (the Retreatment regimen or the MDR-TB regimen).

WHO recommends that **all previously treated TB patients** should have specimens obtained for culture and DST before or at the start of treatment. The country's laboratory capacity determines when or if DST results are available for deciding the best regimen for an individual patient. The clinician may send sputum to an appropriate laboratory for culture and DST, or refer the patient to a higher-level facility.

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. If rapid DST is available, a clinician may detect MDR-TB before the start of treatment and begin an MDR-TB regimen.

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

Ask the TB patient:

- **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.

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.

HIV status is important for decisions about treatment, such as the need for ART and co-trimoxazole. 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. It is recommended that all HIV-positive patients take daily co-trimoxazole to help prevent other bacterial infections. HIV status is also important for counselling and advice on TB and HIV regarding prognosis, side-effects and associated diseases.

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

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

There are three standard TB 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 sputum smear-negative pulmonary TB 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).

To select the appropriate regimen or to decide to refer the patient to a clinician, consider:

- the type of TB patient
- history of previous treatment and the likelihood that the patient may have MDR-TB
- HIV status¹ and current HIV care.

Your country has specified a standard regimen for defined patient groups. Refer to your national TB manual for the regimens recommended in your country.

The HIV status of the TB patient does not change the treatment regimen. However, **do not start TB treatment at the first-level facility for an HIV-positive patient who is on ART** because there are potential problems with simultaneous ART and TB treatment (such as drug interactions and 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 TB treatment.**

As a health worker, you can select:

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

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 (a paediatrician or second-level clinician will diagnose TB in a child and prescribe treatment.)

The table on the next page indicates the appropriate treatment regimen for different patient groups.

¹ Note: Do not delay TB treatment if there is no HIV test result or while awaiting the result of an HIV test.

Select a treatment regimen based on the **type of TB patient** and **history of previous treatment**, which determines the likelihood of MDR-TB. Note that the selected regimen is the same regardless of whether the disease is pulmonary or extrapulmonary and whether or not the sputum smear or culture results are positive.

If type of TB patient is: →		Then 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: 2RHZES/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 isoniazid resistance is high.

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

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) Con		tinuation 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

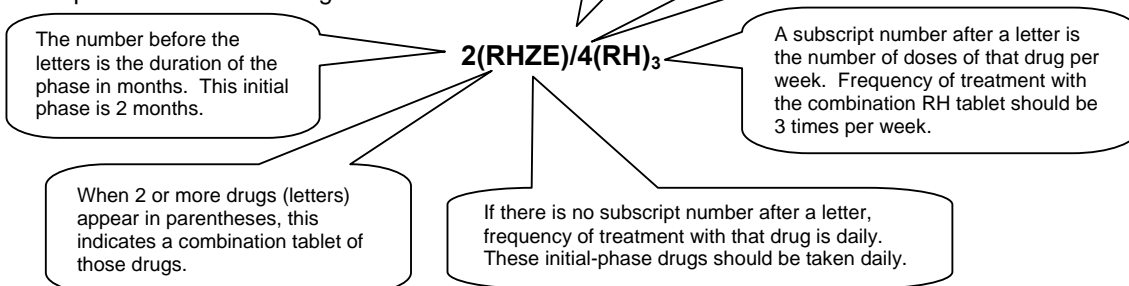
* 750 mg for patients aged over 60 years.

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 (RHZE).

In the continuation phase, the TB patient takes 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. If the FDC (RHE) is supplied, the regimen for the continuation phase is 5(RHE) given daily.

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	

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 drug 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 does not usually 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.

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. A household contact is a person who lives (that is, sleeps and eats at least one meal per day) in the home of a TB patient and who is therefore at greater risk of being infected.

TB patients should 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 a contact has TB, begin treatment for TB. For household contacts aged less than 5 years who do not have TB, give preventive therapy as described below.

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.

Give BCG immunization 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.

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.

III. TREATMENT ADMINISTRATION

Prepare a *TB Treatment Card*

Whenever a patient is classified as having TB or is a TB patient transferred in from another health facility, open a *TB Treatment Card*. This 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.

Begin by recording the patient information at the top of the card as shown on the next page. Be sure to get a complete address, one that you could use to visit the patient. If the patient has a TB treatment supporter outside the health facility, also write that name and address. Tick boxes for the disease site and type of patient. Record results of sputum examination, patient's weight and the results of HIV testing if available.

The **District TB Number** is assigned when the patient is entered in the *District TB Register*. The District TB Coordinator or your supervisor should inform you of the number when it is assigned or record it on the *TB Treatment Card*.

Record the TB treatment regimen for the initial phase on the front of the *TB Treatment Card*. Tick the appropriate regimen (New or Retreatment). In the box with the drug abbreviation, write a digit to indicate the number of tablets in each dose. Write a subscript number to the right of the drug abbreviation to indicate the frequency (number of days per week that the drugs should be taken, such as ₃ or no subscript if daily). Use the patient's weight and refer to the drug table in your national TB manual to determine the number of tablets per dose. For streptomycin (S), which is given by injection, write the number of grams in one dose.

Record the TB treatment regimen and dosage for the continuation phase on the back of the *TB Treatment Card*. Also record additional information for an HIV-positive patient and the results of chest X-ray (if done). List all contacts in the Household contacts box. Record the name and address of a **contact person** on the back of the card (at the bottom). The contact person should be someone, 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.)

Throughout the course of treatment, keep the *TB Treatment Card* up-to-date.

Use tick marks (✓) to indicate days that a dose is directly observed. Use a dash (–) to show a Sunday or regular day off. Use a zero (Ø) to show a missed appointment. Use a longer line to show days that drugs were given to the patient for self-administration.

Record results of **follow-up sputum examination** when they are received. If culture results are received, record in the Comments section. When each household contact is assessed, record the results.

For the HIV-positive TB patient, update information on HIV care and drug treatment whenever changes occur.

Instructions and example: Front of TB Treatment Card

Tick the box for the treatment regimen.

Tick who referred the patient to your facility for diagnosis or treatment. If a private provider, record name, address and telephone number of the provider to contact later with the results.

Tuberculosis Treatment Card

Name: Miranda Celli

Sex: ☐ M ☒ F Date of registration in District TB Register: 25 May 2009

Age: 9 Health facility: Emeru Health Centre

Address: Cross Street 205, Marili

Name / address of treatment supporter (if applicable)

Disease site

☒ Pulmonary

Type of

☒ New

☐ Retreatment

☐ Other

☐ Treatment after default

☐ Treatment after failure

☐ Other

Enter results of sputum examinations here.

I. INITIAL PHASE - prescribed regimen and dosages

Regimen: ☒ New ☐ Retreatment

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

(RHZE) 3 S

Cotrimoxazole ARV

Referral by:

☐ Self-referral

☒ Community member

☐ Public facility

☐ Private facility/provider:

☐ Other, specify:

Enter results of HIV test and if positive, enter dates that drug treatment began.

Sputum smear microscopy

Month	Date	Lab No.	Result	Weight (kg)
0	4/5	630	++	48
2	8/7	820	neg	49

TB/HIV

	Date	Result*
HIV test	4/5/09	neg
HIV test		
CPT start		
ART start		

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

Tick appropriate boxes

Write the number of tablets for one dose.

Drugs administered

When drugs are collected and draw a horizontal line (—) through number of days supplied. Ø = drugs not taken

D Month																																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
Ma						✓	✓	✓	✓	—	✓	✓	✓	✓	✓	—	✓	✓	✓	✓	✓	✓	✓	—	✓	—	—	—	✓	✓	—	21	21		
Jun	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	—	✓	✓	✓	✓	✓	✓	—	✓	✓	✓	✓	✓	✓	✓	✓	✓	36	47			
Jul	✓	✓	✓	✓	—				✓	✓																					9	56			

For an HIV-positive TB patient taking CPT, record the dose of co-trimoxazole here.

This patient received her first dose on 6 May. 10 May was a Sunday. She missed an appointment on 20 May. She was given drugs for self-administration on 26–28 May.

At the end of each month, record the doses given in the month and the cumulative total doses received.

If there is a community TB treatment supporter, enter date and number of doses given to the supporter for the next month.

Back of TB Treatment Card

Use the back of the *TB Treatment Card* to record the regimen for the continuation phase and doses given during that phase. Use the "Observations" section to record comments at any time. At the appropriate time, record the treatment outcome.

Example: This patient comes three times weekly (Monday, Wednesday and Friday) **for directly-observed treatment**. The blank days are non-scheduled days. The dashes indicate Sundays, when the health facility is closed. The zeroes (0) indicate missed appointments.

II. CONTINUATION PHASE

Number of tablets per dose, doses per week

(RH)	(RHE)	Other
3		

Daily intake observed: enter ✓. Periodic supply: enter X on day when drugs are collected and draw a horizontal line () in number of days supplied. 0 = 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
July																																	
Aug																																	
Sept																																	

Record date and results of a chest X-ray if one was done. Otherwise circle ND.

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: Transferred 12 September to Grace Health Centre, Tupelo

Use this space to record a referral, transfer or other comments.

Household contacts

First names and surname	Age	Relationship to case	Date seen	Result
Melia Celli	10	daughter	9/5/09	healthy
Sarah Celli	8	daughter	9/5/09	healthy

Name and address of contact person: Nicola Pera, Main Street Bakery, Marili

For a transferred patient, contact the receiving health facility to find out the final treatment outcome.

Be sure to record the name and address of a person who will always know how to locate or contact the TB patient.

Record the date each household contact is seen for assessment and the findings.

Recording additional information for an HIV-positive TB patient

Record information about HIV care given to an HIV-positive patient, including any drug therapy, so that health workers can be aware of and coordinate with the care that is provided for HIV.

► Record dosage for co-trimoxazole preventive therapy (CPT)

It is recommended that all HIV-positive people take daily co-trimoxazole to help prevent other infections. If an HIV-positive patient is not currently taking daily co-trimoxazole, start giving CPT:

- **one double-strength (960mg), or**
- **two single-strength (480mg) tablets of co-trimoxazole daily.**

Write drug dosage needed in co-trimoxazole box on the front of the *TB Treatment Card*. Write today's date as start date. If the patient is already taking CPT, record the dose and date that CPT was started.

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

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

Obtain this information from the patient, such as on an *HIV Care/ART Care Card*, or 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	poz
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		

► Record information about the patient's current HIV care

Information to complete the HIV care box on 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 the box below 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.	

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 Primos 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) _____				
Sputum smear microscopy				Weight (kg)
Month	Date	Lab No.	Result	
0	16/10/09	667-2	+++	50 kg
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 (RHZE) S Other				
Drugs and dosage: 3 0.75g 				
II. CONTINUATION PHASE (RH) ₃ (RHE) E 3 Other				
Drugs and dosage: 3 4				
REMEMBER Come for TB drugs 6 days each week!				

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 then 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*.

Summary:

Marking the *TB Treatment Card*

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

If a community TB treatment supporter is directly observing treatment, copy the ticks or other marks from the treatment supporter's card each month when you resupply the treatment supporter with anti-TB drugs.

Side-effects of anti-TB drugs and their management

Each time that you see the patient, ask how the patient is feeling and listen carefully for any complaints that may indicate side-effects.

Minor side-effects	Management
<ul style="list-style-type: none"> Anorexia, nausea, abdominal pain 	Take drugs with food, yogurt or gruel.
<ul style="list-style-type: none"> Joint pains 	Give acetylsalicylic acid (aspirin) or paracetamol.
<ul style="list-style-type: none"> Burning sensation in feet 	Give pyridoxine (100 mg daily).
<ul style="list-style-type: none"> 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.

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.

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)

Conduct home visits for patients who miss a dose

- **ASK:**
 - Why did you miss your appointment?
 - What problems caused you to miss?
- **LISTEN** carefully to find out whether there have been difficulties related to:
 - attitudes of the health facility staff who observe treatment
 - waiting time at the health facility
 - transportation
 - work or family commitments
 - side-effects of treatment or other health problems.
- **HELP** the patient to solve problems.

Examples of possible causes of missed doses:	Possible solutions:
Coming to the health facility is inconvenient.	Identify a convenient community TB treatment supporter.
Patient dislikes coming to the health facility because of the long queue.	Make arrangements so that TB patients do not have to wait in a queue. For example, let them enter through a back or side door.
Supervisor at work kept the patient late.	<ul style="list-style-type: none"> – Offer to talk with the supervisor and explain the importance of the treatment, or – Identify a community TB treatment supporter at work.
Patient had troublesome side-effects.	Give appropriate advice or remedies for side-effects, or refer the patient if necessary. (<i>See side-effects tables on pages 23–24.</i>)
Patient had difficulty swallowing because of pain (due to oral candidiasis, common in AIDS patients).	Give appropriate advice or remedies or refer patient as necessary.
Patient cannot leave small children at home and is tired of bringing them to the health facility.	<p>Suggest that a family member or neighbour watch the children. Remind family members and/or neighbours that the patient must continue treatment to protect their health, particularly the health of the children.</p> <p>If possible, identify a community TB treatment supporter closer to the patient's home.</p>

- **MOTIVATE** the patient with statements such as the following:
 - TB can be cured if you keep coming for the medicine. Then you will not worry about it anymore.
 - You only have ___ more doses to take every day. After that, you will come less often.
 - These are the safest, most effective drugs available to treat TB anywhere in the world.
 - Almost all patients who take their medicines as recommended are cured.
 - If you keep taking your medicine, you will not spread TB to your family.
 - Taking only some of the drugs, or taking them irregularly, is dangerous and can make the disease difficult or impossible to cure.
- **GIVE** the missed dose(s) one day at a time. Do not give an extra dose on any day.
- **If a patient is also on CPT, ART, or other treatments related to HIV or another illness**, ask if this treatment was also missed. If so, encourage the patient to resume that treatment and/or inform someone familiar with the patient's other care.
- **RECORD** a zero (0) on the *TB Treatment Card* for each day missed. Add a comment on the action taken, for example, "home visit, resumed treatment."

Summary of actions after interruption of TB treatment

Interruption for less than 1 month

- Trace the patient
- Determine and address the cause of interruption
- Continue treatment and prolong it to compensate for missed doses.

The need to trace patients who interrupt treatment is urgent to prevent drug resistance.

Interruption for 1 up to 2 months

First:	Then, take action based on results of sputum examination:	
<ul style="list-style-type: none"> • Trace the patient • Solve the cause of interruption • Collect 2 sputum samples and send for microscopy 	If all smears are negative, or if patient has extrapulmonary TB	Continue treatment and prolong it to compensate for missed doses. Ensure that the total number of doses planned for the initial phase are given.
	If one or more smears are positive	Restart the same regimen.

Interruption for 2 months or more (default)

First:	Then, take action based on results of sputum examination:	
<ul style="list-style-type: none"> • Trace the patient • Solve the cause of the interruption, if possible • Collect 2 sputum samples for smear microscopy, culture, and DST 	If all smears are negative, or if patient has extrapulmonary TB	Clinician decides on individual basis whether to restart or continue treatment, or prescribe no further treatment.
	If one or more smears or cultures are positive	Clinician selects treatment regimen based on likelihood of MDR-TB, how quickly DST results will be available and policy on starting MDR-TB regimens.

Instructions for Tuberculosis Treatment Referral/Transfer : Use this form to refer a patient to a clinician or hospital for diagnosis or for special care, or to transfer a patient who is moving to another area. Make three copies of the form: send one with the patient, keep one at the health facility and send one to the District TB Coordinator.

Tuberculosis Treatment Referral/Transfer
 (Complete top part in triplicate)

Tick this box when referring a patient to a different health facility to begin treatment after diagnosis of TB

Tick to indicate the reason for this referral or transfer:

☐ Referral¹ to register and begin TB treatment
 ☐ Referral for special care²

or ☐ Transfer³

Tick when a patient is moving to another district

Date of referral/ transfer _____

Name/address of referring/transferring facility

From sending facility: _____

Sending District _____

To receiving facility: _____

Receiving District _____

Name of patient _____ Age _____ Sex: ☐ M ☐ F

Address of patient (if moving, future address): _____

Diagnosis: _____

(For Transfer) District TB Register No. _____ Date TB treatment started: _____

TB Treatment Regimen:

☐ New ☐ Retreatment

Other (CPT, ART etc):

Drugs patient is receiving _____

Remarks (e.g. side-effects observed): _____

Here, write the full name and dosage of the current drugs, for the information of non-TB physicians.

Name / signature of person sending the patient _____

Documented evidence of HIV tests (and results) during or before TB treatment should be reported.

Return this part to facility that referred / transferred patient as soon as patient has reported.

To be completed by facility receiving referred / transferred patient

District _____ Facility _____

District TB Register No. _____ Name of patient _____

The above patient reported at this facility on _____ (date)

Name / signature of person receiving the patient _____

¹ **Referral** is the process of moving a TB patient **prior to registration in a District TB Register** for the purpose of start of treatment (treatment closer to patient's home). The district receiving a "referred" patient is responsible to inform the facility sending the patient about the care provided.

² **Referral for special care** is indicated when the patient is very sick or has major side effects and is referred to a clinician or hospital for special care. When discharged, the patient should return to the original health facility to continue TB treatment.

³ **Transfer** is the process of moving between 2 districts a **TB patient registered in a District TB Register** to continue his treatment in another area with a different **District TB Register**. The district 'transferring-out' a patient is responsible to report the treatment outcome, after getting the information from the district completing the treatment. The district receiving a patient 'transferred-in' is responsible for informing the district sending the patient 1) of the arrival of the patient and 2) at the end of the treatment, of the treatment outcome.

TB Infection Control in Your Health Facility

- ▶ Good ventilation in waiting areas and examination rooms of a health facility can reduce the spread of TB and other airborne infections. Good ventilation uses open doors, windows, skylights and exhaust fans to dilute and exchange room air with fresh air, thereby reducing the concentration of particles remaining in room air, such as those containing tubercle bacilli. The minimum acceptable ventilation involves openings on opposite ends of a room (window – window, window – door).
- ▶ To increase ventilation and decrease the risk of TB transmission in your facility:
 1. Check that all windows and doors can be opened and are easy to keep open.
 2. Check that doors allow some airflow, even when closed.
 3. Check that all exhaust fans and air-conditioners are in good working order and clean.
 4. Place fans in windows to blow room air to the outdoors.
 5. Keep doors, windows and skylights open as much as possible (while still respecting privacy).
- ▶ The most infectious TB cases are people with smear-positive pulmonary TB who have not yet been detected or who have been on anti-TB treatment for less than 2 weeks. Because any TB suspect may be infectious, attend to every TB suspect quickly. Identify coughers quickly and ask them to wait near an open window or in a comfortable area separate from the general waiting room (outdoors when possible).
- ▶ Send the TB suspect outdoors to collect a sputum sample in the open air if possible, away from other people. Do not stand in front of the TB suspect when he or she is coughing to produce sputum (or anytime).
- ▶ Educate TB suspects, TB patients and their families about the need to cover their mouths and noses when coughing or sneezing, to prevent transmission of TB as well as colds, influenza and other respiratory infections.
- ▶ Take precautions to reduce the spread of HIV or other bloodborne pathogens in needles. Follow recommended procedures for sterile injections and to prevent needle-stick injuries. Use a safety box (or sharps container) for safe disposal of all medical sharps waste.
- ▶ To reduce your own risk:
 - Always follow recommended infection control procedures in your work at the health facility.
 - If you have risk factors for TB disease such as smoking, malnutrition, diabetes or alcohol dependency, decrease your risk factors for TB disease to the extent possible, such as by stopping smoking, or following treatment for diabetes to increase your immune function.
 - Know your HIV status; get retested periodically. If you are HIV-infected, you may decrease your risk of developing TB by taking CPT, ART and IPT if appropriate.
 - Get a BCG immunization if you have not had one.
 - Stay alert for possible signs and symptoms of TB in yourself. If one or more of these develop, report promptly for assessment and care. If you are diagnosed with TB, start treatment promptly and adhere to treatment until it is completed.

IV. COMMUNITY TB TREATMENT SUPPORTERS

1. Help the TB patient choose a community TB treatment supporter

Some TB patients live far away or do not want to come to a health facility for treatment. If the patient decides not to come to a health facility for treatment, the patient's should select a **TB treatment supporter** in the community to directly observe the treatment.

Help the patient identify a suitable person. Discuss with the patient the characteristics of an effective community TB treatment supporter. A TB treatment supporter must be reliable, convenient and acceptable to the patient. The treatment supporter must be able to be supplied with drugs and willing to accept supervision by the health facility. Talk with the TB patient about possible treatment supporters in the community, keeping these factors in mind.

A treatment supporter must be able and willing to:

- be trained by the health services to perform the tasks of a TB treatment supporter
- attend every appointment for the duration of the regimen (initial and continuation phases)
- be kind to the patient and interested in the patient's welfare
- be careful in administering drugs and writing on the *TB Treatment Card*
- respect confidentiality
- follow up if any problems occur or if the patient does not come for an appointment
- come to the health facility for supervision and to obtain a resupply of drugs (or a health worker will need to visit and deliver the drugs)

Note: If the patient will be treated using the Retreatment regimen, which includes streptomycin injections for the first two months, then only a person who is trained to give sterile injections can be the treatment supporter.

Ask the patient about:

- the patient's situation, including where and when the patient works, whom the patient sees each day, available transport, and whether the family is supportive or disapproving
- possible TB treatment supporters who would be reliable, convenient and acceptable, such as a neighbour, a co-worker or supervisor in the workplace, a community health worker or a village leader
- where and when the patient could meet regularly with a community TB treatment supporter.

Listen carefully to understand the patient's situation and the factors that may make it difficult to receive treatment every day. Listen to the patient's suggestions for a community TB treatment supporter who would be convenient and acceptable to the patient.

Some individuals already have an established relationship with the health services because they are already paid for or have responsibility for health-related activities. These individuals are most likely to carry out all the responsibilities of a community TB treatment supporter effectively. The order of preference in terms of supervision by the health services is as follows:

1. trained community health worker
2. health facility staff in the community (such as in his or her own village after work)
3. member of the community willing to volunteer.

Family members may be treatment supporters if they have the respect of the patient and are trained and supervised.

If the patient is currently receiving HIV care, an individual who is already providing support to the patient related to HIV care may be an acceptable TB treatment supporter. However, the individual will require additional training and supervision to perform the duties of a TB treatment supporter.

Agree on the best candidate for the TB treatment supporter. Then plan how you can meet together to discuss whether the candidate is suitable and interested.

2. Meet with a possible community TB treatment supporter

Provide directly-observed treatment at the health facility for a few days until the treatment supporter can begin. Ensure that treatment will be well-organized and can continue. Determine whether the individual is interested, will be available and understands the responsibilities.

- ▶ Explain why directly-observed treatment is important to cure TB.
- ▶ Review the tasks of a TB treatment supporter (including directly observing treatment daily and coming to the health facility monthly for supervision and to obtain a resupply of drugs) (see page 31).
- ▶ Explain how long the supporter will be needed (for the duration of the regimen).

If the individual is suitable and agrees to be a TB treatment supporter for this patient, help the patient and supporter agree on the time and place that they will meet daily for directly-observed treatment.

3. Prepare a community TB treatment supporter

▶ Copy the patient's *TB Treatment Card* for the community TB treatment supporter

Keep the original card at the health facility. Give the duplicate card to the treatment supporter to keep.

▶ Train the community TB treatment supporter

- **Decide what to teach the community TB treatment supporter** based on what the individual already knows about TB and directly-observed treatment.
- **Provide basic information** about TB and its treatment. See the list on page 32. Unless the treatment supporter is a health worker, expect him or her to answer only basic questions about TB or concerns about treatment and refer patients to a health worker for more information.
- **Teach how to perform the specific tasks.** See the list on page 31. Use good teaching methods: provide information, examples and practice. Doing a task helps a person learn and remember it much more effectively than just hearing a description or watching you. Give just enough instruction that the treatment supporter is able to practise the task successfully.
- **Provide practice that reflects the task, such as**
 - *making a decision.* For example, ask the treatment supporter what to do if the patient came for treatment a day late.
 - *communicating information.* For example, pretend to be a TB patient who is losing interest in coming for TB treatment. Ask the community TB treatment supporter to practise encouraging you to continue your treatment.
 - *doing a manual task.* For example, describe the treatment observed or days missed, and ask the TB treatment supporter to record the treatment given on the *TB Treatment Card*.

Make the practice as similar to the real work situation as possible. For example, arrange for the community TB treatment supporter to give treatment to one of your TB patients at the health facility. Watch the supporter give directly-observed treatment to the patient, correct any mistakes on the spot and give additional instruction if needed.

► **Use checking questions to assess what the community TB treatment supporter has learnt**

Checking questions find out what a person has learnt, so that you can provide more information or clarify your instructions as needed. Ask checking questions that require more of an answer than simply “yes” or “no.” Ask questions that begin with “What,” “When” or “How.”

► **Provide the first month's drug supply**

Give the patient's first month's supply of drugs to the TB treatment supporter (not the patient). Record on both copies of the *TB Treatment Card* the date and the number of doses that you have given to the TB treatment supporter. Ask where the treatment supporter will keep the drugs. It should be in a cool, dry place, safe from children.

Ask the treatment supporter to bring the *TB Treatment Card* to the health facility and collect the next month's supply **before** this month's supply of drugs are all gone.

Plan to visit the community TB treatment supporter during the first month to be sure that he or she knows what to do, and to answer any questions.

Essential tasks of a community TB treatment supporter

- Agree on a time and place to meet the TB patient. It is best to take the drugs at the same time each day. Do not make the patient wait.
- Give the patient the anti-TB drugs at each appointment according to the schedule. Check the drugs to be sure that they are correct. Watch the patient swallow all the drugs for the day. They must be taken together to make sure that they work together.
- Record on the *TB Treatment Card* each time the patient takes the drugs.
- Be aware of possible side-effects. Have the patient eat food with the tablets if needed to reduce nausea. Refer the patient to the health facility if the side-effects continue.
- If the patient is HIV-positive, pay close attention to the patient's symptoms and if the patient worsens, refer the patient to a health facility for care.
- Encourage the patient to continue coming for TB treatment.
- Respond quickly if the patient misses a scheduled treatment. When a patient misses a dose for more than 24 hours, visit the patient's home. Find out what caused the interruption. Give the treatment. If you are unable to find the patient or convince the patient to continue the treatment, contact the health facility for help without delay.
- Go to the health facility to collect a resupply of drugs each month. Ask the patient to accompany you if possible. Show the patient's *TB Treatment Card*. Review how the patient is doing and discuss any problems.
- Make arrangements if you or the patient will be away for a few days. Give the patient enough drugs to self-administer for a maximum of 1 week or refer the patient to the health facility to decide what is to be done. Someone else may be asked to help during this time.
- Be sure that the patient goes to the health facility when the next follow-up sputum examination is due. If the patient is a child, be certain that the child visits a clinician for assessment every 2 months.

Important information for a community TB treatment supporter

About TB:

- TB is a disease caused by germs. It spreads most easily when it is in a person's lungs.
- TB spreads when someone with TB coughs or sneezes TB germs into the air, and others breathe in these germs and become infected. It is not spread by food, dishes or clothes.
- TB can be stopped from spreading by treating and curing people who have it.
- People with TB have many different symptoms. The major symptom of TB in the lungs is coughing for more than 2 weeks. Other symptoms are bloody sputum, night sweats, fever and weight loss.
- TB can be cured if the patient takes anti-TB drugs regularly, on schedule, for the full duration of treatment, that is, until the patient has taken all doses needed.
- It is important for the TB patient to take all the anti-TB drugs for the entire treatment, or the disease may become incurable.
- A patient can prevent the spread of TB by:
 - Taking regular treatment to become cured of TB,
 - Covering the mouth and nose when coughing or sneezing, and
 - Opening windows and doors to allow fresh air to flow through the home.

About giving treatment

- Give the patient the drugs in a well-ventilated place. If the patient takes the drugs regularly, he or she will become non-infectious in about 2 weeks.
- Mark the *TB Treatment Card* with a tick (✓) on the corresponding date after you have observed the patient swallowing the drugs.
- For a daily regimen, it is customary to give 6 doses per week. (One dose may be self-administered on the weekend.)
- Possible minor side-effects:
 - No desire to eat, nausea, abdominal pain – give drugs with food or gruel.
 - Joint pains – refer patient to health facility.
 - Burning sensation in the feet – refer patient to health facility.
 - Orange or red urine – reassure the patient that this is normal for the drug.
- Possible major side-effects:

Itching of skin, skin rash, deafness, dizziness, jaundice, vomiting repeatedly, difficulty with vision. If any major side-effect occurs, stop anti-TB drugs immediately and inform the health facility worker. Refer the patient urgently to the health facility.
- If the patient misses a dose, give the missed dose on return. Do not give a double dose on any day. Then continue according to the schedule. The duration of treatment will be extended to complete all doses in the regimen.
- Periodically, the patient will need to go the health facility for sputum collection for follow-up sputum smear examinations. Most patients must go for follow-up sputum examinations at the end of the initial phase, after 5 months of treatment, and in the last month of treatment.

4. Supervise and resupply the community TB treatment supporter with anti-TB drugs

A staff member at the health facility should be assigned responsibility for supervising the community TB treatment supporter. Treatment supporters need regular instruction and supervision by health facility staff to sustain their motivation and ensure a quality outcome.

Each month the community TB treatment supporter will come to the health facility to collect the patient's supply of drugs for another month. If possible, the patient should also come. In some locations, it is necessary for a health worker to visit the community TB treatment supporter to deliver the next month's supply of drugs and carry out monthly supervision.

► **Copy the entries onto the *TB Treatment Card***

Check the community TB treatment supporter's *TB Treatment Card* to see whether the patient is taking the drugs on schedule and the supporter is marking the card correctly. Copy the ticks on the supporter's copy of the *TB Treatment Card* onto the original *TB Treatment Card* kept at the health facility. Be sure to copy the ticks accurately. Also copy any comments written at the bottom of the card.

► **Identify problems and discuss them with the community TB treatment supporter**

As you copy the entries, check whether the patient is receiving treatment according to schedule or is missing doses. Also ask the community TB treatment supporter whether there were any problems in the past month such as drug side-effects, missed days, or reluctance to take drugs. Ask the community TB treatment supporter (or the patient) to describe how the problem was discussed or addressed. Listen carefully to be certain that the treatment supporter has advised the patient correctly. Review or provide key information as needed.

If you suspect that the patient may default, first try to determine or understand the patient's situation, and then help the patient and treatment supporter improve it. This could include talking with the patient to reinforce the importance of continuing the treatment, or helping to find ways to overcome a problem (such as discussing a quicker way to accomplish the treatment each day).

If you suspect the treatment supporter may be discouraging the patient, because of attitude or unavailability or for any other reason, discuss this problem with the treatment supporter and speak with the patient. Sometimes the solution is to select a different community TB treatment supporter.

► **Check whether the patient is soon due for a follow-up sputum examination or visit to a clinician**

Check the patient's *TB Treatment Card* to see whether the patient will be due in the next month for a sputum smear microscopy examination. If so, tell the community TB treatment supporter (and the patient if present) the week when sputum should be collected. Give the treatment supporter a sputum container to give to the patient when the time comes. If needed, review the reason for the sputum examination so that the supporter can explain this to the patient.

When the week for follow-up sputum examination arrives:

- The community TB treatment supporter should give the sputum container to the patient to collect the first sputum sample at home early the next morning.
- The patient should collect the sample and carry it to the health facility.
- At the health facility, the patient should hand over the first sample and collect a second sputum sample.

A few days later, the patient and the community TB treatment supporter should return to the health facility to learn the results of the follow-up sputum smear examination and the patient's treatment progress.

If the patient should go for a follow-up visit to a clinician, tell the community TB treatment supporter when and where to send the patient. Patients should meet with a clinician or other health worker when the results of follow-up sputum examinations are available. A patient may also be examined periodically by a clinician who can assess clinical progress.

► Resupply the community TB treatment supporter with anti-TB drugs

Read the card to determine the drugs needed in the next month. Take the drugs from the patient's drug box kept at the health facility. Record the drugs provided to the community TB treatment supporter on both the original *TB Treatment Card* and the treatment supporter's copy. This will be 28 doses for a daily regimen or 12 doses for a 3-times-per-week regimen.

At the end of the initial phase, inform the patient and treatment supporter about the results of the smear examination and provide the drugs for the first month of the continuation phase of treatment.

If the patient's sputum smear examination results were positive:

- Explain to the patient and the TB treatment supporter that the sputum examination found that tubercle bacilli are still present.
- Discuss with the patient and the community TB treatment supporter to confirm whether treatment has actually been directly observed each day. If not, try to solve the problem.
- Ask the treatment supporter to continue directly-observed treatment and record this on the front of the patient's *TB Treatment Card* each day.
- For a patient on the New patient regimen, ask the supporter to send the patient for another sputum examination after one more month (at the end of the 3rd month).

If the patient's sputum smear results were negative:

- Explain to the patient that the initial phase of treatment has worked well. The patient is no longer infectious.

To begin the continuation phase of treatment:

- Explain that the patient must finish all doses of the initial-phase drugs, and then start the continuation-phase drugs.
- Check the back of the patient's *TB Treatment Card* for the correct drugs for the continuation phase. Be sure that the correct drugs are in the patient's drug box.
- Explain to the patient about the continuation phase of treatment, including what to do differently from the initial phase, the drugs to take and the schedule, and how long this treatment phase will last (how many doses to take).
- Give one month's supply of drugs to the community TB treatment supporter.
 - Ask checking questions to be sure that the treatment supporter knows the correct dose and frequency (for example, this may be a change from daily to 3 times per week).
 - Show the TB treatment supporter how to mark the back of the card each time treatment is observed.

► Thank and give support to the community TB treatment supporter

Each month give assurance that support has an important impact—ensuring that the patient takes the correct treatment, motivating the patient to keep coming for treatment, and preventing the spread of TB to family members and the community. Tell the treatment supporter that you realize that this job requires considerable time and effort and you appreciate it.

V. INFORMING PATIENTS ABOUT TB

Guide for initial patient information about TB

Use this guide to remind you of what to ask and say during an initial information session with a TB patient. The left column includes examples of questions to ask TB patients. The right column lists messages related to the questions on the left. Emphasize different messages with different patients, depending on their current knowledge about TB.

Throughout the visit: Demonstrate a caring, respectful attitude. Praise and encourage the patient. Speak clearly and simply. Encourage the patient to ask questions.	
Ask the patient questions such as:	Then give relevant messages:
What do you understand tuberculosis (TB) to be? What do you think may have caused your illness?	<u>What is TB?</u> Tuberculosis, or TB, is an illness caused by a germ that is breathed into the lungs. TB germs can settle anywhere in the body, but we most often hear about TB of the lungs. When the lungs are damaged by TB, a person coughs up sputum (mucus from the lungs) and cannot breathe easily. Without correct treatment, a person can die from TB.
Have you ever known anyone with TB? What happened to that person? Do you know that TB can be completely cured?	<u>TB can be cured</u> TB can be cured with the correct drug treatment, usually in 6–8 months. The patient must take all of the recommended drugs for the entire period of treatment in order to be cured. Some 50% of people with TB who are not treated will die within 5 years. Drugs for treatment of TB are provided free of charge. Treatment can be done without interrupting normal life and work.
How do you think that TB spreads?	<u>How TB spreads</u> TB is spread when an infected person coughs or sneezes, spraying TB germs into the air. Others may breathe in these germs and become infected. It is easy to pass germs to family members when many people live closely together. Anyone can get TB. However, not everyone who is infected with TB will become sick.
How can you avoid spreading TB?	<u>How to prevent TB from spreading</u> <ul style="list-style-type: none"> – Take regular treatment to become cured. – Cover the mouth and nose when coughing or sneezing. – Open windows and doors to allow fresh air through the home. There is no need to eat a special diet or to sterilize dishes or household items.
What are signs or symptoms of TB?	Cough of long duration (2 weeks or longer) is the most common sign of TB. Other signs are bloody sputum, night sweats, fever and weight loss. Signs suggestive of TB in children are cough or other respiratory symptoms lasting more than 2 weeks, fever for more than 14 days, and loss of weight or failure to gain weight (failure to thrive).

Ask the patient questions such as:	Then give relevant messages:
<p>How many people live with you? What ages?</p> <p>Does anyone else in your household have cough? Who has cough?</p>	<p><u>Who else should be examined or tested for TB?</u></p> <p>All children under 5 years of age living in the household should be examined for TB symptoms. This is especially important because children aged under 5 years are at risk of severe forms of the disease. Young children may need preventive therapy or referral to a clinician.</p> <p>Other household members should be tested for TB if they have cough.</p>
<p>(If there are young children living in the household)</p>	<p>Children aged 0–4 years and immunocompromised children are the most vulnerable to progression of TB disease and its severe forms. Most children who have TB were infected by an adult in the household who has infectious TB.</p> <p>It is difficult to diagnose TB in children, and children may respond differently than adults to TB treatment. Therefore, a paediatrician or clinician diagnoses TB and prescribes TB treatment for a child. The treatment can be given by a health worker, or a parent or other family member can give the treatment after some brief training. The health worker will supply the parent with the drugs to give. The paediatrician will see the child periodically to check the child's progress.</p>
<p>Do you know why TB is a problem for people with HIV infection?</p>	<p>People who are HIV-positive have increased probability of getting TB and dying from TB. HIV-positive patients are more likely to be very ill when they present with TB. Although TB can be cured in HIV-infected people, the chance of death during treatment and of TB relapse is greater.</p> <p>It is recommended that all TB patients are tested for HIV. HIV status is important for decisions about treatment, such as the need for ART and co-trimoxazole preventive therapy (CPT). HIV status is also important for counselling and advice on TB and HIV regarding prognosis, side-effects and associated diseases.</p>
<p>What are factors that increase a person's risk of developing TB?</p> <p>How do you think people can decrease their risk?</p>	<p>Diabetes, malnutrition, alcohol dependency and decreased immune function (such as from HIV, chemotherapy for cancer or treatment with corticosteroids) can increase a person's risk of developing TB.</p> <p>Smoking increases the risk of developing TB or TB relapse, and smoking during treatment for TB decreases the probability of cure. People can decrease their risk of developing TB if they control their risk factors to the extent possible, such as by controlling diabetes and stopping smoking.</p>

<p>Explain the necessity of directly-observed treatment</p>	<p>A health worker must watch you swallow all the drugs according to schedule. This will ensure that you take the correct drugs regularly for the required length of time. If injections are needed, they will be given properly. By seeing you regularly, the health worker will notice if you have side-effects or other problems.</p> <p>If you do not take all of the drugs, you will continue to spread TB to others in the family or community, and the TB will not be cured. It is dangerous to stop or interrupt treatment because then the disease may become incurable. With directly-observed treatment, the health worker will know if you miss a dose and will quickly investigate the problem.</p> <p>If you must travel, or if you plan to move, tell the health worker so that arrangements can be made to continue your treatment without interruption.</p>
<p>Describe details of patient's treatment regimen</p>	<p>Explain for the specific patient:</p> <ul style="list-style-type: none"> – duration of treatment – frequency of visits for taking treatment – where to go for treatment <p><i>(If preassembled drug boxes are used)</i> All the drugs for treatment are kept in a box with your name on it, so the health facility will not run out of drugs for you.</p>
<p>Explain what to expect and what to do next</p>	<p><i>(If the patient is taking rifampicin)</i> Your urine may turn orange or red as a result of the drug. This is expected and not harmful. If you feel nauseous from the drugs, bring a bit of food to eat when taking the next dose.</p> <p>Treatment should not interfere with normal life and work.</p> <p>Make sure that the patient knows exactly where and when to go for the next treatment. Ask questions to ensure that this will be possible and that the patient is committed to return.</p> <p>Remind the patient to bring family and other close contacts for TB testing as needed.</p> <p>Explain that the patient has the right to care, dignity and privacy, the right to be informed about the disease and its treatment and to make decisions independently. The patient has the responsibility to share relevant information with the health worker, to take the anti-TB drugs and to try not to infect others.</p>
<p>Review: Ask checking questions (to ensure that the patient remembers important messages and knows what to do next). Reinforce earlier messages, or give more information as needed.</p>	

Guide for continuing patient information about TB

Use good communication skills at every visit. At different points in treatment, discuss the messages that are most relevant at the time. When administering directly-observed treatment be very brief so the patient does not lose time or get bored by repetitive questions; just ask if there are any problems (give time for the reply) and act to solve them. During periodic reassessment (discussion of sputum examination results or clinical visits), review the patient's status in more detail, as shown below.

At every visit: Demonstrate a caring, respectful attitude. Praise and encourage the patient. Speak clearly and simply. Encourage the patient to ask questions.	
Be alert for side-effects of anti-TB drugs:	
<p>Ask general questions to identify side-effects:</p> <ul style="list-style-type: none"> – How are you feeling? – Have you had any problems? <p>Listen and look for major side-effects:</p> <ul style="list-style-type: none"> – Itching of skin, skin rash – Deafness – Dizziness, lack of balance – Jaundice (yellow skin or eyes) – Vomiting repeatedly – Difficulty with vision 	<p>Respond as directed:</p> <p>If minor side-effects, give reassurance and advice:</p> <ul style="list-style-type: none"> • If anorexia, nausea or abdominal pain, take drugs with food, yogurt or gruel. • If joint pains, take aspirin or paracetamol. • If burning sensation in feet, take pyridoxine (100 mg daily). • If orange or red urine, this is normal and expected. <p>If major side-effects, stop anti-TB drugs and refer urgently to a clinician.^a</p>

^a If the patient must be referred or hospitalized, explain that it is necessary to continue TB treatment during referral care, and to return to the health facility afterwards to continue treatment.

Be alert for side-effects of simultaneous anti-TB treatment⁺ and ART⁺⁺	
Minor side-effects	Respond as directed:
▶ 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 (of simultaneous TB treatment ⁺ and ART ⁺⁺)	Respond as directed: <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)

If it is time for a follow-up sputum examination:	
Explain the need for the sputum examination.	TB germs cannot be seen with the eye. A laboratory technician must examine sputum under a microscope to see if there are still TB germs and if you are getting better.
<i>After 2 (and/or 3) months initial treatment</i> →	If the laboratory sees no TB germs in your sputum, the treatment is progressing well.
<i>During continuation Phase (5 months)</i> →	If no TB germs are seen, you will continue the same treatment. If TB germs are seen, the treatment must be changed.
<i>Just before end of treatment</i> →	If no TB germs are found at this examination, you are considered cured.

Give other relevant advice:	
<p><i>If a smoker</i> →</p>	<p>Do not smoke. Counsel the patient or refer for counselling and support for stopping smoking.</p> <p>If the patient has stopped smoking, congratulate the patient and reinforce the importance of not smoking for curing TB and avoiding TB relapse.</p>
<p><i>If the patient has other risk factors or health problems that might be improved</i> →</p>	<p>It is important that you try to control all risk factors that decrease immunity to the extent possible. For example, seek care to keep diabetes under control, and improve nutritional problems such as undernutrition or anaemia.</p>
<p><i>If the patient has not yet brought in all of the household contacts who should be assessed for TB</i> →</p>	<p>Urge the patient to bring in household contacts so that they may be checked for TB by a health worker. Bring:</p> <ul style="list-style-type: none"> – every child under 5 years of age – every other person living in the household who has a cough.
<p><i>If a child is being treated for TB</i> →</p>	<p>Give your child a healthy diet so that the child can continue to grow in height and weight during treatment for TB. Explain the feeding recommendations for the child's age including foods to give, serving size, and number of meals and snacks each day.</p>
<p>Review: Ask checking questions (to ensure that the patient remembers important messages and knows what to do next). Reinforce earlier messages, or give more information as needed.</p>	

Guide for informing patients about HIV and TB

Use this guide for TB patients in areas where HIV is common.

Note the special messages for pregnant women.

At every visit: Demonstrate a caring, respectful attitude. Praise and encourage the patient. Speak clearly and simply. Encourage the patient to ask questions.	
<p>Ask TB patients:</p> <p>What do you understand HIV to be? →</p> <p>(Explain what the patient does not know)</p>	<ul style="list-style-type: none"> HIV (human immunodeficiency virus) is a viral infection transmitted in three primary ways: by sexual activities, by blood such as in transfusions or infected needles, and from mother to child during pregnancy, delivery and breastfeeding. The best prevention is to always use condoms during sex. Infection with HIV interferes with the body's capacity to resist other infections (immunity) including TB. Some of these infections can be treated and cured. However, no drugs currently exist that can cure HIV. Current HIV drugs (ARVs) improve resistance to other infections, but must be taken for life, are expensive, have side-effects and require specialized care. In addition, co-trimoxazole can be taken to reduce the risk of other bacterial infections. TB is more frequent in HIV-infected people. Treatment for TB in an HIV-positive person is the same and can cure most cases if the drugs are taken regularly. However, if drugs to treat TB and for HIV will be taken simultaneously, selection of drugs may need to be adjusted.
<p>Do you know your HIV status?</p> <p>If status is unknown (or undocumented) or if negative test was done more than 3 months ago, recommend HIV testing</p>	<ul style="list-style-type: none"> It is recommended that all TB patients be tested for HIV. There are benefits to knowing your HIV status: <ul style="list-style-type: none"> It helps in diagnosis of TB, because TB in HIV-infected people may present differently than TB in people who are not HIV-infected. TB is much more frequent in HIV-infected people, and other pulmonary infections are also more common. It guides decisions on treatment, such as the need for ART (antiretroviral treatment) and CPT. It is important for counselling and advice on TB and HIV regarding your prospects of recovery, side-effects and associated diseases. It guides possible preventive measures in HIV-infected people without TB, such as isoniazid preventive therapy (IPT). <i>If a TB patient is a woman of childbearing age, also ask: Are you pregnant? If yes, explain:</i> An additional benefit to knowing your HIV status is that it may be possible to provide drug therapy to prevent transmission of HIV to your child. All children born to an HIV-positive mother will test positive for the first 7 months of life because of antibodies received from the mother. The chances that children born to HIV-positive mothers will be infected with HIV and continue HIV-positive are 1 in 3. With ART during pregnancy, the chances can be reduced to 2%.
<p>Do you agree to be tested?</p>	<ul style="list-style-type: none"> Explain options available for HIV testing: whether the patient may be tested now at this facility, or whether they should go to another facility. In high HIV-prevalence areas, TB patients should be retested for HIV after several months, in case an HIV test at the beginning of treatment did not accurately reflect the patient's HIV status (window period) or they got the HIV infection later.

<p>If the HIV test is negative, briefly remind about preventive behaviours →</p>	<ul style="list-style-type: none"> • Congratulations, your HIV test was negative. • Remember that you are still at risk of infection with HIV. Infection mainly happens through unprotected sex, so any sexually active person should always use condoms. Never use needles or syringes that may be infected or have been used by another person. • There is a small possibility that you might have been infected recently and the test did not identify the infection. You may consider repeating the test after three months, to be sure.
<p>If TB patient is HIV-positive, inform about TB and HIV →</p>	<ul style="list-style-type: none"> • The laboratory reported that your HIV test is positive, which means that you are infected with HIV. This will gradually interfere with your defences against many infections, including TB, and can also cause other damage. • An HIV-infected person is much more likely to develop TB. TB can be cured in HIV-infected people, but the chance of death during treatment and TB relapse is greater. • Knowing that you have HIV will help the health services to: <ul style="list-style-type: none"> – prevent complications, and diagnose and treat any other diseases that you may develop. – make decisions on treatment to help you stay healthier, such as co-trimoxazole (to prevent other infections) and ART (to improve your immune function). – give you better information on your prospect of recovery, side-effects of the drug therapy and associated diseases. • If you are receiving care for HIV to help you stay healthy, your TB is more likely to be cured and less likely to come back (relapse). Taking co-trimoxazole daily can prevent other infections. ART can help you feel better and live longer. You can be assessed for eligibility for ART at (<i>Explain options available locally for HIV care</i>). • If you are pregnant, it may be possible to provide drug therapy to prevent transmission of HIV to your child. All children born to an HIV-positive mother will test positive for the first 7 months of life because of antibodies received from the mother. The chances that children born to HIV-positive mothers will be infected with HIV and continue HIV-positive are 1 in 3. With ART during pregnancy, the chances can be reduced to 2%.
<p>Review: Ask checking questions (to ensure that the patient remembers important messages and knows what to do next). Reinforce earlier messages, or give more information as needed.</p>	

VI. MONITORING A PATIENT'S TREATMENT

Monitor progress of treatment

- ▶ **Determine when the patient is due for follow-up sputum examinations. (See the schedule on the next page.)**
 - New patient regimen: Do follow-up sputum smear microscopy examinations at the end of 2 months, 5 months, and 6 months (the last month of treatment). If smear-positive at the end of 2 months, repeat smear microscopy at the end of 3 months.
 - Retreatment regimen: Do follow-up sputum smear examinations at the end of 3 months, 5 months, and 8 months of treatment.
- ▶ **Collect sputum for follow-up examination.**
- ▶ **If a TB patient was HIV-negative, recommend HIV testing at the end of the initial phase of treatment.**
- ▶ **If a TB patient is HIV-positive, update the information on the *TB Treatment Card* about HIV care.**
- ▶ **Record results of sputum smear microscopy examination on the *TB Treatment Card*.**
- ▶ **Decide on appropriate action needed. (See page 45.)**
 - **Assess treatment progress at the end of the initial phase.**
 - **Use sputum examination results at 5 months to assess effectiveness of treatment.**
- ▶ **Record the results of sputum culture and DST, if received.**

If the patient is resistant to at least rifampicin and isoniazid, the patient has MDR-TB and is classified as a treatment failure. Refer the patient to a clinician for prescription of an MDR-TB regimen.

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.

Schedule for follow-up sputum examinations

Treatment regimen	Months of treatment							
	1	2	3	4	5	6	7	8
New patient regimen 2RHZE/4RH <i>(smear-positive at start of treatment)</i>	[=====]	===== ● 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 regimen 2RHZE/4RH <i>(smear-negative at start of treatment)</i>	[=====]	===== ● 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) 2RHZES/1RHZE/5RHE <i>(smear-positive at start of treatment)</i>	[=====]	=====	===== ● 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 the 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.

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 (page 44).
- Exception: If patient who was 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).

Treatment outcomes

The treatment regimen is completed when the patient has taken the correct number of doses of the continuation-phase drugs. When each patient completes treatment or stops coming for treatment, record that patient's outcome on the *TB Treatment Card*.


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 ^a
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

^a 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.

VII. MONITORING THE HEALTH FACILITY'S WORK

Key points about monitoring

- Each health facility should monitor its work in TB case detection and treatment activities. Monitoring involves keeping good records, reviewing them regularly, compiling data and analysing key indicators.
- Regularly review the *Register of TB Suspects* and ask:
 - Have microscopy results been received for all sputum samples sent?
 - Has a treatment card been opened for all sputum smear-positive cases?If not, take action to find causes of the problems and solve them.
- Worksheets are provided to help you compile data and calculate indicators. Just after the end of each quarter, use the worksheets to compile data on activities related to four different groups of people:
 - TB suspects (aged 15 years and older) identified and tested in the **previous quarter** (i.e. the quarter that just ended)
 - TB patients (any age, any type of TB) who began treatment in the **previous quarter**
 - New sputum smear-positive TB cases (aged 15 years and older) who began treatment in the **quarter that ended 3 months ago**
 - New sputum smear-positive TB cases (aged 15 years and older) who began treatment in the **quarter that ended 12 months ago**.
- Key indicators related to **TB case detection** are:
 - Proportion of outpatients aged 15 years and older who were identified as TB suspects
 - Proportion of TB suspects whose sputum was examined for TB
 - Proportion of TB suspects tested who were sputum smear-positive.
- Key indicators related to **HIV testing and HIV status** are:
 - Proportion of all TB patients who began treatment during the quarter who were tested for HIV before or during TB treatment
 - Proportion of HIV-tested TB patients who are HIV-positive
 - Proportion of HIV-positive TB patients who are on CPT
- Key indicators related to **TB treatment** are:
 - Proportion of new sputum smear-positive TB cases aged 15 years and older that converted at 2 or 3 months (**conversion rate**)
 - Proportion of new sputum smear-positive TB cases that:
 - were cured
 - completed treatment
 - defaulted
 - were a treatment failure
 - died
 - transferred out **treatment outcomes**
- Analysis of indicators may involve:
 - comparing the actual proportion achieved to the expected or desired proportion
 - comparing one indicator to other indicators (such as comparing the proportion of cases that defaulted to the proportion that completed treatment or were cured)
 - comparing results achieved from one quarter to the next.
- To see the health facility's improvement keep a line graph from quarter to quarter of:
 - the number of TB suspects whose sputum was examined for TB
 - the number of sputum smear-positive cases detected.
- The purpose of monitoring is to recognize success and solve problems. It is important to thoroughly describe the problem and investigate its causes before identifying and implementing solutions. Solutions must be appropriate for the causes of a problem.

Worksheet 1: Data on TB case detection

Case detection in the previous quarter (the quarter that just ended)

Soon after the end of a quarter, use this worksheet to compile data on TB case detection at the health facility during that quarter. Use the results of this worksheet to calculate indicators related to TB case detection. See *Summary Worksheet A: Indicators to monitor TB case detection and HIV testing*.

Circle the previous quarter: 1 2 3 4 of year: _____

Record the dates included in the previous quarter: _____ – _____

Write answers in the blanks to the left of each step:

- 1a. _____ Determine the total number of outpatients aged 15 years and older seen for any reason during the quarter. To do this, use whatever health facility records are available.
- 1b. _____ Determine the number of TB suspects aged 15 years and older identified during the quarter. To do this, mark the beginning and ending dates for the quarter in the *Register of TB Suspects*. Then count the entries for suspects aged 15 years and older.*
- 1c. _____ Determine the number of these TB suspects whose sputum was examined.¹ Do this by counting the number of entries in the column headed "Date sputum sent to laboratory."
- 1d. _____ Count the number of these TB suspects who had one or more smear-positive results. Do this by looking in the three columns headed "Results of sputum examinations."

*Be careful not to count any entries for children aged under 15 years. If there were any TB suspects aged under 15 years during the quarter, lightly cross through the entire row for these younger TB suspects so that you do not count them in this step.

¹ By sputum smear microscopy.

Worksheet 2: Data on HIV testing

HIV testing in the previous quarter (the quarter that just ended)

Soon after the end of a quarter, use this worksheet to compile data on HIV testing and HIV status of TB patients who began treatment at the health facility during the previous quarter. Use the results of this worksheet to calculate indicators related to HIV testing and HIV status. See *Summary Worksheet A: Indicators to monitor TB case detection and HIV testing*.

Circle the previous quarter: 1 2 3 4 of year: _____

Record the dates included in the previous quarter: _____ – _____

Write answers in the blanks to the left of each step:

- 2a. Determine the total number of TB patients (any age, any type of TB) who began treatment in the previous quarter.

In the *Register of TB Suspects*, mark the beginning and ending dates of the quarter. For that quarter, look in the column headed "TB treatment card opened." This column should have dates for most TB patients who began treatment during the quarter. Find the *TB Treatment Cards* for all of these patients. (Remember to omit any patient whose *TB Treatment Card* was opened after the quarter ended.)

Also look back in the *Register of TB Suspects* for suspects identified shortly before the quarter began but who began treatment during the quarter. Find the *TB Treatment Cards* for all of these patients.

Also find the *TB Treatment Cards* for any patients referred to your health facility to begin treatment during the quarter.

- 2b. _____ Look at the *TB Treatment Cards* found in step 2a. Count the cards. **This is the number of TB patients who began treatment in the quarter.**
- 2c. _____ On these *TB Treatment Cards*, look at the box "TB/HIV" to see whether each TB patient was tested for HIV. Count the patients who have an HIV test date and result recorded. **This is the number of TB patients who were HIV-tested before or during TB treatment.**
- 2d. _____ On these same cards, look at the box "TB/HIV" and count the patients who are HIV-positive. **This is the number of HIV-positive TB patients.**
- 2e. _____ Determine the number of HIV-positive TB patients on CPT. On these same cards (all HIV-positive TB patients), look at the box "TB/HIV" and count the patients who have a date recorded for CPT start. **This is the number of HIV-positive TB patients on CPT.**

Worksheet 3: Data on TB treatment

Use this worksheet to compile data on TB treatment. Use the results to complete the bottom half of the *Summary Worksheet B: Indicators to monitor TB case detection and treatment*.

Part A – Conversion (for the quarter that ended 3 months ago)

Circle the quarter that ended 3 months ago: 1 2 3 4 of year: _____

Record the dates in that quarter: _____ – _____

Find the number of new, sputum smear-positive cases put on treatment in the quarter. Then find the number of these cases that converted at 2 or 3 months. To do this, complete steps 3a–3e below. Write answers in the blanks for 3d and 3e.

- 3a. In the *Register of TB Suspects*, mark the beginning and ending dates of the quarter. For that quarter, look in the column headed “TB treatment card opened?” This column should have dates for most TB patients put on treatment during the quarter. Find the *TB Treatment Cards* for all of these patients. Also find the *TB Treatment Cards* for any patients referred to your health facility to begin treatment during the quarter. (Omit any children aged under age 15 years.)
- 3b. Look at the *TB Treatment Cards* found in step 3a. Put the cards for any extrapulmonary or sputum smear-negative cases back in the files.
- 3c. On each *TB Treatment Card* remaining in your hand, look in the section titled “Type of Patient” to see whether the case was new. If new, keep the card out. If not new (anything else ticked), put the card back in the files.
- 3d. _____ Count the cards remaining in your hand. **This is the number of new, sputum smear-positive cases put on treatment in the quarter.**
Important: Mark or tag these cards so that you can easily find them later (to determine treatment outcomes 12 months after starting treatment).
- 3e. _____ On these same cards, look at the “Results of sputum examination” in the row for month 2 or 3. Count the cases who had a negative result for month 2 or 3. **This is the number of new smear-positive cases that converted at 2 or 3 months.**

Part B – Treatment outcomes (for the quarter that ended 12 months ago)

Circle the quarter that ended 12 months ago: 1 2 3 4 of year: _____

Record the dates in that quarter: _____ – _____

- 3f. _____ Determine the number of new smear-positive cases put on treatment during the quarter that ended 12 months ago. To do this, find the *TB Treatment Cards* for these cases. (*The cards should have been tagged or marked.*) Count the cards. How many cards are there?

Determine the number of these cases with each outcome. To do this, look at treatment outcomes recorded on the back of the *TB Treatment Cards*. Count the number of cases with each outcome:

- | | | |
|-----------------------------|-------------------------------|------------------------|
| 3g. _____ Cure | 3h. _____ Treatment completed | 3i. _____ Default |
| 3j. _____ Treatment failure | 3k. _____ Died | 3l. _____ Transfer out |

Summary Worksheet A: Indicators to monitor TB case detection and HIV testing

To monitor:	Measure these indicators:	Record time frame: ^a	How to calculate (numerator / denominator) ^b	$\frac{x}{y}$	Calculate and record result (%) here:
TB case detection (using data from Register of TB Suspects, compiled on Worksheet 1)	Proportion of outpatients aged 15 years and older who were identified as TB suspects	previous quarter:	<u>Number TB suspects identified (1b)</u> Total outpatients aged 15 years and older (1a)	_____	
	Proportion of TB suspects whose sputum was examined for TB		<u>Number TB suspects whose sputum was examined (1c)</u> Number TB suspects identified (1b)	_____	
	Proportion of TB suspects tested who were sputum smear-positive		<u>Number smear-positive cases detected (1d)</u> Number TB suspects whose sputum was examined (1c)	_____	
HIV testing and HIV status (Using data from TB Treatment Cards, compiled on Worksheet 2)	Proportion of all TB patients who were tested for HIV before or during TB treatment		<u>Number of TB patients tested for HIV (2c)</u> Number of TB patients (2b)	_____	
	Proportion of all HIV-tested TB patients who are HIV-positive		<u>Number of HIV-positive TB patients (2d)</u> Number of HIV-tested TB patients (2c)	_____	
	Proportion of all HIV-positive TB patients who are on CPT		<u>Number of HIV-positive TB patients on CPT (2e)</u> Number of HIV-positive TB patients (2d)	_____	

^a The time frame applies to the denominator. The persons in the numerator are part of this group.

^b Numbers in parentheses tell where to find the numerator and denominator on Worksheet 1, 2 or 3.

Summary Worksheet B: Indicators to monitor TB treatment

To monitor:	Measure these indicators:	Record time frame: ^a	How to calculate (numerator / denominator) ^b	$\frac{x}{y}$	Calculate and record result (%) here:
TB treatment <i>(using data from Register of TB Suspects and TB Treatment Cards, compiled on Worksheet 3)</i>	Conversion rate: Proportion of new sputum smear-positive TB cases that converted at 2 or 3 months	quarter that ended 3 months ago:	Number new smear-positive cases <u>that converted at 2 or 3 months (3e)</u> Number new smear-positive cases put on treatment (3d)	_____	
	Treatment outcomes: Proportion of new sputum smear-positive cases that: <ul style="list-style-type: none"> – were cured 	quarter that ended 12 months ago:	<u>Number new smear-positive cases cured (3g)</u> Number new smear-positive cases put on treatment (3f)	_____	
	<ul style="list-style-type: none"> – completed treatment 		<u>Number new smear-positive cases that completed treatment (3h)</u> Number new smear-positive cases put on treatment (3f)	_____	
	<ul style="list-style-type: none"> – defaulted 		<u>Number new smear-positive cases that defaulted (3i)</u> Number new smear-positive cases put on treatment (3f)	_____	
	<ul style="list-style-type: none"> – were a treatment failure 		<u>Number new smear-positive cases that failed treatment (3j)</u> Number new smear-positive cases put on treatment (3f)	_____	
	<ul style="list-style-type: none"> – died 		<u>Number new smear-positive cases that died (3k)</u> Number new smear-positive cases put on treatment (3f)	_____	
	<ul style="list-style-type: none"> – transferred out 		<u>Number new smear-positive cases that transferred out (3l)</u> Number new smear-positive cases put on treatment (3f)	_____	

^a The time frame applies to the denominator. The persons in the numerator are part of this group.

^b Numbers in parentheses tell where to find the numerator and denominator on Worksheet 1, 2 or 3.

Analyse indicators

Indicator	Compare to:	Possible interpretation, or investigation needed:
Proportion of outpatients aged 15 years and older who were identified as TB suspects	Expected result: ^a 2–10%	If lower than 2%, it is likely that patients are not routinely being asked about cough. If higher than 10%, consider whether patients with cough less than 2 weeks are being recorded.
Proportion of TB suspects whose sputum was tested for TB	Desired result: 100%	If less than 100%, find out why. Have suspects failed to produce sputum samples? Has the laboratory failed to return test results?
	Results from previous quarters	If the proportion is less than previous quarters, find out what new problems are occurring. If the proportion has increased, find out what made the difference.
Proportion of TB suspects tested who were sputum smear-positive	Expected result: ^a 2–15%	If higher, check procedures used to identify TB suspects. It is possible that only people with severe respiratory symptoms have sputum samples sent for testing.
	Results from previous quarters	If the proportion varies greatly from one quarter to the next, check procedures used to identify TB suspects and send sputum samples. There may have been a change. Over a longer period of time, an increase or decrease could indicate a change in the actual level of TB in the community.
Proportion of all TB patients who were tested for HIV before or during TB treatment	Desired result in countries with high HIV prevalence: 100%	If less than 100%, find out why. Do health workers recommend HIV testing to all TB cases? Is this a TB programme policy? Do patients decline HIV testing? Is testing difficult for patients to access (distance, cost)? Are supplies and trained staff consistently available to do HIV testing?
	Results from previous quarters	If the proportion is less than previous quarters, find out whether new problems are occurring. If the proportion has increased, find out what made the difference.
Proportion of all HIV-tested TB patients who are HIV-positive	Expected result: About five times the HIV prevalence in the general population	There is no target, because the proportion depends on the HIV prevalence in the population. The indicator is useful to evaluate the workload (drugs, staff) and priority of TB/HIV co-treatment and the expected impact of HIV on the TB treatment outcomes
Proportion of all HIV-positive TB patients who are on CPT	Desired result: 100%	If less than 100%, find out why. Do health workers recommend and give CPT to HIV-positive patients? Is co-trimoxazole consistently available?
	Results from previous quarters	If the proportion is less than previous quarters, find out what new problems are occurring. If the proportion has increased, find out what made the difference.

Indicator	Compare to:	Possible interpretation, or investigation needed:
Proportion of new sputum smear-positive cases that converted at 2 or 3 months (conversion rate)	Desired result: more than 80% (8 out of 10)	If patient compliance is high and treatment is consistently done correctly, more than 80% should convert. If the proportion is 80% or less, look for reasons (e.g. follow-up sputum examinations not done, defaults, transfers)
	Results from previous quarters	An increase in this proportion suggests that patient compliance and treatment are improving. A decrease suggests problems. Look for problems related to monitoring, patient compliance and treatment.
Proportion of new sputum smear-positive cases that: – were cured	Results from previous quarters	An increase suggests that patient compliance and treatment are improving and/or that follow-up sputum examinations are being done to confirm cures. A decrease suggests problems in one or both of these areas. (See below.)
– completed treatment	For the same quarter, the proportion of cases with other outcomes	Added together, the proportion cured plus the proportion that completed treatment (called “treatment success”) should increase towards 100% and reach at least 85% with good case management. Considered separately, the proportion that completed treatment should be much lower than the proportion cured. Otherwise, it is likely that the final follow-up sputum examinations are not being done to confirm cures.
– defaulted	Desired result: less than 5%	If greater than 5% default, investigate problems related to patient compliance, organization of services, etc.
– were a treatment failure	Results from previous quarters	An increase may suggest that patient compliance is declining or that the incidence/prevalence of MDR-TB is increasing.
– died	Results from previous quarters	An increase may suggest that more TB cases are HIV-positive and are dying during treatment. An increase may indicate problems with delays in diagnosis or quality of care that should be investigated. A decrease may suggest that TB cases are being diagnosed earlier and treated more effectively.
– transferred out	Results from previous quarters	A high proportion of transfers usually indicates poor follow-up of patients who have moved to other facilities or districts, and lack of reclassification of the outcome based on the information received.

^a Based on results from well-organized TB control programmes worldwide.

VIII. DRUG BOX ASSEMBLY

Assemble drug boxes for TB patients

If a health facility does not receive boxes of drugs packaged in complete regimens, it will be necessary to assemble drug boxes. A drug box should contain the correct number of doses for the entire course of treatment for a patient. How each dose is packaged will depend on what drugs are provided by the national TB control programme. One possibility is to prepare small envelopes each containing the correct combination of loose tablets for one dose of the regimen. Alternatively, the tablets may be packaged in blisters such as 28 tablets on one card, or doses for one week on one card. In that case, place the correct number of blister cards in a drug box.¹

To plan for making a drug box, complete steps a–e below, writing the numbers on a piece of paper or a *Worksheet for drug box assembly* (example on the next page):

- a) Refer to a table of TB treatment regimens and find the appropriate regimen for the patient. At the top of the worksheet, record the regimen and weight range for which the box will be assembled.
- b) Read the code for the regimen to determine the drugs needed for the initial phase. Record the tablets that will be used for the initial phase, listing each FDC or separate tablet on a different line. Specify the formulation (content and strength) of each tablet. Specify the frequency (daily or 3 times per week).
- c) Read the table of treatment regimens to find out the number of each tablet per dose for the patient's weight. Record the number of tablets per dose. (See your national TB control programme's table of treatment regimens.)
- d) Write the number of doses per month and the number of months in the phase.
 - 28 doses is the standard number of doses per month for a daily regimen.
 - 12 doses is the standard number of doses per month for a 3-times-per-week regimen.Multiply to determine the number of doses to include for the phase.
- e) Repeat steps b, c and d for the continuation phase. Refer to the code for the regimen to determine the frequency (daily or 3 times per week) and the duration of the phase in months.

Keep the completed worksheet for reference whenever you need to assemble a drug box for this regimen and weight range.

A blank *Worksheet for drug box assembly* is provided on page 64.

¹ For a Retreatment regimen, which includes streptomycin during the first 2 months, you will not place the streptomycin in the drug box, but must put 56 doses (streptomycin vials, water for injection, sterile needles and syringes) in reserve for use by the TB patient.

EXAMPLE

Worksheet for drug box assembly

Box to be made: *New patient*
 Code for regimen: *2(RHZE)/4(RH)₃*
 Patient's weight: *40-54 kg*

a) On table of treatment regimens, find regimen for New patient or Retreatment and record on worksheet. Also record the weight of patient (range).

b) List each tablet on a separate line and note the formulation and strength. Specify frequency.

Initial phase

Drugs and formulation	Frequency	Number of tablets per dose
<i>(RHZE)</i> <i>(R 150mg + H 75mg + Z 400 mg + E 275 mg tablet)</i>	<i>daily</i>	<i>3</i>

c) From table of treatment regimens, determine number of tablets per dose for this weight range.

Doses per month	Duration in months	Number of doses
<i>28</i>	<i>2</i>	<i>56</i>

d) Write the number of doses per month and duration in months. Then multiply to calculate the number of doses to include in the drug box.

e) Repeat steps b, c and d for the continuation phase to specify the tablets needed for each dose, and calculate the number of doses to include.

Continuation phase

Drugs and formulation	Frequency	Number of tablets per dose
<i>(RH)</i> <i>(R 150mg + H 150mg tablet)</i>	<i>3 times per week</i>	<i>3</i>

Doses per month	Duration in months	Number of doses
<i>12</i>	<i>4</i>	<i>48</i>

IX. BLANK FORMS

REQUEST FOR SPUTUM SMEAR MICROSCOPY EXAMINATION

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

Referring facility¹ _____ Date _____

Name of patient _____ Age _____ Sex: ☐ M ☐ F

Complete address _____

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 _____

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. _____

Date collected ³	Sputum specimen	Visual appearance ⁴	RESULTS				
			NEG	(1–9)	(+)	(++)	(+++)
	1						
	2						
	3						

3. To be completed by the person collecting the sputum

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

Examined by _____

Date _____ Signature _____

Year _____

REGISTER OF TB SUSPECTS

Facility _____

Date (dd/mm)	TB suspect number	Name of TB suspect	Age		Complete address	Result of HIV test *	Date first sputum collected	Date sputum sent to laboratory	Date results received	Results of sputum examinations			TB Treatment Card opened (record date)	Observations/ Clinician's diagnosis
			M	F						1	2	3		

* (Pos) Positive; (Neg) Negative; (I) Discordant/Inconclusive; (ND) Not Done /unknown. Documented evidence of HIV test performed during or before TB treatment is reported here.

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

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

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

(RH)	(RHE)	Other

Number of tablets per dose, doses per week

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 is supplied. Enter X on day when drugs are collected and draw a horizontal line (---) through number of days supplied. 2 = 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

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

First names and surnames	Age	Relationship to case	Date seen	Result

Name and address of contact person: _____

Tuberculosis Identity Card

Name _____

Address _____

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 previously treated

I. INITIAL PHASE

<input type="checkbox"/> New	<input type="checkbox"/> Retreatment	(RHZE)	S	Other
Drugs and dosage:				

II. CONTINUATION PHASE

(RH)	(RHE)	Other
Drugs and dosage:		

District TB Register No. _____

Appointment dates: _____

REMEMBER

Tuberculosis Treatment Referral/Transfer

(Complete top part in triplicate)

Tick to indicate the reason for this referral or transfer:

☐ Referral¹ to register and
begin TB treatment

☐ Referral for special care²

or ☐ Transfer³

Date of referral/ transfer _____

Name/address of referring/transferring facility

From sending facility: _____

_____ Sending District _____

To receiving facility: _____

_____ Receiving District _____

Name of patient _____ Age _____ Sex: ☐ M ☐ F

Address of patient (if moving, future address): _____

Diagnosis: _____

(For Transfer) District TB Register No. _____ Date TB treatment started: _____

TB Treatment Regimen:

☐ New ☐ Retreatment

Other (CPT, ART etc):

Drugs patient is receiving _____

Remarks (e.g. side-effects observed): _____

Name / signature of person sending the patient _____

Documented evidence of HIV tests (and results) during or before TB treatment should be reported.



Return this part to facility that referred/transferred patient as soon as patient has reported.

To be completed by facility receiving referred / transferred patient

District _____ Facility _____

District TB Register No. _____ Name of patient _____

The above patient reported at this facility on _____ (date)

Name / signature of person receiving the patient _____

¹ **Referral** is the process of moving a TB patient **prior to registration in a District TB Register** for the purpose of start of treatment (treatment closer to patient's home). The district receiving a "referred" patient is responsible to inform the facility sending the patient about the care provided.

² **Referral for special care** is indicated when the patient is very sick or has major side-effects and is referred to a clinician or hospital for special care. When discharged, the patient should return to the original health facility to continue TB treatment.

³ **Transfer** is the process of moving between 2 districts a **TB patient registered in a District TB Register** to continue his treatment in another area with a different *District TB Register*. The district 'transferring-out' a patient is responsible to report the treatment outcome, after getting the information from the district completing the treatment. The district receiving a patient 'transferred-in' is responsible for informing the district sending the patient 1) of the arrival of the patient and 2) at the end of the treatment, of the treatment outcome.

Worksheet for drug box assembly

Box to be made:
Code for regimen:
Patient's weight:

Initial phase

Drugs and formulation	Number of tablets per dose	Frequency

Doses per month	Duration in months	Number of doses

Continuation phase

Drugs and formulation	Number of tablets per dose	Frequency

Doses per month	Duration in months	Number of envelopes

